MEDICUS PHARMA LTD.

2025 ANNUAL REPORT

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended **December 31, 2025**

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from ___ to _____
Commission File Number **001-42408**

MEDICUS PHARMA LTD.

(Exact name of Registrant as specified in its Charter)

Ontario, Canada	**98-1778211**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

300 Conshohocken State Rd., Suite 200
W. Conshohocken, PA 19428
(Address of principal executive offices and zip code)
Registrant's telephone number, including area code: (610) 636-0184
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common shares, no par value	**MDCX**	**The Nasdaq Capital Market**
Warrants, each exercisable for one common share at an exercise price of $4.64 per share	**MDCXW**	**The Nasdaq Capital Market**

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes ☐ No ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.
Yes ☐ No ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 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 ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files).
Yes ☒ No ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐
Non-accelerated filer ☒ Smaller reporting company ☒
Emerging growth company ☒

If an emerging growth company, indicate by the check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. YES ☐ NO ☒

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
YES ☐ NO ☒

The aggregate market value of the Registrant's common shares outstanding, other than shares held by persons who may be deemed affiliates of the Registrant, at June 30, 2025, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $28.3 million, based on the Nasdaq Capital Market (the "Nasdaq") closing price for such shares on June 30, 2025. For purposes of this computation, all officers, directors and holders of more than 10% of our common shares have been excluded in that such persons may be deemed to be affiliates. Such determination should not be deemed to be an admission that such officers, directors and holders are, in fact, affiliates of the registrant.

As of March 17, 2026, there were 39,362,109 common shares, no par value, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this Annual Report, to the extent not set forth herein, is incorporated herein by reference from the registrant's definitive proxy statement relating to the Annual Meeting of Shareholders to be held in 2025, which definitive proxy statement shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Annual Report relates, unless such definitive proxy statement is not filed prior to 120 days after the end of the fiscal year to which this Annual Report relates, in which case the information relating to this item will be filed by amendment to this Annual Report.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report includes, and oral statements made from time to time by representatives of the Company may include, forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We have based these forward-looking statements on our current expectations and projections about future events. These forward-looking statements are subject to known and unknown risks, uncertainties and assumptions about us that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by such forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may", "on track", "aim", "might", "will", "will likely result", "could," "designed," "would", "should", "estimate", "plan", "project", "forecast", "intend", "expect", "anticipate", "believe", "seek", "continue", "target", "potential" or the negative and/or inverse of such terms or other similar expressions. Such statements include, but are not limited to, possible business combinations and the financing thereof, and related matters, as well as all other statements other than statements of historical fact included in this annual report. Factors that might cause or contribute to such a discrepancy include, but are not limited to, those described in our other Securities and Exchange Commission ("SEC") filings. Forward-looking statements in this annual report may include, for example, statements about:

- our financial results, including our ability to continue as a going concern, generate earnings and achieve and sustain profitability, which may vary significantly from forecasts and from period to period
- the progress, timing and completion of our research, development and preclinical studies and clinical trials for our products and product candidates, and any progress or developments regarding the regulatory approvals sought and process related thereto;
- our ability to successfully integrate Antev Limited ("Antev") into our business and operations, successfully develop Teverelix (as defined herein) and realize the benefits currently anticipated from the transaction;
- our ability to market, commercialize, achieve market acceptance for and sell our products and product candidates and the potential market opportunities related thereto;
- our ability to develop, manage and maintain our direct sales and marketing organizations;
- our estimates regarding anticipated operating losses, future revenues, capital requirements and our needs for additional financing;
- market risks regarding consolidation in the healthcare, pharmaceutical and biotech/life sciences industry;
- the willingness of healthcare providers to purchase our products if coverage, reimbursement and pricing from third party payors for procedures using our products significantly declines;
- our ability to adequately protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- the market price of our securities may be volatile and fluctuate substantially, which could cause the value of your investment to decline;
- the fact that product quality issues or product defects may harm our business;
- any product liability claims; and
- the regulatory, legal and certain operating risks that our operations subject us to.

The forward-looking statements contained in this annual report are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described under the heading "Item 1A. Risk Factors." Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

BASIS OF PRESENTATION

In this annual report, all dollar amounts referenced, unless otherwise indicated, are expressed in U.S. dollars and are referred to as "$" or "U.S.$". Canadian dollars are referred to as "C$".

Unless the context otherwise requires, in this annual report, the term(s) "we," "us," "our," "Company," "our company," "Medicus" and "our business" refer to Medicus Pharma Ltd. and our subsidiaries.

In connection with our U.S. initial public offering, we effected a 1-for-2 consolidation, or reverse stock split (the "Share Consolidation"), of our issued and outstanding common shares. Except where otherwise indicated, all share and per share data in this annual report have been retroactively restated to reflect the Share Consolidation.

PART I

Item 1. Business.

Our company (formerly, Interactive Capital Partners Corporation) was incorporated pursuant to the Business Corporations Act (Ontario) on April 30, 2008 under the name Interactive Capital Partners Corporation.

On September 29, 2023, the Company completed a business combination (the "Business Combination") with SkinJect Inc. ("SkinJect"), a company existing under the laws of Pennsylvania. The Business Combination was completed pursuant to a business combination agreement dated May 12, 2023, as amended, among the Company, SkinJect and RBx Capital, LP ("RBx"), an investment entity owned and managed by Dr. Raza Bokhari, and resulted in a reverse takeover of the Company by the former shareholders of SkinJect, with SkinJect becoming a wholly owned operating subsidiary of the Company, and the Company being renamed "Medicus Pharma Ltd."

On October 11, 2023, the Company's common shares commenced trading on the TSX Venture Exchange (the "TSXV") under the symbol "MDCX". On November 15, 2024, we completed our initial public offering in the United States and our common shares and our outstanding public warrants to purchase common shares, issued as a component of the units sold by the Company in its U.S. initial public offering with an exercise price of $4.64 and expiration date of November 15, 2029 (the "Public Warrants"), began trading on Nasdaq under the symbols "MDCX" and "MDCXW", respectively. Effective on February 21, 2025, the Company's common shares were voluntarily delisted from the TSXV. The common shares continue to be listed on Nasdaq.

On August 29, 2025, we completed the acquisition of 98.6% of the issued and outstanding shares of Antev for aggregate consideration consisting of approximately US$2.97 million in cash and 1,603,164 common shares of Medicus, pursuant to a securities exchange agreement among Medicus, Antev and certain securityholders of Antev, dated as of June 29, 2025, as amended. The share-based consideration was subject to staggered release from escrow.

Antev's former shareholders will be entitled to receive up to approximately US$65 million in additional contingent consideration tied to potential future FDA Phase 2 and New Drug Application approvals based on the following development milestones:

Phases	**Contingent Consideration agreed for Antev shares acquired through issue of shares**	**Contingent Consideration agreed for Antev shares acquired by cash payment**
(i) Advanced Prostate Cancer - Phase 2 success or registration	$2.00 per common share issued	$1.47 per Antev share (pro rata interest in $5,333,200)
(ii) Acute Urinary Retention Prevention - Phase 2 success or registration	$7.50 per common share issued	$5.52 per Antev share (pro rata interest in $19,999,500)
(iii) FDA NDA approval - Hormone therapy for prostate cancer	Up to $20,000,000 (subject to pro rata reduction)	$5.52 per Antev share (pro rata interest in $20,000,000
(iv) FDA NDA approval - AUR prevention	Up to $20,000,000 (subject to pro rata reduction)	$5.52 per Antev share (pro rata interest in $20,000,000)

We are a clinical stage, multi-strategy biotech company focused on advancing novel and potentially disruptive select therapeutic assets through Phase 2 proof-of-concept and pursue out-licensing or strategic partnerships with established pharmaceutical companies that are best positioned to conduct late-stage development and commercialization.

The Company is actively engaged in multiple countries spread over three continents and opportunistically identifies, evaluates, acquires and in-licenses accretive assets and businesses. We are currently focused on two companies, SkinJect, a clinical stage biotech company developing doxorubicin containing microneedle arrays ("D-MNA"), a novel localized immunogenic precision therapy focused on non-melanoma skin diseases, especially basal cell carcinoma (BCC) of the skin representing ~$2 billion in potential market opportunity and Antev, a clinical stage biotech company, developing Teverelix, a next generation gonadotrophin-releasing hormone (GnRH) antagonist, as potentially a first in market product for advanced prostate cancer (APC) patients with high cardiovascular risk and patients with acute urinary retention relapse (AURr) episodes due to enlarged prostate, collectively representing ~$6 billion in potential market opportunity.

SkinJect:

Through our wholly owned subsidiary, SkinJect, we focus on the development of our in-licensed drug device combination product using novel dissolvable microneedle arrays for the treatment of non-melanoma skin cancers, especially BCC, and Gorlin Syndrome, a rare autosomal dominant disease also called nevoid BCC syndrome.

Our combination product candidate is a doxorubicin tip-loaded D-MNA filed with the FDA under an Investigational New Drug Application (IND) # 139837 and is regulated by the Center for Drug Evaluation and Research, Oncology Division. The Company received written responses from the FDA for a meeting category C on September 19, 2025, which, among other things, provided guidance that the Division of Dermatology and Dentistry under IND # 178051 shall manage the IND application and all future submissions.

The business conducted by the Company prior to the Business Combination was undertaken by SkinJect. References to the Company in this section as of a date prior to the completion of the Business Combination relate to the business undertakings of SkinJect.

In 2016, SkinJect licensed certain intellectual property from the University of Pittsburgh. During 2016 and 2017, SkinJect developed validated manufacturing methods for the manufacture of the microneedle arrays covered by the licensed patents. In 2017 and 2018, SkinJect completed pre-clinical animal studies and related verification analyses.

In 2018, SkinJect prepared an IND application and submitted it to the FDA for the conduct of a dose escalation study in human subjects ("Phase 1 study"). The FDA issued a Study May Proceed letter in November 2018.The study was completed in March 2021 and the clinical study report showed that the study met its primary objective of safety and tolerability. The investigational product, D-MNA was found to be well-tolerated across all dose levels in all thirteen (13) participants enrolled in the study, with no dose-limiting toxicities (DLTs), serious adverse events (SAE), or study discontinuations. Furthermore, there were no systemic effects or clinically significant abnormal findings in laboratory parameters, vital signs, ECGs, and physical examination. The clinical study report (CSR) also describes the efficacy of the investigational product, D-MNA and C-MNA (as defined below), with 6 participants experiencing complete responses. The complete response is defined as the disappearance of BCC histologically in the final excision at the end of study visit. The participants profile, demonstrating complete responses, was diverse and all participants (6/6) had nodular subtype of BCC.

Basal Cell Carcinoma Market Overview

Basal cell carcinoma is a type of skin cancer that begins in the basal layer of the epidermis. It is the most common type of skin cancer.

Basal cell carcinoma often appears as a slightly transparent bump on the skin, though it can take other forms. Basal cell carcinoma occurs most often on areas of the skin that are exposed to the sun, such as your head and neck. Most basal cell carcinomas are thought to be caused by "long-term exposure to ultraviolet (UV) radiation from sunlight" (Mayo Clinic). Additional factors that increase your risk of developing basal cell cancer include radiation therapy, fair skin, increasing age, family history and immune suppressing drugs.

Basal cell carcinomas account for approximately 80 percent of all non-melanoma skin cancers worldwide. (The Johns Hopkins University). Based on studies of populations in the United States, 40-50% of Americans who live to age 65 will experience BCC or squamous cell carcinoma at least once.

More than 5 million cases of basal cell carcinoma are diagnosed in the United States each year. Untreated BCCs can become locally invasive, grow wide and deep into the skin and destroy skin, tissue and bone.

The most common treatment for basal cell carcinoma in the United States is surgical removal. Surgery is the standard treatment for most BCC patients, either standard excision or Mohs Micrographic surgery. The treatment of basal cell carcinoma by a surgical procedure can result in high costs and clearly visible scarring.

Basal cell carcinoma is the most common cancer in humans, with an estimated annual incidence in the United States of 5.4 million cases (American Cancer Society). BCC arises from the basal cells in the epidermis and is associated with both chronic and intermittent acute UV exposure. The development of basal cell carcinoma is thought to be attributable, in part, to a deregulation of the Hedgehog signaling pathway. The Hedgehog pathway is involved in stem cell maintenance, regulation of cell proliferation and differentiation, and carcinogenesis. Unregulated activation has been implicated in the development of multiple cancers, including BCC (Gupta et. al. 2010). Chemotherapeutic inhibition of Hedgehog signaling has been demonstrated to be effective against advanced BCC (Soura et. al. 2015).

The Microneedle Array Solution and Doxorubicin Hydrochloride

Why Doxorubicin Hydrochloride

The binding of doxorubicin to cellular membranes may affect a variety of cellular functions. Enzymatic electron reduction of doxorubicin by a variety of oxidases, reductases and dehydrogenases generates highly reactive species including the hydroxyl free radical (• OH). Cells treated with doxorubicin have been shown to manifest the characteristic morphologic changes associated with apoptosis or programmed cell death. Doxorubicin-induced apoptosis may be an integral component of the cellular mechanism of action relating to therapeutic effects, toxicities, or both. Doxorubicin is a particularly well-suited chemotherapeutic drug for the chemo-immunization strategy, because it creates an immunogenic "good death" for tumor cells (Galluzzi et. al. 2012) and (Storkus and Falo Jr 2007). As shown in the figure below, doxorubicin chemotherapy has been shown to result in innate immune activation, including the attraction and activation of antigen presenting cells, and a cell death process that facilitates the activation of antigen presenting cells and their internalization and processing of dying tumor cell derivatives through underlying mechanisms that include ATP and HMGB1 release, and calreticulin exposure (Zitvogel et al 2010 and Obeid et. al.) 2007). The doxorubicin-containing microneedle arrays, or D-MNA, in development by us utilizes this immunogenic apoptosis by applying very low doses of doxorubicin via the D-MNA to basal cell lesions. Doxorubicin is not currently approved for the treatment of BCC.

Utility of Microneedle Arrays to Deliver Doxorubicin to Basal Cell Lesions

The D-MNA is a dissolvable, tip-loaded 15 x 15 mm microneedle array delivering doxorubicin to the tumor microenvironment for non-melanoma skin cancer therapy. The arrays are "pressed" into the skin where an appropriate-size lesion is growing and left on the lesion site for up to 30 minutes, allowing the microneedles to penetrate the skin, dissolve, and deliver defined quantities of doxorubicin to the lesion. The micro-needle array's main excipient is buffered carboxymethyl cellulose. Doses of 25 µg, 50 µg, 100 µg, or 200 µg of doxorubicin hydrochloride can be contained in the array's 400 microneedles. A device only array without doxorubicin hydrochloride but alike in every other respect ("C-MNA") has been fabricated for clinical testing and "device-only" for analytical testing.

The goal of our program is to demonstrate the D-MNA as a more robust alternative to the currently available non-surgical, and in many cases, surgical treatments for BCC.

Clinical Development of D-MNA:

Protocol SKNJCT-001 (Phase 1 Study)

Study Design: This study was designed as an open-label dose escalation trial of D-MNA in participants with BCC (subtype: superficial or nodular). The study followed a traditional 3+3 dose escalation design with 4 dose groups plus device only to define a maximum tolerated dose ("MTD") by evaluating DLTs. Treatments consisted of one application administered weekly, three times over a two-week period. The goal of the dose escalation was to determine the MTD and assess lesion responses in the different dose groups to inform a decision on the doses to be tested in a subsequent Phase 2 study.

The study was composed of a screening visit, three treatment visits at one-week intervals over a two-week period, an end of treatment visit, and three follow-up visits. The total duration for study recruitment was completed in approximately five to seven months. Individual participant participation was approximately up to 11 weeks (four weeks screening + seven weeks from the first treatment to the final follow up visit).

Escalation followed a traditional 3+3 design. Specifically, in each dose group n=3 participants were treated. If no DLTs were observed, the study was escalated to the next dose level. If DLTs had been observed in 2 or more participants, then the MTD would have been exceeded. If one DLT had been observed, an additional three participants would have been added at the same dose level. If no DLTs had been observed in the additional three participants, the study would have escalated to the next dose level. If DLTs had been observed in one or more of the three additional participants, the MTD would have been exceeded. The first two dose groups, device only and 25 µg, screened and enrolled subjects concurrently in the study.

SkinJect hypothesized that treatment with D-MNA would result in tumor destruction and the induction of potent, immunogenic anti-tumor responses. Because MNAs enable this agent to be delivered at very low doses to a confined tumor microenvironment, the study sponsor expected only minimal, if any, systemic drug toxicity; thus, facilitating optimal local dose levels and durable clinical responses.

The study design also included a device-only group (C-MNA). Inclusion of C-MNA allowed the evaluation of two questions:

- Tolerability: to assess if there was a cutaneous response to microneedle penetration that was independent of microneedle delivery of doxorubicin to the target tissue.
- Efficacy: to assess if a device only array could stimulate a non-specific immune response in reaction to microneedle penetration of the skin, and compare to the response with the active compound doxorubicin delivered by the D-MNA.

In addition, the clinical design also assessed the pre-established secondary efficacy endpoint described below.

- Secondary Endpoint: Lesion response as assessed by a central reader after the 3-week course of treatment to be categorized as either absence or presence of a complete response defined as no evidence of residual BCC in the resected specimen on histological examination.

Subject populations included adult males and females, 18+ years in general good health as assessed by the study's principal investigator. BCC (subtype: superficial or nodular) had to confirmed histologically by diagnostic shave biopsy at the screening visit. If previously confirmed, participants could only have diagnosed BCC via shave biopsy within 6 months of first study treatment. The disease had to be primary BCC (i.e., no previous treatment), and the lesion size was required to = 64 mm2 or 8 x 8 mm and = 169 mm2 or 13 x 13 mm, i.e., the entire lesion must be covered by 13 x 13 mm area of the array containing the microneedles. Laboratory values had to be within normal ranges.

Subjects were excluded from participation in this study if they had evidence of clinically significant, unstable medical conditions as assessed by the principal investigator; if they had an excisional biopsy performed on the lesion to be treated in this study; if they had recent therapy(ies) to the BCC treatment area; if they had recurrent BCC (previously treated) at the site presented for treatment; and if they previously demonstrated sensitivity to doxorubicin or carboxymethyl cellulose. Other reasons for exclusion included current active malignancies, metastatic disease, in other regions; pregnancy; and any other reason that the investigator deemed as prejudicial to the outcome of the study.

The investigational product is chemotherapeutic agent, doxorubicin (25 µg, 50 µg, 100 µg, or 200 µg) delivered to the basal layer of skin by a novel delivery system, a MNA. The delivery system is a square array 15 x 15 mm in dimension edge to edge. The dissolvable array of 400 microneedles is in a 13 x 13 mm area. The microneedles are 750 microns in length. Each MNA patch delivers 9.6 µL of drug product into the peri-epidermal space.

Conclusions: The Phase 1 study was designed as an open-label dose escalation trial of D-MNA in participants with BCC (subtype: superficial or nodular). The study followed a traditional 3+3 dose escalation design with 4 dose groups plus device only to define a MTD by evaluating DLTs. Treatments consisted of one application administered weekly, three times over a two-week period. The goal of the dose escalation was to determine the MTD and assess lesion responses in the different dose groups to inform a decision on the doses to be tested in a subsequent Phase 2 study. Of the 13 subjects enrolled, all 13 subjects completed the study and were included in all analysis populations; no subjects discontinued the study prematurely. Most subjects (8 of 13) were male, all subjects were White, and all but one subject were Non-Hispanic/Latino. Age range across the 13 subjects was 31 to 94 years.

The primary study endpoint was the assessment of DLT through Visit 4 (21 days) as defined using the LSR grading scale. No subjects reached DLT at any treatment assessment.

At screening, both the site and central reader were in agreement for 7 of 13 subjects (5 were considered nodular and 2 superficial at screening); however, for 6 subjects, the site and central reader assessments differed. For one subject (01-014), the Central Reader found no BCC present in the screening biopsy. Consultants reviewing the study results stated that multiple reasons could possibly be attributable, including human error misreading at the site, confusion of BCC with certain benign follicular tumors, and the presence of BCCs with both nodular and superficial components.

At the end of study, three subjects (01-001, device only; 01-008, D-MNA 25 µg and 01-011, D-MNA 50 µg) had differing results when Local/Site evaluation were compared to the Central Reader evaluation. In all three subjects, the Local/Site evaluation noted the presence of residual BCC compared to the Central Reader results which noted no residual BCC for all three subjects. It should be noted that the central reader was blinded to study treatment. In addition, another contributing factor to the noted differences may have been related to different slices of the tumor being evaluated by each of the readers; the local/site reader had the tissue sample obtained at the time of the excision, whereas the Central Reader tissue samples were sliced from the same block for each subject and stained several months later; the slides used in the Local/Site evaluation were not available for reading by the Central Reader.

For the secondary endpoint of BCC clinical response, evaluations were performed both at the local/site level as well as independently by a central reader. For the local/site assessment, complete lesion response was observed in one subject each for device only, D-MNA 25 µg, D-MNA 100 µg, and D-MNA 200 µg. For D-MNA 50 µg, no subjects were observed to have Complete Response. For the central reader assessment, histopathologic assessment showed six subjects (one device only, two D-MNA 25 µg, one D-MNA 50 µg, one D-MNA 100 µg, and one D-MNA 200 µg) with no residual BCC. A "complete response" was considered the absence of BCC in the final excision at 4 weeks. For the device only subject (001-003) although it was assessed as a clinical responder according to the local site assessment, the local PI noted a new squamous cell carcinoma in situ, but no residual basal cell carcinoma, that was also confirmed as squamous cell carcinoma in-situ by the Central Reader assessment of the end of study excision. Consultants stated that it could be difficult to tell by skin examination alone if there was residual BCC, and that a minority of subjects do not have any residual BCC after having had a biopsy, possibly due in part to local post-procedural inflammatory response.

For the exploratory endpoint of quantification of doxorubicin released by the MNAs, doxorubicin delivery was confirmed, but across all dose groups it was observed that there was inconsistent doxorubicin deposition by the MNAs.

For the secondary endpoint of local tolerance of the MNA, at post-MNA application, assessments indicated that subjects had mild to moderate erythema restricted to the treatment area, at each visit with each dose level, including device only. Flaking/scaling was minimal and isolated to the lesions. Crusting was generally absent or isolated. Swelling, vesiculation/pustulation, and erosion/ulceration were absent. Based on the proposed mechanism of action, some erythema evidencing an inflammatory reaction at the site of D-MNA application was to be expected.

For the secondary endpoint of pain assessment, for most subjects, no pain was noted. Some subjects experienced mild or moderate pain, generally at Visit 2 or Visit 3. At the Visit 4 End of Treatment assessment, no pain was noted for any subject.

Only two subjects reported a total of three adverse events ("AEs") in this study. All three AEs were considered mild in severity, and only one was considered probably related to study treatment mild application site pain that resolved the same day; this AE was associated with a low pain assessment scale score (1) at Visit 3. No deaths, serious adverse events, or AEs leading to treatment discontinuation were reported. No clinically significant abnormal findings were observed with regard to laboratory parameters, vital signs, ECGs, and physical examination.

The SKNJCT-001 study was designed to assess the safety of the D-MNA patch in patients with BCC. There were no serious adverse events nor any demonstrated alterations in any clinical measurements during the trial. The conclusion of the study was that D-MNA patch was well tolerated with no evidence of dose limiting toxicity.

The SKNJCT-001 study also had a pre-established secondary efficacy endpoint as described above. Six of the 13 patients were categorized as complete response by the central reader.

As a result, the clinical study report concluded that SKNJCT-001 study met both its primary and secondary endpoints.

Protocol SKNJCT-002 (Suspended Phase 1/Phase 2 Study)

This study was written by SkinJect, Inc. prior to its acquisition by the Company and submitted as part of the IND. The FDA approved this protocol in 2021. It was designed as a two-part study. The first part involved the enrollment of 15 healthy volunteers and was designed to study the penetration of device only-containing DMA patches at five different anatomic locations. After the first seven health volunteers were enrolled, due to the variability of array application observed by the investigator, SkinJect made the decision to pause the trial. The study was never resumed, and it was ultimately closed without further enrollment. There were no adverse events reported in the enrolled subjects.

Protocol SKNJCT-003 (Phase 2 Study)

Study Design: The clinical study, SKNJCT-003, is designed to be a randomized, double-blinded, three arm study evaluating two dose levels of microneedle-mediated delivery of doxorubicin (D-MNA) compared with a device-only control (C-MNA) in patients with nodular type of basal cell carcinoma (nBCC). It is multi-center study enrolling up to 90 subjects presenting with nodular type BCC of the skin. The study will evaluate the efficacy of two dose levels of D-MNA compared to C-MNA in patients with nodular BCC. The participants will be randomized 1:1:1 to one of three groups: a device only group receiving C-MNA, a low-dose group receiving 100µg of D-MNA, and a high-dose group receiving 200µg of D-MNA. The clinical design was initially submitted to the FDA in January 2024 to seek comments to revise and amend the IND and finalize the protocol. The FDA responded in March 2024 and requested additional clinical information. A final protocol was submitted to the FDA in July 2024, which included the information requested by the FDA, along with updated CMC, stability and sterility data. On July 31, 2024, the FDA responded to the latest submission and requested certain additional information and clarification. The Company responded to the FDA on August 2, 2024. Beginning August 13, 2024, the Company commenced activating its clinical trial sites and first participant was recruited on August 27, 2024. On March 6, 2025, the Company announced a positively trending interim analysis for its SKNJCT- 003 Phase 2 clinical study. The interim analysis showed the clinical study SKNJCT-003 is trending positively with a proportion of subjects with complete clinical clearance of more than 60%. The analysis also shows the investigational product, D-MNA was well tolerated for both dose levels, a low-dose group receiving 100ug of D-MNA and a high-dose group receiving 200ug of D-MNA in all participants enrolled in the study at that time, with no dose limiting toxicities (DLTs), or serious adverse events (SAEs). In addition, there were no systemic effects or clinically significant abnormal findings in laboratory parameters, vital signs, ECGs, and physical examination. The findings of the interim analysis were preliminary and may or may not correlate with the findings of the study once completed. On July 8, 2025, the Company submitted a comprehensive package to the FDA seeking a Type C meeting during the week of October 6, 2025. On August 21, 2025, the Company announced that the FDA accepted the Company's Type C Meeting request to formally discuss the D-MNA product development and gain further alignment on the clinical pathway. In September 2025, the FDA provided written responses to the Company's queries and agreed that the Company can rely on the 505(b)(2) regulatory pathway to treat BCC using D-MNA. On November 13, 2025, the Company announced that it received full regulatory and ethical approvals in the United Kingdom to expand its ongoing Phase 2 clinical study (SKNJCT-003) evaluating D-MNA for the non-invasive treatment of BCC. On November 17, 2025, the Company announced that it applied for an FDA Commissioner's National Priority Voucher in connection with SKNJCT-003. On December 15, 2025, the Company announced that its Phase 2 clinical study (SKNJCT-003) evaluating safety and efficacy of D-MNA and C-MNA to non-invasively treat nodular BCC of the skin, has successfully completed enrolment of ninety (90) patients in the United States.

Protocol SKNJCT-004 (Phase 2 Study)

On May 22, 2025, the Company announced that it has received study may proceed approval from the United Arab Emirates (UAE) Department of Health to commence Phase 2 clinical study (SKNJCT-004) to non-invasively treat BCC of the skin. The clinical study, SKNJCT-004, is designed to be a randomized, double-blind, three arm study evaluating two dose levels of microneedle-mediated delivery of doxorubicin (D-MNA) compared with a device-only control (C-MNA) in patients with BCC. It is a multi-center study enrolling up to 36 subjects presenting with BCC of the skin at four sites in the UAE. On September 8, 2025, the Company announced that the SKNJCT-004 phase 2 clinical study, to non-invasively treat BCC of the skin, commenced patient recruitment in Cleveland clinic Abu Dhabi. On October 22, 2025, the Company announced the enrollment of the first patient in its SKNJCT-004 Phase 2 clinical study evaluating a non-invasive treatment for BCC.

Patents and Proprietary Information

License Agreement with the University of Pittsburgh

SkinJect entered into an exclusive license agreement with the University of Pittsburgh on April 26, 2016 (as amended, the "License Agreement"). The License Agreement was amended on February 26, 2020 and on April 23, 2024.

The License Agreement covers products designed to deliver drugs and bioactive agents, such as, but not limited to doxorubicin, for the treatment of cancers and pre-cancerous lesions, but specifically excluding the treatment of in-transit melanoma. Such treatments may include, but are not limited to, the use of agents that stimulate an immune response, which is different from vaccines, where an immune response is provoked by presentation of an antigen (the "Field").

The term of the License Agreement runs until the expiration of the last claim of the Patent Rights listed in the License Agreement, which is projected to be November 6, 2035 and could be extended, unless terminated earlier (the "Term"). The University of Pittsburgh has the right to terminate the License Agreement if breaches are not cured within 30 days of our receipt of written notice thereof from the University of Pittsburgh or in certain insolvency-related situations or if we cease to carry out its business.

The License Agreement covers any product or part thereof or service which is (a) covered in whole or in part by an issued, unexpired or pending claim contained in the Patent Rights in the country in which any such product or part thereof is made, used or sold or in which any such service is used or sold; (b) manufactured by using a process or is employed to practice a process which is covered in whole or in part by an issued, unexpired claim or a pending claim contained in the Patent Rights in the country in which any such process that is included in Licensed Technology is used or in which such product or part thereof or service is used or sold; or (c) manufactured by or otherwise makes use of Know How (as defined below) (the "Licensed Technology").

The License Agreement also covers Know How that includes: (a) the University of Pittsburgh's IND Application 122488 for Microneedle Array (carboxymethylcellulose matrix) containing the active drug, doxorubicin for the treatment of cutaneous T-cell lymphoma, (b) experimental protocols, data, and any supporting materials relating to B16 Melanoma murine experiments comparing tumor growth over time for Microneedle Array -delivered chemo-immunotherapy for B16 melanoma, including control mice that did not receive any treatment and mice that were treated with doxorubicin incorporated into Microneedle Arrays, and (c) Response from the University of Pittsburgh for SkinJect's Know How Request provided April 29, 2016 and accompanying Batch Analysis documentation (the "Know How").

We have been granted an exclusive, worldwide license to make, have made, use and sell the Licensed Technology in the Field and to practice under the patent rights listed in the table below for the Term of the License. We have also been granted a non-exclusive worldwide license to practice under the Know How in the Field for the Term of the License.

The University of Pittsburgh has also granted to us an option to enter into a non-exclusive license in the Field to Future Intellectual Property Rights upon such terms and conditions as the parties may agree and which contain similar standard terms and conditions as contained hereunder to the extent not prohibited by law, regulation, or third-party obligations within sixty (60) days after University informs us that the clinical trial under the University of Pittsburgh's IND 122488 is closed and the final report for such clinical trial is completed ("Option Exercise"). Upon University's timely receipt of such written notice from us, the parties shall negotiate in good faith, which negotiations shall commence no later than sixty (60) days following Option Exercise and shall endeavor to enter into a definitive royalty-bearing license agreement as soon thereafter as reasonably possible. In furtherance of the foregoing, University has agreed to disclose from time to time at University's sole discretion to SkinJect Future Intellectual Property Rights until expiration of the option. Future Intellectual Property Rights are defined as specific Know How encompassed within the University of Pittsburgh's IND 122488 and/or deriving from studies conducted under such IND which the University of Pittsburgh owns or controls before or after the April 26, 2016.

The University of Pittsburgh and Carnegie Mellon University have retained a royalty-free, nonexclusive right to practice under the Patent Rights and to use the Licensed Technology for Non-Commercial Education and Research Purposes. Non-Commercial Education and Research Purposes are defined as the use of Patent Rights (including distribution of biological materials covered by the Patent Rights) in the Field for academic research or other not-for-profit scholarly purposes which are undertaken at a nonprofit or governmental institution that does not use the Patent Rights in the production or manufacture of products for sale or the performance of services for a fee. The license granted is subject to the rights of the U.S. government, if any, as set forth in 35 U.S.C. §200, et seq. The U.S. government may have acquired a nonexclusive, nontransferable, paid-up license to practice or have practiced for or on behalf of the United States the inventions described in the Patent Rights throughout the world. Pursuant to 35 U.S.C. §200, et seq. Licensed Technology produced for sale in the United States shall be substantially manufactured in the United States (unless a waiver under 35 U.S.C. §204 is granted by the appropriate U.S. government agencies).

We have the right to enter into sublicensing arrangements for the rights, privileges and licenses granted hereunder upon prior written approval of each sublicensee by the University of Pittsburgh, except that sublicensee shall not have rights to sublicense. Such sublicense agreements shall include a royalty rate upon sublicense Net Sales in an amount at least equal to the rate set forth in Article 5.1(c). Rights of any sublicensee shall terminate upon termination of this Agreement.

We are obligated to pay annual maintenance fees, which are non-refundable, non-creditable, and not to be prorated against any other payment or royalties due, in the amount of $5,000 until the first Net Sales occurs. we are further obligated to pay 15.0% of any execution fees, maintenance fees, milestone fees and all other non-royalty payments received by us from any of our sublicensees a share of Non-Royalty Sublicense Income.

Royalties are payable in an amount equal to 3.0% of Net Sales payable each calendar quarter with a minimum annual royalty of $50,000 per calendar year, but only to the extent such minimum royalty is greater than the aggregate annual royalty.

The License Agreement contains six milestones listed below:

1. Establish validated analytical methods related to licensed technology.

2. Submit IND application to FDA relating to licensed technology.

3. Raise $2.5 million of capital from investors or strategic partners (or combination thereof) in support of development or commercializing the licensed technology.

4. Submit a completed report to FDA of a Phase 2 trial of licensed technology or foreign equivalent.

5. Submit an NDA or foreign equivalent for a covered product under Licensed Technology.

6. First commercial sale of Licensed Technology within five years of submission of a NDA or foreign equivalent for a product covered under Licensed Technology.

The first four milestones have been achieved and noted as completed by the University of Pittsburgh on January 6, 2022.

Payments made to the University of Pittsburgh in connection with the License Agreement, including patent legal expense reimbursement, have amounted to $720,256 since April 2016. We expect the patent legal expense reimbursement to continue at an average of approximately $7,000 per month. Should sales commence in the future, royalties are payable to the University of Pittsburgh as described above.

Our failure to perform or to fulfill on a timely basis any one of the milestones set forth above shall be grounds for university to terminate this Agreement and upon termination all rights and interest to the Licensed Technology, Patent Rights, Know How, and Future Intellectual Property shall revert to university. Notwithstanding the foregoing, for a single time, if one of the milestones defined above has not been achieved within the required timeframe, through no fault of ours, and following best efforts of ours to meet the milestone, we shall be deemed to have fulfilled the milestone requirement if we make a payment of $50,000. In such case, in addition to the payment required, we shall negotiate with the University of Pittsburgh in good faith a new date for attainment of such missed milestone. If we fail to meet the revised milestone date, the University of Pittsburgh may terminate the License Agreement and upon termination all rights and interest to the Licensed Technology shall revert to the University of Pittsburgh.

Except as described above, there are no future milestone payments to be paid pursuant to the License Agreement.

We are in compliance with the License Agreement (after giving effect to such waivers and amendments as have been granted or entered into). The time taken to reach future milestones is dependent on several factors, not all of which are controlled by us. Although there can be no assurance that it will do so, we expect the University of Pittsburgh will grant any necessary future extensions to milestone requirements commensurate with our progress with its clinical development plan.

We have licensed three patent families from the University of Pittsburgh that include several granted U.S. patents and pending U.S. patent applications, as well as granted patents and pending patent applications in foreign jurisdictions, relating to microneedle arrays for delivering various drugs and bioactive agents to the skin, their use, and manufacture. The first patent family entitled "dissolvable microneedle arrays for transdermal delivery to human skin" includes 3 issued U.S. patents expiring in 2030 and 2031 claiming dissolvable microneedle arrays including a variety of bioactive components. This family also includes a pending U.S application. The second patent family entitled "Tip-loaded microneedle arrays for transdermal insertion" includes 1 issued U.S. patent expiring in 2033 claiming dissolvable microneedle arrays including one or more bioactive components. This family also includes issued patents in Australia, Canada, Japan and Mexico, India, and pending applications in the U.S., Australia, Brazil, China, Europe, Hong Kong, Japan, and Mexico. The third patent family entitled "Microneedle arrays for cancer therapy applications" includes issued patents in Canada and Israel, a pending U.S. patent application as well as pending patent applications in Australia, Canada, Europe, Japan, Korea and Singapore relating to the use of microneedle arrays comprising one or more bioactive agents for the treatment of various cancers, which if issued, would have a natural expiration in 2035. The table below summarizes the patents covered by the License Agreement, each of which is a utility patent.

Country Name	Title	Application No.	Priority Date	Filed Date	Patent No.	Issue Date	Projected Expiration Date	Status	Assignee(s)
United States	Dissolvable microneedle arrays for transdermal delivery to human skin	12/910,516	10/23/2009	10/22/2010	8,834,423	9/16/2014	6/14/2031	Issued	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
United States	Dissolvable microneedle arrays for transdermal delivery to human skin	16/861,112	10/23/2009	4/28/2020	11,744,927	9/5/2023	10/22/2030	Issued	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
United States	Dissolvable microneedle arrays for transdermal delivery to human skin	18/454,628	10/23/2009	8/23/2023	12,239,767	3/4/2025	10/22/2030	Issued	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University

Country Name	Title	Application No.	Priority Date	Filed Date	Patent No.	Issue Date	Projected Expiration Date	Status	Assignee(s)
United States	Dissolvable microneedle arrays for transdermal delivery to human skin	19/046,918	10/23/2009	2/6/2025			10/22/2030	Pending	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
United States	Tip-loaded microneedle arrays for transdermal insertion	14/398,375	5/1/2012	10/31/2014	9,944,019	4/17/2018	7/5/2033	Issued	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
Canada	Tip-loaded microneedle arrays for transdermal insertion	2871770	5/1/2012	5/1/2013	2871770	7/7/2020	5/1/2033	Issued	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
Mexico	Tip-loaded microneedle arrays for transdermal insertion	MX/a/2014/ 013234	5/1/2012	5/1/2013	370579	12/17/2019	5/1/2033	Issued	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
Australia	Tip-loaded microneedle arrays for transdermal insertion	2013256348	5/1/2012	5/1/2013	2013256348	9/28/2017	5/1/2033	Issued	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
India	Tip-loaded microneedle arrays for transdermal insertion	10161/DELNP /2014	5/1/2012	5/1/2013	555176	11/27/2024	5/1/2033	Issued	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
Europe	Tip-loaded microneedle arrays for transdermal insertion	22192026.7	5/1/2012	5/1/2013			5/1/2033	Pending	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University

Country Name	Title	Application No.	Priority Date	Filed Date	Patent No.	Issue Date	Projected Expiration Date	Status	Assignee(s)
Japan	Tip-loaded microneedle arrays for transdermal insertion	2017-078229	5/1/2012	5/1/2013	6712963	6/4/2020	5/1/2033	Issued	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
Canada	Tip-loaded microneedle arrays for transdermal insertion	3077452	5/1/2012	5/1/2013	3077452	8/9/2022	5/1/2033	Issued	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
Mexico	Tip-loaded microneedle arrays for transdermal insertion	MX/a/2018/ 009573	5/1/2012	5/1/2013			11/6/2035	Pending	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
Australia	Tip-loaded microneedle arrays for transdermal insertion	2017225155	5/1/2012	5/1/2013	2017225155	9/19/2019	5/1/2033	Issued	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
China	Tip-loaded microneedle arrays for transdermal insertion	202110125343.0	5/1/2012	5/1/2013			5/1/2033	Pending	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
United States	Tip-loaded microneedle arrays for transdermal insertion	18/119,197	5/1/2012	3/8/2023			5/1/2033	Pending	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
Brazil	Tip-loaded microneedle arrays for transdermal insertion	112014027242-5	5/1/2012	5/1/2013			5/1/2033	Pending	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University

Country Name	Title	Application No.	Priority Date	Filed Date	Patent No.	Issue Date	Projected Expiration Date	Status	Assignee(s)
Australia	Tip-loaded microneedle arrays for transdermal insertion	2021201365	5/1/2012	5/1/2013	2021201365	1/12/2023	5/1/2033	Issued	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
Japan	Tip-loaded microneedle arrays for transdermal insertion	2021-148376	5/1/2012	5/1/2013			5/1/2033	Pending	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
Australia	Tip-loaded microneedle arrays for transdermal insertion	2022291555	5/1/2012	5/1/2013			11/6/2035	Pending	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
Hong Kong	Tip-loaded microneedle arrays for transdermal insertion	42021044396.6	5/1/2012	5/1/2013			5/1/2033	Pending	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
Japan	Tip-loaded microneedle arrays for transdermal insertion	2023-175104	5/1/2012	5/1/2013			5/1/2033	Pending	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
Europe	Microneedle arrays for cancer therapy applications	15857785.8	11/6/2014	11/6/2015			11/6/2035	Pending	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
Canada	Microneedle arrays for cancer therapy applications	2967017	11/6/2014	11/6/2015	2967017	3/24/2020	11/6/2035	Issued	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University

Country Name	Title	Application No.	Priority Date	Filed Date	Patent No.	Issue Date	Projected Expiration Date	Status	Assignee(s)
Israel	Microneedle arrays for cancer therapy applications	252096	11/6/2014	11/6/2015	252096	10/2/2022	11/6/2035	Issued	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
United States	Microneedle arrays for cancer therapy applications	17/576,141	11/6/2014	1/14/2022			11/6/2035	Pending	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
Israel	Microneedle arrays for cancer therapy applications	293291	11/6/2014	11/6/2015	293291	2/1/2024	11/6/2035	Issued	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
Australia	Microneedle arrays for cancer therapy applications	2024256083	11/6/2014	11/6/2015			11/6/2035	Pending	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
Korea	Microneedle arrays for cancer therapy applications	10-2022-7039076	11/6/2014	11/6/2015			11/6/2035	Pending	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
Japan	Microneedle arrays for cancer therapy applications	2024189676	11/6/2014	11/6/2015			11/6/2035	Pending	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
Singapore	Microneedle arrays for cancer therapy applications	1002004900T	11/6/2014	11/6/2015			11/6/2035	Pending	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University
Korea	Microneedle arrays for cancer therapy applications	10-2024-7043044	11/6/2014	11/6/2015			11/6/2035	Pending	University Of Pittsburgh of The Commonwealth System of Higher Education/ Carnegie Mellon University

Antev:

On August 29, 2025, we completed the acquisition of 98.6% of the issued and outstanding shares of Antev, a clinical stage biotech company, developing Teverelix, a next generation GnRH antagonist, potentially as a first in market product for APC patients with high cardiovascular risk and patients with AURr episodes due to enlarged prostate.

Antev's flagship drug candidate is **Teverelix** trifluoroacetate (Teverelix TFA), a long-acting GnRH antagonist. Unlike GnRH agonists, which can cause an initial surge in testosterone levels, Teverelix directly suppresses sex hormone production without this surge, potentially reducing cardiovascular risks. This mechanism is particularly beneficial for patients with existing cardiovascular conditions. Teverelix is formulated as a microcrystalline suspension, allowing for sustained release and a six-week dosing interval, which may improve patient compliance and outcomes**.**

Clinical Development:

In September 2020 Antev completed a Phase 1 clinical trial in which Teverelix was shown to be well tolerated with no dose-limiting toxicities and demonstrated rapid testosterone suppression. The study included 48 healthy male volunteers. In February 2023 Antev also completed a Phase 2a study in fifty (50) patients with APC, where Teverelix achieved the primary endpoint of greater than 90% probability of castration levels of testosterone suppression (97.5%) but the secondary endpoint of maintaining this rate above 90% was not met with the probability dropping to 82.5% by Day 42.

In January 2023, the U.S. Food and Drug Administration (FDA), reviewed the Phase 1 and Phase 2a data and provided written guidance on Antev's proposed Phase 3 trial design for Teverelix. This milestone supports the Company's clinical plans to develop Teverelix as a treatment for advanced prostate cancer patients with increased cardiovascular risk. In December 2023, the FDA approved the Phase 2b study design in advanced prostate cancer covering 40 patients. In November 2024, the FDA approved the Phase 2b study design in acute urinary retention covering 390 patients.

1. **Antev Acute Urinary Retention (AURr) Indication**:

Teverelix is aiming to be the ***first-in-class indication*** product for preventing recurrence of AURr in males 45 years or older, who suffer from benign prostate hyperplasia (BPH). Antev has an FDA approved Phase 2b study designed to randomize 390 men after a successful trial without catheterization (TWOC). 85% of nearly one million annual AUR episodes in the United States occur in men 60+ who suffer from enlarged prostate that manifests with age and is followed by a recurrent episode within 6 months for approximately 30% of men.

Antev planned Phase 2b Study Design in Acute Urinary Retention*:*

Randomized controlled double blinded study in 390 men after a successful TWOC in 60-70 sites in United States and European Union. The participants shall receive either single intramuscular (IM) or subcutaneous (SC) injection (90mg or 120mg) or placebo in addition to standard therapy. Primary endpoint is a composite of AURr, need for surgery or poor urinary flow metrics in the first 28 weeks plus 24 weeks follow up.

2. Antev High Cardiovascular (CV) Risk Advanced Prostate Cancer indication:

Teverelix is aiming to be the ***best-in-class indication*** product for hormone therapy for APC patients with increased CV risk. Antev has an FDA approved Phase 2b open label study designed to recruit 40 men with advanced prostate cancer. Antev is targeting a niche in patients with CV risk, aiming to provide an androgen deprivation therapy (ADT) option with potentially lower cardiac toxicity than conventional GnRH agonists. If approved, Teverelix could become the first hormone therapy labeled specifically for treating prostate cancer in patients with a history of cardiovascular disease. 300,000 to 500,000 men in the United States are living with advanced stage prostate cancer.

Antev planned Phase 2b Study Design in Advanced Prostate Cancer

Open label study in 40 men with advanced prostate cancer suitable for ADT. The participants shall receive a loading dose of 180mg IM plus x2 180mg SC (total 540mg), followed by x2 180mg (360mg) SC day 29 and every 6 weeks. The total duration of the treatment is 22 weeks. Primary endpoint is to confirm castration rate by day 29, sustaining to day 155, probability greater than 90%.

Patents and Proprietary Information

Composition of matter patents for Teverelix have a natural expiration in 2039 and pending method of use patent applications, if issued, will have a natural expiration between 2044 and 2045, subject to any patent term adjustment that may be awarded. The table below summarizes the patents we hold for Teverelix, each of which is a utility patent.

Country Name	Title	Application No.	Priority Date	Filed Date	Patent No.	Issue Date	Projected Expiration Date	Status	Assignee (s)
United States	Composition for treating one or more estrogen related diseases	17/050,430	4/26/2018	10/23/2020	11,446,351	8/31/2022	4/25/2039	Issued	LifeArc
China	Composition for treating one or more estrogen related diseases	112041028	4/26/2018	4/25/2019			4/25/2039	Pending	Life Arc
Israel	Composition for treating one or more estrogen related diseases	277876	4/26/2018	4/25/2019			4/25/2039	Pending	LifeArc
Japan	Composition for treating one or more estrogen related diseases	2021522227	4/26/2018	4/25/2019			4/25/2039	Pending	LifeArc
Mexico	Composition for treating one or more estrogen related diseases	2020011341	4/26/2018	4/25/2019			4/25/2039	Pending	LifeArc

Country Name	Title	Application No.	Priority Date	Filed Date	Patent No.	Issue Date	Projected Expiration Date	Status	Assignee (s)
United States	Reconstitutable teverelix-TFA composition	17/254,859	7/5/2018	12/22/2020	11,633,453	4/5/2023	7/2/2039	Issued	Antev Limited
United States	Reconstitutable teverelix-TFA composition	18/122,991	7/5/2018	3/17/2023			7/2/2039	Pending	Antev Limited
Europe	Reconstitutable teverelix-TFA composition	18181931.9	7/5/2018	7/5/2018	3590524	11/4/2020	7/2/2039	Issued	Antev Limited
Europe	Reconstitutable teverelix-TFA composition	19740498.1	7/5/2018	7/2/2019	3817759	7/27/2022	7/2/2039	Issued	Antev Limited
Germany	Reconstitutable teverelix-TFA composition	19740498.1	7/5/2018	7/2/2019	3817759	7/27/2022	7/2/2039	Issued	Antev Limited
France	Reconstitutable teverelix-TFA composition	19740498.1	7/5/2018	7/2/2019	3817759	7/27/2022	7/2/2039	Issued	Antev Limited
Great Britain	Reconstitutable teverelix-TFA composition	19740498.1	7/5/2018	7/2/2019	3817759	7/27/2022	7/2/2039	Issued	Antev Limited
Sweden	Reconstitutable teverelix-TFA composition	19740498.1	7/5/2018	7/2/2019	3817759	7/27/2022	7/2/2039	Issued	Antev Limited
Canada	Reconstitutable teverelix-TFA composition	3142967	7/5/2018	7/2/2019			7/2/2039	Pending	Antev Limited
China	Reconstitutable teverelix-TFA composition	112423777	7/5/2018	7/2/2019			7/2/2039	Pending	Antev Limited
United States	Teverelix-TFA composition	17/254864	7/5/2018	7/2/2019	11,357,818	5/25/2022	7/2/2039	Issued	Antev Limited
United States	Teverelix-TFA composition	17/740,743	7/5/2018	5/10/2022	12,070,484	5/10/2022	7/2/2039	Issued	Antev Limited

Country Name	Title	Application No.	Priority Date	Filed Date	Patent No.	Issue Date	Projected Expiration Date	Status	Assignee (s)
Canada	Teverelix-TFA composition	3141519	7/5/2018	7/2/2019			7/2/2039	Pending	Antev Limited
China	Teverelix-TFA composition	112423775	7/5/2018	7/2/2019	112423775	3/15/2024	7/2/2039	Issued	Antev Limited
China	Teverelix-TFA composition	118161591	7/5/2018	7/2/2019			7/2/2039	Pending	Antev Limited
Europe	Teverelix-TFA composition	19739941.3	7/5/2018	7/2/2019	3817758	1/5/2022	7/2/2039	Issued	Antev Limited
Germany	Teverelix-TFA composition	19739941.3	7/5/2018	7/2/2019	3817758	1/5/2022	7/2/2039	Issued	Antev Limited
France	Teverelix-TFA composition	19739941.3	7/5/2018	7/2/2019	3817758	1/5/2022	7/2/2039	Issued	Antev Limited

Country Name	Title	Application No.	Priority Date	Filed Date	Patent No.	Issue Date	Projected Expiration Date	Status	Assignee (s)
Great Britain	Teverelix-TFA composition	19739941.3	7/5/2018	7/2/2019	3817758	1/5/2022	7/2/2039	Issued	Antev Limited
Sweden	Teverelix-TFA composition	19739941.3	7/5/2018	7/2/2019	3817758	1/5/2022	7/2/2039	Issued	Antev Limited
Europe	Teverelix-TFA composition	22150163.8	7/5/2018	7/2/2019			7/2/2039	Pending	Antev Limited
Japan	Teverelix-TFA composition	2021529165	7/5/2018	7/2/2019	7181318	11/30/2022	7/2/2039	Issued	Antev Limited
Japan	Teverelix-TFA composition	2025004006	7/5/2018	7/2/2019			7/2/2039	Pending	Antev Limited
United States	A lyophilization process and a Teverelix-TFA lyophilizate obtained thereby	17/255,372	7/5/2018	7/2/2019	11,719,488	7/19/2023	7/2/2039	Issued	Antev Limited
United States	A lyophilization process and a Teverelix-TFA lyophilizate obtained thereby	18/348,722	7/5/2018	7/7/2023			7/2/2039	Pending	Antev Limited
Canada	A lyophilization process and a Teverelix-TFA lyophilizate obtained thereby	3141521	7/5/2018	7/2/2019			7/2/2039	Pending	Antev Limited
China	A lyophilization process and a Teverelix-TFA lyophilizate obtained thereby	112423776	7/5/2018	7/2/2019	112423776	5/31/2024	7/2/2039	Issued	Antev Limited

Country Name	Title	Application No.	Priority Date	Filed Date	Patent No.	Issue Date	Projected Expiration Date	Status	Assignee (s)
Europe	A lyophilization process and a Teverelix-TFA lyophilizate obtained thereby	19742691.9	7/5/2018	7/2/2019	3817760	9/7/2022	7/2/2039	Issued	Antev Limited
Germany	A lyophilization process and a Teverelix-TFA lyophilizate obtained thereby	19742691.9	7/5/2018	7/2/2019	3817760	9/7/2022	7/2/2039	Issued	Antev Limited
France	A lyophilization process and a Teverelix-TFA lyophilizate obtained thereby	19742691.9	7/5/2018	7/2/2019	3817760	9/7/2022	7/2/2039	Issued	Antev Limited
Great Britain	A lyophilization process and a Teverelix-TFA lyophilizate obtained thereby	19742691.9	7/5/2018	7/2/2019	3817760	9/7/2022	7/2/2039	Issued	Antev Limited

Country Name	Title	Application No.	Priority Date	Filed Date	Patent No.	Issue Date	Projected Expiration Date	Status	Assignee (s)
Sweden	A lyophilization process and a Teverelix-TFA lyophilizate obtained thereby	19742691.9	7/5/2018	7/2/2019	3817760	9/7/2022	7/2/2039	Issued	Antev Limited
Japan	A lyophilization process and a Teverelix-TFA lyophilizate obtained thereby	2021529166	7/5/2018	7/2/2019	7177859	11/24/2022	7/2/2039	Issued	Antev Limited
WO	A dosage regime for use in the treatment of prostate cancer	2024079225	10/18/2023	10/16/2024			10/16/2044	Pending	Antev Limited
Germany	Composition for treating acute urinary retention	212018000251	6/30/2017	6/28/2018	212018000251	6/18/2020	6/28/2038	Issued	Antev Limited
China	Composition for treating acute urinary retention	110891607	6/30/2017	6/28/2018			6/28/2038	Pending	Antev Limited
Japan	Composition for treating acute urinary retention	2020525528	6/30/2017	6/28/2018			6/28/2038	Pending	Antev Limited
Canada	A composition comprising at least one GNRH antagonist	3051182	6/30/2017	1/30/2018	3051182	5/282024	6/30/2038	Issued	Antev Limited
China	A composition comprising at least one GNRH antagonist	110248679	6/30/2017	1/30/2018			6/30/2038	Pending	Antev Limited

Country Name	Title	Application No.	Priority Date	Filed Date	Patent No.	Issue Date	Projected Expiration Date	Status	Assignee (s)
Europe	A composition comprising at least one GNRH antagonist	18707414.1	6/30/2017	1/30/2018	3573663	4/7/2021	6/30/2038	Issued	Antev Limited
Germany	A composition comprising at least one GNRH antagonist	18707414.1	6/30/2017	1/30/2018	3573663	4/7/2021	6/30/2038	Issued	Antev Limited
France	A composition comprising at least one GNRH antagonist	18707414.1	6/30/2017	1/30/2018	3573663	4/7/2021	6/30/2038	Issued	Antev Limited
Great Britain	A composition comprising at least one GNRH antagonist	18707414.1	6/30/2017	1/30/2018	3573663	4/7/2021	6/30/2038	Issued	Antev Limited
Sweden	A composition comprising at least one GNRH antagonist	18707414.1	6/30/2017	1/30/2018	3573663	4/7/2021	6/30/2038	Issued	Antev Limited
Japan	A composition comprising at least one GNRH antagonist	2020506229	6/30/2017	1/30/2018	6990717	2/3/2022	6/30/2038	Issued	Antev Limited
Mexico	A composition comprising at least one GNRH antagonist	382676	6/30/2017	1/30/2018			6/30/2038	Pending	Antev Limited
South Africa	A composition comprising at least one GNRH antagonist	201904119	6/30/2017	1/30/2018			6/30/2038	Pending	Antev Limited

Collaborations:

Skinject™ Platform Expansion

In August 2025, the Company announced its entry into a non-binding memorandum of understanding (MoU) with Helix Nanotechnologies, Inc. (HelixNano), a Boston-based biotech company focused on developing a proprietary advanced mRNA platform, in respect of their shared mutual interest in the development or commercial arrangement contemplated by the MoU. The MoU is non-binding and shall not be construed to obligate either party to proceed with a joint venture or any further development or commercial arrangement, unless and until definitive agreements are executed, and there can be no assurance that such definitive agreements will be executed.

The Company is exploring co-development of thermostable infectious disease vaccines combining HelixNano's proprietary mRNA technology with the Medicus microneedle array delivery platform.

Patient Access and Advocacy

In October 2025, the Company announced a strategic collaboration with the Gorlin Syndrome Alliance (GSA) to advance compassionate access to SkinJect for patients suffering from Gorlin Syndrome, also known as nevoid basal cell carcinoma syndrome.

In collaboration with the Gorlin Syndrome Alliance, Medicus is pursuing an Expanded Access IND program to provide Gorlin Syndrome patients with multiple or inoperable BCCs access to SkinJect™, the Company's investigational D-MNAs, under physician supervision.

AI Enabled Clinical Development

In December 2025, the Company signed a non-binding letter of intent to collaborate with Reliant AI Inc., a decision-intelligence company specializing in generative AI for the life sciences, to develop an AI-driven clinical data analytics platform to support capital-efficient and time-efficient clinical development through data-driven dynamic clinical-site selection, pharmacodynamic (PD) informed patient stratification, and enrollment forecasting. The initial phase of the collaboration is expected to support the upcoming Teverelix clinical study planned for 2026. There can be no assurance that a definitive agreement will be executed or that the proposed collaboration will proceed as contemplated.

Recent Developments

SkinJect

On March 5, 2026, the company announced topline results from SKNJCT-003 evaluating safety and efficacy of the D-MNA and C-MNA to non-invasively treat nodular BCC of the skin. The dataset demonstrates that clearance rates increased between Day 29 and Day 57, consistent with continued biological activity over time. The 200µg cohort demonstrated the highest observed activity at Day 57, achieving 73% Clinical Clearance and 40% Histological Clearance (CR).

These results reflect the analysis of the primary and key secondary efficacy endpoints. Final compilation of the Clinical Study Report (CSR), including full safety analyses and procedural observations such as post-excisional biopsy site assessments, remains ongoing and is expected to be completed in Q2 2026. The Company does not anticipate material changes to the reported efficacy findings.

The Company believes the topline results are not only positive but decision-grade that should support an end of phase 2 (EOP2) meeting with the FDA. There can be no assurance that SKNJCT-003 will be granted regulatory approval from the FDA.

Teverelix

On January 12, 2026, the company announced that that detailed clinical data on Teverelix, its long-acting GnRH antagonist, have been accepted for e-Poster presentation at the American Association of Clinical Endocrinology Annual Meeting 2026, to be held April 22-24 in Las Vegas, Nevada. The Company's accepted abstract*: "Evaluation of Teverelix, a Long-Acting GnRH Antagonist: Pharmacokinetics, Pharmacodynamics, Bone Turnover and Safety in Two Phase 1 studies in Healthy Female Volunteers"* contains results from two randomized, placebo-controlled Phase I clinical studies involving 48 healthy premenopausal women, designed to evaluate how Teverelix is absorbed, how it suppresses reproductive hormones, its effects on bone turnover markers, and its overall safety following single subcutaneous injections.

On January 22, 2026, the Company announced that its subsidiary, Antev Ltd., has entered into Amendment No. 3 to its license agreement with LifeArc relating to Teverelix. Under the amended agreement, the royalty rate payable on worldwide net sales of Teverelix has been reduced from ~4% to 2%, with the royalty term clarified on a country-by-country basis in line with standard industry practice. The amendment does not alter the scope of the license, the underlying intellectual property, or the respective development responsibilities of the parties, and all other terms of the original agreement remain in full force and effect.

On February 10, 2026, the Company announced that it has received "study may proceed" clearance from the FDA to initiate its Phase 2b dose-optimization study of Teverelix.

Employees

As of the date of this annual report, including our subsidiaries, we have 16 employees, all of which are full-time employees.

Corporate information

Our executive offices are located at 300 Conshohocken State Rd., Suite 200, W. Conshohocken, PA 19428. We maintain a corporate website at www.medicuspharma.com. The information contained on or accessible through our corporate website or any other website that we may maintain is not part of this annual report.

Implications of Being an Emerging Growth Company

As a company with less than $1.235 billion in revenues during our last fiscal year, we qualify as an "emerging growth company" as that term is defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). As an emerging growth company we expect to take advantage of specified reduced reporting requirements that are otherwise applicable generally to public companies. These reduced reporting requirements include, but are not limited to:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended ("Sarbanes-Oxley Act");
- reduced disclosure about our executive compensation arrangements in our periodic reports, proxy statements and registration statements; and
- an exemption from the requirements to obtain a non-binding advisory vote on executive compensation or stockholder approval of any golden parachute arrangements.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1.235 billion or we issue more than $1 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. As an emerging growth company, we have elected to take advantage of certain of the reduced disclosure obligations in this annual report and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information in this annual report and that we provide to our shareholders in the future may be different than what you might receive from other public reporting companies in which you hold equity interests.

Implications of Being a Smaller Reporting Company

Additionally, we are a "smaller reporting company," meaning that the market value of our common shares held by non-affiliates is less than $700 million and our annual revenue is less than $100 million during the most recently completed fiscal year. As such, we are eligible for exemptions from various reporting requirements applicable to other public companies that are not smaller reporting companies, including, but not limited to, reduced disclosure obligations regarding executive compensation. We may continue to be a smaller reporting company as long as either (i) the market value of our common shares held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our common shares held by non-affiliates is less than $700 million.

Implications of Regulatory Environment

The production and manufacture of the Products and their research and development activities for use in the United States are subject to regulation for safety, efficacy and ethics by various governmental authorities in the United States. These authorities regulate research, development, testing, manufacturing, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing and import/export of pharmaceutical products, among other things. In the United States drugs and biological products are subject to regulation by the FDA.

Drug approval laws in the United States generally require licensing of manufacturing facilities, carefully controlled research and testing of products, government review and approval of results prior to marketing and sale of drugs and drug delivery products. In addition, they require adherence to best practices as defined by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, as well as national guidelines. The process for pharmaceutical development and approval are subject to inherent risks, described in "*Risk Factors*."

The principal steps generally required for approval of drug and drug delivery products in the United States and rest of the world are described below.

Preclinical Toxicology Studies

Preclinical studies are conducted *in vitro* and in animals to evaluate toxicokinetics and pharmacokinetics to provide evidence of the safety and bioavailability of the product prior to its administration to humans in clinical studies and throughout development. Such studies compliant with FDA guidelines have been completed.

Human Testing

The process of conducting clinical trials with a new drug product generally cannot begin until a company has submitted to the appropriate regulatory authorities an application to do so and the required number of days have lapsed without objection from the applicable regulatory authority. (In certain jurisdictions, a no objection letter or approval may be required before the clinical trial can proceed). In the United States, this application is called an investigational new drug study, or "IND", and in Canada and most European countries, a clinical trial application, or "CTA."

For the United States, the sponsor of the study must submit the results of the non-clinical tests, manufacturing information, analytical data and available clinical data or literature, within the IND, to the FDA. Some information may be omitted from the IND in instances where prior FDA findings of safety or efficacy of a drug product are being relied upon. Even once the IND is submitted, non-clinical testing may continue to occur. An IND becomes effective automatically 30 days after receipt of the document by the FDA, unless within that time the FDA raises concerns or questions, in which case a clinical hold may be put in place until the concerns are adequately addressed by the study sponsor with the FDA.

Two key factors influencing the rate of progression of clinical trials are the rate at which patients can be enrolled to participate in the research program and whether effective treatments are currently available for the disease that the drug is intended to treat. Patient enrollment is largely dependent upon the incidence and severity of the disease, the treatments available and the potential side effects of the drug to be tested and any restrictions for enrolment that may be imposed by regulatory agencies. For further information see "*Risk Factors*."

Phase 1 Clinical Trials

Phase 1 clinical trials are typically conducted, on a small number of individuals (healthy volunteers or patients), to determine safety, dose limiting toxicities, tolerability, pharmacokinetics and to determine dose ranging for Phase 2 clinical trials in humans.

Phase 2 Clinical Trials

Phase 2 clinical trials typically involve a larger patient population than is required for Phase 1 and are conducted to evaluate the safety and efficacy of a drug candidate in patients having the disease for which the drug is indicated. This phase also serves to identify possible common short-term side effects and risks.

Phase 3 Clinical Trials

Phase 3 clinical trials typically involve tests in a much larger population of patients suffering from the targeted condition or disease. These studies involve controlled and/or uncontrolled testing in an expanded patient population (several hundred to several thousand patients) at geographically dispersed test sites to establish clinical safety and effectiveness. These trials also generate information from which the overall risk-benefit relationship relating to the drug can be determined.

Marketing Application

Upon successful completion of Phase 3 clinical trials, the sponsor company assembles all the non-clinical, clinical and manufacturing data and submits a marketing application to the applicable regulatory authority for their review in order to obtain approval to sell the drug.

Before the applicable regulatory authority approves the marketing application, they will initiate an inspection of the facility or facilities where the product is manufactured. Products will not be approved unless there is compliance with Good Manufacturing Practices, or "GMP." Approval will occur if the inspection is satisfactory and the marketing application contains data that provides substantial evidence that the drug is safe and effective in the studied indication. In addition to manufacturing inspections, the regulatory authority will typically inspect one or more clinical sites to assure compliance with Good Clinical Practices.

The testing and approval process for a new drug candidate requires substantial time, effort and financial resources, and may take several years to complete. Data obtained from non-clinical and clinical testing are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Approval may not be granted on a timely basis, or at all.

Even if a regulatory authority approves a product candidate, the relevant authority may limit the approved indications for use, require specific contraindications, warnings or precautions be included in the product label, including a black box warning, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms. For example, the FDA may require a Risk Evaluation and Mitigation Strategy ("REMS"), (also known as a Risk Management Plan ("RMP") in Europe) as a condition of, or following, approval to mitigate any identified or suspected serious risks and ensure safe use of the drug. The REMS or RMP could include medication guides, physician communication plans, assessment plans, and elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. A REMS or RMP could materially affect the potential market and profitability of the product. A regulatory authority may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional label claims, are subject to further testing requirements, notification, and regulatory authority review and approval. Further, should new safety information arise, additional testing, product labeling or regulatory notification may be required.

Regulation of Combination Products in the United States

Certain products may be comprised of components, such as drug components and device components that would normally be subject to different regulatory frameworks by the FDA and frequently regulated by different centers at the FDA. These products are known as combination products. Under the FDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a drug-device combination product is attributable to the drug product, the FDA center responsible for premarket review of the drug product would have primary jurisdiction for the combination product. The FDA has also established an Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute.

A combination product with a primary mode of action attributable to the drug component generally would be reviewed and approved pursuant to the drug approval processes set forth in the FDCA. In reviewing the new drug application for such a product, however, FDA reviewers could consult with their counterparts in the device center to ensure that the device component of the combination product met applicable requirements regarding safety, effectiveness, durability and performance. In addition, under FDA regulations, combination products are subject to current GMP requirements applicable to both drugs and devices, including the Quality System Regulations applicable to medical devices.

Implications of Healthcare Laws and Regulations

Coverage and Reimbursement

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, the product. In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In the United States, Medicare tends to have a greater role than private insurers in determining reimbursement for the treatment of conditions, such as basal cell cancer, that disproportionately affect patients over the age of 65.

Applicable Laws in the United States

If we obtain FDA approval for the Products and begin commercializing the Products in the United States, our operations may be directly, or indirectly through our future potential customers and third-party payors, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act ("FCA"), and data privacy and physician sunshine laws and regulations. These laws or their relevant foreign counterparts may impact, among other things, our proposed sales, marketing, and education programs and its relationships with healthcare providers, physicians and other parties through which we market, sell and distribute its products for which it obtains marketing approval. In addition, we may be subject to patient privacy regulation by the federal government and the states in the United States as well as other jurisdictions. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual, or the purchase, lease, order, arrangement, or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. The term remuneration has been interpreted broadly to include anything of value. Further, courts have found that if "one purpose" of remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. Violations are subject to significant civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, a claim submitted for payment to any federal healthcare program that includes items or services that were made as a result of a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers, among others, on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;

- the federal civil and criminal false claims laws, including the FCA, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs; knowingly making, using, or causing to be made or used, a false record or statement material to a false, fictitious or fraudulent claim or an obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government. A claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim under the FCA. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring qui tam actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery or settlement. When an entity is determined to have violated the FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- the federal *Health Insurance Portability and Accountability Act of 1996* ("HIPAA") which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA fraud provisions without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by the *Health Information Technology for Economic and Clinical Health Act of 2009*, or "HITECH", and their respective implementing regulations, which impose, among other things, certain requirements relating to the privacy, security and transmission of individually identifiable health information on certain covered healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their respective "business associates," those independent contractors or agents of covered entities that create, receive, maintain, transmit or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws, including but not limited to: (i) *General Data Protection Regulation* (European Union); (ii) the *Personal Information Protection and Electronic Documents Act* (Canada); and (iii) *Personal Information Protection Act* (Canada), which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;

- the federal *Physician Payments Sunshine Act*, created under the *Patient Protection and Affordable Care Act,* as amended by the Health Care and Education Reconciliation Act of 2010, and its implementing regulations, which require manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS, information related to direct or indirect payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made in the previous year to certain non-physician providers such as physician assistants and nurse practitioners;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous U.S. state, local and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers and may be broader in scope than their federal equivalents; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and other relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information, some of which may be more stringent than those in the United States (such as the European Union, which adopted the General Data Protection Regulation, which became effective in May 2018) in certain circumstances, and may differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Healthcare Reform

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

There have been a number of proposals during the last few years regarding the pricing of pharmaceutical products, limiting coverage and the amount of reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States. For example, in March 2010, the ACA was enacted in the United States, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States and significantly affected the pharmaceutical industry. The ACA, among other things, subjected biologic products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program (the "MDRP"), are calculated for drugs and biologics that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the MDRP, extended manufacturer Medicaid rebate obligations to utilization by individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs and biologics, and established a new Medicare Part D coverage gap discount program. Since its enactment, there have been judicial, congressional, and executive branch challenges to the ACA, which have resulted in delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. The first Trump administration issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA**.** In addition, there were a number of health reform initiatives by the Biden administration that have impacted the ACA. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act (the "IRA") into law, which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. In addition, the IRA imposes new manufacturer financial liability on certain drugs under Medicare Part D, allowing the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition, subject to certain exemptions applicable to orphan drugs. It is possible that the ACA will be subject to judicial or congressional challenges in the future. It is unclear how such challenges, and the healthcare reform measures of the Biden administration, will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011 ("Budget Control Act") was signed into law, which, among other things, resulted in reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2032. In certain countries outside the United States, reimbursement for products that have not yet received marketing authorization may be provided through national managed access programs.

Moreover, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Presidential executive orders, congressional inquiries, and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. The IRA, among other things, (i) directs the U.S. Department of Health and Human Services ("HHS") to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions took effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first ten drugs that were subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. HHS will select up to fifteen additional drugs covered under Part D for price negotiation in 2025. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center, which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs using march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of march-in eights, which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

We expect that the ACA, the IRA, and any other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products, if approved.

Further, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the Governmental Accounting Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the recall and withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products or require safety surveillance or patient education. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials and the drug approval process. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or comparable foreign regulatory authorities more likely to terminate or suspend clinical trials before completion or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their products. Such scrutiny has resulted in several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Several regulations have also been proposed partly in response to several executive orders issued by President Trump during his first term related to prescription drug pricing that seek to implement several of the administration's proposals. While some of these and other measures may require additional authorization to become effective, Congress has indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Previous administrations have issued multiple executive orders seeking to reduce prescription drug costs, and the current Trump administration has signaled that lowering the cost of prescription drugs is a top priority.

Changing regulatory environments could negatively impact our business.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Many European Economic Area ("EEA") Member States periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in the EEA Member States will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some EEA Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. Health Technology Assessment ("HTA") of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EEA Member States, including those representing the larger markets. The HTA process is the procedure to assess the therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EEA Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States.

In December 2021, Regulation No. 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted in the European Union. This Regulation, which entered into force in January 2022 and will apply as of January 2025, is intended to boost cooperation among EEA Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at European Union level for joint clinical assessments in these areas. The Regulation foresees a three-year transitional period and will permit EEA Member States to use common HTA tools, methodologies, and procedures across the European Union, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EEA Member States will continue to be responsible for assessing non-clinical (*e.g.*, economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EEA Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the European Union could be negatively affected.

Legislators, policymakers and healthcare insurance funds in the European Union may continue to propose and implement cost-containing measures to keep healthcare costs down. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of European Union and other foreign countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

Risk Factors Summary

Our business is subject to numerous risks and uncertainties, including those highlighted in "Item 1A. Risk Factors." These risks include, but are not limited to, risks associated with:

- our financial results, including our ability to generate earnings and achieve and sustain profitability (as of December 31, 2025, we had an accumulated deficit of approximately $64.3 million, which was comprised of approximately $12.4 million of accumulated deficit of SkinJect as of September 30, 2023, the day after it became a subsidiary of the Company, and approximately $51.9 million of deficit accumulated by the Company on a consolidated basis), may vary significantly from forecasts and from period to period;
- the progress, timing and completion of our research, development and preclinical studies and clinical trials for our products and product candidates
- we may not successfully integrate Antev into our business and operations or successfully develop Teverelix;
- our ability to market, commercialize, achieve market acceptance for and sell our products and product candidates, our ability to develop, manage and maintain our direct sales and marketing organizations;
- our ability to continue as a going concern and if we are unable to obtain additional financing from outside sources and/or eventually generate enough revenues, we may be forced to curtail or discontinue our operations;
- our estimates regarding anticipated operating losses, future revenues, capital requirements and our needs for additional financing;
- market risks regarding consolidation in the healthcare, pharmaceutical and biotech/life sciences industry;

- the willingness of healthcare providers to purchase our products if coverage, reimbursement and pricing from third party payors for procedures using our products significantly declines;
- our ability to adequately protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- the fact that product quality issues or product defects may harm our business, any product liability claims; and
- the regulatory, legal and certain operating risks that our operations subject us to.

Item 1A. Risk Factors.

An investment in our securities involves a high degree of risk. You should consider carefully all of the risks described below, together with all other information contained in this annual report, including the financial statements, before making an investment decision. If any of the following risks actually occur, our business, financial condition and results of operations could be materially and adversely affected. In that event, the trading price of our securities could decline, and you may lose part or all of your investment. This annual report also contains forward-looking information that involves risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of many factors, including the risks described below and elsewhere in this annual report.

Risks Relating to Our Business

We have a limited operating history, which may make it difficult to evaluation our current business and predict our future performance.

We have a limited operating history and, in particular, no history of earnings; we have not paid any dividends and we are unlikely to pay any dividends in the immediate or foreseeable future. Our success will depend to a large extent on the expertise, ability, judgement, discretion, integrity and good faith of our management.

As we are at an early stage of product development, we have not generated revenues to date. We expect to spend a significant amount of capital to fund research and development and clinical trials. As a result, we expect that our operating expenses will increase significantly and, consequently, we will need to generate significant revenues to become profitable. We cannot predict when, if ever, we will be profitable. Even if we do become profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis. There can be no assurances that our products will be capable of being produced in commercial quantities at reasonable costs, or be successfully marketed.

We have a novel technology with uncertain market acceptance.

The Products are at an early stage of development, with uncertain market acceptance. Product approval, should this be achieved, does not infer that the Products will garner a good market price or be reimbursed by public or private insurers. Further, there are no guarantees that the Products will be positively received by the target patient population. The acceptability of the Products to regulators, payors and patients will depend on the relative risk versus benefit of the Products as proven in clinical trials, the acceptability of the price, and the relative attractiveness as compared to other treatments.

We could also suffer the consequences of non-compliance or breaches by licensors in connection with any license agreements we may enter into in the future. Such non-compliance or breaches by such third parties could in turn result in breaches or defaults under any agreements with other collaboration partners, and we could be found liable for damages or lose certain rights, including rights to develop and/or commercialize the Products. Loss of our rights to any license granted to us in the future, or the exclusivity rights provided therein, could harm our financial condition and operating results.

The University of Pittsburgh may terminate our license agreement in certain circumstances.

The License Agreement is our main asset and the basis for the development of SkinJect™. The University of Pittsburgh of the Commonwealth System of Higher Education (the "University of Pittsburgh") has the right to terminate the License Agreement if breaches are not cured within 30 days of our receipt of notice thereof from the University of Pittsburgh or in certain insolvency-related situations or if we cease to carry out our business. There can be no assurance that we will be able to comply with the License Agreement going forward or that the University of Pittsburgh will grant any necessary waivers if we are unable to do so. The obligations under the License Agreement principally require the trial of SkinJect™ on specified timelines. If the University of Pittsburgh were to terminate the License Agreement our assets would essentially be rendered worthless and it would have a material adverse effect on our ability to pursue our business objective.

We may not successfully integrate Antev into our business and operations or successfully develop Teverelix.

On August 29, 2025, we completed the Antev Transaction and acquired 98.6% of the issued and outstanding shares of Antev. We may not be able to successfully integrate Antev's business into our business and operations or develop its assets acquired pursuant to the Antev Transaction, including Teverelix, and may not otherwise realize the expected benefits of the transaction. Difficulties in integrating Antev's rights into our operations may result in the Company performing differently than expected, in operation challenges or in the failure to realize anticipated benefits in the time frame or at all. Difficulties in developing Teverelix, including challenges associated with clinical trials, product approvals, bringing Teverelix to market (and receiving positive reception or obtaining favorable pricing if Teverelix is brought to market), may have an material adverse effect on our results of operations.

The integration of Antev and the development of Teverelix may result in material challenges, including the diversion of management's attention from ongoing business concerns, including the development of SkinJect™; retaining key employees; the possibility of faulty assumptions underlying expectations regarding the integration process and associated expenses; consolidating corporate and administrative infrastructures and eliminating duplicative operations; retaining existing research, business and operational relationships; coordinating geographically separate organizations; difficulties in the assimilation of employees and corporate cultures; unanticipated issues in integrating information technology, communications and other systems; and unforeseen expenses related to the integration. If we are not successful in integrating Antev, the benefits currently anticipated from the acquisition of Antev, our results of operations, cash flows and financial condition may be materially adversely affected.

Certain of our intellectual property is held under third-party licenses.

Certain of our intellectual property is held under a third-party license and we may require additional third-party licenses to effectively develop and manufacture our key products or future technologies. There can be no assurance as to the availability or cost of such additional licenses. A substantial number of patents have already been issued to other biotechnology and pharmaceutical companies. To the extent that valid third-party patent rights cover our products or services, we or our strategic collaborators would be required to seek licenses from the holders of these patents in order to manufacture, use or sell these products and services, and payments under them would reduce our profits from these products and services. It is not possible to predict the extent to which we may wish or be required to acquire rights under such patents, the availability and cost of acquiring such rights, and whether a license to such patents will be available on acceptable terms or at all. There may be patents in the United States or in foreign countries or patents issued in the future that are unavailable to license on acceptable terms. Our inability to obtain such licenses may hinder or eliminate an ability to manufacture and market products.

If we breach any of the agreements under which we license rights to intellectual property, we could lose license rights that are important to our business. Our current license agreement may not provide an adequate remedy for any breach by the licensor.

For information on the License Agreement, see "Item 1. Business - Patents and Proprietary Information."

Our technology may not be successful for its intended use.

Although the SkinJect Phase 1 study indicated that the patch is well-tolerated, there is no guarantee that the Phase 2 study will produce similar results or that SkinJect™ will ultimately be brought to market or, if it does, that it will be positively received or obtain favorable pricing, which would have a material adverse effect on our results of operations. In addition, there is no guarantee that the open and planned Phase 2b studies involving Teverelix will be successfully or that Teverelix will ultimately be brought to market, or, if it does, that it will be positively received or obtain favorable pricing, which would have a material adverse effect on our business plans and results of operations.

Substantial doubt exists about the Company's ability to continue as a going concern and if the Company is unable to obtain additional financing from outside sources and/or eventually generate enough revenues, it may be forced to curtail or discontinue its operations.

The Company's current auditor has indicated in its report accompanying the Company's audited annual financial statements that substantial doubt exists about the Company's ability to continue as a going concern. The Company is in the preliminary stages of its planned operations and has not yet determined whether its processes and business plans are economically viable. The continued operations of the Company and the recoverability of amounts shown for certain operational expenses in the Company's audited annual financial statements are dependent upon the ability of the Company to obtain sufficient financing to commercialize its product and to become profitable, all of which are uncertain. Importantly, the inclusion in the Company's financial statements of a going concern opinion may negatively impact the Company's ability to raise future financing and achieve future revenue. If the Company is unable to obtain additional financing from outside sources and/or eventually generate enough revenues, the Company may be forced to cut costs, by among other things, curtailing or discontinuing its operations. These measures could cause significant delays or entirely prevent the Company's continued efforts to commercialize its current or future products, which are critical to the realization of its business plan and the future operations of the Company. If any of these events happens, the Company's investors could lose all or part of their investments. In addition, the Company's financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern.

Future technology will require regulatory approval, which is costly and we may not be able to obtain it and we may fail to obtain regulatory approvals or only obtain approvals for limited uses or indications.

Market authorization of the Products falls under the regulatory purview of the FDA and other equivalent regulatory bodies worldwide. There can be no assurance that these regulatory bodies will approve the Products in the manner or time frame suggested. Although we intend to work with regulatory consultants and third parties knowledgeable in the area, we cannot ensure that the Products will obtain market authorization in a timely manner, or at all. Market authorization may also be contingent on a less competitive product label, which would negatively impact revenue.

Changes in methods of manufacturing or formulation may result in additional costs or delay.

As the Products are developed through further clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause the Products to perform differently and affect the results of future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of the Products and jeopardize our ability, or our strategic partners' ability, to commence product sales and generate revenue.

The manufacture of the Products is complex. We or our third-party manufacturers may encounter difficulties in production. If we encounter any such difficulties, our ability to supply the Products for clinical trials or, if approved, for commercial sale could be delayed or halted entirely.

The manufacture of biopharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. The processes of manufacturing the Products are susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, contamination and inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in the Products or in the manufacturing facilities in which the Products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Any adverse developments affecting manufacturing operations for the Products, if any are approved, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

We rely on external contract research organizations to provide clinical and nonclinical research services and agreements with these organizations of which one agreement is currently in place.

The outsourcing of functions to contract research organizations involves the risk that third party providers may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. If any contract research organization fails to comply with applicable regulatory requirements, the research and data generated may be deemed unreliable to regulatory authorities. Additional pre-clinical and clinical trials may be required before approval of marketing applications will be given. We cannot provide assurance that all third-party providers will meet the regulatory requirements for research and pre-clinical trials. Failure of third-party providers to meet regulatory requirements could result in repeat pre-clinical and clinical trials, which would delay the regulatory approval process or result in termination of pre-clinical and clinical trials. Any of the foregoing could have a material adverse effect on our business, prospects, results of operations and financial condition.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell the Products, if approved, we may be unable to generate any product revenue.

To successfully commercialize the Products, we will need to build out sales and marketing capabilities, either on our own or with others. The establishment and development of our own commercial team or the establishment of a contract field force to market the Products will be expensive and time-consuming and could delay launch. Moreover, we cannot be certain that we will be able to successfully develop this capability. We may seek to enter into collaborations with other entities to use their established marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If any current or future collaborators do not commit sufficient resources to commercialize the Products, or we are unable to develop the necessary capabilities on our own, we may be unable to generate sufficient revenue to sustain our business. We may compete with many companies that currently have extensive, experienced and well-funded marketing and sales operations to recruit, hire, train and retain marketing and sales personnel. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

We rely on key personnel.

Our success depends in large measure on certain key personnel, including our chairman & chief executive officer, Dr. Raza Bokhari. The loss of the services of such key personnel could have a material adverse effect on us. The contributions of these individuals to our operations have been, and are expected to continue to be, of central importance. In addition, the competition for qualified personnel in the biotech industry is intense and there can be no assurance that we will be able to continue to attract and retain all personnel necessary for the development and operation of our business. Investors must rely upon the ability, expertise, judgment, discretion, integrity and good faith of our management. Other biotechnology companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than those that we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate of and success with which we can develop and commercialize the Products would be limited.

As a technology-driven company, intellectual input from key management and personnel is critical to achieve our business objectives. Consequently, our ability to retain these individuals and attract other qualified individuals is critical to our success. The loss of the services of key individuals might significantly delay or prevent achievement of our business objectives. In addition, because of a relative scarcity of individuals with the high degree of education and scientific achievement required for our business, competition among biotech companies for qualified employees is intense and, as a result, we may not be able to attract and retain such individuals on acceptable terms, or at all.

SkinJect also has or may have relationships with scientific collaborators at academic and other institutions, some of whom conduct research at SkinJect's request or assist SkinJect in formulating the SkinJect's research and development strategies. These scientific collaborators are not SkinJect employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, even though SkinJect's collaborators are required to sign confidentiality agreements prior to working, they may have arrangements with other companies to assist such other companies in developing technologies that may prove competitive to us.

Incentive provisions for our key executives include base salary and the granting of stock options that vest over time, designed to encourage such individuals to stay with us. However, a low share price could render such agreements of little value to our key executives. In such event, our key executives could be susceptible to being hired away by our competitors who could offer a better compensation package. If we are unable to attract and retain key personnel our business, financial conditions and results of operations may be adversely affected.

We may not be able to successfully execute our business strategy.

The execution of our business strategy poses many challenges and is based on a number of assumptions. If we experience significant regulatory delays, supply chain disruptions, cost overruns on our programs, or if our business plan is more costly than we anticipate, certain research and development activities may be delayed or eliminated, resulting in changes or delays to our commercialization plans, or we may be compelled to secure additional funding (which may or may not be available) to execute our business strategy. We cannot predict with certainty future revenues or results from operations. If the assumptions on which our revenue or expenditure forecasts are based change, the benefits of our business strategy may change as well.

We will require additional financing in the future, which may not be available on favorable terms or at all.

The development of our business is expected to require additional financing. Failure to obtain sufficient financing may result in the delay or indefinite postponement of our business plans. The initial primary source of funding available to us consists of equity financing. There can be no assurance that additional capital or other types of financing will be available if needed or that, if available, the terms of such financing will be favorable to us.

The ongoing volatility in global capital markets has generally made the raising of capital by equity or debt financing more difficult. Access to financing has been negatively impacted by ongoing global economic risks and increased inflation. We will require substantial additional funds for further research and development, and the marketing and sale of our technology. We may attempt to raise additional funds for these purposes through public or private equity or debt financing, collaborations with other therapeutic companies, government grants or other sources. There can be no assurance that additional funding or partnerships will be available on terms acceptable to us and which would foster the successful commercialization of the Products. If additional funds are raised through further issuances of equity or convertible debt securities, existing shareholders could suffer significant dilution, and any new equity securities issued could have rights, preferences and privileges superior to those of the common shares or terms superior to those of the existing warrants. Any debt financing secured in the future could involve restrictive covenants relating to capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital or to pursue business opportunities, including potential acquisitions. If adequate funds are not obtained, we may be required to reduce, curtail or discontinue operations.

We have had negative operating cash flows since inception and expect to incur losses for the foreseeable future.

We have had negative cash flow from operating activities and have incurred operating losses since its inception. We anticipate that we will continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates, prepare for and begin to commercialize any approved product candidates and add infrastructure and personnel to support our product development efforts and operations as a public company. The net losses and negative cash flows incurred to date, together with expected future losses, have had, and likely will continue to have, an adverse effect on our shareholders' deficit and working capital. As of December 31, 2025, we had an accumulated deficit of approximately $64.3 million, which was comprised of approximately $12.4 million of accumulated deficit of SkinJect as of September 30, 2023, the day after it became a subsidiary of the Company, and approximately $51.9 million of deficit accumulated by the Company on a consolidated basis). The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

To the extent that we have negative operating cash flow in future periods, we may need to allocate a portion of our cash reserves to fund such negative cash flow. We may also be required to raise additional funds through the issuance of equity or debt securities. There can be no assurance that we will be able to generate positive cash flow from our operations or that additional capital or other types of financing will be available when needed or on terms favorable to us.

We are in a highly competitive industry which is continuously evolving with technological changes.

We are engaged in an industry that is highly competitive, evolving and characterized by technological change. As a result, it is difficult for us to predict whether, when and by whom new competing technologies or new competitors may enter the market. We face competition from companies with strong positions in certain markets we are currently targeting, and in new markets and regions we may enter. Some of these companies have significantly greater financial, technical, human, research and development, and marketing resources than us. We cannot assure that we will be able to compete effectively against current and future competitors who may discover and develop products in advance of us that are more effective than those developed by us. As a consequence, our current and future technologies may become obsolete or uncompetitive, resulting in adverse effects on revenue, margins and profitability. In addition, competition or other competitive pressures may result in price reductions, reduced margins or loss of market share, any of which could have a material adverse effect on our business, financial condition or results of operations. To the extent that new or improved pharmaceutical drug treatments are introduced that demonstrate better long-term efficacy and safety, patients and physicians may further delay the introduction of patches, such as SkinJect™, if approved, in the non-melanoma skin cancer treatment continuum or delay the use of Teverelix for the treatment of for the treatment of cardiovascular high-risk prostate cancer patients and patients with first AUR episodes due to an enlarged prostate. SkinJect™ could also face competition from other formulations or devices that deliver chemotherapeutic agents on an extended basis.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staffs and experienced commercial and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products or drug delivery technologies that are more effective or less costly than the Products.

We believe that our ability to compete effectively depends upon many factors both within and beyond our control, including:

- the usefulness, ease of use, performance and reliability of our technology compared to our competitors;
- the activity and tolerability of the Products, including relative to marketed products and product candidates in development by third parties;
- the ability to distinguish safety and efficacy from existing, alternative therapies;
- the timing for the Products to complete clinical development and receive market approval;
- acceptance of the Products by patients, physicians and other health providers;
- our ability to monetize our technology;
- the selection of licensing partners for our technology with the necessary skills and resources to drive uptake;
- our marketing and selling efforts;

- our financial condition and results of operations;
- the ability to maintain a good relationship with regulatory authorities;
- the price of our future products, including in comparison to branded or generic competitors;
- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans;
- acquisitions or consolidations within our industry, which may result in more formidable competitors;
- our ability to protect our intellectual property rights,
- our ability to attract, retain and motivate talented employees;
- our ability to cost-effectively manage and grow our operations; and
- our reputation and brand strength relative to that of our competitors.

Our future success will depend on our ability to continually enhance and develop the Products.

There is a broad pipeline of potential new therapies that may compete with the Products. The market is characterized by rapid technological change and the possibility of frequent new product introductions. Accordingly, our future success depends upon our ability to enhance the Products and to develop, introduce and sell the most accurate products at competitive prices. The development of new technologies and products involves time, substantial costs and risks. Our ability to successfully develop new technologies depends in large measure on our ability to maintain a technically skilled research and development staff and to adapt to technological changes and advances in the industry.

The success of new product introductions depends on a number of factors including the efficacy and safety as demonstrated in clinical trials, the ability to demonstrate the impact of real world evidence, timely and successful product development, the timing and market introduction of competitive products, market acceptance, the effective management of purchase commitments and inventory levels in line with anticipated product demand, the availability of pharmaceutical components in appropriate quantities and costs to meet anticipated demand, the risk that new products may have quality or other defects in the early stages of introduction and our ability to manage distribution and production issues related to new product introductions, the clinical indications for which the product is approved, acceptance by physicians, the medical community and patients of the product as a safe and effective treatment, the ability to distinguish safety and efficacy from existing, less expensive alternative therapies, the convenience of prescribing, administrating and initiating patients on the product, the potential and perceived advantages and/or value of the product over alternative treatments, the cost of treatment in relation to alternative treatments, including any similar generic treatments, the availability of coverage and adequate reimbursement by third-party payors and government authorities to support the product's pricing, the prevalence and severity of adverse side effects and the effectiveness of sales and marketing efforts.

If we are unable, for any reason, to enhance, develop, introduce and sell new products in a timely manner, or at all, in response to changing market conditions or customer requirements or otherwise, our business would be harmed.

If we are unable to differentiate SkinJect™ from existing therapies for treatment of skin cancer or Teverelix from therapies for high cardiovascular risk advanced prostate cancer patients or from treatment of recurrent AUR ("AURr") episodes, or if the FDA or other applicable regulatory authorities approve generic products that compete with the Products, the ability to successfully commercialize the Products would be adversely affected.

It is possible that we will receive data from additional clinical trials in respect of either or both of SkinJect™ and Teverelix, or in a post marketing setting from physician and patient experiences with the commercial products, that does not continue to support such interpretations. It is also possible that the FDA, physicians and healthcare payers will not agree with our interpretation of existing and future clinical trial data. If we are unable to demonstrate the value of the Products based on clinical data, patient experience, as well as real world evidence, the opportunity for the Products to maintain premium pricing and be commercialized successfully would be adversely affected.

Additionally, the FDA or other applicable regulatory authorities may approve other generic products that could compete with the Products if we cannot adequately protect it with our patent portfolio. For example, in the United States, once an NDA is approved, the product covered thereby becomes a "listed drug" which can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application ("ANDA"). The Federal Food, Drug, and Cosmetic Act (the "FDCA"), FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient(s), dosage form, strength, route of administration, conditions of use, or labeling as our product candidate and that the generic product is bioequivalent to us, meaning it is absorbed in the body at the same rate and to the same extent as the Products. These generic equivalents, which must meet the same quality standards as branded pharmaceuticals, would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product is typically lost to the generic product. Accordingly, competition from generic equivalents to our products would materially adversely impact our ability to successfully commercialize the Products.

A variety of risks associated with potential international business relationships could materially adversely affect our business.

We may enter into agreements with third parties for the development and commercialization of the Products in international markets. If we do so, we would be subject to additional risks related to entering into international business relationships, including:

- differing regulatory requirements in other countries including, among others, marketing approval, pricing, reimbursement and sales and marketing practices;
- potentially reduced protection for intellectual property rights;
- potential for so-called parallel importing, which is when a local seller, faced with higher local prices, opts to import goods from a foreign market with lower prices, rather than buying them locally;
- unexpected changes in tariffs, trade barriers and regulatory requirements, including the imposition of new tariffs by the U.S. government on imports to the U.S. and/or the imposition of retaliatory tariffs by foreign countries;
- economic weakness, including inflation, or political instability in foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees traveling and working abroad;
- foreign taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other risks incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad or supply chain disruptions; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, tsunamis, hurricanes and fires.

These and other risks may materially adversely affect our ability to develop and commercialize products in international markets and may harm our business.

Collaboration arrangements we may enter into in the future may not be successful.

We may seek future partnerships, collaborations and other strategic transactions to maximize the commercial potential of the Products. We may enter into such arrangements on a selective basis depending on the merits of retaining commercialization rights for ourself as compared to entering into selective collaboration arrangements with leading pharmaceutical or biotechnology companies, both in the United States and internationally. We face competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we choose to enter into such arrangements. The terms of any collaborations or other arrangements that we may establish may not be favorable to us.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators.

Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations.

Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters could lead to delays in the development process or commercialization of our product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority.

Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration could adversely affect us financially and could harm our business reputation.

We have and may in the future acquire businesses or products, or form strategic alliances in the future, and we may not realize the benefits of such acquisitions or alliances.

We have, and in the future may, acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction. In addition, we may require significant additional funds to either acquire such businesses or products or to commercialize them, which may result in significant dilution to shareholders or the incurrence of significant indebtedness by us.

We do not have any customer commitments.

We may negotiate clinical and/or commercial supply agreements for the Products or product sub-components. At the time of this annual report, there are no commitments from customers for the Products. Because we do not have any contracts for the Products, management may not accurately predict future revenue streams and there may be no assurance that customers would continue to use our products, or that we would be able to replace departing potential customers with new potential customers that provide us with comparable revenue.

Our business and operations would suffer in the event of computer system failures, cyberattacks, or a deficiency in our cyber security.

Despite the implementation of security measures, our internal computer systems, and those of the third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our commercialization or further development of our technology. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development or the commercialization of our products could be delayed or disrupted.

We may fail to manage growth successfully which may adversely impact operating results.

Our failure to manage our growth successfully may adversely impact our operating results. Our ability to manage growth will require us to continue to build our operational, financial and management controls, contracting relationships, marketing and business development plans and controls and reporting systems and procedures. Our ability to manage our growth will also depend in large part upon a number of factors, including the ability for us to rapidly:

- expand our internal and operational and financial controls significantly so that we can maintain control over operations;
- attract and retain qualified technical personnel in order to continue to develop reliable and flexible products and provide services that respond to evolving customer needs;
- build a sales team to keep customers and channel partners informed regarding the technical features issues and key selling points of our products and services;
- develop support capacity for customers as sales increase; and
- build a channel network to create an expanding presence in the evolving marketplace for our products and services.

An inability to achieve any of these objectives could harm our business, financial condition and results of operations.

Any products we develop will be subject to extensive, lengthy and uncertain regulatory requirements, which could adversely affect the ability to obtain regulatory approval in a timely manner, or at all.

It is understood that pharmacologic therapies are subject to an extensive, lengthy and unpredictable regulatory approval process by the FDA and equivalent regulatory bodies in other countries. This entails significant investment in time and resources, with no guarantee on the outcome or timeframe. We may encounter significant delays or excessive costs in our efforts to secure necessary market authorizations. Even if approved, the different regulatory bodies have numerous regulations governing the manufacturing, labeling, distributing, marketing, promotion and advertising after product approval. The regulatory requirements governing new technologies might be subject to change, and the products themselves may be subject to substantial review by the FDA and/or other governmental regulatory authorities that could prevent or delay approval of these products. Regulatory constraints ultimately imposed on our products, if approved, could limit our ability to commercialize, thus impacting on our financial condition and results.

Manufacture and marketing of the Products is subject to government regulation. In most countries, we will be required to complete extensive non-clinical studies and clinical trials to demonstrate the safety and efficacy of the Products in order to apply for regulatory approval to market the product. Prior to marketing approval in the United States, required steps include non-clinical (animal and laboratory) testing; performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the Products in the intended target population; performance of a consistent and reproducible manufacturing process intended for commercial use; and successful filing and approval of an NDA. These processes are costly and the timeframe and success are uncertain and may be out of our control. We also have no control over the extent of approval, which can be restricted to specific jurisdictions and/or conditions on the product label and limit our revenues.

Once approved, we will be subjected to continuing regulatory review, including adverse event reporting requirements and the FDA's general prohibition against promoting products for unapproved uses. We may also have other forms of post approval commitments, such as clinical trials or enhanced safety reporting and commitments. Failure to comply with any post-approval requirements can have consequences including warning letters, product seizures, recalls, substantial fines, injunctions, withdrawal of approvals, operating restrictions and criminal prosecutions. Any of these enforcement actions, any unanticipated changes in existing regulatory requirements or the adoption of new requirements, or any safety issues that arise with any approved products, could negatively impact on our ability to market products and generate revenues and thus our ability to continue our operations.

We also may be restricted or prohibited from marketing or manufacturing a product, even after obtaining product approval, if previously unknown problems with the product or our manufacturer are subsequently discovered. Moreover, we cannot provide assurance that newly discovered or developed safety issues will not arise following any regulatory approval. If our product is used by a large patient population, serious adverse events may occur from time to time that initially may seem unconnected to the treatment, and only when it repeatedly occurs over a period of time does the treatment become suspect as having a causal relationship to the adverse event. Any safety issues could cause us to suspend or cease marketing of our approved products, possibly subject us to substantial liabilities, and adversely affect our ability to generate revenues.

We may not be able to obtain marketing approval.

Even if we complete the necessary non-clinical studies and clinical trials, the marketing approval process is expensive, time-consuming, and uncertain and may prevent us from obtaining approvals for the commercialization of the Products. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, the Products, and our ability to generate revenue will be materially impaired.

We rely on the protection of intellectual property rights.

Our commercial success depends to a significant degree upon our ability to develop new or improved technologies, instruments and products, and to obtain patents or other intellectual property rights or statutory protection for these technologies and products in Canada, the United States and other countries, such as the countries in the European Union and Asia. We intend to patent concepts, components, processes, industrial designs and methods, and other inventions and technologies that we consider having commercial value or that will likely give us a competitive advantage. Despite devoting resources to the research and development of proprietary technology, we may not be able to develop new technology that is patentable or protectable. Further, patents issued to us, if any, could be challenged, held invalid or unenforceable, or be circumvented and may not provide us with necessary or sufficient protection or a competitive advantage.

In addition, despite our efforts to protect and maintain our patents competitors and other third parties may be able to design around our patents, if so awarded, or develop products similar to our products that are not within the scope of such patents. Finally, patents provide certain statutory protection only for a limited period of time that varies depending on the jurisdiction and type of patent. The statutory protection term of our licensed SkinJect^{TM} patents expire between 2030 and 2035 and the statutory term of Antev's issued U.S. patents expire in 2039 (between 2044 and 2045 with respect to certain pending patent applications that have yet to issue) and, thereafter, the underlying technology of such patents will be allowed to be used by any third party, including our competitors. Moreover, the inventions covered by patents may be free to be used in countries for which there is no patent protection. A number of our competitors and other third parties have been issued patents, or may have filed patent applications, or may obtain additional patents or other intellectual property rights for technologies similar to those that we have developed, used or commercialized, or may develop, use or commercialize, in the future. As certain patent applications in the United States and other countries are maintained in secrecy for a period of time after filing, and as publication or public awareness of new technologies often lags behind actual discoveries, we cannot be certain that we have been the first to develop the technology covered by our pending patent applications. In addition, the disclosure in our patent applications, including in respect of the utility of our claimed inventions, may not be sufficient to meet the statutory requirements for patentability in all cases. As a result, we can provide no assurance that our patent applications will result in valid or enforceable patents.

Prosecution and protection of the rights sought in patent applications and patents can be costly and uncertain, often involve complex legal and factual issues and consume significant time and resources. In addition, the breadth of claims allowed in our future patents, their enforceability and our ability to protect and maintain them cannot be predicted with any certainty. The laws of certain countries may not protect intellectual property rights to the same extent as the laws of Canada or the United States Even if our patents are held to be valid and enforceable in a certain jurisdiction, any legal proceedings that we may initiate against third parties to enforce such patents will likely be expensive, take significant time and divert management's attention from other business matters. We can provide no assurance that any of our pending patent applications will provide any protectable, maintainable or enforceable rights or competitive advantages to it.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

Once granted, patents may remain open to invalidity challenges including opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked or may lose the allowed or granted claims altogether.

In addition, the degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- others may be able to make product that is similar to product candidates we intend to commercialize that is not covered by the patents that we own;
- we, or any collaborators might not have been the first to make or reduce to practice the inventions covered by the issued patents or pending patent applications that we own;
- we or any collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; and we may not develop additional proprietary technologies that are patentable;
- third parties performing manufacturing or testing for us using our products or technologies could use the intellectual property of others without obtaining a proper license;
- parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;
- we may not develop additional proprietary technologies that are patentable;
- we may not be able to obtain and maintain necessary licenses on commercially reasonable terms, or at all; and
- the patents of others may harm our business.

Should any of these events occur, they could significantly harm our business and results of operations. We can provide no assurance that we will be successful in protecting, maintaining or enforcing our intellectual property rights. If we are not successful in protecting, maintaining or enforcing our intellectual property rights, then our business, operating results and financial condition could be materially adversely affected.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of Canada and the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences.

To the extent that we have obtained or are able to obtain patents or other intellectual property rights in any foreign jurisdictions, it may be difficult for us to stop the infringement of our patents or the misappropriation of other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the availability of certain types of patent rights and enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

Many countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

Guidelines and recommendations published by various organizations can reduce the use of products that we may commercialize.

Government agencies promulgate regulations and guidelines directly applicable to us and our products. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the healthcare and patient communities with respect to specific products. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines that do not recognize our future products, suggest limitations or inadequacies of our future products, or suggest the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers, could result in decreased use or adoption of our future products.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our technology and products..

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining, defending, maintaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, and may diminish our ability to protect our inventions, obtain, maintain, enforce and protect our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our future owned and licensed patents. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the "AIA"), could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future issued patents. On September 16, 2011, the AIA was signed into law. The AIA includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the AIA, the United States transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent application will be entitled to the patent. The AIA also includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, re-define prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the U.S. Patent and Trademark Office ("USPTO") during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, PGR, IPR and derivation proceedings.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our licensors' ability to obtain new patents and patents that we or our licensors might obtain in the future. We cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse change in the patent laws of other jurisdictions could also adversely affect our business, financial condition, results of operations and prospects.

Further, the AIA also includes significant changes in the way patent applications will be prosecuted and may also affect patent litigation. These include allowing third parties to submit prior art during patent prosecution by the USPTO, and additional procedures to attack the validity of a patent in post-grant proceedings including opposition, derivation, re-examination, inter partes review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

Patent reform legislation in the United States, including the AIA, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The AIA was signed into law on September 16, 2011, and includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third -party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. After March 15, 2013, under the AIA, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications, our ability to obtain future patents, and the enforcement or defense of our issued patents, all of which could harm our business, financial condition, results of operations and prospects.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our owned patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. The statutory protection term of patents of our licensed SkinJect^{TM} patents expire between 2030 and 2035 and the statutory term of Antev's issued U.S. patents expire in 2039 (between 2044 and 2045 with respect to certain pending patent applications that have yet to issue) and, thereafter, the underlying technology of such patents will be allowed to be used by any third party, including our competitors. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, in June 2023, a new unitary patent system was introduced, which will significantly impact European patents, including those granted before the introduction of the system. Under the unitary patent system, after a European patent is granted, the patent proprietor can request unitary effect, thereby getting a European patent with unitary Effect (the "Unitary Patent"). Each Unitary Patent is subject to the jurisdiction of the Unitary Patent Court (the "UPC"). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC may be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of the new unitary patent system.

If we do not obtain protection under the Hatch-Waxman Amendments by obtaining data exclusivity, our business may be harmed.

Our commercial success will largely depend on our ability to obtain market exclusivity in the United States and other countries with respect to our drug candidates and their target indications. Depending upon the timing, duration and specifics of FDA marketing approval of our drug candidates, certain of our product candidates may be eligible for marketing exclusivity. The FDCA provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages, dosage forms or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and prohibits the FDA from approving an ANDA, or a 505(b)(2) NDA submitted by another company with overlapping conditions associated with the new clinical investigations for the three-year period. Clinical investigation exclusivity does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. The three-year exclusivity will not delay the submission or approval of an NDA for the same drug. However, an applicant submitting an NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

If we are unable to obtain such marketing exclusivity for our product candidates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products and launch their product earlier than might otherwise be the case.

Risk of reduced or eliminated patent protection from non-compliance with regulatory requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedurals, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in unenforceability, invalidity, abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in unenforceability, invalidity, abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or any future licensors fail to maintain the patents and patent applications covering the Products, our competitive position would be adversely affected.

We may infringe the intellectual property rights of others.

Our commercial success depends, in part, upon it not infringing or violating intellectual property rights owned by others. The industry in which we compete has participants that own, or claim to own, intellectual property. We cannot determine with certainty whether any existing third-party patents, or the issuance of any new third-party patents, would require us to alter our technologies or products, obtain licenses or cease certain activities, including the sale of certain products.

We may in the future receive claims from third parties asserting infringement and other related claims. Litigation may be necessary to determine the scope, enforceability and validity of third-party intellectual property rights or to protect, maintain and enforce our intellectual property rights. Some of our competitors have, or are affiliated with companies having, substantially greater resources than we have, and these competitors may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we can. Regardless of whether claims that it is infringing or violating patents or other intellectual property rights have any merit, those claims could:

- adversely affect our relationships with current or future distributors and dealers of our products;
- adversely affect our reputation with customers;
- be time-consuming and expensive to evaluate and defend;
- cause product shipment delays or stoppages; divert management's attention and resources;
- subject us to significant liabilities and damages;
- require us to enter into royalty or licensing agreements; or
- require us to cease certain activities, including the sale of products.

If it is determined that we have infringed, violated or is infringing or violating a patent or the intellectual property right of any other person or if we are found liable in respect of any other related claim, then, in addition to being liable for potentially substantial damages, we may be prohibited from developing, using, distributing, selling or commercializing certain of our technologies and products unless we obtain a license from the holder of the patent or other intellectual property right. We can provide no assurance that we will be able to obtain any such license on a timely basis or on commercially favorable terms, or that any such licenses will be available, or that workarounds will be feasible and cost-efficient. If we do not obtain such a license or find a cost-efficient workaround, our business, operating results and financial condition could be materially adversely affected and we could be required to cease related business operations in some markets and restructure our business to focus on our continuing operations in other markets.

Our general liability insurance expires in October 2026. There can be no assurance that we will be able to renew our liability insurance on favorable terms or at all.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might harm our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is or may be relevant to or necessary for the commercialization of our product candidates in any jurisdiction. Patent applications in the United States and elsewhere are not published until approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. In addition, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Therefore, patent applications covering our products could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our products.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our products that are held to be infringing. We might, if possible, also be forced to redesign products or services so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

We may become involved in lawsuits to protect or enforce our patents or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe or otherwise violate our patents or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. As a result, we cannot predict with certainty how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court. Further, even if we prevail against an infringer in U.S. district court, there is always the risk that the infringer will file an appeal and the district court judgment will be overturned at the appeals court and/or that an adverse decision will be issued by the appeals court relating to the validity or enforceability of our patents. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of written description or statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as *ex parte* reexaminations, *inter partes* review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates.

We may not be able to detect or prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could harm the price of our securities.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities and have a harmful effect on the success of our business.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could adversely impact the price of our securities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials and internal research programs. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development collaborations that would help us commercialize our product candidates, if approved.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our shareholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

The issuance of a patent does not give us the right to practice the patented invention. A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our product candidates. Third parties may also have blocking patents that could prevent us from marketing our products or practicing our own patented technology. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our drug candidates, in which case we would be required to obtain a license from these third parties on commercially reasonable terms. Such a license may not be available, or it may not be available on commercially reasonable terms, in which case our business would be harmed.

The risks described elsewhere pertaining to our intellectual property rights also apply to any intellectual property rights that we may in-license, and any failure by us or our potential licensors to obtain, maintain, defend and enforce these rights could harm our business. In some cases we may not have control over the prosecution, maintenance or enforcement of the patents that we may license, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and our potential licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents.

We may be subject to claims arising from consultants or contractors misappropriating intellectual property.

Many of our consultants and contractors were previously or are concurrently employed at or engaged by biotechnology companies, and/or other pharmaceutical companies, including our competitors or potential competitors, or academic research institutions. Some of these consultants and contractors, including each member of our senior management or our other employees, may have executed proprietary rights, nondisclosure and non-competition agreements in connection with such previous or concurrent employment. We may be subject to claims that we or our consultants and contractors have used or disclosed the intellectual property and other proprietary information or know-how or trade secrets of others in their work for us. Litigation may be necessary to defend against these claims. We are not aware of any threatened or pending claims related to these matters or concerning agreements with our senior management, or other of our employees, consultants and contractors, but litigation may be necessary in the future to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, or personnel or access to consultants and contractors. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while our policy is to require our consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we expect to rely on third parties to manufacture our product candidates, and we expect to continue to collaborate with third parties on the development of our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Further, adequate remedies may not exist in the event of unauthorized use or disclosure. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may harm our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Policing unauthorized use of our intellectual property is difficult, expensive and time-consuming, and we may be unable to determine the extent of any unauthorized use. Moreover, enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for our product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Trade secrets are difficult to protect, and we have limited control over the protection of trade secrets used by our collaborators and suppliers. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may unintentionally or willfully breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. We would expect any trade secret dispute to be governed by federal law, and the Defend Trade Secrets Act ("DTSA") of 2016. However, in the event we are not able to utilize the DTSA, we would then be limited to resolving such a dispute in state court. State trade secret laws in the United States vary, and state courts are sometimes less willing to protect trade secrets. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

The increasing use of artificial intelligence ("AI") and machine learning in drug discovery and development introduces new and evolving risks that could harm our business and competitive position.

The increasing use of AI and machine learning in drug discovery and development introduces new and evolving risks related to ownership, inventorship, and protection of intellectual property generated by or with the assistance of AI technologies. Regulatory and legal frameworks governing AI-generated inventions are still developing and may create uncertainty regarding our ability to secure and enforce rights in such inventions.

We use hazardous chemicals and biological materials in their business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our product manufacturing, research and development, and testing activities involve the controlled use of hazardous materials, including chemicals and biological materials. We cannot eliminate the risks of accidental contamination or the accidental discharge of these materials, or any resulting injury from such an event. We may be subjected to litigation for any injury that results from our use or the use by third parties of these materials, and our liability may exceed our insurance coverage and our total assets. Our use, manufacture, storage, handling and disposal of these hazardous materials and specified waste products, as well as the discharge of pollutants into the environment and human health and safety matters, are governed by federal, state, provincial and local legislation. We are also subject to various laws and regulations relating to safe working conditions, laboratory and manufacturing practices. Our operations may require that environmental permits and approvals be issued by applicable government agencies, which can be costly and time-consuming to attain. These regulations and legislation can change, or new ones come into place, due to future legislative or administrative actions. These events could cause us to incur additional expense or restrict our operations. Compliance with environmental laws and regulations, current or future, may be expensive and prohibitive for our research, development or production efforts. Failure to comply could incur substantial costs and liabilities, including civil or criminal fines and penalties, clean-up costs or capital expenditures to achieve and maintain compliance.

If product liability lawsuits are brought against us then we may incur substantial liabilities and may be required to limit commercialization of the Products, if approved, and any other future products.

We face a potential risk of product liability as a result of distribution of our product candidate for testing and commercialization of the Products. For example, we may face claims if use of the Products allegedly cause injury or are found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in product quality, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourself against product liability claims, we may incur substantial liabilities or be required to limit commercialization of the product subject to such claims. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for current and future products;
- injury to our reputation;
- costs to defend any related litigation;
- diversion of management's time and our resources;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- inability to commercialize the Products and other products, if approved;
- decline in our share price; and
- exposure to adverse publicity.

Although we currently have general liability insurance in place, we do not know whether the limits of the insurance will be sufficient to satisfy any claims should they arise. We may not have sufficient resources to pay for any liabilities resulting from a claim excluded from or beyond the limits of, our insurance coverage. If we cannot successfully defend ourselves against a product liability claim, we may incur substantial liabilities.

Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading, which could significantly harm our business.

We are exposed to the risk that employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in fraudulent or other illegal activity, fraud or other misconduct. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the law and regulations of the FDA and non-U.S. regulators, including those laws that require the reporting of true, complete and accurate information to the FDA and non-U.S. regulators, (ii) healthcare fraud and abuse laws and regulations in the United States and elsewhere and (iii) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct in violation of these laws may also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by our executives, employees, consultants and other third parties, and any precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourself or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in national healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We rely on trade secrets to protect our proprietary technological advances and know-how, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our consultants, contractors, outside scientific collaborators, sponsored researchers and other advisors, including the third parties we rely on to manufacture the product, to protect our trade secrets and other proprietary information. However, any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets.

Accordingly, these agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. In addition, others may independently discover our trade secrets and proprietary information. Failure to obtain or maintain trade secret protection could enable competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse effects upon our competitive business position and financial results.

Lawsuits relating to intellectual property infringement will be costly and time consuming.

We may be required to initiate litigation to enforce or defend our intellectual property rights. These lawsuits can be very time consuming and costly. There is a substantial amount of litigation involving patent and other intellectual property rights in the pharmaceutical industry generally. Such litigation or proceedings could substantially increase our operating expenses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

In infringement litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information and trade secrets could be compromised by disclosure during litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are resolved. Further, any claims we assert against a perceived infringer could provoke these parties to assert counterclaims against us alleging that we have infringed their patents. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

In addition, our patents and patent applications could face other challenges, such as interference proceedings, opposition proceedings, reissue, *inter partes* review, re-examination proceedings, third-party submissions of prior art, and other forms of post-grant review. Any of these challenges, if successful, could result in the invalidation of, or in a narrowing of the scope or preventing the issuance of, any of our patents and patent applications subject to challenge. Any of these challenges, regardless of their success, would likely be time consuming and expensive to defend and resolve and would divert our management and scientific personnel's time and attention.

In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the market price of our securities.

Intellectual property disputes could distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our securities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings.

Our directors may serve as directors of other biotech companies and may have conflicts of interest.

Certain of our directors and executive officers may, from time to time, be employed by or affiliated with organizations which have entered into agreements or will enter into agreements with us. As disputes may arise between these organizations and us, or certain of these organizations may undertake or have undertaken research with our competitors, there exists the possibility for such persons to be in a position of conflict. We cannot assure that any decision or recommendation made by these persons involving us will be made in accordance with his or her duties and obligations to deal fairly and in good faith with us and such other organizations.

Our business is affected by macroeconomic conditions.

Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, interest rates and foreign currency exchange rates, tariffs and trade sanctions on goods, and overall economic conditions and uncertainties, including those resulting from political instability and the current and future conditions in the global financial markets. For instance, if inflation or other factors were to significantly increase our business costs, it may not be feasible to pass through price increases to patients. Interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect the value of our investments and our ability to liquidate our investments in order to fund our operations, if necessary.

Interest rates and the ability to access credit markets could also adversely affect the ability of payors and distributors to purchase, pay for and effectively distribute our products if and when approved. Similarly, these macroeconomic factors could affect the ability of our current or potential future contract manufacturers, sole-source or single-source suppliers, or licensees to remain in business or otherwise manufacture or supply our products. Failure by any of them to remain in business could affect our ability to manufacture our products.

We may be responsible for corruption and anti-bribery law violations.

Our business activities are subject to the to the U.S. Foreign Corrupt Practices Act (the "FCPA") and other anti-bribery and anti-corruption laws of the United States and other countries in which we operate, as well as U.S. and certain foreign export controls and trade sanctions which generally prohibit companies and company employees from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business.

Our employees or other agents may, without our knowledge and despite our efforts, engage in prohibited conduct under our policies and procedures and the FCPA or other anti-bribery laws for which we may be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties and other consequences that may have a material adverse effect on our business, financial condition and results of operations.

We are subject to foreign exchange risks.

As we grow and do business in foreign markets, including the United States and Europe, it is quite possible that transactions will take place in foreign currencies. At this point we do not participate in hedging activities. Although we cannot predict the effect of possible foreign exchange losses in the future, if such losses occurred, they could have a material adverse effect on our business, results of operation, and financial condition. In addition, fluctuations in exchange rates could affect the pricing of our products and negatively influence customer demand.

We are subject to taxation risks and changing rules by different tax authorities or challenges to our tax positions.

We are subject to taxation in the United States, Canada and other jurisdictions in which we operate. Our future income tax obligations could be affected by changes in, or interpretations of, tax laws in the United States, Canada or in other jurisdictions. Changes in tax laws or regulations may be enacted that could significantly affect our overall tax liabilities and our effective tax rate. In addition, tax authorities could interpret or issue guidance on how provisions of certain tax laws and regulations will be applied or otherwise administered that is different from our interpretation, and we may be required to make adjustments to amounts that we have recorded that may adversely affect our results of operations and financial condition. Our tax reporting positions may be challenged by relevant tax authorities, and we might incur significant expense in our efforts to defend those challenges, and we might be unsuccessful in those efforts. Developments in examinations and challenges might materially change our provision for taxes in the affected periods and might differ materially from our historical tax accruals. Any of these risks might have a materially adverse impact on our business operations, our cash flows, and our financial position or results of operations.

We believe that we will be treated as a U.S. corporation for U.S. federal income tax purposes.

We believe that, pursuant to Section 7874 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), even though we are organized as a corporation under the laws of Ontario, Canada, the Company will be treated as a U.S. domestic corporation for all purposes of the Code. The Company will therefore be taxed as a U.S. domestic corporation for U.S. federal income tax purposes. As a result, the Company will be subject to U.S. federal income tax on its worldwide income. The Company is also subject to tax in Canada. It is unclear how the foreign tax credit rules under the Code will operate in certain circumstances, given our treatment as a U.S. domestic corporation for U.S. federal income tax purposes and the taxation of the Company in Canada. Accordingly, it is possible that we will be subject to double taxation with respect to all or part of our taxable income.

In addition, if the Company pays dividends to a non-U.S. shareholder, it will be required to withhold U.S. income tax at the rate of 30%, or such lower rate as may be provided in an applicable income tax treaty. Each investor is urged to consult its own tax adviser regarding the U.S. federal income tax position of the Company and the tax consequences of holding our securities.

Our ability to use our net operating losses and certain other attributes may be subject to certain limitations.

Under Section 382 and Section 383 of the Code, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating losses ("NOLs") and other tax attributes, including research and development tax credits, to offset its post-change income or taxes may be limited. In general, an "ownership change" will occur if there is a cumulative change in our ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. If we have undergone previous ownership changes, or if we undergo an ownership change in the future, including as a result of this offering, our ability to use NOLs and other tax attributes to reduce future taxable income may be subject to substantial restrictions.

We are subject to a number of risks and hazards, of which not all of them may be sufficiently insured for.

Our business will be subject to a number of risks and hazards generally, including general liability. Such occurrences could result in damage to property, inventory, facilities, personal injury or death to end-customers or operators, damage to our properties or the properties of others, monetary losses and possible legal liability. Although we maintain insurance to protect against certain risks in such amounts as we consider to be reasonable, our insurance will not cover all the potential risks associated with our operations. We may also be unable to maintain insurance to cover these risks at economically feasible premiums. Insurance coverage may not continue to be available or may not be adequate to cover any resulting liability. We might also become subject to liability which may not be insured against or which we may elect not to insure against because of premium costs or other reasons. Losses from these events may cause us to incur significant costs that could have a material adverse effect upon our financial performance and results of operations.

Risks related to health epidemics and pandemics.

Unfavorable global conditions, including as a result of health and safety concerns related to global pandemics, could adversely affect our business, financial condition or results of operations. Our operations could be adversely affected by general conditions in the global economy, including conditions that are outside of our control, such as the impact of health and safety concerns from global pandemics like the coronavirus (COVID-19) outbreak. The most recent global financial crisis caused by the coronavirus outbreak has resulted in extreme volatility and disruptions in the capital and credit markets. A weak or declining economy could also strain our supply channels.

Risks Related to Marketing, Reimbursement, Healthcare Regulations and Ongoing Regulatory Compliance

Coverage and reimbursement may be limited or unavailable in certain market segments for the Products, which could make it difficult for us to sell the Products profitably.

The success of the Products, if approved, depends on the availability of adequate coverage and reimbursement from third-party payors, including government agencies. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Coverage may be more limited than the purposes for which a therapeutic is approved by the FDA or comparable regulatory authorities in other jurisdictions.

In the United States and some other jurisdictions, patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the United States and commercial payors are critical to new product acceptance.

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services ("CMS"), an agency within the United States

Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare, and private payors often follow CMS' coverage decisions. Other jurisdictions have agencies, such as the National Institute for Health and Care Excellence in the United Kingdom, that evaluate the use and cost effectiveness of therapies, which impact the utilization and price of the medicine in such jurisdiction.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time consuming and costly process that could require Medicus to provide to each payor supporting scientific, clinical and cost effectiveness data for the use of products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if Medicus obtains coverage for a given product, the resulting reimbursement payment rates might not be adequate for Medicus to maintain pricing sufficient to achieve or sustain profitability or may require copayments that patients find unacceptably high.

Medicus intends to seek approval to market the Products in different jurisdictions, which could include Canada and other selected foreign jurisdictions in addition to the United States. If Medicus obtains approval in any of these jurisdictions for the Products, Medicus will be subject to rules and regulations in those jurisdictions. Market acceptance and sales of the Products will depend significantly on the availability of adequate coverage and reimbursement from third party payors for the Products and may be affected by existing and future health care reform measures.

Our relationship with healthcare providers and physicians and third-party payors will be subject to applicable antikickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States, Canada, and elsewhere play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. If we obtain FDA approval for any product candidates and begin commercializing those products in the United States, our current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. In particular, the research of product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business or financial arrangements.

The applicable U.S. federal, state and other healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual, or the purchase, lease, order, arrangement, or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. The term remuneration has been interpreted broadly to include anything of value. Further, courts have found that if "one purpose" of renumeration is to induce referrals, the federal Anti-Kickback statute is violated. Violations are subject to significant civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, a claim submitted for payment to any federal healthcare program that includes items or services that were made as a result of a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act, or FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers, among others, on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;

- the federal civil and criminal false claims laws, including the FCA, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs; knowingly making, using, or causing to be made or used, a false record or statement material to a false, fictitious or fraudulent claim or an obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government. A claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim under the FCA. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring qui tam actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery or settlement. When an entity is determined to have violated the FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA fraud provisions without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose, among other things, certain requirements relating to the privacy, security and transmission of individually identifiable health information on certain covered healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their respective "business associates," those independent contractors or agents of covered entities that create, receive, maintain, transmit or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there are additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;

- the federal Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the Affordable Care Act, and its implementing regulations, which require manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made in the previous year to certain non-physician providers such as physician assistants and nurse practitioners;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous U.S. state, local and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers and may be broader in scope than their federal equivalents; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and other relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information, some of which may be more stringent than those in the United States (such as the European Union, which adopted the General Data Protection Regulation, which became effective in May 2018) in certain circumstances, and may differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time-and resource-consuming, costly, and can divert a company's attention from the business.

It is possible that governmental and enforcement authorities will conclude that our business practices, including our arrangements with physicians and other healthcare providers, may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to significant sanctions, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, reputational harm, exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to similar penalties. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. In addition, the approval and commercialization of any product candidate in other countries will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. All of these could harm our ability to operate our business and our financial results.

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

Changes in U.S., Canadian, and foreign regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States and in some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative initiatives and regulatory changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, (collectively, the "ACA") was enacted, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, expands the types of entities eligible for the 340B drug discount program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations; established annual fees and taxes on manufacturers of certain branded prescription drugs; and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, or BBA, effective as of January 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and our expects there will be additional challenges and amendments to the ACA in the future. For example, various portions of the ACA are currently undergoing legal and constitutional challenges in the U.S. Supreme Court. Additionally, the Trump Administration has issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. We cannot predict what affect further changes to the ACA would have on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, on August 2, 2011, the Budget Control Act, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs, including aggregate reductions of Medicare payments to providers of up to 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, unless additional Congressional action is taken. However, pursuant to the Coronavirus Aid, Relief and Economic Security Act, or CARES Act, and subsequent legislation, these Medicare sequester reductions are suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, the BBA, among other things, amended the ACA, effective January 1, 2019, by increasing the point-of-sale discount (from 50% under the ACA to 70%) that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole."

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their products. Such scrutiny has resulted in several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, at the federal level, the Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out of pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. HHS has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule that would allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS' policy change that was effective January 1, 2019. While there had been some questions about the Trump Administration's position on the program for negotiating Medicare drug prices, CMS issued a public statement on January 29, 2025, declaring that lowering the cost of prescription drugs is a top priority of the new administration and CMS is committed to considering opportunities to bring greater transparency in the negotiation program. The effects of the IRA on our business is not yet known.

Several regulations have also been proposed partly in response to several executive orders issued by President Trump related to prescription drug pricing that seek to implement several of the administration's proposals. For example, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. The Interim Final Rule has not been finalized and is subject to revision and challenge. Additionally, on November 20, 2020, HHS finalized a regulation removing the safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Government actions to impose most-favored-nation drug pricing could materially reduce our product revenues and profit margins and subject us to significant regulatory uncertainty. On May 12, 2025, President Trump signed an Executive Order titled "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients" (the "MFN EO"). The MFN EO directs multiple federal agencies, including the HHS, to take specific actions aimed at compelling drug manufacturers to lower drug prices in the United States in a manner comparable with other developed nations. The MFN EO states that the United States has less than five percent of the world's population yet funds approximately three quarters of global pharmaceutical profits. The Trump administration asserts that drug manufacturers deeply discount their products to access foreign markets while subsidizing those discounts through higher prices charged in the United States. The MFN EO declares that Americans should not be forced to subsidize low-cost prescription drugs in other developed countries and must have access to the "most-favored-nation price" for pharmaceutical products. Federal agencies are also developing and proposing new drug pricing and payment pilot programs based on international pricing metrics under Medicare Parts B and D as well as Medicaid. If we are required to reduce prices to MFN levels, whether through voluntary agreement, regulatory mandate, or other government action, our product revenues and profit margins could be materially and adversely affected, particularly with respect to our single-source products that do not currently face generic or biosimilar competition. Compliance with direct-to-consumer distribution requirements, such as participation in TrumpRx.gov, a website sponsored by the federal government that is anticipated to offer pharmaceuticals direct-to-consumer channels may also require significant operational changes and investments. We cannot predict the ultimate scope, timing, or impact of the MFN EO or related government actions, and such actions could have a material adverse effect on our business, financial condition, and results of operations. While some of these and other measures may require additional authorization to become effective, and the Trump administration may reverse or otherwise change these measures, Congress has indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biologic product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions on coverage or access could harm our business, results of operations, financial condition and prospects. In January 2024, the FDA authorized Florida's Agency for Health Care Administration's drug importation program, which is the first step toward Florida facilitating importation of certain prescription drugs from Canada. Authorization of other state programs may follow as other states have submitted importation program proposals. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for the Products or put pressure on product pricing.

It is expected that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the extent to which state and federal governments cover particular healthcare products and services and could limit the amounts that the federal and state governments will pay for healthcare products and services. This could result in reduced demand for the Products or could result in additional pricing pressures.

Other government regulations, including general budget control measures, actions may affect prices or payments for prescription drugs. For example, new or increased tariffs implemented under the Trump administration, including the implementation of a recently announced tariff on branded or patented drugs for manufacturers that do not invest in manufacturing plants in the United States or reach a drug pricing agreement with the Trump administration, could adversely affect the ability of pharmaceutical companies to realize an adequate return on sales of products imported from abroad or manufactured using materials or products imported from abroad. The timeline for implementing such tariff on branded or patented drugs has not been finalized. As another example, the Budget Control Act resulted in the imposition of reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect into 2032 unless additional Congressional action is taken.

The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS, and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. Further, in June 2024, the U.S. Supreme Court reversed its longstanding approach under the Chevron doctrine, which provided for judicial deference to regulatory agencies' interpretation of statutes that are silent or ambiguous, including the FDA and CMS. As a result of this decision, we cannot be sure whether there will be increased challenges to existing agency regulations or how lower courts will apply the decision in the context of other regulatory schemes without more specific guidance from the U.S. Supreme Court. For example, this decision may result in more companies bringing lawsuits against the regulatory agencies to challenge current regulations and longstanding decisions and policies of the FDA or CMS, which could lead to uncertainties in the industry. We cannot predict the full impact of this decision, future judicial challenges brought against the FDA, CMS, or other regulatory agencies, or the nature or extent of government regulation that may arise from future legislation or administrative action.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, the Products may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

We are currently operating in a period of global economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability. Changes and instability in global economic conditions and geopolitical matters could have a material adverse effect on our business, financial condition and results of operations.

The United States and global markets are experiencing and may in the future experience volatility and disruption, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, high inflation and interest rates, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of geopolitical conflicts, including in Russia and Ukraine, the Middle East and other areas, terrorism or other events. Sanctions and enhanced export controls imposed by the United States and other countries focusing on national security-related technologies, including biotechnology, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability.

Changes in regulations and policies in the United States and the resulting political and economic uncertainty in the United States may also impact us, the financial markets and the global economy. The U.S. has imposed increased tariffs on certain countries, focusing on those with which it has the largest trade deficits. Other countries have responded, and may continue to respond, by announcing retaliatory tariffs on U.S. imports. The tariff have disrupted, and may continue to, disrupt the global markets and escalate tensions between the U.S. and other countries. The extent of the impact that such tariffs, trade policies, or new legislation or regulations will have on our business specifically, or on the U.S. market and global economy generally, are uncertain and in the long term, unpredictable, and could adversely affect our business, financial condition, and results of operations. In addition, the increased tariffs could impact our ability to commercialize future drug candidates for the U.S. market, which is relevant to our ability to generate future revenues from these activities. As a result, the continued impact of these tariffs may impair our plans for further product development in the U.S. market as well as our ability to generate revenues.

The United States may also enact other regulations or policies that affect trade with China or otherwise impact the pharmaceutical industry by restricting U.S. pharmaceutical companies from contracting with certain countries for the development, research or manufacturing of pharmaceutical products. In April 2025, the U.S. Department of Commerce initiated national security investigations into the importation of pharmaceuticals and pharmaceutical ingredients pursuant to Section 232 of the Trade Expansion Act of 1962, which could result in the imposition of new tariffs on imports within the pharmaceutical industry. Further, executive orders were signed to implement Most Favored Nation drug pricing policies designed to align certain prescription drug prices in the U.S. to lower prices available in other countries. Investigations are being conducted to examine price differentials and consider policy approaches for implementation, including through administrative action. If such Most Favored Nation policies are implemented, changes to drug pricing are expected to affect the profitability of pharmaceutical and biotech companies in the U.S. as well as in other countries, as a price constrained market. The details of the proposed policies are unclear, and the final terms and impact remain uncertain, and may pose long-term risks to our business.

Any executive order, legislative action or potential sanctions on certain countries could materially impact our current manufacturing partners. In addition, natural and man-made disasters and global health emergencies, including pandemics and epidemics, may also adversely affect the financial markets and the global economy and result in significant business disruption.

The volatile business environment or continued unpredictable and unstable market conditions may result in further deterioration of the equity and credit markets, significant volatility in commodity prices, as well as supply chain interruptions and result in an economic downturn, which would make any equity or debt financing more difficult, costly and dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay, limit, reduce, or terminate our product development or future commercialization efforts.

Although our business has not been materially impacted by the tariffs adopted to date or adverse effects of geopolitical events, natural or man-made disasters or other business disruptions to date, such matters may affect our business in the future and it is impossible to predict the extent to which our operations, or those of our suppliers and manufacturers, will be impacted in the short and long term, or the ways in which such matters may impact our business. The extent and duration of such adverse geopolitical events, natural or man-made disasters or other business disruptions and actual or perceived political or economic instability and resulting market disruptions are impossible to predict but could be substantial. Any such disruptions may also magnify the impact of other risks described herein.

Risks Relating to Our Securities

We may experience fluctuations in market value.

The market price of publicly-traded securities is affected by many variables not directly related to our corporate performance, including the markets in which we are traded, the strength of the economy generally, the global economic situation and outlook, the availability and attractiveness of alternative investments, and the breadth of the public market for the securities. The effect of these and other factors on the market price of our securities in the future cannot be predicted.

Our securities could be subject to large price and volume volatility.

Market prices for the securities of biotechnology companies have historically been highly volatile. Our securities have and may continue to experience extreme price and volume volatility that may result in losses to shareholders. Accordingly, the trading price of our securities could be subject to wide fluctuations in response to a variety of factors including announcement of material events such as changes relating to new or improved technology, drug safety concerns and other general and industry-specific economic conditions.

Additionally, the securities markets in the United States have recently experienced a high level of price and volume volatility. It is expected that such fluctuations in volume and price will continue to occur which may make it difficult for a shareholder to sell our securities at a price equal to or above the price at which they were purchased.

Due to the relatively small size of our public float, our securities may experience extreme price volatility unrelated to our actual or expected operating performance, financial condition, or prospects, making it difficult for prospective investors to assess the rapidly changing value of our securities.

In addition to the risks described elsewhere in this annual report, we may be subject to extreme volatility that is unrelated to the underlying performance of our business. We have a relatively small public float due to the ownership percentage of our executive officers, directors and significant shareholders. As a relatively small-capitalization company with a relatively small public float, we may experience greater share price volatility, extreme price run-ups, lower trading volume, and less liquidity than large-capitalization companies. In particular, our securities may be subject to rapid and substantial price volatility, low volumes of trades, and large spreads in bid and ask prices. For example, since our initial public offering in November 2024 and as of March 17, 2026, our common shares have traded at a range with a high price of $8.94 on May 20, 2025 and a low price of $0.37 on March 6, 2026. Such volatility, including any stock run-up, may be unrelated to our actual or expected operating performance, financial condition, or prospects, making it difficult for prospective investors to assess the rapidly changing value of our securities.

In addition, if the trading volumes of our securities are low, persons buying or selling in relatively small quantities may easily influence prices of our securities. This low volume of trades could also cause the price of our securities to fluctuate greatly, with large percentage changes in price occurring in any trading day session. Holders of our securities may also not be able to readily liquidate their investment or may be forced to sell at depressed prices due to low volume trading. Broad market fluctuations and general economic and political conditions may also adversely affect the market price of our securities. As a result of this volatility, investors may experience losses on their investment in our securities. A decline in the market price of our securities also could adversely affect our ability to issue additional securities and our ability to obtain additional financing in the future. No assurance can be given that an active market in our securities will be sustained. If an active market in our securities is not sustained, holders of our securities may be unable to readily sell the securities they hold or may not be able to sell their securities at all.

Sales of a significant number of our common shares in the public markets, or the perception that such sales could occur, could depress the market price of our common shares.

Pursuant to a standby equity purchase agreement dated February 10, 2025 (the "SEPA") with YA II PN, Ltd. ("Yorkville"), Yorkville may sell up to $15 million of our common shares. In addition, our at-the-market offering ("ATM") provides that we may sell up to $15.3 million of our common shares and we also have registration statement filed for the resale of approximately 4.0 common shares underlying the private warrants (the "Private Warrants"). Further, subject to compliance with applicable securities laws, our officers, directors and significant shareholders may sell some or all of their common shares in the future. Sales of a substantial number of our common shares in the public markets, or the perception that such sales may occur, could depress the market price of our common shares and impair our ability to raise capital through the sale of additional equity securities. We cannot predict the effect that future sales of our common shares would have on the market price of our common shares.

We will need to raise additional financing in the future and our shareholders may experience substantial dilution in the value of their investment if we issue additional common shares.

To raise additional capital, we may in the future sell additional common shares or other securities convertible into or exchangeable for our common shares at prices that are lower than the prices paid by existing shareholders, and investors purchasing shares or other securities in the future could have rights superior to existing shareholders, which could result in substantial dilution to the interests of existing shareholders. In addition, to the extent that outstanding warrants or options are exercised, new options or other equity awards are issued under our equity incentive plan, or we issue additional shares in the future, including pursuant to our SEPA and our ATM, shareholders may experience further dilution.

We have in the past, and may in the future, issue debt and equity securities or securities convertible into equity securities, any of which may be senior to our common shares as to distributions and in liquidation, which could negatively affect the value of our common shares.

We have in the past, and may in the future as well, attempt to increase our capital resources by entering into debt or debt-like financing that is unsecured or secured by up to all of our assets, or by issuing additional debt or equity securities, which could include issuances of secured or unsecured commercial paper, medium-term notes, senior notes, subordinated notes, guarantees, preferred shares, hybrid securities, or securities convertible into or exchangeable for equity securities. In the event of our liquidation, our lenders and holders of our debt and preferred securities would receive distributions of our available assets before distributions to the holders of our common shares. Because our decision to incur debt and issue securities in future offerings may be influenced by market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of our future offerings or debt financings. Further, market conditions could require us to accept less favorable terms for the issuance of our securities in the future.

If our common shares are delisted, market liquidity for our common shares could be severely affected and our shareholders' ability to sell their our common shares could be limited. A delisting of our common shares from Nasdaq would negatively affect the value of our common shares. A delisting of our common shares could also adversely affect our ability to obtain financing for our operations and could result in the loss of confidence in our Company.

We have no history of paying, and do not intend to pay, dividends on our common shares, so any returns will be substantially limited to the value of our common shares.

To date, we have not paid any dividends on our outstanding common shares. We currently intend to retain future earnings to finance the operation, development and expansion of our business. We do not anticipate paying cash dividends on our common shares in the foreseeable future. Any decision to pay dividends on our shares will be made at the discretion of our board of directors and will depend on our earnings, financial requirements and other conditions existing at such time. In addition, our ability to pay dividends is, and may in the future be, limited by our indebtedness and by covenants of any current or future indebtedness we incur. As a result, you may not receive any return on an investment in our common shares unless you sell our common shares for a price greater than that which you paid for it. See "Item 5. Dividends."

We may issue, without shareholder approval, preferred shares that have rights and preferences potentially superior to those of our common shares.

Our articles permit the issuance of an unlimited number of preferred shares (the "Medicus Preferred Shares") in one or more series. Medicus Preferred Shares are entitled to priority over our common shares with respect to the distribution of our assets in the event of any liquidation, dissolution or winding up of our affairs, whether voluntary or involuntary. Subject to any applicable regulatory approvals, our board of directors may set the rights and preferences of any series of Medicus Preferred Shares in its sole discretion without shareholder approval. The rights and preferences of those Medicus Preferred Shares may be superior to those of our common shares. Accordingly, the issuance of Medicus Preferred Shares may adversely affect the rights of holders of our common shares.

If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our common shares, the price of our securities could decline.

The trading market for our securities could be influenced by research and reports that industry and/or securities analysts may publish about us, our business, the market or our competitors. We do not have any control over these analysts and cannot assure that such analysts will cover us or provide favorable coverage. If any of the analysts who may cover our business change their recommendation regarding our common shares adversely, or provide more favorable relative recommendations about our competitors, the share price would likely decline. If any analysts who may cover our business were to cease coverage or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the share price or trading volume to decline.

Risks Related to Being a Public Company

As a result of recently becoming a public company in the United States, we are subject to additional regulatory compliance requirements, including Section 404 of the Sarbanes-Oxley Act, and if we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud.

Our management team may not continue to successfully or effectively manage our recent transition to a U.S. public company that is subject to significant regulatory oversight and reporting obligations under U.S. and Canadian securities laws. Our limited experience in dealing with the increasingly complex laws pertaining to U.S. and Canadian public companies could be a significant disadvantage in that it is likely that an increasing amount of their time may be devoted to these activities which will result in less time being devoted to the management and growth of the post-combination company. We may not have adequate personnel with the appropriate level of knowledge, experience and training in the accounting policies, practices or internal control over financial reporting required of public companies in the United States and Canada.

As a public company listed on Nasdaq, the Sarbanes-Oxley Act requires, among other things that we assess the effectiveness of our internal control over financial reporting at the end of each fiscal year. We have started and continue the process of designing, implementing and testing our internal control over financial reporting required to comply with Section 404(a) of the Sarbanes-Oxley Act. This process is time-consuming, costly and complicated. Our management may not be able to effectively and timely implement controls and procedures that adequately respond to the increased regulatory compliance and reporting requirements that are applicable to us as a public company listed on Nasdaq. If we fail to maintain internal control over financial reporting adequate to meet the demands that will be placed upon us as a public company listed in the United States, our business and reputation may be harmed, the accuracy and timeliness of our financial reporting may be adversely affected, and the price of our shares may decline.

In addition, unless we still qualify as a non-accelerated filer, our independent registered public accounting firm will be required to attest to the effectiveness of our internal controls over financial reporting beginning with our annual report following the date on which we are no longer an "emerging growth company," which may be up to five fiscal years following the date of our initial public offering in the United States.

If we are unable for any reason to meet the continued listing requirements of Nasdaq, such action or inaction could result in a delisting of our common shares and our Public Warrants, as applicable.

If we fail to satisfy the continued listing requirements of Nasdaq (for example, Nasdaq corporate governance requirements or the minimum closing bid price requirement), such exchanges may take steps to delist our common shares and our Public Warrants, as applicable. Such a delisting would likely have a negative effect on the price of our common shares and our Public Warrants and would impair your ability to sell or purchase our common shares and our Public Warrants, as applicable, when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common shares and our Public Warrants, as applicable, to become listed again, stabilize the market price or improve the liquidity of our common shares and our Public Warrants, as applicable, prevent such securities from dropping below any minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

There is a risk that we will fail to maintain an effective system of internal controls and our ability to produce timely and accurate financial statements or comply with applicable regulations could be adversely affected.

As a U.S. public company, we operate in an increasingly demanding regulatory environment, which requires us to comply with the Sarbanes-Oxley Act, the regulations of Nasdaq, the rules and regulations of the SEC and Canadian securities regulators, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud. Prior to the closing of our initial public offering in the United States, we have never been required to test our internal controls within a specified period and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

We anticipate that the process of building our accounting and financial functions and infrastructure may require significant additional professional fees, internal costs and management efforts. We may need to enhance and/or implement a new internal system to combine and streamline the management of our financial, accounting, human resources and other functions. However, the enhancement and/or implementation of a system may result in substantial costs. Any disruptions or difficulties in implementing or using such a system could adversely affect our controls and harm our business. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management's attention. In addition, we may discover additional weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we do not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, investors could lose confidence in our reported financial information and we could be subject to sanctions or investigations by Nasdaq, the SEC, Canadian securities regulators or other regulatory authorities.

We have identified material weaknesses in our internal controls over financial reporting in the past. Although all previously identified material weaknesses have been remediated, if we identify future material weaknesses in our internal controls and if any material weaknesses identified are not adequately remediated, our failure to establish and maintain effective internal control over financial reporting could result in material misstatements in our financial statements and a failure to meet our reporting and financial obligations, each of which could have a material adverse effect on our business, results of operations, financial condition and the trading price of our securities. In addition, investors' perceptions that our internal control over financial reporting is inadequate or that we are unable to produce accurate financial statements may materially adversely affect the price of our securities, which in turn could make it more difficult for us to obtain financing on favorable terms or at all.

We have and will continue to incur increased costs as a result of our operation as a dual U.S.-Canadian reporting company, and our management will be required to devote substantial time and resources to employing new compliance initiatives in order to comport with the regulatory requirements applicable to public companies.

In connection with becoming a public company in the United States in November 2024 , we have and will continue to incur significant legal, accounting and other expenses that we did not previously incur. As a U.S. public company, domiciled in Ontario, Canada, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules adopted, and to be adopted, by the SEC, Canadian securities regulators and Nasdaq. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be forced to accept reduced policy limits or incur substantially higher costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our securities may be volatile, and in the past companies that have experienced volatility in the market price of their shares have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could adversely impact our business. Any adverse determination in litigation could also subject us to significant liabilities.

As we are organized under the laws of a Canadian province and certain of our directors and officers reside in Canada or the provinces thereof, it may be difficult for U.S. shareholders to effect service on us to realize on judgments obtained in the United States. Similarly, it may be difficult for Canadian investors to enforce civil liabilities against our directors and officers residing outside of Canada.

We are governed by the *Business Corporations Act* (Ontario), as now enacted or as the same may from time to time be amended, re-enacted or replaced ("OBCA"), certain of our directors and officers reside or are organized outside of the United States and a portion of our assets or the assets of these persons may be located outside the United States. Consequently, it may be difficult for investors who reside in the United States to effect service of process in the United States upon us or upon such persons who are not residents of the United States, or to realize upon judgments of courts of the United States predicated upon the civil liability provisions of the U.S. federal securities laws. A judgment of a U.S. court predicated solely upon such civil liabilities may be enforceable in Canada by a Canadian court if the U.S. court in which the judgment was obtained had jurisdiction, as determined by the Canadian court, in the matter. Investors should not assume that Canadian courts: (i) would enforce judgments of U.S. courts obtained in actions against us or such persons predicated upon the civil liability provisions of the U.S. federal securities laws or the securities or blue sky laws of any state within the United States, or (ii) would enforce, in original actions, liabilities against us or such persons predicated upon the U.S. federal securities laws or any such state securities or blue sky laws. Similarly, some of our directors and officers are residents of countries other than Canada and all or a substantial portion of the assets of such persons are located outside Canada. As a result, it may be difficult for Canadian investors to initiate a lawsuit within Canada against these persons. In addition, it may not be possible for Canadian investors to collect from these persons judgments obtained in courts in Canada predicated on the civil liability provisions of securities legislation of certain of the provinces and territories of Canada. It may also be difficult for Canadian investors to succeed in a lawsuit in the United States based solely on violations of Canadian securities laws.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk Management and Strategy

We are a biotech/life sciences company focused on accelerating the clinical development programs of novel and disruptive therapeutic assets. We current do not sell any products or maintain any customer lists and have exposure to cybersecurity risks commensurate with the small size of our company and the nature of our operations, which we believe at this time is limited. Assessment, identification and management of cybersecurity related risks are integrated into our overall risk management process. Our risk management process is designed to identify, prioritize, and monitor risks that could affect our ability to execute our corporate strategy and fulfill our business objectives and to appropriately mitigate such risks. We believe we appropriately assess material risks from cybersecurity threats, including any potential unauthorized occurrence on or conducted through our information systems that may result in adverse effects on the confidentiality, integrity, or availability of our information systems or any information residing therein. As our company grows, we plan to expand our strategy for cybersecurity in accordance with nationally accepted standards. As of the date of this annual report we do not currently engage assessors, consultants, auditors, or other third parties in connection with cybersecurity processes or have processes to oversee and identify such risks from third-party service providers.

Governance

Management is responsible for the day-to-day management of the risks we face, while our board of directors has responsibility for the oversight of risk management, including risks from cybersecurity threats. Our audit and risk assessment committee is responsible for overseeing the Company's risk management policies and procedures with regard to identification of the Company's principal risks and implementation of appropriate systems to manage such risks.

As of the date of this annual report, we are not aware of any material risks from cybersecurity threats that have materially affected or are reasonably likely to materially affect the business strategy, results of operations or financial condition of the Company. However, there is no guarantee that we will not be subject to future threats or incidents.

Item 2. Properties.

Our registered and head office is located at One First Canadian Place, 100 King Street West, Suite 3400, Toronto, Ontario M5X 1A4, Canada. Our principal executive office is located at 300 Conshohocken State Rd., Suite 200, W. Conshohocken, PA 19428. We believe that our current facilities are suitable and adequate to meet our current needs. We believe that suitable additional space or substitute space will be available in the future to accommodate our operations as needed.

Item 3. Legal Proceedings.

There is no material litigation, arbitration or governmental proceeding currently pending against us or any members of our management team in their capacity as such, and we and the members of our management team have not been subject to any such proceeding in the 12 months preceding the date hereof.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information.

Our common shares and Public Warrants are traded on the Nasdaq under the symbols "MDCX" and "MDCXW", respectively.

Holders

As of March 17, 2026, there were approximately 189 record holders of our common shares and one holder of record of our Public Warrants. Such numbers do not include beneficial owners holding our securities through nominee names.

Dividends

We have not paid any cash dividends on our common shares to date and we do not anticipate that we will declare or pay dividends in the foreseeable future on our common shares. Instead, we anticipate that all of our earnings will be used for the operation and growth of our business. Any future determination to declare cash dividends would be subject to the discretion of our board of directors and would depend upon various factors, including our results of operations, financial condition and liquidity requirements, restrictions that may be imposed by applicable law and our contracts and other factors deemed relevant by our board of directors.

Equity Incentive Plans

Information relating to the Company's equity incentive plan will be included in the proxy statement for our 2026 Annual Meeting of Shareholders and is hereby incorporated by reference in this Annual Report on Form 10-K, unless the Proxy Statement is not filed prior to 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, in which case the information relating to this item will be filed by amendment to this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities; Use of Proceeds from Registered Offerings

We have not issued or sold securities without registration under the Securities Act in the prior three years and required to reported hereunder other than has been previously disclosed in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K, except for 1,000,000 common shares sold to Yorkville pursuant to the SEPA on March 11, 2026 for gross proceeds to the Company of $477,300. On November 13, 2024, our Registration Statement on Form F-1 (SEC File No. 333-279771), for the initial public offering (the "IPO") of 970,000 units (each, a "Unit") at a price of $4.125 per Unit, each Unit consisting of one common share and one Public Warrant, was declared effective by the SEC. On November 14, 2024, the underwriter partially exercised its overallotment option and purchased an additional 145,500 Public Warrants at $0.01 per Public Warrant for additional gross proceeds of $1,455. In the aggregate, the IPO generated approximately $1.88 million in net proceeds for the Company, which amount is net of approximately $0.42 million in underwriters' discounts and commissions and offering costs of approximately $1.7 million. Maxim Group LLC acted as the sole book-running manager for the offering and Brookline Capital Markets, a division of Arcadia Securities, LLC, acted as co-manager. There has been no material change in the use of proceeds described in the final prospectus for the IPO.

Item 6. [Reserved].

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

This discussion contains forward-looking statements that involve risks and uncertainties. When reviewing the discussion below, you should keep in mind the substantial risks and uncertainties that impact our business. In particular, we encourage you to review the risks and uncertainties described in "Risk Factors" in Part I, Item 1A in this Annual Report on Form 10-K. These risks and uncertainties could cause actual results to differ materially from those projected or implied by our forward-looking statements contained in this report. These forward-looking statements are made as of the date of this annual report, and we do not intend, and do not assume any obligation, to update these forward-looking statements, except as required by law. All amounts are expressed in United States dollars unless otherwise stated. This discussion should be read in conjunction with the Company's audited consolidated financial statements for the years ended December 31, 2025 and 2024.

Company Overview

The Company is a clinical stage, multi-strategy biotech/life sciences company focused on investing in and accelerating clinical development programs of novel and potentially disruptive therapeutic assets. The Company looks into opportunities across all therapeutics areas where an unmet need exists for improved patient safety and efficacy. The Company is opportunistically exploring to expand its drug development pipeline through qualified and accretive acquisitions and partnerships.

The Company has two wholly owned subsidiaries, Medicus Pharma Inc., a company incorporated in the state of Delaware on October 12, 2023, and SkinJect. The Company also has one non-wholly owned subsidiary, Antev, of which it owns 98.6% of the issued and outstanding shares.

SkinJect is focused on the development of a novel "innovation combination product", as an investigational new drug, using uniquely designed, patent protected dissolvable microneedle arrays ("C-MNAs") and doxorubicin containing dissolvable microneedle arrays ("D-MNAs") for the treatment of certain skin cancers. To that end, the Company licensed certain technology co-developed by the University of Pittsburgh and Carnegie Mellon University. The Company established and validated fabrication processes relative to the C-MNAs and D-MNAs, completed pre-clinical testing and secured approval to proceed with clinical trials activity from the FDA.

The Company then completed a dose escalation study ("SKNJCT-001") that assessed the safety of D-MNA patch in patients with BCC. There were no serious systemic or local adverse events nor any demonstrated alterations in any clinical measurements during the trial. The conclusion of the study was that D-MNA patch was well tolerated with no evidence of dose limiting toxicity.

The Company had initiated a clinical study ("SKNJCT-002") aimed at evaluating clinical efficacy. The first part involved the enrollment of 15 healthy volunteers and was designed to study the penetration of device only-containing Dynamic Mechanical Allodynia patches at five different anatomic locations. After the first seven health volunteers were enrolled, due to the variability of array application observed by the investigator, SkinJect made the decision to pause the trial. The study was never resumed, and it was ultimately closed without further enrollment. There were no adverse events reported in the enrolled subjects.

In January 2024, the Company submitted the clinical design for a randomized, double-blinded, three arm study evaluating two dose levels of microneedle-mediated delivery of doxorubicin (D-MNA) compared with a device-only control (C-MNA) in patients with nodular type of basal cell carcinoma (nBCC). It was a multi-center study ("SKNJCT-003") enrolling up to 60 subjects presenting with nodular type of BCC of the skin. The FDA responded in March 2024 and requested additional clinical information. A final protocol was submitted to the FDA in July 2024, which included the information requested by the FDA, along with updated CMC, stability and sterility data. On July 31, 2024, the FDA responded to the latest submission and requested certain additional information and clarification. The Company responded to the FDA on August 2, 2024 and commenced patient recruitment on August 27, 2024.

The SKNJCT-003 Phase 2 clinical study is currently underway in nine clinical sites across United States. In March 2025, the Company announced a positively trending interim analysis for SKNJCT-003 demonstrating more than 60% clinical clearance. The interim analysis was conducted after more than 50% of the then-targeted 60 patients in the study were randomized. The findings of the interim analysis were preliminary and may or may not correlate with the findings of the study once completed. In April 2025, the investigational review board increased the number of participants in SKNJCT-003 to 90 subjects. The Company also announced expanding clinical trial sites in Europe. In December 2025, the Company announced it has successfully completed enrolment of 90 patients in the United States.

In May 2025, the Company received notice that a study may proceed with approval from United Arab Emirates (UAE) Department of Health (DOH) to commence clinical study (SKNJCT-004) to non-invasively treat BCC of the skin. The study is expected to randomize 36 patients in four clinical sites in the UAE. Cleveland Clinic Abu Dhabi is the principal investigator, along with Sheikh Shakbout Medical City, Burjeel Medical City, and American Hospital of Dubai. Insights Research Organization and Solutions (IROS), a UAE-based contract research organization that is an M42 portfolio company, is coordinating the clinical study for the Company. In October 2025, the Company announced the enrollment of the first patient in its SKNJCT-004 Phase 2 clinical study.

In June 2025, the Company entered into a definitive agreement to acquire Antev Limited, a UK-based clinical biotech company developing Teverelix, a next-generation GnRH antagonist, as first in market product for cardiovascular high-risk prostate cancer patients and patients with first acute urinary retention episodes due to enlarged prostate. Subsequently, in August 2025, the Company completed the acquisition of Antev and acquired 98.6% of the issued and outstanding shares of Antev for aggregate consideration consisting of approximately $2.97 million in cash and 1,603,164 common shares of the Company.

In July 2025, the Company submitted a comprehensive package to the FDA seeking a Type C meeting. In August 2025, the Company announced that the FDA accepted the Company's Type C Meeting request to formally discuss the D-MNA product development and gain further alignment on the clinical pathway. In September 2025, the FDA provided written responses to the Company's queries, and agreed that the Company can rely on the 505(b)(2) regulatory pathway to treat BCC using D-MNA.

In August 2025, the Company announced its entry into a non-binding memorandum of understanding ("MoU") with Helix Nanotechnologies, Inc., a Boston-based biotech company focused on developing a proprietary advanced mRNA platform, in respect of their mutual interest in the development or commercial arrangement contemplated by the MoU.

On October 22, 2025, the Company announced the enrollment of the first patient in the SKNJCT-004 phase 2 clinical study, to non-invasively treat basal cell carcinoma ("BCC") of the skin. On October 29, 2025, the Company announced a strategic collaboration with the Gorlin Syndrome Alliance to advance compassionate access to SkinJect™ for patients suffering from Gorlin Syndrome (nevoid basal cell carcinoma syndrome). Under the collaboration, the parties intend to pursue an Expanded Access IND program with the FDA to allow physician-supervised access for patients with multiple, recurrent, or inoperable BCCs.

In November 2025, the Company announced that it received full regulatory and ethical approvals in the United Kingdom to expand its ongoing Phase 2 clinical study (SKNJCT-003) evaluating D-MNA for the non-invasive treatment of BCC and announced that it submitted an application for an FDA Commissioner's National Priority Voucher in connection with SKNJCT-003.

On December 15, 2025, the Company announced that its Phase 2 clinical study (SKNJCT-003) evaluating safety and efficacy of D-MNA and C-MNA to non-invasively treat nodular BCC of the skin, has successfully completed enrolment of ninety (90) patients in the United States.

On December 22, 2025, the Company announced that it has entered into a non-binding letter of intent with Reliant AI Inc., a decision-intelligence company for the life sciences, specializing in generative AI, to collaborate on the development of an artificial-intelligence-powered data analytics platform designed to support clinical trial execution through data-driven insights.

The Share Consolidation

On June 25, 2024, the Company's shareholders approved an amendment to the Company's articles of incorporation to provide for the Share Consolidation, or reverse stock split, of the Company's issued and outstanding common shares at such a consolidation ratio to be determined by the Company's board of directors in its sole discretion, to permit the Company to satisfy all conditions and necessary regulatory approvals to list the common shares on a U.S. national securities exchange as the Company's board of directors may determine in its sole direction. Our board of directors approved the Share Consolidation on October 15, 2024, and the Share Consolidation was completed by the Company on October 28, 2024, at the ratio of 1-for-2.

After the completion of the Share Consolidation, the number of the Company's issued and outstanding common shares decreased from 21,693,560 to 10,846,721. The par value of the Company's common shares remains unchanged at $0 per share after the Share Consolidation. The Share Consolidation was completed in preparation for a U.S. listing.

Initial Public Offering

On November 14, 2024, the Company completed its initial public offering with the sale of 970,000 Units at the price of $4.125 per Unit, with each Unit (the "Unit") consisting of one common share and one Public Warrant. The Public Warrants expire five years from their date of issuance on November 15, 2029. In addition, the underwriters exercised an option to purchase 145,500 Public Warrants (the "Overallotment Warrants") at a price of $0.01 per warrant.

Total gross proceeds from our initial public offering were $4.0 million, including the proceeds from the Overallotment Warrants. The Company incurred total issuance costs of $2.1 million, including underwriter fees, and legal and other professional fees incurred directly related to the issuance. As of December 31, 2025, 129,905 Warrants issued as part of the IPO have been exercised for cash for proceeds to the Company of $602,756 during the year ended December 31, 2025.

Regulation A Offering

On March 10, 2025, the Company completed an offering (the "Regulation A Offering") of 1,490,000 units at $2.80 per unit pursuant to Tier II of Regulation A under the Securities Act, with each unit consisting of one common share and one warrant (each, a "Regulation A Warrant"). The Regulation A Warrants have an exercise price of $2.80 and expire on March 10, 2030. The aggregate gross proceeds to the Company from the Regulation A Offering were $4.2 million. As of December 31, 2025, 1,473,800 of the 1,490,000 Regulation A Warrants have been exercised for cash, for proceeds to the Company of $4,126,639 during the year ended December 31, 2025.

Debentures

On May 2, 2025, the Company entered into a securities purchase agreement with YA II PN, Ltd. ("Yorkville"), under which the Company has issued and sold three debentures (the "Initial Debentures") to Yorkville in an aggregate principal amount totaling $5,000,000. The Initial Debentures were issued at a discounted price of 90% for proceeds to the Company of $4,500,000. Interest accrued on the outstanding principal amount of each Initial Debentures at an annual rate of 8%, subject to a potential increase to 18% per annum upon the occurrence of certain events of default. The Initial Debentures had a maturity date of February 2, 2026.

On September 17, 2025, the Company entered into securities purchase agreement with Yorkville to issue a new debenture (the "Debenture") with the principal amount of $8,000,000 issued at a discount of $633,707 for proceeds of approximately $7,366,293. Interest will accrue on the outstanding principal amount of the Debenture at an annual rate of 8%, subject to a potential increase to 18% per annum upon the occurrence of certain events of default. The Debenture will mature on September 17, 2026 and will be partially repaid using proceeds from the SEPA (as defined below).

June 2025 Public Offering

On June 2, 2025, the Company closed a public offering with gross proceeds of $7.0 million (the "June 2025 Public Offering"). The Company issued 2,260,000 units at a price of $3.10 per unit. Each unit consisted of one common share of the Company and one warrant to purchase one common share (the "June 2030 Warrants"). The June 2030 Warrants have an exercise price of $3.10 per share and will expire on June 2, 2030. As of December 31, 2025, no June 2030 Warrants have been exercised.

The Company incurred equity issuance costs of $809,606 related to this transaction during the period ended December 31, 2025.

Warrant Inducement

On July 14, 2025, the Company entered into a warrant inducement agreement (the "Warrant Inducement Agreement") with an institutional investor, pursuant to which the investor agreed to exercise existing Regulation A Warrants to purchase up to 1,340,000 of the Company's common shares issued on March 10, 2025 and with an exercise price of $2.80 per Common Share, in consideration for receiving the 2,680,000 Series A and B Warrants with an exercise price of $3.75. In accordance with the Warrant Inducement Agreement, the investor exercised its existing warrants for cash, for gross proceeds of $3.8 million to the Company.

On December 5, 2025, the Company entered into a warrant inducement agreement with an institutional investor (the "Second Warrant Inducement Agreement"), pursuant to which the investor agreed to exercise existing Series A and B Warrants to purchase up to 2,680,000 of the Company's common shares issued on July 14, 2025 with an amended exercise price of $1.92 per Common Share, in consideration for receiving 4,020,000 Series C and D Warrants with an exercise price of $2.00. In accordance with the Second Warrant Inducement Agreement, the investor exercised its existing warrants for cash, for gross proceeds of approximately $5.1 million to the Company.

At-The-Market Program

On December 29, 2025, we entered into an equity distribution agreement (the "Equity Distribution Agreement") with Maxim Group LLC and Yorkville Securities, LLC, an affiliate of Yorkville as agents, whereby the agents may sell up to $15.3 million of our common shares as part of an at-the-market program (the "ATM").

Results of Operations

The following table outlines our statements of loss and comprehensive loss for the years ended December 31, 2025 and 2024:

	Years Ended December 31,	
	2025	**2024**
Operating expenses:		
General and administrative	**$ 17,920,391**	$ 7,653,116
Research and development	**7,721,436**	3,527,786
In-process research and development (IPR&D) - Teverelix	**8,717,475**	-
Total operating expenses	**34,359,302**	11,180,902

Loss from operations	**(34,359,302)**	(11,180,902)
Other income (expense)		
Interest income (expense)	**(197,382)**	25,386
Loss on SEPA settlements	**(278,854)**	-
Change in fair value of debentures	**(583,823)**	-
Loss on extinguishment of debentures	**(25,000)**	-
Total other income (expense)	**(1,085,059)**	25,386
Net loss for the year	**(35,444,361)**	(11,155,516)
Net loss per common share (basic and diluted)	**(2.74)**	(1.16)

General and administrative

General and administrative expenses increased by 10,267,275 or 134.2% for the year ended December 31, 2025, compared to the equivalent periods in the prior year. This increase was primarily due to salaries and wages with increased headcount at board and management level and fees. General and administrative expenses primarily include professional fees, consulting fees, salaries, wages and benefits, general office, insurance, administration expenditures, costs related to business development and investor relations, public relations, market awareness, advocacy and stock-based compensation associated with maintaining investor relations, public relations, market awareness, advocacy, director and officer insurance and compliance with applicable securities law requirements. In addition, there are additional costs, recurring and non-recurring, associated with increased regulatory requirements following the Company's initial public offering, transition to U.S domestic issuer status, multiple financing transactions and the Antev acquisition.

Research and development ("R&D")

Research and development costs include costs incurred under agreements with third-party contract research organizations, contract manufacturing organizations and other third parties that conduct preclinical and clinical activities on our behalf and manufacture our product candidates, and other costs associated with our R&D programs, including laboratory materials and supplies.

R&D expenses increased by $4,193,650 or 118.9% for the year ended December 31, 2025, compared to the equivalent periods in the prior year. This increase is primarily due to costs incurred related to SKNJCT-003, SKNJCT-004 and Teverelix, which had increased clinical trial activity in the current year.

We expect our R&D expenses to increase substantially for the foreseeable future as we continue with the study and trials of Skinject and Teverelix.

The principal risks related to the Company's future performance are that the trials are unsuccessful, the Company does not receive FDA approval to proceed with the next stage of its research and development, or the Company is unsuccessful in obtaining future funding needed to continue its research and development. These are customary risks for a development stage pharmaceutical Company and are less acute than for a Company with a less advanced product. Nevertheless, there can be no assurance that the Company will be able to complete its trials of the MNA, that the trials will be successful, or that the product will ultimately reach commercialization.

Other income (expense)

Other income (expense) for the year ended December 31, 2025, was an expense of $1,085,059 compared to an income of $25,386 for the year ended December 31, 2024. Other expense for the year ended December 31, 2025, is primarily related to interest expense of $197,382, loss of SEPA settlements of $278,854, change in fair value of debentures of $583,823 and loss on extinguishment of debentures of $25,000. Other income for the year ended December 31, 2024, is primarily related to interest income earned on short-term money market investments of $104,411, offset by interest expense of $79,025 on convertible notes.

Liquidity and Capital Resources

We are a clinical stage development company, and we currently do not earn any revenues from our drug development programs and are therefore considered to be in the R&D stage. As required, the Company will continue to finance its operations through the sale of equity or pursue non-dilutive funding sources available to the Company in the future. The continuation of our R&D activities is dependent on our ability to obtain financing.

The financial statements and this MD&A have been prepared on the basis of accounting principles applicable to a going concern, which assumes that the Company will continue in operation for the foreseeable future and will be able to realize its assets and discharge its liabilities in the normal course of operations.

The Company expects to continue to incur significant operating losses for the foreseeable future and may never become profitable. In addition to the ATM, SEPA and Debenture (as defined below), management believes that the Company has access to additional capital resources through public and/or private equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, it is possible that the Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into strategic alliances or other arrangements on favorable terms, or at all. Further, the terms of any financing may adversely affect the holdings or the rights of the Company's shareholders. If the Company is unable to secure additional capital, it may be required to take additional measures to reduce costs in order to conserve its cash in amounts sufficient to sustain operations and meet its obligations. These measures could cause significant delays or entirely prevent the Company's continued efforts to progress its research and development program, pursue product portfolio expansion or commercialize its current or future products, each of which is critical to the realization of the Company's business plan and its future operations. This uncertainty, along with the Company's history of losses, indicates that substantial doubt exists about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. The financial statements and this MD&A do not include any adjustments that may be necessary should the Company be unable to continue as a going concern.

The Company is subject to risks associated with any specialty biotechnology company that has substantial expenditures for research and development. There can be no assurance that the Company's research and development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially viable.

As of December 31, 2025, the Company had cash and cash equivalents of $8,705,218 compared to cash and cash equivalents of $4,164,323 as of December 31, 2024. During the year ended December 31, 2025, the Company received $9,790,015 of proceeds from issuance of common shares other than under the SEPA, $11,866,293 of proceeds from issuance of the Debentures, $8,427,416 of proceeds from issuance of common shares under the SEPA, $9,874,998 of proceeds from exercise of the warrants and $162,400 of proceeds from exercise of the stock options. For the year ended December 31, 2025, cash used in operating activities was $22,776,769 compared to $10,247,231 for the equivalent period in the prior year. As of December 31, 2025, the Company has an accumulated deficit of $64,348,118 (December 31, 2024 - $28,903,903) and net loss of $35,444,361 for the year ended December 31, 2025 (2024 - $11,155,516). The Company has a working capital deficit of $47,418 as of December 31, 2025 (December 31, 2024 - $3,072,078).

On March 10, 2025, the Company completed the Regulation A Offering of 1,490,000 units at $2.80 per unit. As of December 31, 2025, 1,473,800 of the 1,490,000 Regulation A Warrants have been exercised for cash, for proceeds to the Company of $4,126,639 during the year ended December 31, 2025.

On June 2, 2025, the Company closed its public offering with gross proceeds of $7.0 million. The Company issued 2,260,000 units at a price of $3.10 per unit. Each unit consisted of one common share of the Company and one June 2030 Warrant. The June 2030 Warrants have an exercise price of $3.10 per share and will expire June 2, 2030. As of December 31, 2025, no June 2030 Warrants have been exercised.

On July 14, 2025, the Company entered into the Warrant Inducement Agreement with an institutional investor, pursuant to which the investor agreed to exercise existing Regulation A Warrants to purchase up to 1,340,000 of the Company's common shares issued on March 10, 2025 and with an exercise price of $2.80 per Common Share, in consideration for receiving the 2,680,000 Series A and B Warrants with an exercise price of $3.75. In accordance with the Warrant Inducement Agreement, the investor exercised its existing warrants for cash, for gross proceeds of $3.8 million to the Company.

On December 5, 2025, the Company entered into The Second Warrant Inducement Agreement with an institutional investor, pursuant to which the investor agreed to exercise existing Series A and B Warrants to purchase up to 2,680,000 of the Company's common shares issued on July 14, 2025 with an amended exercise price of $1.92 per Common Share, in consideration for receiving 4,020,000 Series C and D Warrants with an exercise price of $2.00. In accordance with the Second Warrant Inducement Agreement, the investor exercised its existing warrants for cash, for gross proceeds of approximately $5.1 million to the Company.

On December 29, 2025, the Company entered into the Equity Distribution Agreement with Maxim Group LLC and Yorkville Securities, LLC, an affiliate of Yorkville as agents, whereby the agents may sell up to $15.3 million of our common shares as part of an at-the-market program.

As of December 31, 2025, 129,905 Warrants issued as part of the IPO have been exercised for cash for proceeds to the Company of $602,756 during the year ended December 31, 2025.

As of December 31, 2025, the Company issued 3,677,853 common shares at market price of $8,706,270 for proceeds of $8,427,416 under the SEPA.

Standby Equity Purchase Agreement

The Company has entered into a standby equity purchase agreement dated February 10, 2025 (the "SEPA") with Yorkville, an investment fund managed by Yorkville Advisors Global, LP. Pursuant to the SEPA, the Company has the option, at its sole discretion, to sell up to $15,000,000 of the Company's common shares to Yorkville at any time during the 36-months following the date of the SEPA.

The Investor's obligation to purchase the common shares is subject to a number of conditions, including that the Company file a registration statement with the SEC registering the resale of the common shares issuable thereunder, and that the registration statement is declared effective by the SEC. Such registration statement has been filed with the SEC on September 29, 2025 and declared effective by the SEC on November 14, 2025.

The total number of common shares issuable under the terms of the SEPA is limited to a number equivalent to 19.99% of the outstanding common shares, as of the date of the SEPA unless certain pricing conditions are met, which could have the effect of limiting the total proceeds made available to the Company under the SEPA. The issuance of common shares under the SEPA is subject to further limitations, including that the common shares beneficially owned by Yorkville and its affiliates at any one time will not exceed 4.99% of the then-outstanding common shares.

Common shares issued and sold to Yorkville under the SEPA will be priced at 97% of the market price (as defined in the SEPA) of the common shares during a specified three-day pricing period. The Company reserves the right to set a minimum acceptable price for the common share issuances.

As of December 31, 2025, the Company issued 3,677,853 common shares at market price of $8,706,270 for proceeds of $8,427,416. During the year ended December 31, 2025, $4,430,833 of the gross proceeds were held back to partially repay the Company's outstanding debenture and interest to Yorkville.

Cash flows

	For the year ended December 31	
	2025	**2024**
	$	**$**
Cash used in operating activities	**(22,776,769)**	(10,247,231)
Cash provided by financing activities	**31,939,785**	12,692,216
Cash used in investing activities	**(4,619,152)**	-
Foreign currency effect on cash and cash equivalents	**(2,969)**	-
Net change in cash during the year	**4,540,895**	2,444,985
Cash, beginning of the year	**4,164,323**	1,719,338
Cash, end of the year	**8,705,218**	4,164,323

Cash flows used in operating activities

Cash flows used in operating activities for the year ended December 31, 2025 were $22,776,769 compared to cash flows used in operating activities of $10,247,231 for the year ended December 31, 2024. The increase is primarily due to increased spending on research and development and general and administrative expenses.

Cash flows provided by financing activities

Cash flows provide by financing activities for the year ended December 31, 2025, were $31,939,785 compared to cash flows provided by financing activities of $12,692,216 for the year ended December 31, 2024. The increase is primarily due to increased proceeds from issuance of common shares in equity offerings and under SEPA, issuance of debentures and exercise of warrants and stock options during the year ended December 31, 2025, compared to proceeds from our initial public offering, issuance of convertible notes and issuance of common shares during the year ended December 31, 2024.

Cash flows provided by investing activities

Cash flows used in investing activities for the year ended December 31, 2025, were $4,619,152 compared to $0 for the year ended December 31, 2024. The increase is related to the payment for the Antev asset acquisition which occurred during the year ended December 31, 2025.

Contractual Obligations

We have no significant contractual arrangements other than those noted in our financial statements.

Off-Balance Sheet Arrangements

As of December 31, 2025, we have not entered into any off-balance sheet arrangements.

Critical Accounting Policies

Critical Accounting Policies and Estimates

We periodically review our financial reporting and disclosure practices and accounting policies to ensure that they provide accurate and transparent information relative to the current economic and business environment. As part of this process, we have reviewed our selection, application and communication of critical accounting policies and financial disclosures. Management has discussed the development and selection of the critical accounting policies with our audit committee, and our audit committee has reviewed the disclosure relating to critical accounting policies in this MD&A.

Significant accounting judgments and estimates

Management's assessment of our ability to continue as a going concern involves making a judgment, at a particular point in time, about inherently uncertain future outcomes and events or conditions. Please see the "Liquidity and Capital Resources" section in this document for a discussion of the factors considered by management in arriving at its assessment.

Other important accounting policies and estimates made by management are the assumptions used in determining the valuation of stock-based compensation.

Acquisition

The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If so, the transaction is accounted for as an asset acquisition. If not, further determination is required as to whether or not the Company has acquired inputs and processes that have the ability to create outputs, which would meet the definition of a business. Significant judgment is required in the application of the screen test to determine whether an acquisition is a business combination or an acquisition of assets.

Acquisitions meeting the definition of business combinations are accounted for using the acquisition method of accounting, which requires that the purchase price be allocated to the net assets acquired at their respective fair values. In a business combination, any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill.

For asset acquisitions, a cost accumulation model is used to determine the cost of an asset acquisition. Direct transaction costs are recognized as part of the cost of an asset acquisition. The Company also evaluates which elements of a transaction should be accounted for as a part of an asset acquisition and which should be accounted for separately. The cost of an asset acquisition, including transaction costs, is allocated to identifiable assets acquired and liabilities assumed based on a relative fair value basis. Goodwill is not recognized in an asset acquisition. Any difference between the cost of an asset acquisition and the fair value of the net assets acquired is allocated to the non-monetary identifiable assets based on their relative fair values. When a transaction accounted for as an asset acquisition includes an in-process research and development ("IPR&D") asset, the IPR&D asset is only capitalized if it has an alternative future use other than in a particular research and development project. For an IPR&D asset to have an alternative future use: (a) the Company must reasonably expect that it will use the asset acquired in the alternative manner and anticipate economic benefit from that alternative use, and (b) the Company's use of the asset acquired is not contingent on further development of the asset subsequent to the acquisition date (that is, the asset can be used in the alternative manner in the condition in which it existed at the acquisition date). Otherwise, amounts allocated to IPR&D that have no alternative use are expensed to research and development. Asset acquisitions may include contingent consideration arrangements that encompass obligations to make future payments to sellers, contingent upon the achievement of future financial targets.

Contingent consideration is not recognized until it is probable and the amount can be reasonably estimated, at which point the consideration is allocated to the assets acquired on a relative fair value basis.

Research and development

All research and development costs are expensed as incurred. Research and development costs consist primarily of salaries, employee benefits, costs associated with preclinical studies and clinical trials (including amounts paid to clinical research organizations and other professional services). Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

The Company records accruals for estimated research and development costs, comprising payments for work performed by third party contractors, laboratories, participating clinical trial sites, and others. Some of these contractors bill monthly based on actual services performed, while others bill periodically based upon achieving certain contractual milestones. For the latter, the Company accrues the expenses as goods or services are used or rendered. Clinical trial site costs related to patient enrollment are accrued as patients enter and progress through the trial. Upfront costs, such as costs associated with setting up clinical trial sites for participation in the trials, are expensed immediately once incurred as research and development expenses.

Fair Value Measurements

Our recurring fair value measurements primarily include cash and cash equivalents and Initial Debenture, for which we elected the fair value option.

The fair value option was elected to account for the Initial Debentures. We used the discounted cash flow approach to determine the fair value and it was determined that there was no difference between the transaction price and the fair value and therefore there was no gain or loss was recorded at the issuance date. We subsequently remeasured the Initial Debentures at fair value at each reporting period with the gain or loss recognized in the statements of operations and comprehensive loss.

We measure the fair value of financial assets and liabilities based on the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. We maximize the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value.

Stock-based compensation

The Company expenses stock-based compensation to employees and non-employees over the requisite service period based on the estimated grant-date fair value of the awards. The Company records the expense for stock-based compensation awards subject to vesting over the requisite service period using an estimate of the number of options that will eventually vest. The Company estimates the fair value of stock option grants and shares purchasable under the Company's Equity Incentive Plan (the "Plan") using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. The Company accounts for forfeitures as they occur. All stock-based compensation costs are recorded in the statements of operations and comprehensive loss based upon the underlying employees or non-employee's roles within the Company.

Warrants

The Company records warrants based on the estimated grant-date fair value of the warrants. The Company estimates the fair value of the warrants using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of the warrants represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

Updated share information

As of December 31, 2025, we had 25,176,303 Common Shares issued and outstanding. In addition, there were 2,505,000 Common Shares issuable upon the exercise of outstanding stock options and 7,281,795 Common Shares issuable upon the exercise of warrants.

Recent Accounting Pronouncements

See Note 2 to our consolidated financial statements.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

As a smaller reporting company, we are not required to provide the information required by this Item.

Item 8. Financial Statements and Supplementary Data.

This information appears following Item 15 of this Report and is included herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

On December 19, 2024, MNP LLP ("MNP") resigned its position as the independent registered public accounting firm of the Company. On December 19, 2024, our board of directors approved the engagement of EisnerAmper LLP as the Company's new independent registered public accounting firm. On June 3, 2025, the Company dismissed EisnerAmper LLP ("EisnerAmper") as the Company's independent registered public accounting firm. The dismissal of EisnerAmper was recommended by the audit committee of our board of directors. On June 4, 2025, our board of directors approved the engagement of KPMG LLP as the Company's new independent registered public accounting firm.

MNP's reports on the Company's consolidated financial statements as of and for the fiscal years ended December 31, 2023 and 2022 did not contain any adverse opinion or a disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles. EisnerAmper's report on the Company's consolidated financial statements as of and for the year ended December 31, 2024 contained a separate paragraph stating that "The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company experienced negative cash flows from operating activities and has incurred operating losses that substantial doubt exists about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty."

During the Company's two most recent fiscal years ended December 31, 2025 and 2024, the Company has not had any disagreement with MNP or EisnerAmper on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedures, which disagreements, if not resolved to MNP's or EisnerAmper's satisfaction, would have caused MNP or EisnerAmper to make reference to the subject matter of disagreement in their reports on the Company's consolidated financial statements. In addition, during such periods, there were no "reportable events" as that term is defined in Item 304(a)(1)(v) of Regulation S-K.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Disclosure controls are procedures that are designed with the objective of ensuring that information required to be disclosed in our reports filed under the Exchange Act, such as this Report, is recorded, processed, summarized, and reported within the time period specified in the SEC's rules and forms. Disclosure controls are also designed with the objective of ensuring that such information is accumulated and communicated to our management, including the chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure. Our management evaluated, with the participation of our current chief executive officer and chief financial officer (our "Certifying Officers"), the effectiveness of our disclosure controls and procedures as of December 31, 2025, pursuant to Rule 13a-15(b) under the Exchange Act. Based upon that evaluation, our Certifying Officers concluded that, as of December 31, 2025, our disclosure controls and procedures were effective.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate or that the degree of compliance with the policies or procedures may deteriorate.

Our management, including our Executive Chairman & Chief Executive Officer and President & Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2025 based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013. Based on the results of this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2025.

All control deficiencies that contributed to the material weaknesses as of December 31, 2024 were found to be effectively remediated. Our management implemented the following remedial measures to address the material weaknesses, which were then tested and found to be operating effectively:

- The Company enhanced its financial reporting processes by leveraging third-party advisory consultants and implementing a multi-level review process with increased precision over complex and material transactions.
- The Company strengthened its information technology environment by centrally managing security patches, implementing antivirus and malware protection and establishing comprehensive, documented information technology, user access and cybersecurity policies.

Attestation report of the registered public accounting firm

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to our status as an emerging growth company under the JOBS Act.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

On November 20, 2025, Ajay Raju, a member of our board of directors, adopted a trading plan intended to satisfy Rule 10b5-1(c) under the Exchange Act to sell, between March 23, 2026, and March 23, 2027, up to 1,000,000 shares of our common shares.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information relating to this item will be included in the proxy statement for our 2026 Annual Meeting of Shareholders (the "Proxy Statement") and is hereby incorporated by reference in this Annual Report on Form 10-K, unless the Proxy Statement is not filed prior to 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, in which case the information relating to this item will be filed by amendment to this Annual Report on Form 10-K.

Item 11. Executive Compensation.

Information relating to this item will be included in the proxy statement for our 2026 Annual Meeting of Shareholders and is hereby incorporated by reference in this Annual Report on Form 10-K, unless the Proxy Statement is not filed prior to 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, in which case the information relating to this item will be filed by amendment to this Annual Report on Form 10-K.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information relating to this item will be included in the proxy statement for our 2026 Annual Meeting of Shareholders and is hereby incorporated by reference in this Annual Report on Form 10-K, unless the Proxy Statement is not filed prior to 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, in which case the information relating to this item will be filed by amendment to this Annual Report on Form 10-K.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information relating to this item will be included in the proxy statement for our 2026 Annual Meeting of Shareholders and is hereby incorporated by reference in this Annual Report on Form 10-K, unless the Proxy Statement is not filed prior to 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, in which case the information relating to this item will be filed by amendment to this Annual Report on Form 10-K.

Item 14. Principal Accountant Fees and Services.

Information relating to this item will be included in the proxy statement for our 2026 Annual Meeting of Shareholders and is hereby incorporated by reference in this Annual Report on Form 10-K, unless the Proxy Statement is not filed prior to 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, in which case the information relating to this item will be filed by amendment to this Annual Report on Form 10-K.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this Form 10-K:

(1) Financial Statements:

(2) Financial Statement Schedules:

None.

(3) Exhibits

We hereby file as part of this Report the exhibits listed in the attached Exhibit Index. Exhibits which are incorporated herein by reference can be accessed on the SEC website at www.sec.gov. In addition, we file or furnish periodic reports and amendments thereto, including our Annual Reports on Form 10-K, our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, proxy statements and other information with the SEC. The SEC maintains a website www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically.

Exhibit Number	Description
2.1	Amended and Restated Business Combination Agreement, dated May 12, 2023, by and among the Registrant, RBx Capital LP, SkinJect, Inc. and the Shareholders of SkinJect, Inc. (incorporated by reference from Exhibit 2.1 to the Registrant's Registration Statement on Form F-1, filed with the SEC on May 29, 2024)
2.2	Amendment No. 1 to Amended and Restated Business Combination Agreement, dated May 18, 2023, by and among the Registrant, RBx Capital LP, SkinJect, Inc. and the Shareholders of SkinJect, Inc. (incorporated by reference from Exhibit 2.2 to the Registrant's Registration Statement on Form F-1, filed with the SEC on May 29, 2024)
2.3	Amendment No. 2 to Amended and Restated Business Combination Agreement, dated August 29, 2023, by and among the Registrant, RBx Capital LP, SkinJect, Inc. and the Shareholders of SkinJect, Inc. (incorporated by reference from Exhibit 2.3 to the Registrant's Registration Statement on Form F-1, filed with the SEC on May 29, 2024)
2.4#	Share Exchange Agreement, dated June 29, 2025, by and between Medicus Pharma Ltd., Antev Limited and each of the securityholders of Antev Limited party thereto (incorporated by reference from Exhibit 2.1 to Amendment No. 1 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 3, 2025)
2.5#	Deed of Variation, dated August 1, 2025, relating to that certain Securities Exchange Agreement, dated June 29, 2025, by and between Antev Limited, the Antev Vendors' Representatives and Medicus Pharma Ltd. (incorporated by reference from Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 2, 2025)
2.6#	Further Deed of Variation, dated August 15, 2025, relating to that certain Securities Exchange Agreement, dated June 29, 2025, by and between Antev Limited, the Antev Vendors' Representatives and Medicus Pharma Ltd. (incorporated by reference from Exhibit 2.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 2, 2025)
3.1	Articles of Incorporation of Medicus Pharma Ltd. (incorporated by reference from Exhibit 3.1 to the Registrant's Registration Statement on Form F-1, filed with the SEC on May 29, 2024)
3.2	Articles of Amendment of Medicus Pharma Ltd., effective as of September 29, 2023 (incorporated by reference from Exhibit 3.2 to the Registrant's Registration Statement on Form F-1, filed with the SEC on May 29, 2024)
3.3	Articles of Amendment of Medicus Pharma Ltd., effective as of October 28, 2024 (incorporated by reference from Exhibit 3.4 to the Registrant's Registration Statement on Form F-1, filed with the SEC on October 29, 2024)
3.4	Articles of Amendment of Medicus Pharma Ltd., effective as of August 8, 2025 (incorporated by reference from Exhibit 3.2 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 11, 2025)
3.5	Bylaws of Medicus Pharma Ltd. (incorporated by reference from Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 11, 2025)
4.1*	Description of Securities of Medicus Pharma Ltd.
4.2	Warrant Agency Agreement, dated November 15, 2024 by and between Medicus Pharma Ltd. and Odyssey Transfer and Trust Company, as warrant agent (incorporated by reference from Exhibit 99.3 to the Registrant's Form 6-K, furnished to the SEC on November 18, 2024)

4.3	Public Warrant (incorporated by reference from Exhibit 99.4 to the Registrant's Form 6-K, furnished to the SEC on November 18, 2024)
4.4	Regulation A Warrant (incorporated by reference from Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on March 11, 2025)
4.5	Warrant Agency Agreement, dated March 10, 2025, by and between the Registrant and Odyssey Transfer and Trust Company, as Warrant Agent (incorporated by reference from Exhibit 4.3 to the Registrant's Current Report on Form 8-K, filed with the SEC on March 11, 2025)
4.6	Form of Subscription Agreement (incorporated by reference from Exhibit 4.8 to the Company's Registration Statement on Form S-1, filed with the SEC on May 27, 2025)
4.7	June 2030 Warrant (incorporated by reference from Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on June 2, 2025)
4.8#	Warrant Agency Agreement, dated June 2, 2025, by and between Medicus Pharma Ltd. and Odyssey Transfer and Trust Company, as warrant agent (incorporated by reference from Exhibit 4.3 to the Registrant's Current Report on Form 8-K, filed with the SEC on June 2, 2025)
4.9	Form of Private Warrant (incorporated by reference from Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 14, 2025)
4.10	Debenture (incorporated by reference from Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 18, 2025)
4.11	Form of Series C Private Warrant (incorporated by reference from Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 8, 2025)
4.12	Form of Series D Private Warrant (incorporated by reference from Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 8, 2025)
10.1†	Exclusive License Agreement, dated April 29, 2016, by and between the University of Pittsburgh - Of the Commonwealth System of Higher Education and SkinJect, Inc. (incorporated by reference from Exhibit 10.1 to the Registrant's Registration Statement on Form F-1, filed with the SEC on May 29, 2024)
10.2	First Amendment to Exclusive License Agreement, dated February 26, 2020, by and between the University of Pittsburgh - Of the Commonwealth System of Higher Education and SkinJect, Inc. (incorporated by reference from Exhibit 10.2 to the Registrant's Registration Statement on Form F-1, filed with the SEC on May 29, 2024)
10.3	Second Amendment to Exclusive License Agreement, dated April 23, 2024, by and between the University of Pittsburgh - Of the Commonwealth System of Higher Education and Medicus Pharma Ltd. (incorporated by reference from Exhibit 6.3 to the Registrant's Offering Statement on Form 1-A, filed with the SEC on February 14, 2025)
10.4†	Clinical Trial Agreement, dated December 3, 2021, by and between SkinJect, Inc., The Trustees of Columbia University in the City of New York, the New York and Presbyterian Hospital and Faramarz Samie, M.D. (incorporated by reference from Exhibit 10.4 to the Registrant's Registration Statement on Form F-1, filed with the SEC on May 29, 2024)
10.5+	Medicus Pharma Ltd. Equity Incentive Plan (as amended) (incorporated by reference from Exhibit 4.6 to the Registrant's Registration Statement on Form S-8, filed with the SEC on November 14, 2024)

10.6+	Employment Agreement, dated November 14, 2024, by and between Medicus Pharma Ltd. and Faisal Mehmud (incorporated by reference from Exhibit 6.7 to the Registrant's Offering Statement on Form 1-A, filed with the SEC on February 14, 2025)
10.7+	Amended and Restated Employment Agreement, dated December 2, 2024, by and between Medicus Pharma Ltd. and Edward Brennan (incorporated by reference from Exhibit 6.8 to the Registrant's Offering Statement on Form 1-A, filed with the SEC on February 14, 2025)
10.8+	Management Agreement, dated October 18, 2023, by and between Medicus Pharma Ltd. and RBx Capital, LP (incorporated by reference from Exhibit 10.9 to the Registrant's Registration Statement on Form F-1, filed with the SEC on May 29, 2024)
10.9	Standby Equity Purchase Agreement, dated as of February 10, 2025, by and between Medicus Pharma Ltd. and YA II PN, LTD. (incorporated by reference from Exhibit 1.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on February 11, 2025)
10.10	Form of Warrant Inducement Agreement (incorporated by reference from Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 14, 2025)
10.11+	Employment Agreement, dated June 13, 2025, by and between Medicus Pharma Ltd. and Andrew Smith (incorporated by reference from Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 11, 2025)
10.12	Securities Purchase Agreement, by and between Medicus Pharma Ltd. and YA II PN, Ltd., dated September 17, 2025 (incorporated by reference from Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 18, 2025).
10.13	Global Guaranty Agreement, by and among the subsidiaries of Medicus Pharma Ltd. set forth in Schedule I thereto, dated September 17, 2025 (incorporated by reference from Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 18, 2025).
10.14	Form of Warrant Inducement Agreement (incorporated by reference from Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 8, 2025)
10.15	Equity Distribution Agreement, dated December 29, 2025, by and among Medicus Pharma Ltd., Maxim Group LLC and Yorkville Securities, LLC (incorporated by reference from Exhibit 1.1 to the Registrant's Registration Statement on Form S-3, filed with the SEC on December 30, 2025)
10.16+*	Amended and Restated Employment Agreement, dated November 25, 2025, by and between Medicus Pharma Ltd. and Carolyn Bonner
19.1	Medicus Pharma Ltd. Insider Trading Policy (incorporated by reference from Exhibit 19.1 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 28, 2025)
21.1	List of Subsidiaries of Medicus Pharma Ltd. (incorporated by reference from Exhibit 21.1 to the Registrant's Registration Statement on Form S-1, filed with the SEC on September 29, 2025)
23.1*	Consent of KPMG LLP
23.2*	Consent of EisnerAmper LLP
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97	Medicus Pharma Ltd. Clawback Policy (incorporated by reference from Exhibit 97 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 28, 2025)
101.INS*	Inline XBRL Instance Document-the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith
+ Indicates a management contract or compensatory plan.
Schedules and certain other private or confidential information (as indicated therein) have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company hereby undertakes to furnish supplementally copies of any of the omitted schedules upon request by the SEC.
† Certain private or confidential information (as indicated therein) have been redacted pursuant to Item 601(a)(6) of Regulation S-K.

Item 16. Form 10-K Summary.

Not applicable.

SIGNATURES

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this annual report to be signed on its behalf by the undersigned, thereunto duly authorized, in W. Conshohocken, Pennsylvania on the 25th day of March, 2026.

MEDICUS PHARMA LTD.

By: /s/ Dr. Raza Bokhari
Name: Dr. Raza Bokhari
Title: Executive Chairman and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this annual report has been signed below by the following persons in the capacities and on the dates indicated.

Name	Position	Date
/s/ Raza Bokhari Dr. Raza Bokhari	Executive Chairman and Chief Executive Officer (Principal Executive Officer)	March 25, 2026
/s/ Carolyn Bonner Carolyn Bonner	President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 25, 2026
/s/ Larry Kaiser Dr. Larry Kaiser	Director	March 25, 2026
/s/ Robert J. Ciaruffoli Robert J. Ciaruffoli	Director	March 25, 2026
/s/ William L. Ashton William L. Ashton	Director	March 25, 2026
/s/ Barry Fishman Barry Fishman	Director	March 25, 2026
/s/ Sara R. May Dr. Sara R. May	Director	March 25, 2026
/s/ Cathy McMorris Rodgers Hon. Cathy McMorris Rodgers	Director	March 25, 2026
/s/ Ajay Raju Ajay Raju	Director	March 25, 2026
/s/ Patrick Mahaffy Patrick Mahaffy	Director	March 25, 2026

MEDICUS PHARMA LTD.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of
Medicus Pharma Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Medicus Pharma Ltd. and Subsidiaries (the "Company") as of December 31, 2024, and the related consolidated statements of operations and comprehensive loss, shareholders' equity, and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2024, and the consolidated results of their operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company experienced negative cash flows from operating activities and has incurred operating losses that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ EisnerAmper LLP

We have served as the Company's auditor since 2024.

EISNERAMPER LLP
Philadelphia, Pennsylvania

March 28, 2025

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders
Medicus Pharma Ltd.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Medicus Pharma Ltd. and subsidiaries (the Company) as of December 31, 2025, the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity, and cash flows for the year then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025, and the results of its operations and its cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred significant operating losses and cash outflows from operating activities that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2025.

New York, New York

March 25, 2026

Medicus Pharma Ltd.
Consolidated Balance Sheets
(expressed in United States dollars except number of shares)

	December 31, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	**$ 8,705,218**	$ 4,164,323
Prepaid expenses and other current assets	**1,086,121**	1,213,984
Deferred financing costs	**99,305**	-
Total current assets	**9,890,644**	5,378,307
Operating lease right-of-use assets	**170,733**	268,571
Total assets	**10,061,377**	5,646,878
Liabilities and Shareholder's equity		
Current liabilities		
Accounts payable	**3,435,297**	1,284,612
Accrued expenses and other current liabilities	**995,290**	762,835
Related party payable	**116,476**	142,459
Operating lease liability, current	**145,456**	116,323
Debentures	**5,245,543**	-
Total current liabilities	**9,938,062**	2,306,229
Loan payable	**25,865**	-
Operating lease liability, non-current	**60,139**	205,945
Total liabilities	**10,024,066**	2,512,174
Commitments and contingencies (Note 13)		
Shareholders' equity		
Common shares, no par value; 25,176,303 and 11,816,721 shares authorized, issued and outstanding at December 31, 2025 and 2024, respectively	**57,076,175**	30,518,195
Common shares to be issued	**313,934**	-
Additional paid-in capital	**6,879,575**	1,520,412
Accumulated other comprehensive income	**10,880**	-
Accumulated deficit	**(64,348,118**	(28,903,903
Total shareholders' equity attributable to Medicus Pharma Ltd.	**(67,554)**	3,134,704
Non-controlling interests	**104,865**	-
Total shareholders' equity	**37,311**	3,134,704
Total liabilities and shareholders' equity	**10,061,377**	5,646,878

The accompanying notes are an integral part of these consolidated financial statements.

Medicus Pharma Ltd.

Consolidated Statements of Operations and Comprehensive Loss

(expressed in United States dollars, except number of shares)

	Years Ended December 31,	
	2025	**2024**
Operating expenses:		
General and administrative	**$ 17,920,391**	$ 7,653,116
Research and development	**7,721,436**	3,527,786
In-process research and development (IPR&D) - Teverelix	**8,717,475**	-
Total operating expenses	**34,359,302**	11,180,902
Loss from operations	**(34,359,302)**	(11,180,902)
Other income (expense)		
Interest income (expense)	**(197,382)**	25,386
Loss on SEPA settlements	**(278,854)**	-
Change in fair value of debentures	**(583,823)**	-
Loss on extinguishment of debentures	**(25,000)**	-
Total other income (expense)	**(1,085,059)**	25,386
Net loss for the year	**(35,444,361)**	(11,155,516)
Deemed dividend on warrant inducement	**(11,837,298)**	-
Net loss for the year attributable to common shareholders	**(47,281,659)**	(11,155,516)
Foreign currency translation adjustment	**(10,730)**	-
Comprehensive loss for the year attributable to common shareholders	**(47,292,389)**	(11,155,516)
Net loss attributable to		
Common shareholders of the Company	**(47,281,513)**	(11,155,516)
Non-controlling interests	**(146)**	-
Comprehensive loss attributable to		
Common shareholders of the Company	**(47,292,239)**	(11,155,516)
Non-controlling interests	**(150)**	-
Net loss per share attributable to common shareholders - basic and diluted	**$ (2.74)**	$ (1.16)
Weighted average number of common shares outstanding - basic and diluted	**17,283,824**	9,619,184

The accompanying notes are an integral part of these consolidated financial statements

Medicus Pharma Ltd.

Consolidated Statements of Changes in Shareholders' Equity

(expressed in United States dollars, except number of shares)

	Common shares		Shares to be issued		Additional paid-in capital	Accumulated deficit	Accumulated Other Comprehensive Income	Non-Controlling Interest	Total
	#	$	#	$	$	$	$	$	$
Balance as of December 31, 2023	8,076,673	18,761,250	-	-	98,585	(17,748,387)	-	-	1,111,448
Issuance of common shares upon conversion of debt	1,308,798	5,210,962	-	-	-	-	-	-	5,210,962
Issuance of common shares in connection with a private placement, net of issuance costs of $375,000	1,461,250	5,470,000	-	-	-	-	-	-	5,470,000
Issuance of common shares and warrants in connection with initial public offering, net of issuance costs of $2,218,014	970,000	1,075,983	-	-	708,708	-	-	-	1,784,691
Stock-based compensation	-	-	-	-	713,119	-	-	-	713,119
Net loss and comprehensive loss for the year	-	-	-	-	-	(11,155,516)	-	-	(11,155,516
Balance as of December 31, 2024	**11,816,721**	**30,518,195**	**-**	**-**	**1,520,412**	**(28,903,903)**	**-**	**-**	**3,134,704**
Issuance of common shares and warrants in connection with Regulation A offering, net of issuance costs of $483,020	1,490,000	2,076,507	-	-	1,612,474	-	-	-	3,688,981
Issuance of common shares in connection with SEPA	3,783,693	9,006,270	-	-	-	-	-	-	9,006,270
Issuance of common shares and warrants in connection with June equity financing, net of offering costs of $809,606	2,260,000	3,961,899	-	-	2,234,495	-	-	-	6,196,394
Issuance of common shares for asset acquisition	1,397,184	2,129,410	205,980	313,934	-	-	-	105,161	2,548,505
Share issuance costs	-	(653,504)	-	-	-	-	-	-	(653,504)
Issuance of common shares upon exercise of stock warrants	4,283,705	9,874,998	-	-	-	-	-	-	9,874,998
Issuance of common shares upon exercise of stock options	145,000	162,400	-	-	-	-	-	-	162,400
Stock-based compensation	-	-	-	-	1,512,194	-	-	-	1,512,194
Warrants issued under warrant inducements	-	-	-	-	11,837,298	-	-	-	11,837,298
Deemed dividend on warrant inducements	-	-	-	-	(11,837,298)	-	-	-	(11,837,298)
Net loss and comprehensive loss for the year		-	-	-	-	(35,444,215)	-	(146)	(35,444,361)
Other comprehensive income for the year	-	-	-	-	-	-	10,880	(150)	10,730
Balance as of December 31, 2025	**25,176,303**	**57,076,175**	**205,980**	**313,934**	**6,879,575**	**(64,348,118)**	**10,880**	**104,865**	**37,311**

The accompanying notes are an integral part of these consolidated financial statements.

Medicus Pharma Ltd.
Consolidated Statements of Cash Flows
(expressed in United States dollars)

	Years Ended December 31,	
	2025	**2024**
Cash flows from operating activities		
Net loss for the year	**$ (35,444,361)**	$ (11,155,516)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	1,512,194	713,119
Non-cash interest expense	429,061	74,005
Change in operating lease right-of-use assets	97,838	88,234
Change in fair value of debentures	583,823	-
Loss of extinguishment of debentures	25,000	-
IPR&D - Teverelix	8,717,475	-
Foreign exchange gain/loss	41,947	-
Loss on SEPA settlements	278,854	-
Issuance cost related to SEPA	300,000	-
Cost of issuance of debentures	111,725	-
Changes in operating assets and liabilities:		
Prepaid expenses	352,825	(1,040,265)
Deferred financing costs	(99,305)	-
Accounts payable	923,552	808,745
Accrued expenses and other current liabilities	(438,802)	358,018
Operating lease liability	(142,612)	(70,080)
Related party payable	(25,983)	(23,491)
Net cash used in operating activities	**(22,776,769)**	**(10,247,231)**
Cash flows from financing activities		
Proceeds from issuance of convertible promissory notes	-	5,172,500
Proceeds from initial public offering, net of offering expenses	-	2,049,716
Proceeds from issuance of common shares and warrants, net of issuance costs	9,790,015	5,470,000
Proceeds from issuance of debentures	11,866,293	-
Repayment of the debentures and other loan	(7,391,107)	-
Proceeds from issuance of common shares under SEPA	8,427,416	-
Proceeds from exercise of warrants	9,874,998	-
Proceeds from exercise of stock options	162,400	-
Costs to issue debentures	(136,726)	-
Issuance costs for common shares	(653,504)	-
Net cash provided by financing activities	**31,939,785**	**12,692,216**
Cash flows from investing activities		
Net cash paid for Antev asset acquisition including transaction costs	(4,619,152)	-
Net cash used in investing activities	**(4,619,152)**	-
Foreign currency effect on cash and cash equivalents	(2,969)	-
Net increase in cash and cash equivalents during the year	**4,540,895**	2,444,985
Cash and cash equivalents, beginning of the year	**4,164,323**	1,719,338
Cash and cash equivalents, end of the year	**8,705,218**	**4,164,323**

Supplemental information			
Cash paid for interest	**$**	**221,663**	40,563
Supplemental disclosure of non-cash investing and financing activities			
Right-of-use assets obtained in exchange for lease liabilities	**$**	**-**	356,805
Deemed dividend on warrant inducement	**$**	**11,837,298**	**-**
Issuance costs included in accounts payable	**$**	**95,360**	265,025
Shares issued for Antev asset acquisition	**$**	**2,129,410**	**-**
Shares to be issued for Antev asset acquisition	**$**	**313,934**	-
Issuance of shares related to SEPA agreement	**$**	**300,000**	**-**
Accrued interest converted into common shares	**$**	**-**	38,462

The accompanying notes are an integral part of these consolidated financial statements.

1. Description of business

Medicus Pharma Ltd. (the "Company"), formerly Interactive Capital Partners Corporation, is a clinical stage, multi-strategy, life sciences, biotech company focused on investing in and accelerating clinical development programs of novel and potentially disruptive therapeutic assets.

The Company is a public limited Company originally incorporated pursuant to the provisions of the Business Corporations Act (Ontario) on April 30, 2008, as a private company named Interactive Capital Partners Corporation, with nominal assets and liabilities. The Company's registered office is located at 100 King Street West, Suite 3400, One First Canadian Place, Toronto, Ontario, Canada, and its head office is located at 300 Conshohocken State Rd., Suite 200, W. Conshohocken, PA.

Liquidity and Going Concern

The Company has incurred significant operating losses and cash outflows from operating activities since its inception. As of December 31, 2025 and 2024, the Company had an accumulated deficit of $64,348,118 and $28,903,903, respectively.

From the Company's inception through the year ended December 31, 2025, the Company has funded its operations primarily through equity and debt financings.

On February 10, 2025, the Company announced that it had entered into the SEPA (as defined below). Subject to the satisfaction of certain conditions, Yorkville (as defined below) has committed to purchase the Company's common shares up to an aggregate gross sales price of $15,000,000 during the 36 months following the date of the SEPA. See Note 5 for further details.

The Company expects to continue to incur significant operating losses for the foreseeable future and may never become profitable. If the Company is unable to secure additional capital, it may be required to take additional measures to reduce costs in order to conserve its cash in amounts sufficient to sustain operations and meet its obligations. These measures could cause significant delays or entirely prevent the Company's continued efforts to commercialize its current or future products, which are critical to the realization of its business plan and the future operations of the Company. This uncertainty, along with the Company's history of losses, indicates that there is substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. The accompanying consolidated financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern.

In addition to accessing public markets through the exercise of outstanding warrants, additional public and private debt and equity financings, the SEPA and the ATM (as defined below), management believes that the Company has access to additional capital resources through public and/or private equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, it is possible that the Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into strategic alliances or other arrangements on favorable terms, or at all. The terms of any financing may adversely affect the holdings or the rights of the Company's shareholders. If the Company is unable to obtain funding, the Company could be required to delay, reduce or eliminate research and development programs, product portfolio expansion, or future commercialization efforts, which could adversely affect its business prospects. The Company is subject to risks associated with any specialty biotechnology company that has substantial expenditures for research and development. There can be no assurance that the Company's research and development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially viable.

Reverse Share Split

On June 25, 2024, the Company's shareholders approved an amendment to the Company's articles of incorporation to provide for the share consolidation, or reverse share split, of the Company's issued and outstanding common shares at such a consolidation ratio to be determined by the Board of Directors of the Company in its sole discretion, to permit the Company to satisfy all conditions and necessary regulatory approvals to list the common shares on a U.S. national securities exchange as the Board of Directors of the Company may determine in its sole direction (the "Share Consolidation"). The Board of Directors of the Company approved the Share Consolidation on October 15, 2024, and the Share Consolidation was completed by the Company on October 28, 2024, at the ratio of 1-for-2.

After the completion of the Share Consolidation, the number of the Company's issued and outstanding common shares decreased from 21,693,560 to 10,846,721. The par value of the Company's common shares remains unchanged at $0 per share after the Share Consolidation.

Share and per share data presented in these consolidated financial statements for all periods presented has been adjusted for the Share Consolidation.

2. Summary of significant accounting policies

Basis of presentation

The accompanying consolidated financial statements ("financial statements") are presented in United States dollars, and are prepared in conformity with accounting principles generally accepted in the United States of America ("US GAAP") and pursuant to the rules and regulations of the U.S. Securities and Exchange Commission ("SEC") for financial information.

Basis of consolidation

These consolidated financial statements include the financial statements of the Company and its wholly-owned subsidiaries, SkinJect, Inc., Medicus Pharma Inc and Antev Limited ("Antev"). All intercompany balances and transactions have been eliminated on consolidation. The functional currency of the Company and its two wholly-owned subsidiaries, SkinJect, Inc. and Medicus Pharma Inc., is the United States dollar (USD). The functional currency of the Company's other subsidiary, Antev, is Pound Sterling (GBP).

Use of estimates

The preparation of these consolidated financial statements in accordance with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the consolidated financial statements, and the reported amounts of income and expenses during the reporting period. Key estimates include the valuation of stock-based awards, the incremental borrowing rate for lease liabilities, the fair value of Debentures and Warrants, the discount for lack of marketability on shares issued for the Antev acquisition, and the valuation allowance on deferred tax assets, all of which are management's best estimates.

Estimates are based on historical experience, where applicable, and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. By their nature, these estimates are subject to measurement uncertainty and the effect on the consolidated financial statements of changes in estimates in future years could be significant. Management believes that the estimates utilized in preparing the consolidated financial statements are reasonable, however, actual results could differ from those estimates.

Foreign operations remeasurement and translation

Foreign currency transactions are translated into the functional currency using the exchange rates at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions, and from the translation of monetary assets and liabilities denominated in foreign currencies at year end exchange rates, are generally recognized in the consolidated statements of operations and comprehensive loss. The results and financial position of foreign operation which has functional currency different from presentation currency are translated into the presentation currency as follows: assets and liabilities are translated at the closing rate at the date of that consolidated statement of financial position, income and expenses are translated at average exchange rates, and all resulting translated exchange differences are recognized in a separate component of other comprehensive loss within the consolidated statement of changes in shareholders' equity.

Cash and cash equivalents

Cash and cash equivalents include cash held at financial institutions and short-term investments in highly liquid marketable securities, having an original maturity of three months or less.

The Company holds money market accounts with maturities of three months or less. These money market accounts are included in cash and cash equivalents on the accompanying consolidated balance sheets.

Prepaid expenses

Prepaid expenses include payments for goods or services to be received in the future, insurance, subscription services and professional services.

Leases

The Company assess whether a contract is, or contains, a lease at inception of the contract and reassesses that conclusion if the contract is modified. The Company accounts for a contract as a lease when the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

The Company recognizes a right-of-use ("ROU") asset and a lease liability at the lease commencement date. The ROU asset is initially measured based on the initial amount of the lease liability adjusted for any lease payments made at or before the commencement date, plus any initial direct costs incurred and less any lease incentives received. The assets are amortized to the earlier of the end of the useful life of the ROU asset or the lease term using the straight-line method as this most closely reflects the expected pattern of consumption of the future economic benefits. The lease term includes periods covered by an option to extend if the Company is reasonably certain to exercise that option.

The lease liability is initially measured at the present value of the future lease payments at the commencement date, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, the Company's incremental borrowing rate.

Variable lease components and non-lease components are excluded from the lease payments used to calculate the right-of-use assets and lease liabilities and are recorded in the period in which the obligation for the payment is incurred.

The lease liability is measured at amortized cost using the effective interest method. It is remeasured when there is a change in future lease payments arising from a change in an index or rate, or if the Company changes its assessment of whether it will exercise a purchase, extension or termination option. When the lease liability is remeasured, a corresponding adjustment is made to the carrying amount of the ROU asset or is recorded in profit or loss if the carrying amount of the ROU asset has been reduced to zero.

The Company's operating lease cost for lease component payments is recognized on a straight-line basis over the lease term within general and administrative expenses.

The Company has elected to apply the practical expedient not to recognize ROU assets and lease liabilities for short term leases that have a lease term of 12 months or less. The lease payments for short-term leases are recognized as an expense.

Research and development

All research and development costs are expensed as incurred. Research and development costs consist primarily of salaries, employee benefits, costs associated with preclinical studies and clinical trials (including amounts paid to clinical research organizations and other professional services). Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

The Company records accruals for estimated research and development costs, comprising payments for work performed by third party contractors, laboratories, participating clinical trial sites, and others. Some of these contractors bill monthly based on actual services performed, while others bill periodically based upon achieving certain contractual milestones. For the latter, the Company accrues the expenses as goods or services are used or rendered. Clinical trial site costs related to patient enrollment are accrued as patients enter and progress through the trial. Upfront costs, such as costs associated with setting up clinical trial sites for participation in the trials, are expensed immediately once incurred as research and development expenses.

Stock-based compensation

The Company expenses stock-based compensation to employees and non-employees over the requisite service period based on the estimated grant-date fair value of the awards. The Company estimates the fair value of stock option grants and shares purchasable under the Company's Equity Incentive Plan (the "Plan") using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. The Company accounts for forfeitures as they occur. All stock-based compensation costs are recorded in the statements of operations and comprehensive loss based upon the underlying employees or non-employee's roles within the Company.

Acquisition

The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If so, the transaction is accounted for as an asset acquisition. If not, further determination is required as to whether or not the Company has acquired inputs and processes that have the ability to create outputs, which would meet the definition of a business. Significant judgment is required in the application of the screen test to determine whether an acquisition is a business combination or an acquisition of assets.

Acquisitions meeting the definition of business combinations are accounted for using the acquisition method of accounting, which requires that the purchase price be allocated to the net assets acquired at their respective fair values. In a business combination, any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill.

For asset acquisitions, a cost accumulation model is used to determine the cost of an asset acquisition. Direct transaction costs are recognized as part of the cost of an asset acquisition. The Company also evaluates which elements of a transaction should be accounted for as a part of an asset acquisition and which should be accounted for separately. The cost of an asset acquisition, including transaction costs, is allocated to identifiable assets acquired and liabilities assumed based on a relative fair value basis. Goodwill is not recognized in an asset acquisition. Any difference between the cost of an asset acquisition and the fair value of the net assets acquired is allocated to the non-monetary identifiable assets based on their relative fair values. When a transaction accounted for as an asset acquisition includes an in-process research and development ("IPR&D") asset, the IPR&D asset is only capitalized if it has an alternative future use other than in a particular research and development project. For an IPR&D asset to have an alternative future use: (a) the Company must reasonably expect that it will use the asset acquired in the alternative manner and anticipate economic benefit from that alternative use, and (b) the Company's use of the asset acquired is not contingent on further development of the asset subsequent to the acquisition date (that is, the asset can be used in the alternative manner in the condition in which it existed at the acquisition date). Otherwise, amounts allocated to IPR&D that have no alternative use are expensed to research and development. Asset acquisitions may include contingent consideration arrangements that encompass obligations to make future payments to sellers, contingent upon the achievement of future financial targets.

Contingent consideration is not recognized until it is probable and the amount can be reasonably estimated, at which point the consideration is allocated to the assets acquired on a relative fair value basis.

Net loss per share

Basic net loss per share is calculated by dividing net loss by the weighted average number of shares outstanding during the period. Diluted net loss per share is calculated by dividing net loss by the sum of the weighted average number of shares outstanding and all additional shares that would have been outstanding if potentially dilutive shares had been exercised at the beginning of the period.

Financial instruments

Financial instruments, including cash and cash equivalents, accounts payable and debentures are carried at cost, which management believes approximates fair value due to the short-term nature of these instruments. The fair value of lease obligations approximates their carrying amounts as a market rate of interest is attached to their repayment. The Company measures the fair value of financial assets and liabilities based on the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. The Company uses three levels of inputs that may be used to measure fair value:

Level 1-Inputs used to measure fair value are unadjusted quoted prices that are available in active markets for identical assets or liabilities as of the reporting date.

Level 2- Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.

Level 3-Unobservable inputs that are supported by little or no market activity and reflect the use of significant management judgment are used to measure fair value. These values are generally determined using pricing models for which the assumptions utilize management's estimates of market participant assumptions. The determination of fair value for Level 3 investments and other financial instruments involves the most management judgment and subjectivity.

Concentration of credit risk

Cash and cash equivalents are financial instruments that are potentially subject to concentrations of credit risk. The Company's cash and cash equivalents are deposited in accounts at large financial institutions, and amounts may exceed federally insured limits. The Company believes it is not exposed to significant credit risk due to the financial strength of the depository institutions in which the cash and cash equivalents are held. The Company maintains its cash equivalents in money market funds that invest in U.S. Treasury and agency securities.

Foreign currency transactions

Foreign exchange transaction gains and losses are included in general and administrative expense in the Company's consolidated statement of operations and comprehensive loss.

Income taxes

Income taxes are recorded in accordance with ASC 740, *Income Taxes*, which provides for deferred taxes using an asset and liability approach. Deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and net operating loss and credit carryforwards using enacted tax rates in effect for the year in which the differences are expected to impact taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

Tax benefits claimed or expected to be claimed on a tax return are recorded in the Company's consolidated financial statements. A tax benefit from an uncertain tax position is only recognized if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements from such a position are measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate resolution. Uncertain tax positions have had no impact on the Company's consolidated financial condition, results of comprehensive loss or cash flows.

Operating segments

Operating segments are identified as components of an entity about which separate discrete financial information is available for evaluation by the chief operating decision-maker ("CODM") in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment.

Recently adopted accounting pronouncements

In August 2020, the FASB issued ASU 2020-06 "Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40)" to simplify the accounting for convertible instruments by reducing the number of accounting models and to improve the information provided to the financial statement users by reducing the complexity and diversity of accounting practices. ASU 2020-06 is effective for our annual periods beginning January 1, 2024. The impact of adopting the amendment on the Company's financial statements was not significant.

In November 2023, the FASB issued ASU 2023-07 "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures" to expand the disclosures required by public entities for reportable segments, thereby responding to stakeholders' requests for more detailed information about expenses within each reportable segment. The expanded disclosures now require public entities to disclose significant expenses for reportable segments in both interim and in annual reporting periods, while entities with only a single reportable segment must now provide all segment disclosures required both in ASC 280 and under the amendments in ASU 2023-07. ASU 2023-07 is effective for our annual periods beginning January 1, 2024. See Note 14 for enhanced segment reporting disclosures.

In December 2023, the FASB issued ASU 2023-09 "Income Taxes (Topics 740): Improvements to Income Tax Disclosures" to expand the disclosure requirements for income taxes, specifically related to the rate reconciliation and income taxes paid. ASU 2023-09 is effective for our annual periods beginning January 1, 2025, with early adoption permitted. The disclosures have been implemented as required for the year-ended December 31, 2025. See Note 8 for enhanced income tax disclosures.

[expressed in United States dollars, except share amounts]

Recently issued accounting pronouncements

In November 2024, the FASB issued ASU 2024-04 "Debt-Debt with Conversion and Other Options (Subtopic 470-20: Induced Conversions of Convertible Debt Instruments", to improve consistency and relevance of accounting for induced conversions of convertible debt instruments and it addresses scenarios involving convertible debt instruments and cash conversion features and those not currently convertible. ASU 2024-04 is effective for our annual period beginning January 1, 2026, with early adoption permitted for entities that adopted the amendment in ASU 2020-06. We are currently evaluating the potential effect that the updated standard will have on our financial statement disclosures.

In November 2024, the FASB issued ASU 2024-03 "Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures" to provide greater transparency about the components of specific expense categories in the income statements. The effective dates of ASU 2024-03 were subsequently clarified by ASU 2025-01. ASU 2025-01 is effective for our annual period beginning January 1, 2027, with early adoption permitted. We are currently evaluating the impact of adopting the amendment on the Company's financial statements.

There were no other significant updates to the recently issued accounting standards which may be applicable to the Company. Although there are several other new accounting pronouncements issued or proposed by the FASB, the Company does not believe any of those accounting pronouncements have had or will have a material impact on its financial position or operating results.

3. Balance sheet components

Prepaid expenses include the following:

	Year ended December 31,	
	2025	**2024**
Insurance	$ 345,084	$ 583,561
Contract research organizations	410,000	455,810
Professional services	300,033	144,643
Prepaid services	31,004	29,970
	$ 1,086,121	**$ 1,213,984**

[expressed in United States dollars, except share amounts]

Accrued expenses and other current liabilities include the following:

	Year ended December 31,	
	2025	**2024**
Accrued legal fees	$ 352,864	$ 495,016
Accrued compensation and benefits	300,181	140,989
Accrued other	342,245	126,830
	$ 995,290	**$ 762,835**

4. Leases

As of December 31, 2025, the Company had one operating lease for its corporate office that commenced in 2024, for which the Company recorded a right-of-use asset and lease liability as of the commencement date. The Company's lease does not contain a purchase option. Where the Company's lease contains an option to extend the lease term, the extended lease term is only included in the measurement of the lease when it is reasonably certain to remain in the lease beyond the non-cancellable term. The Company's lease also contains variable lease costs, which pertain to common area maintenance and other operating charges, that are expensed as incurred.

Balance sheet information related to the Company's lease is presented below:

	Year Ended December 31,	
	2025	2024
Operating lease		
Operating lease right-of-use assets	$ 170,733	$ 268,571
Operating lease liabilities - current	145,456	116,323
Operating lease liabilities - non-current	60,139	205,945

Other information related to leases is presented below:

	Year Ended December 31,	
	2025	2024
Lease cost		
Operating lease cost	$ 123,777	123,777
Other information		
Operating cash flows used in operating leases	(142,612)	(70,080)
Remaining lease term (in years)	1.50	2.42
Discount rate	10%	10%

[expressed in United States dollars, except share amounts]

As of December 31, 2025, the annual future minimum lease payments of the Company's operating lease liabilities were as follows:

Year ending December 31,	
2026	146,530
2027	74,348
Total future minimum lease payments, undiscounted	220,878
Present value discount	(15,283)
Total lease liability	**$ 205,595**

5. Share capital

Authorized

The Company has authorized an unlimited number of common shares participating, voting and without par value. Each holder of common shares is entitled to one vote for each share owned on all matters voted upon by shareholders.

On October 28, 2024, the Company completed a reverse share split at the ratio of 1-for-2, resulting in 10,846,721 common shares after conversion.

Conversion of convertible notes

On May 3, 2024, the Company issued convertible notes in the principal amount of $5,172,500. The convertible notes accrued interest at the rate of 10% per annum, payable in-kind semi-annually in arrears in the form of either cash or common shares of the Company, at the election of the holder, and had a maturity date of December 31, 2025.

Prior to January 1, 2025, the convertible notes would automatically convert to common shares in the event that the Company completed an initial public offering in the United States, at a conversion price equal to the greater of (i) a 20% discount to the initial public offering price and (ii) $4.00; or if there had been a change of control, at a conversion price of $4.00 per common share. On or after January 1, 2025, conversion would be at the option of the holder at a conversion price of $4.00 per common share. The Company had the option to redeem all or any portion of the convertible notes at a price equal to 100% of the outstanding principal plus accrued and unpaid interest up to but not including the date of redemption. In the event of a change of control, the Company would offer to repurchase the convertible notes at a price equal to 101% of the principal plus accrued and unpaid interest up to but not including the date of repurchase. The Company elected to account for the convertible notes in their entirety at fair value through profit and loss.

Subsequently, the note holders were given the option to convert at a conversion price of $4.00 per share prior to July 31, 2024. On June 28, 2024, all of the holders of the convertible notes elected to convert to common shares. The Company paid cash interest of $40,563 and accrued interest of $38,462 was converted, along with the principal amount of $5,172,500, into 1,308,798 common shares.

Private placement

On June 28, 2024, the Company issued 1,461,250 common shares as part of a private placement for total proceeds of $5,845,000 at $4.00 per common share. The Company incurred finders' fees of $375,000, which were recognized in equity as deduction from the gross proceeds received.

[expressed in United States dollars, except share amounts]

Initial Public Offering

On November 14, 2024, the Company completed the sale of 970,000 Units, with each Unit consisting of one common share and one warrant to purchase one common share (the "Unit") at the price of $4.125 per Unit. In addition, the underwriters exercised an option to purchase 145,500 warrants (the 'Overallotment Warrants") at a price of $0.01 per warrant.

Total gross proceeds from the IPO were $4,002,705, including the proceeds from the Overallotment Warrants. The Company incurred total issuance costs of $2,218,014, including underwriter fees, and legal and other professional fees incurred directly related to the issuance.

The incremental costs directly associated with the issuance were recognized as a deduction in equity and allocated based on the relative fair values of the warrants and common shares on a standalone basis.

The fair value of the common shares was based on the Company's stock price on the day of issuance of $2.65 and the fair value of the warrants was $1.7419 per warrant. The warrants were recognized in additional paid-in capital as they met the criteria for equity classification.

The fair value of the warrants was estimated using the Black-Scholes option pricing model with the following inputs:

		2024
Valuation date share price	$	2.65
Exercise price	$	4.64
Dividend yield		-
Risk-free interest rate		4.32%
Expected warrant life		5 years
Expected volatility		95%

Regulation A Offering

On March 10, 2025, the Company closed a Tier II Regulation A offering for gross proceeds of $4,172,000. The Company issued 1,490,000 units at a price of $2.80 per unit. Each unit consisted of one common share of the Company and one warrant to purchase one common share of the Company (each a "Regulation A Warrant"). The Regulation A Warrants have an exercise price of $2.80 per share and will expire 5 years from the date of issuance on March 10, 2030. The Company incurred total issuance costs of $483,020, including legal fees and placement fees directly related to the issuance. The issuance costs incurred were recognized as a reduction in equity and allocated based on the relative fair values of the Regulation A Warrants and common shares on a standalone basis. The fair value of the common shares was based on the Company's share price on the day of issuance of $3.40 and the fair value of the Regulation A Warrants was $2.63 per warrant. The Regulation A Warrants were recognized in additional paid-in capital as they met the criteria for equity classification.

June 2025 Public Offering

On June 2, 2025, the Company closed a public offering of 2,260,000 units, with each unit consisting of one common share of the Company, and one warrant to purchase one common share, at a price of $3.10 per unit (the "June 2030 Warrants"), for gross proceeds of $7,006,000, before deducting placement agent fees and other estimated offering expenses (the "June 2025 Public Offering"). The June 2030 Warrants were immediately exercisable for one of our common shares at an exercise price of $3.10 per share and will expire 5 years from the date of issuance on June 3, 2030. The units were offered pursuant to the Company's Registration Statement on FormS-1, initially filed with the SEC under the Securities Act on May 27, 2025 and declared effective by the SEC on May 29, 2025. The Company incurred issuance costs of $809,606, including legal fees and placement fees directly related to the issuance. The issuance costs incurred were recognized as a reduction in equity and allocated based on the relative fair values of the June 2030 Warrants and common shares on a standalone basis. The fair value of the common shares were based on the Company's share price on the day of issuance of $2.63 and the fair value of the June 2030 Warrants were $1.92 per warrant. The June 2030 Warrants were recognized in additional paid-in capital as they met the criteria for equity classification.

On July 14, 2025, 1,340,000 of Regulation A Warrants were exercised for cash, for proceeds of $3,752,000 during the year ended December 31, 2025 under inducement offer with a certain accredited and institutional holder (the "Holder"). The Company issued 1,340,000 Series A and 1,340,000 Series B warrants to the Holder as consideration of early exercise of its Regulation A Warrants. The new warrants meet equity classification criteria under ASC 815-40 and are not subject to remeasurement. The fair value of the new warrants is recognized as a deemed dividend, offsetting the increase in additional paid-in capital, resulting in no net impact on equity. The exercise price of each of the Series A and B warrants granted on July 14, 2025 under the inducement offer is $3.75 and expected life is for 5 years. The fair value of the warrants granted is $4,954,518 using the Black Scholes option pricing model.

As of December 31, 2025, 1,473,800 of the 1,490,000 Regulation A Warrants have been exercised for cash, for proceeds to the Company of $4,126,639 during the year ended December 31, 2025.

As of December 31, 2025, 129,905 Warrants issued as part of the IPO have been exercised for cash for proceeds to the Company of $602,756 during the year ended December 31, 2025.

On December 5, 2025, the Company entered into a warrant inducement agreement with the Holder for immediate exercise of all outstanding Series A and Series B warrants that the Company had originally issued on July 15, 2025. The exercise price of the outstanding Series A and Series B warrants was amended to $1.92 per share from the original exercise price of $3.75. As part of this inducement, the Holder agreed to exercise all outstanding warrants to purchase an aggregate of 2,680,000 shares of the Company's common stock at an exercise price of $1.92 per share (the amended exercise price). The gross proceeds from the exercise of the warrants are $5,145,600. In consideration for immediate cash exercise, the Company agreed to issue to the Holder unregistered Series C and Series D warrants to purchase an aggregate of 4,020,000 shares of the Company's common stock, each with an exercise price of $2.00 per share and expected life of 5.5 years. The amended and new warrants meet equity classification criteria under ASC 815-40 and are not subject to remeasurement. The incremental fair value attributable to the amended warrants and the fair value of the new warrants is recognized as a deemed dividend, offsetting the increase in additional paid-in capital, resulting in no net impact on equity. The incremental fair value attributable to the amended warrants is $884,331 and the fair value of the warrants granted is $5,998,449 using the Black Scholes option pricing model.

The Company's Regulation A, June 2025, July 2025 and December 2025 Warrants are not actively traded and are therefore classified as Level 3 within the fair value hierarchy. The fair value of these warrants is estimated using a Black-Scholes option pricing model. The valuation incorporates significant unobservable inputs and management judgment.

[expressed in United States dollars, except share amounts]

The fair value of the Regulation A, June 2025, July 2025 and December 2025 Warrants were estimated using the Black-Scholes model with the following assumptions:

	Issue Date March 10, 2025	Issue Date June 2, 2025	Issue Date July 15, 2025	Issue date December 5, 2025
Valuation date share price	$ 3.40	$ 2.63	$ 3.13	$ 2.05
Exercise price	$ 2.80	$ 3.10	$ 3.75	$ 2.00
Dividend yield	-	-	-	-
Risk-free interest rate	3.98%	4.01%	3.995%	3.72%
Expected warrant life	5.00 years	5.00 years	5.00 years	5.50 years
Expected volatility	97.81%	97.42%	73.19%	87.31%

Warrant activity as below:

	Number of common share warrants outstanding	Weighted average exercise price $	Weighted average remaining life (years)
Outstanding as at December 31, 2023	-	-	-
Granted Warrants issued as part of the IPO	1,115,000	4.64	5
Outstanding as at December 31, 2024	1,115,500	4.64	5
Granted Regulation A Warrants on March 10, 2025	1,490,000	2.80	4
Granted warrants on June 2, 2025	2,260,000	3.10	4
Granted Series A and B warrants issued on July 15, 2025	2,680,000	3.75	5
Exercise of Regulation A Warrants	(1,473,800)	2.80	-
Exercise of Warrants issued as part of the IPO	(129,905)	4.64	-
Exercise of Series A and B warrants issued on July 15, 2025	(2,680,000)	3.75	-
Granted Series C and D Warrants on December 5, 2025	4,020,000	2.00	5
Total Warrants outstanding as at December 31, 2025	**7,281,795**	**2.70**	**4.90**

The number of warrants outstanding as at the year ended December 31, 2025:

		Warrants outstanding		
	Expiry date	**Exercise price**	**Number outstanding**	**Number exercisable**
Warrants issued as part of the IPO	November 15, 2029	$ 4.64	985,595	985,595
Regulation A Warrants	March 10, 2030	$ 2.80	16,200	16,200
June 30, 2030 Warrants	June 2, 2030	$ 3.10	2,260,000	2,260,000
Series C and D Warrants	June 5, 2031	$ 2.00	4,020,000	4,020,000

Standby Equity Purchase Agreement

On February 10, 2025, the Company also announced that it had entered into a standby equity purchase agreement (the "SEPA") with YA II PN, Ltd. ("Yorkville"). Pursuant to the SEPA and subject to the satisfaction of certain conditions, Yorkville has committed to purchase the Company's common shares, no par value, in increments up to an aggregate gross sales price of $15,000,000 during the 36 months following the date of the SEPA (such shares, the "Shares"). The Shares will be sold at the Company's option pursuant to the SEPA at 97% of the Market Price (as defined pursuant to the SEPA) and purchases are subject to certain limitations set forth in the SEPA. As consideration for Yorkville's commitment to purchase the common shares pursuant to the SEPA, the Company paid Yorkville a structuring fee in the amount of $25,000 and issued to Yorkville 105,840 common shares with a share price of $2.83 at issuance. The Company also incurred legal fees of $391,898 related to the SEPA. These costs are expensed to consolidated statement of operations and comprehensive loss. As of December 31, 2025, the Company issued 3,677,853 common shares at market price of $8,706,270 for proceeds of $8,427,416. During the year ended December 31, 2025, $4,430,833 of the gross proceeds were held back to partially repay the Company's outstanding debenture and interest to Yorkville.

On December 29, 2025, the Company entered into an equity distribution agreement (the "ATM Agreement") with Maxim Group LLP and Yorkville Securities LLC ("Yorkville Securities" and together with Maxim, the "Agents") to create an at-the-market equity program (the "ATM"). Under the ATM Agreement, the Company may offer and sell its common shares from time to time through the Agents. The Company agreed to pay the Agents a commission equal to 3% of the gross sales from the sales of the shares pursuant to the ATM Agreement.

6. Stock-based compensation

In 2023, the Company approved the Equity Incentive Plan (the "Plan"). The Plan provides both for the direct award or sale of shares and for the grant of options to purchase shares. Under the plan the total number of shares available for options cannot exceed 10% of the Company's issued and outstanding common shares at the time of any grant. The Company is authorized to issue options to employees, non-employee directors and consultants under the plan.

On June 25, 2024, the Board of Directors approved the acceleration of vesting for all outstanding share options to June 25, 2024, resulting in the Company recognizing the remaining expense for all share options outstanding and unvested as of that date.

On June 13, 2025, the Company granted 100,000 stock options to an employee under the Company's equity incentive plan. The options have an exercise price of $2.60 per share and a term of five years. The options vest in five equal annual installments, with 20,000 options vesting on each anniversary of the grant date.

On July 22, 2025, the Board of Directors of the Company approved the acceleration of vesting for 100,000 share options granted on December 17, 2024, 210,000 share options granted on December 17, 2024, and for 100,000 options granted on June 30, 2025, resulting in the Company recognizing $663,998 of remaining expense for such accelerated share options.

On July 22, 2025, the Company issued 700,000 stock options to individuals of the Company consisting of its directors, officers, and employees. The options are exercisable at $3.08 per share, expire five years from the grant date, and vest quarterly over a one-year period.

On August 29, 2025, the Company issued 25,000 stock options to a director of the Company. The options are exercisable at $1.94 per share, expire five years from the grant date, and vest quarterly over a one year period.

[expressed in United States dollars, except share amounts]

On December 16, 2025, the Company issued 685,000 stock options to individuals of the Company consisting of its directors, officers, and employees. The options are exercisable at $1.80 per share, expire five years from the grant date, and vest quarterly over a one year period.

The following table summarizes option transactions for the Plan:

	Number of options	Weighted average exercise price $	Weighted average remaining contractual life (years)	Aggregate intrinsic value $
Outstanding at December 31, 2023	**812,500**	**0.88**	**4.82**	**2.15**
Granted	**485,000**	**2.66**	**-**	**-**
Forfeited	**(112,500)**	**2.22**	**-**	**-**
Outstanding at December 31, 2024	**1,185,000**	**1.47**	**4.18**	**1.18**
Granted	**1,510,000**	**2.46**	**4.81**	**-**
Exercised	**(145,000)**	**1.11**	**-**	**-**
Forfeited	**(45,000)**	**2.76**	**-**	**-**
Outstanding at December 31, 2025	**2,505,000**	**2.05**	**2.75**	**-**
Exercisable at December 31, 2025	**1,313,750**	**1.81**	**3.49**	**-**
Unvested at December 31, 2025	**1,191,250**	**2.33**	**4.79**	**-**

The weighted average grant-date fair value of options granted during the years ended December 31, 2025 and December 31, 2024 was $1.80 and C$2.82, respectively. The weighted average grant-date fair value of options forfeited during the year ended December 31, 2025 was 2.44 (December 31, 2024 - C$2.36).

As of December 31, 2025 and December 31, 2024, there were $1,701,722 and $565,986 of unrecognized stock-based compensation cost related to share options outstanding, which is expected to be recognized over a weighted-average period of 2.75 and 2.25 years, respectively.

For the years ended December 31, 2025 and 2024, stock-based compensation expense was $1,512,194 and $713,119, respectively. Stock-based compensation expense has been reported in the Company's consolidated statements of operations and comprehensive loss within the line items 'general and administrative' and 'research and development' expenses.

The following table presents the assumptions that were used in the Black-Scholes option pricing model to determine the fair value of share options granted during the year:

	2025	2024
Expected dividend yield	-	-
Risk-free interest rate	3.68% - 4.02%	2.95% - 4.24%
Expected term (in years)	5 years	5 years
Expected volatility	87.31% - 101.54%	95% - 100%

[expressed in United States dollars, except share amounts]

The expected volatility is based on the share price volatility observed for comparable publicly traded companies over a period similar to the life of the options. The expected option life represents the period of time that options granted are expected to be outstanding. The risk-free interest rate is based on Canadian government bonds with a remaining term equal to the expected life of the options.

7. Net loss per share

Basic and diluted net loss per share attributable to ordinary shareholders was calculated as follows:

	Year ended December 31,	
	2025	**2024**
Net loss attributable to shareholders	$ (47,281,513)	$ (11,155,516)
Weighted average number of common shares outstanding during the year	17,283,824	9,619,184
Basic and diluted net loss per share attributable to shareholders	$ (2.74)	$ (1.16)

The Company's potentially dilutive securities as of December 31, 2025 and 2024, include stock options, warrants, and notes payable. The Company excluded the potential ordinary shares outstanding at each period end from the computation of diluted net loss per share attributable to ordinary shareholders for the period ended December 31, 2025 and 2024 because including them would have had an anti-dilutive effect.

8. Income taxes

As a result of the prospective adoption of *ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures (ASU 2023-09)*, certain tables are presented in a different format not comparable to prior year disclosures, and certain data contained within the tables may be presented differently than in prior years.

Canada and foreign components of loss before income taxes were as:

	2025	**2024**
Canada	**(16,817,273)**	(6,187,172)
Foreign	**(18,627,087)**	(4,968,344)
Loss before income taxes	**(35,444,361)**	(11,155,516)

Effective Tax Rate

The items accounting for the differences between income taxes computed at the Canadian federal statutory rate and our effective rate, reflecting the prospective adoption of ASU 2023-09, were as follows:

	%	**2025**
Canadian federal statutory income tax rate	15%	**(5,316,650)**
Domestic Federal		
Non-taxable and non-deductible items	(1.6%)	**568,150**
Statutory income tax differential		
Valuation Allowance Federal	(5.5%)	**1,954,660**
Domestic provincial income taxes, net of federal effect	0.0%	**-**
Foreign Tax Effects		
United States		
Non-deductible and other expenses	0.0%	**-**
Statutory income tax rate differential	3.5%	**(1,228,030)**
Valuation Allowance United States	(7.0%)	**2,492,310**
United Kingdom		
Statutory income tax differential	2.9%	**(1,019,710)**
Valuation Allowance United Kingdom	(7.2%)	**2,549,270**
Income tax (benefit)	0.0%	**-**

[expressed in United States dollars, except share amounts]

Domestic provincial income taxes are attributable to Ontario at a rate of 11.5%. The net effect of domestic provincial income taxes is $0 due to the full valuation allowance applicable to tax losses in this jurisdiction.

The items accounting for the differences between income taxes computed at the U.S. federal statutory rate of 21% and our effective rate, prior to the prospective adoption of ASU 2023-09, were as follows:

	2024
Income tax recovery at the statutory rate	(2,956,212)
Permanent differences	189,075
Impact of tax rate changes	42,865
Change in valuation allowance	2,724,272
	-

The Company's income tax (benefit) expense is allocated as follows:

	2025	**2024**
Current tax (benefit) expense	**-**	-
Deferred tax (benefit) expense	**-**	-
	-	-

The tax effect of temporary differences between US GAAP accounting and income tax accounting creating deferred income tax assets and liabilities were as follow:

	Year ended December 31,	
	2025	**2024**
Non-capital losses carry forward - Canada	**5,326,310**	1,973,535
Net operating losses carryforward - US	**6,194,650**	2,678,919
Net operating losses carryforward - UK	**369,910**	-
Intangible assets	**10,860**	10,855
Accrued expenses	**766,430**	994,653
Research and development tax credits	**210,610**	242,190
Other	**9,240**	14,230
Financing charges and interest	**1,212,190**	668,701
Convertible Debentures	**106,830**	-
Deferred income tax assets	**14,207,007**	6,583,083
Less: valuation allowance	**(14,207,007)**	(6,583,083)
Deferred income tax assets, net of valuation allowance	**-**	-

Deferred income tax balances reflect the effects of temporary differences between the carrying amounts of assets and liabilities and their tax bases and are stated at enacted tax rates expected to be in effect when the taxes are paid or recovered.

Medicus Pharma Ltd intends to be treated as a United States corporation for United States federal income tax purposes under section 7874 of the U.S. Tax Code and is expected to be subject to United States federal income tax. However, for Canadian tax purposes, Medicus Pharma Ltd is expected, regardless of any application of section 7874 of the U.S. Tax Code, to be treated as a Canadian resident company (as defined in the Income Tax Act (Canada) (the "ITA") for Canadian income tax purposes. As a result, Medicus Pharma Ltd will be subject to taxation both in Canada and the United States.

The Company has a valuation allowance on all of its deferred tax assets at December 31, 2025 and 2024, which based on the judgement of management are not more-likely than-not to be realized. In assessing the realizability of deferred tax assets, management considers whether it is more-likely-than-not that all or some portion of the deferred assets will not be realized. This ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period in which those deductible temporary differences become deductible. Based on the history of losses and projections for future taxable income, management believes that it is not more-likely than-not that the Company will realize the benefits of these deductible temporary differences.

The Company has $210,606 of US Research and Development Tax Credits which are available to reduce future US taxes payable and begin to expire in 2036.

In addition, the Company has gross Canadian operating tax loss carryforwards of $20,099,000. To the extent that the operating tax loss carryforwards are not used, they begin to expire in 2028. The Company also has gross US Federal net operating loss carryforward ("NOLs") of $20,949,000 of which approximately $1,253,000 begin to expire in 2035, while approximately $19,696,000 has an indefinite life.

In addition, the Company has approximately $20,949,000 of gross US State NOLs, which begin to expire in 2035.

The US NOL carryforwards may be, or become subject to, an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, as well as similar state tax provisions. This could limit the amount of NOLs that the Company can utilize annually to offset future taxable income or tax liabilities. The amount of the annual limitation, if any, will be determined based on the value of the Company immediately prior to an ownership change. Subsequent ownership changes may further affect the limitation in future years. If and when the Company utilizes the NOL carryforwards in a future period, it will perform an analysis to determine the effect, if any, of these loss limitation rules on the NOL carryforward balances.

The Company files income tax returns with Canada and its provinces and territories and is generally subject to routine examinations by the Canada Revenue Agency ("CRA"). Income tax returns filed with various provincial jurisdictions are generally open to examination for periods of four to five years subsequent to the filing of the respective returns.

The Company also files income tax returns for our U.S. operations and subsidiary with the U.S. federal and state tax jurisdictions. Generally, we are subject to routine examination by taxing authorities in the U.S. jurisdictions, which all years since inception are open to examination due to net operating losses.

There are presently no examinations of our Canadian, U.S. federal and U.S. state jurisdictions.

9. Related party transactions

On October 18, 2023, the Company signed an agreement with RBx Capital, LP ("RBx"), a family office controlled by the Company's Executive Chairman and CEO, that provides for certain managerial positions to be filled from within RBx. RBx is responsible for the payment and provision of all wages, bonuses, and benefits for these positions. Reimbursable salaries paid to RBx pursuant to this agreement are $125,000 per month. In December 2024, reimbursable salaries were changed to $100,000 per month. Reimbursable salaries paid to RBx were $1,200,000 and $1,300,000 during the years ended December 31, 2025, and 2024, respectively. Additional expenses of $446,264 and $180,857 were incurred by RBx on behalf of the Company during the years ended December 31, 2025 and 2024, respectively. The Company paid $1,570,504 and $1,623,316 to RBx during the years ended December 31, 2025 and 2024. The total amount of accounts payable to RBx was $194,152 and $142,459 as of December 31, 2025 and 2024, respectively.

In connection with the convertible notes issued by the Company on May 3, 2024 (Note 5), related parties consisting of key management personnel subscribed for 168,750 convertible notes in the principal amount of $675,000. Upon conversion the Company settled the convertible notes, along with accrued but unpaid interest, with 172,953 common shares.

10. Debentures

On May 2, 2025, the Company entered into a securities purchase agreement with Yorkville, under which the Company has issued and sold three debentures (the "Initial Debenture") to Yorkville in an aggregate principal amount totaling $5,000,000. The Debentures were issued at a discounted price of 90% for proceeds to the Company of $4,500,000. Interest accrued on the outstanding principal amount of the Initial Debenture at an annual rate of 8%, and was subject to a potential increase to 18% per annum upon the occurrence of certain events of default. The Initial Debenture was expected to mature on February 2, 2026 and are required to be repaid using proceeds from the SEPA. The Company elected the fair value option to account for the Initial Debenture. The underlying methodology used was a discounted cash flow approach. The Company initially recorded the Initial Debenture at fair value with any differences between the transaction price and fair value recorded as a gain or loss in the statement of operations and comprehensive loss. It was determined that the Initial Debenture was issued at fair value and therefore there was no gain or loss at the issuance date. Based on the fair value option, the Company subsequently remeasured the Initial Debenture at fair value at each reporting period with the gain or loss recognized in the statements of operations and comprehensive loss. The Initial Debenture was remeasured to reflect changes in market yields at June 30, 2025, resulting in a change in fair value of $200,000 that was recorded in the statements of operations and comprehensive loss for the year ended December 31, 2025.

On September 17, 2025, the Company entered into securities purchase agreement with Yorkville to issue a debenture with the principal amount of $8,000,000 issued at a discount of $633,707 for proceeds of approximately $7,366,293. Interest will accrue on the outstanding principal amount of the debenture at an annual rate of 8%, subject to a potential increase to 18% per annum upon the occurrence of certain events of default. The debenture will mature on September 17, 2026 and will be repaid using proceeds from the SEPA.

Partial proceeds of the debenture issued on September 17, 2025 were used to settle the previously issued debentures. The change in fair value of the previously issued debentures as at September 17, 2025 of $383,823 was recorded in the statements of operations and comprehensive loss for the year ended December 31, 2025.

The Company applied the provisions of ASC Topic 470-50 - Debt Modifications and Extinguishments to the Debenture restructuring. ASC 470-50 provides that substantial modifications of terms should be treated in the same manner as an extinguishment of debt. A cash-flow test is used to determine if the modification is substantial whereby cash flows prior to the modification are compared to cash flows subsequent to the modification. ASC 470-50 states that if the discounted cash flows under the terms of the new debt instrument are at least ten percent different from the discounted cash flows under the terms of the original instrument then the new terms represent a substantial modification and an extinguishment of debt has occurred.

As the new debenture replaced the prior debentures, the Company assessed the transaction under ASC470-50 and determined that the changes were substantial. Accordingly, the transaction was accounted for as an extinguishment of the previous debentures. A loss on extinguishment was recognized based on the difference between the fair value and the carrying amount of the extinguished debentures at settlement date. The loss on extinguishment of $25,000 was recorded in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2025.

The new debenture was initially recorded at fair value, based on the discounted proceeds. Subsequently, the Company accounted for the debenture at amortized cost using the effective interest rate method, resulting in accretion expense of $403,121 for the year ended December 31, 2025. The effective interest rate calculated was 24.86% as December 31, 2025.

[expressed in United States dollars, except share amounts]

Debentures issued on May 2, 2025, and paid back on September 17, 2025

	December 31, 2025
Proceeds of debentures	$ 4,500,000
Fair value loss	583,823
Repayment of debentures	(3,337,073)
Interest payment	(83,823)
Repayment of debentures on extinguishment	(1,662,927)
Ending balance	$ -

New debentures issued on September 17, 2025:	December 31, 2025
Proceeds of new debenture	7,366,293
Repayment of new debenture	(2,386,031)
Interest accretion	403,121
Interest payment	(137,840)
Ending balance	$ 5,245,543

11. Antev Asset Acquisition

On August 29, 2025 (the "Closing date"), the Company completed acquiring shares from securityholders of Antev Limited, or Antev (the "Antev Acquisition").

Pursuant to the terms of the Antev Acquisition, the Company acquired 98.60% of ownership in Antev including all the assets and its In-Process Research and Development (IPR&D) - Teverelix. The Company did so by issuing 1,603,164 common shares and payments of cash consideration of $2,970,166, and transaction costs of $1,992,798. Out of the 1,603,164 common shares, 205,980 shares issued will be delivered 210 days after the registration statement effectiveness. There was additional contingent consideration based on the following development milestones of the IPR&D:

Phases	Contingent Consideration agreed for Antev shares acquired through issue of shares	Contingent Consideration agreed for Antev shares acquired by cash payment
(i) Advanced Prostate Cancer - Phase 2 success or registration	$2.00 per common share issued	$1.47 per Antev share (pro rata interest in $5,333,200)
(ii) Acute Urinary Retention Prevention - Phase 2 success or registration	$7.50 per common share issued	$5.52 per Antev share (pro rata interest in $19,999,500)
(iii) FDA NDA approval - Hormone therapy for prostate cancer	Up to $20,000,000 (subject to pro rata reduction)	$5.52 per Antev share (pro rata interest in $20,000,000
(iv) FDA NDA approval - AUR prevention	Up to $20,000,000 (subject to pro rata reduction)	$5.52 per Antev share (pro rata interest in $20,000,000)

Per the terms of the acquisition, the common shares issued by the Company at Closing are subject to a staggered lock-up schedule. Specifically, 15% of the shares will be released at 30, 60, 90, 120, 150, and 180 days following the effectiveness of the Initial Registration Statement by the SEC, with the remaining 10% released on day 210. Additionally, these shares are subject to a six-month statutory hold under the U.S. Securities Act of 1933. A Registration Statement on Form S-1 was filed with the SEC to register the shares for resale. The SEC registration statement on the Form S-1 was declared effective on November 14, 2025.

[expressed in United States dollars, except share amounts]

The Company accounted for the transaction as an asset acquisition as substantially all of the estimated fair value of the gross assets acquired was concentrated in a single identified IPR&D, thus satisfying the requirements of the screen test in accordance with the criteria under ASC 805-10-55-5C. As the common shares issued by the Company were subject to lock-up restrictions, a discount of 21.4394%, which is a Level 3 input, was applied to the quoted closing price of the Company's shares ($1.94) to determine the fair value of the Company's common share. This resulted in a fair value of $1.52 per share, reflecting a discount of $0.42 per share.

The following is a summary of the considerations paid:

Fair value of 1,603,164 common shares	**$**	**2,443,344**
Cash paid		2,970,166
Transaction expenses		1,992,798
Contingent consideration		-
Total fair value consideration		7,406,308
Fair value of non-controlling interest		105,161
Total fair value for allocation to net assets of Antev		7,511,469

Due to the nature of the regulatory, sales and financing-based milestones, the contingent consideration was not included in the initial cost of assets acquired as they are contingent upon events that are outside the Company's control. Contingent consideration will be recognized when it becomes probable that the milestone conditions will be met and the amount can be estimated. As of December 31, 2025, none of the contingent events had occurred, nor were the milestone conditions considered probable to be met.

The allocation of Antev's net assets acquired were as follows:

Cash	$	13,353
Assets		224,719
Accrued and other accounts payable		(1,327,429)
Other liabilities		(116,649)
IPR&D - Teverelix		8,717,475
Net assets acquired	$	7,511,469

All costs allocated to IPR&D by the Company were recognized as research and development expenses in the Company's consolidated statement of operations and comprehensive loss as these assets had no alternative future use at the time of the acquisition transaction.

12. Fair value measurements

The accounting guidance for fair value establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;
Level 2: Inputs, other than the quoted prices in active markets that are observable either directly or indirectly; and
Level 3: Unobservable inputs in which there is little or no market data, or which require the reporting entity to develop its own assumptions.

[expressed in United States dollars, except share amounts]

The Company's cash and cash equivalents are classified as Level 1. The fair value of the Company's cash and cash equivalents is determined based on market pricing that is both objective and publicly available. As of December 31, 2025, and 2024, the fair value of the Company's cash and cash equivalents was $8,705,218 and $4,164,323, respectively. As of December 31, 2025, and 2024, the Company's cash equivalents are invested in money market funds.

	December 31, 2025			
	Level 1	**Level 2**	**Level 3**	**Total**
Current assets:				
Cash and cash equivalents	$ 8,705,218	$ -	$ -	$ 8,705,218
Total assets measured at fair value	$ 8,705,218	$ -	$ -	$ 8,705,218

	December 31, 2024			
	Level 1	**Level 2**	**Level 3**	**Total**
Current assets:				
Cash and cash equivalents	$ 4,164,323	$ -	$ -	$ 4,164,323
Total assets measured at fair value	$ 4,164,323	$ -	$ -	$ 4,164,323

The Company did not reclassify any investments between levels in the fair value hierarchy during the periods presented.

The carrying value of the debenture approximates the fair value since the financial instrument is short-term with a maturity date of September 17, 2026. As of December 31, 2025, and 2024, the carrying amounts of the Company's other financial instruments, which include cash and cash equivalents, accounts payable and accrued expenses approximate fair values because of their short-term maturities.

13. Commitment and contingencies

Commitments

As part of the acquisition of Antev, the Company may be required to make future payments contingent on the achievement of specified milestones. These potential payments represent a commitment and may result in future cash outflows. As these milestones conditions are not considered probable, the Company has not recognized liability related to the contingent consideration.

As of December 31, 2025, the Company had no long-term commitments.

Contingencies

In the ordinary course of business, from time to time, the Company may be involved in various claims related to operations, rights, commercial, employment or other claims. Although such matters cannot be predicted with certainty, management does not consider the Company's exposure to such claims to be material to these consolidated financial statements.

14. Segment reporting

The Company manages the business activities on a consolidated basis and operates as one reportable segment that constitutes all of the consolidated entity, which is the business of advancing the clinical development program of the Company's product, while opportunistically identifying, evaluating, and acquiring accretive assets, properties or businesses. The Company's CODM is its Chief Executive Officer. The accounting policies of the segment are the same as those described in the summary of significant accounting policies. The CODM uses consolidated net loss to measure segment loss, allocate resources and assess performance. The significant segment expense categories (general and administrative and research and development) are consistent with those presented on the face of the statements of operations and comprehensive loss. Other segment items are interest (income) expenses which are consistent with those presented on the face of the statements of operations and comprehensive loss. Additionally, the CODM reviews cash forecast models to determine where the Company will invest in planned research and development activities.

15. Subsequent events

Subsequent to year end, the Company completed sales under its ATM pursuant to which it issued 8,849,026 common shares for gross proceeds of approximately $5,868,435 or approximately $5,692,382 after incurring commissions payable to the Agents.

Subsequent to year end, on January 9, 2026, January 15, 2026, January 29, 2026, February 10, 2026, February 18, 2026 and February 23, 2026, March 5, 2026, March 6, 2026 and March 11, 2026, the Company sold 100,000, 44,680, 7,100, 175,000, 250,000, 275,000, 2,060,000, 1,425,000 and 1,000,000 common shares to Yorkville under the SEPA for proceeds of approximately $4,102,741. The Yorkville debenture has an outstanding balance of $2,437,240 after being paid down by the SEPA issuances noted above subsequent to year end.