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

FORM 10-K

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

For the fiscal year ended December 31, 2024

OR

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

Commission file number: 001-39811

DOGWOOD THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**85-4314201**
(State of Other Jurisdiction of incorporation or Organization)	(I.R.S. Employer Identification No.)
44 Milton Avenue, Alpharetta, GA	**30009**
(Address of principal executive offices)	(Zip code)

Registrant's telephone number, including area code: (866) 620-8655

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 Stock, $0.0001 Par Value per Share	DWTX	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 Section 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 (§232.0405 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 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. ☐

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 Section 240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

As of June 30, 2024, the last business day of the Registrant's most recently completed second fiscal quarter, the aggregate market value of the Registrant's common stock held by non-affiliates of the registrant was $5,755,555.38 based on the closing sale price as reported on the Nasdaq Capital Market.

The number of outstanding shares of the Registrant's Common Stock as of March 27, 2025 was 1,911,128.

Documents Incorporated by Reference

Part III incorporates certain information by reference from the definitive proxy statement to be filed by the registrant in connection with the 2025 Annual Meeting of Stockholders (the "Proxy Statement") with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the year ended December 31, 2024, provided that if such Proxy Statement is not filed within such period, such information will be included in an amendment to this Annual Report on Form 10-K to be filed within such 120-day period.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7, contains forward-looking statements. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this Annual Report on Form 10-K are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of risks, uncertainties and assumptions described under the sections in this Annual Report on Form 10-K titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Annual Report on Form 10-K. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

SUMMARY OF RISK FACTORS

The following is a summary of the principal risks described below in Part I, Item 1A. “Risk Factors” in this Annual Report on Form 10-K. We believe that the risks described in the “Risk Factors” section are material to investors, but other factors not presently known to us or that we currently believe are immaterial may also adversely affect us. The following summary should not be considered an exhaustive summary of the material risks facing us, and it should be read in conjunction with the “Risk Factors” section and the other information contained in this Annual Report on Form 10-K.

Risks Related to Our Financial Position and Need for Additional Capital

- Our recurring losses from operations raise substantial doubt that we will be able to continue as a going concern and our independent registered public accounting firm has issued an audit report that includes an explanatory paragraph referring to the uncertainty regarding our ability to continue as a going concern without additional capital becoming available.
- We have incurred losses since inception and anticipate that we will continue to incur losses for the foreseeable future.
- We will require additional capital to fund our operations.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.
- We have a limited operating history and no history of commercializing pharmaceutical products.

Risks Related to Development, Clinical Testing, Manufacturing and Regulatory Approval

- We are heavily dependent on the success of our product candidates, Halneuron®, IMC-1 and IMC-2, which are still under clinical development, and if these product candidates do not receive regulatory approval or, if approved, our commercialization efforts are unsuccessful, our business may be harmed.
- We may face future business disruption and related risks from the spread of infectious disease, which could have a material adverse effect on our business.
- Clinical trials are expensive, time-consuming and difficult to design and implement, and involve an uncertain outcome.
- If we are ultimately unable to obtain regulatory approval for any of our product candidates, our business will be substantially harmed.
- Results of preclinical studies, early clinical trials or analyses may not be indicative of results obtained in later trials.
- The market opportunities for our product candidates, if approved, may be smaller than we anticipate.
- We may never obtain approval for or commercialize Halneuron®, IMC-1, IMC-2 or any other product candidate in any other jurisdiction, which would limit our ability to realize their full global market potential.

Risks Related to Commercialization

- We face significant competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.
- Even if Halneuron®, IMC-1, IMC-2 or any other product candidate we develop receives marketing approval, it may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.
- If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing Halneuron®, IMC-1 or IMC-2, if approved.

Risks Related to Our Dependence on Third Parties

- We currently rely on third-party contract manufacturing organizations, or CMOs, for the production of clinical supply of Halneuron®, IMC-1 and IMC-2 and intend to rely on CMOs for the production of commercial supply of Halneuron®, IMC-1 and IMC-2, if approved.
- We intend to rely on third parties to conduct, supervise and monitor our clinical trials.

Risks Related to Healthcare Laws and Other Legal Compliance Matters

- Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates.
- We are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.
- If we become profitable, our ability to use our net operating loss carryforwards and other tax attributes to offset future taxable income or taxes may be subject to limitations.

Risks Related to Our Intellectual Property

- Our patents may be challenged in courts or in patent offices.
- Changes in patent laws or patent jurisprudence could diminish the value of patents in general.
- We enjoy only limited geographical protection with respect to certain patents.
- We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

Risks Related to Our Employees, Managing Our Growth and Our Operations

- Our future success depends on our ability to retain our key personnel and to attract, retain and motivate qualified personnel.
- We expect to expand our development, regulatory, and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.
- We may engage in acquisitions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources.
- We may be materially adversely affected by currency fluctuations in the United States dollar versus the Canadian dollar.

Risks Related to Our Common Stock

- If we are unable to maintain listing of our common stock on the Nasdaq Capital Market or another national stock exchange, it may be more difficult for our stockholders to sell their shares of common stock.
- The market price of our common stock is highly volatile.
- We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

Risks Related to the Combination

- There is no guarantee that the Combination (as defined below) will increase stockholder value.
- We may be required to settle shares of Series A Non-Voting Convertible Preferred Stock ("Series A Non-Voting Convertible Preferred Stock" or "Series A Preferred Stock") for cash, which could have a material adverse effect on our business and financial condition.
- The failure to successfully integrate the businesses of the Company and Pharmagesic (Holdings) Inc., ("Pharmagesic") in the expected timeframe could adversely affect Dogwood's results of operations, financial condition, and future results.

PART I

Item 1. Business

Our Company

We are a pre-revenue, development-stage biopharmaceutical company focused on developing new medicines to treat pain and fatigue-related disorders. Following the closing of the Combination described below, we became the sole owner of Pharmagesic (Holdings) Inc. ("Pharmagesic") and their wholly owned subsidiary, Wex Pharmaceuticals, Inc. ("Wex"), and Wex's wholly owned subsidiaries, IWT Bio, Inc. ("IWT"), Wex Medical Corporation ("WMC"), and Wex Medical Limited ("WML").

Our pipeline is focused on two separate pillars: Na_v 1.7 modulation to treat chronic and acute pain disorders and combination antiviral therapies targeting reactivated herpes virus mediated illnesses. The proprietary non-opioid Na_V 1.7 analgesic program is centered on our lead development candidate Halneuron®, which is a voltage-gated sodium channel modulator, a mechanism known to be effective for reducing pain. The antiviral program includes IMC-1 and IMC-2, which are novel, proprietary, fixed dose combinations of nucleoside analog, anti-herpes antivirals and the anti-inflammatory agent celecoxib for the treatment of fibromyalgia ("FM") and Long-COVID ("LC").

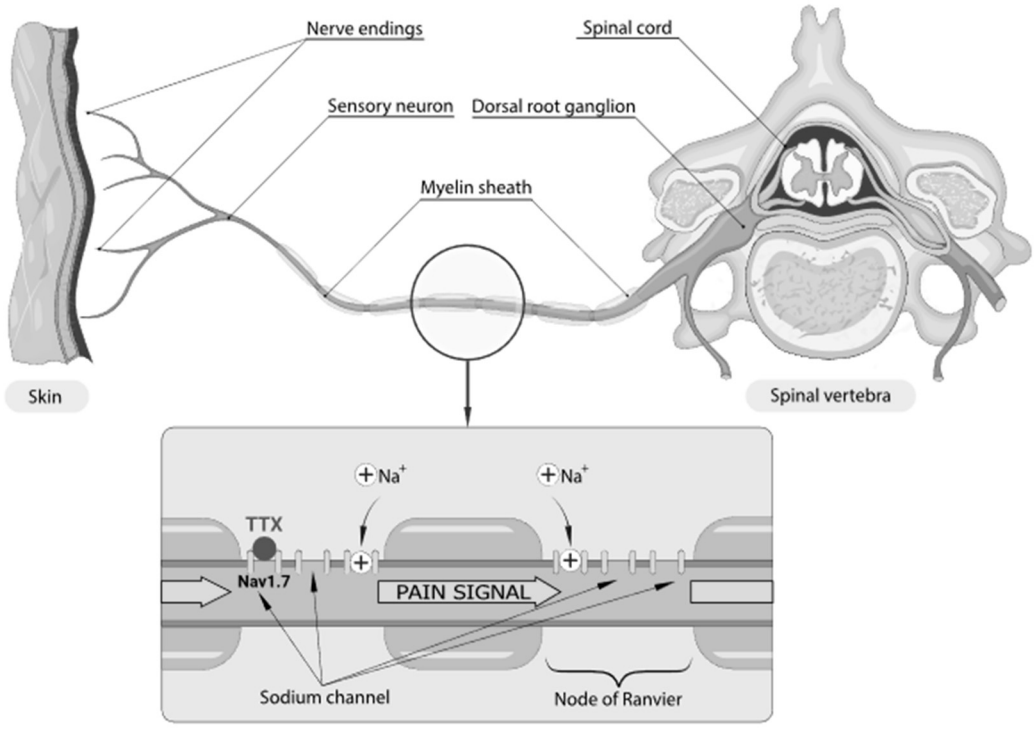
Na_v1.7 Non-Opioid Analgesic Program

Our lead product candidate, Halneuron®, is in late-stage clinical development for the treatment of chemotherapy-induced neuropathic pain ("CINP"). The active pharmaceutical ingredient is highly purified Tetrodotoxin ("TTX"), a potent sodium channel modulator found in puffer fish and several other marine animals. Halneuron® works as an analgesic by modulating the activity of Na_v1.7, a key sodium channel involved in pain signal transmission. By reducing the activity of the Na_v1.7 channel, Halneuron® has the potential to reduce pain associated with conditions involving neuropathic pain.

Mechanism of Action

Pain signals are transmitted as electrical nerve impulses that travel along a nerve. An electrical impulse is generated when the nerve cell depolarizes, triggering what is known as an action potential. This depolarization is triggered by an inflow of sodium ions through specific ion channels on the surface of the cell membrane. Halneuron® is known to bind to the Na_v1.7 sodium ion pore found on nociceptive pain fibers in a highly selective manner, reducing the inflow of sodium ions, and thereby reducing the propagation of pain signals.

As shown below, the mechanism via which Halneuron® exerts its analgesic properties is thought to be related to the product's ability to stabilize neuronal membranes by inhibiting the Na+ ionic fluxes required for membrane depolarization.



Background of Chemotherapy Induced Neuropathic Pain (CINP)

Different pathophysiologic mechanisms are responsible for the development of chronic pain disorders. Pain pathways are triggered in part by ectopic discharges of voltage-sensitive sodium channels containing neurons, which are in abundance in both the peripheral and central nervous systems.

CINP is a side effect of many chemotherapeutic agents, including vincristine, paclitaxel, cisplatin, oxaliplatin, bortezomib, and ixabepilone. In one review, chemotherapy-induced peripheral neuropathy was found to commonly occur in 30 to 40% of patients. More recently, prevalence was reported to be 68.1% (57.7-to 78.4) within the first month of the end of chemotherapy, 60.0% (36.4-81.6) at 3 months and 30.0% (6.4-53.5) at 6 months or later in a meta-analysis of 31 studies. Considerable heterogeneity is observed in the estimates from different studies. Breaking this down by type of chemotherapy, the incidence was 28% to 100% for cisplatin, 85% to 95% for oxaliplatin, 57% to 83% for paclitaxel, and 11% to 64% for docetaxel. In response to the development of peripheral neuropathy, chemotherapy dosing is often either decreased or discontinued, potentially affecting prognosis, and survival.

The CINP Market Opportunity

Peripheral neuropathic pain is an aspect of peripheral neuropathy, and there is an unmet medical need for treatment of patients who develop chemotherapy-induced neuropathic pain.

Common side effects of cancer chemotherapy include fever, fatigue, infection, hair loss, and both acute and chronic pain. Chemotherapy with agents in the platinum/taxane classes are estimated to be responsible for 70% of CINP cases. Approximately one-in-three CINP patients exhibit neuropathic pain six months following

treatment, which are classified by patients as being mild, moderate or severe in intensity. There are currently no treatments approved by the U.S. Food and Drug Administration (the "FDA") for any type of CINP.

Today, opioids account for approximately 30% of the global CINP treatment market. There are approximately 1.7 million CINP patients in just the 7 major markets alone (the US, Japan, the United Kingdom Germany, Spain, Italy, and France). With the potential of Halneuron® being the first FDA approved treatment for CINP, the global opportunity for Halneuron® is significant. Currently, our market research indicates that the CINP drug market is approximately $1.5 billion annually, with the larger cancer related pain market reaching approximately $5 billion in yearly sales. Chemotherapy treatment is expected to increase by over 50% over the next decade, suggesting the unmet medical need and the commercial opportunity will continue to grow for the foreseeable future.

Halneuron® Research Program Background

Cancer Related Pain Program

In the Company's previous Phase 2 study in cancer related pain treatment, 165 cancer-related pain patients were enrolled at 19 sites, and 77 (46.7%) of these patients were randomly assigned to the Halneuron® arm, or group, and 88 (53.3%) patients were assigned to the placebo arm. In total, 147 (89.1%) patients completed the study, including 64 (83.1%) in the Halneuron® arm and 83 (94.3%) in the placebo arm. An analysis of pain reduction in this study demonstrated a statistical and clinically relevant benefit of Halneuron® compared to placebo on the pre-specified pain intensity reduction endpoint. More specifically, 51% of patients receiving Halneuron® experienced at least a 30% reduction in pain versus only 35% of patients in the placebo group. Halneuron® treated patients reported two-times greater improvement in their global health improvement as compared with placebo treated patients, and Halneuron® treated patients also demonstrated a durable pain reduction response. After 4 days of initial treatment, the patients who met the pain reduction response criteria at the primary endpoint from either arm were monitored to assess how long their pain reduction lasted without further treatment. The average pain response duration for Halneuron® responders was 57.7 days vs 10.5 days for those responders treated with placebo.

In the Halneuron® group, all patients (100%) experienced at least 1 treatment-emergent adverse event ("TEAE") considered related to the study drug while 77 patients (88%) in the placebo group reported at least 1 TEAE related to the study drug. The most common TEAEs and study drug-related TEAEs involved the gastrointestinal system, including nausea, oral hypoaesthesia (numbness), oral paraesthesia (tingling), and vomiting. Adverse events ("AEs") related to the nervous system included dizziness, hypoaesthesia, paraesthesia, somnolence, headache and ataxia; and AEs related to general disorders and administration site conditions included injection site irritation, fatigue, injection site pain, and gait disturbance. These TEAEs have all been observed previously with Halneuron® and are described in the Investigator Brochure (and therefore are considered expected based on the known safety profile of Halneuron®). The majority of these most common TEAEs were shown to have a quick onset and a short duration and did not persist beyond the 4-day dosing interval.

Chemotherapy Induced Neuropathic Pain

CINP-201 was a randomized, double-blind, dose-finding, placebo-controlled, multicenter study of the potential efficacy and safety of Halneuron® in patients with CINP. One hundred and twenty-five patients were randomly assigned to 1 of 5 dosing cohorts: placebo BID, HAL 7.5 µg BID, HAL 15 µg BID, HAL 30 µg QD, or HAL 30 µg BID. Patients received Halneuron® or placebo by subcutaneous ("SC") injection in the thigh and/or abdomen for 4 consecutive days. All patients received BID injections, regardless of their dosing cohort; and those patients assigned to once-daily Halneuron® received active drug for the first injection and placebo for the second injection each day.

The key results from this study were that:

- higher doses of Halneuron® delivered greater pain reduction as compared to lower doses;
- pain reduction with the Halneuron® QD dose was comparable to BID dosing but exhibited better tolerability;
- Halneuron® pain relief was evident four weeks post treatment;
- Halneuron® high doses delivered clinically meaningful pain reduction for 35-40% of patients;
- the Halneuron® QD dose group exhibited a mean reduction of -0.4 points versus placebo on NRS pain recall assessment; and
- this Halneuron® treatment effect size has been used to project the sample size for the ongoing HALT-CINP-203 study referenced below.

The safety results showed that in the overall population, 105 of 125 patients (84.0%) experienced at least 1 TEAE. Most TEAEs reported were mild or moderate and were considered possibly related or related to the study drug. Oral paraesthesia was the most frequently reported TEAE for the overall population, followed by oral hypoaesthesia.

Four serious adverse events ("SAEs") were reported in three patients, but these events did not result in any patient withdrawals and none of the SAEs were considered related or possibly related to the study drug. One death was reported during the study resulting from progression of the patient's underlying metastatic disease that was not related to the study drug. In addition, two patients withdrew from the study because of an AE or vertigo, and one of the discontinuing patients also experienced a second AE of influenza-like illness.

No trends or clinically significant abnormal values were noted for safety laboratory assessments, vital signs, or electrocardiogram data.

In the first quarter of 2025, we commenced the HALT-CINP-203 Phase 2b clinical trial in the United States. HALT-CINP-203 is a double-blind, placebo controlled clinical trial to access the efficacy and safety of eight 30 µg Halneuron® SC injections given once a day over a 2-week period versus a placebo in 200 patients (on a 1:1 ratio of Halneuron® to placebo) with moderate to severe neuropathic pain caused by previous platinum and/or taxane chemotherapy. The primary efficacy endpoint is the change from baseline at week 4 in the weekly average of daily 24-hour recall pain intensity scores, comparing Halneuron® to the placebo. The secondary endpoints are patient global impression of change ("PGIC"), PROMIS regarding fatigue, PROMIS related to sleep, PROMIS-29, pain interference, hospital anxiety and depression scale ("HADS") and neuropathic pain symptom inventory. The initial 200 patient target sample size for this study is based on the results from the CINP-201 trial. We will conduct an interim analysis in the fourth quarter of 2025 to confirm or modify the HALT-CINP-203 sample size based on the treatment effect observed in approximately 40-50% of the current target study population.

Other Select Clinical Experience

There has been extensive prior clinical experience with Halneuron®, and the safety profile is well understood. The most commonly reported AEs in clinical trials have been numbness and tingling at peripheral sites (e.g., fingers, toes and lips), which is related to sodium channel inhibition.

The first study, WEX-001, "A Sequential Design, Randomized, Double-Blind, Acute Single Ascending Dose Trial of the Tolerance of Intramuscular Halneuron® in Healthy Volunteers," tested single doses of Halneuron® from 2.5 µg up to 45 µg, with each dose tested in a separate group of 8 patients (with 6 receiving the active

drug and 2 receiving the placebo). All doses, including the highest dose of 45 µg, were well tolerated. The most commonly reported AEs were numbness and tingling at peripheral sites, such as the fingers, toes, and lips.

The second study, WEX-002, "A Randomized, Double-Blind, Placebo-Controlled Trial of Multiple-Dose Tolerance of Intramuscular Halneuron® in Healthy Volunteers," tested Halneuron® intramuscularly in doses of 12 µg to 48 µg 4 times per day for 4 days. Each dose was tested in a separate group of 8 subjects (6 receiving the active drug and 2 receiving the placebo). This study indicated that 4 daily doses of up to 36 µg for 4 days were well tolerated, however, dose-related AEs of mild nausea and numbness and tingling at peripheral sites such as the lips, fingers, and toes were observed. No evidence of cumulative toxicity was observed over time. According to this study, the maximum tolerated multiple doses of Halneuron® in healthy normal volunteers was determined to be 36 µg given 4 times a day (every 4 hours) for 4 days.

HAL-TQT-101 was a phase 1 healthy adult study to determine if a single SC administration of Halneuron® at 15 µg, 30 µg and 45 µg dose levels has any effect on the QT/QTcF intervals when assessing concentration QT (C-QT) relationship (i.e., QT/QTc intervals prolongating in relation to plasma levels of Halneuron®). The finding of the study demonstrated that positive QTcF prolongations were not observed in patients administered 15, 30, or 45 µg Halneuron® and that the single SC administration of 15, 30, and 45 µg Halneuron® is generally safe and well tolerated in healthy adult patients. This is an important differentiating feature of Halneuron® given off target cardiovascular effects have been observed with other non-$Na_v1.7$ specific development candidates.

Antiviral Program

We are advancing novel antiviral therapies to treat diseases associated with a viral triggered abnormal immune response such as FM and LC. Overactive immune response related to activation of tissue resident herpesvirus has been postulated to be a potential root cause of chronic illnesses such as FM, irritable bowel disease ("IBS"), LC, chronic fatigue syndrome and other functional somatic syndromes, all of which are characterized by a waxing and waning manifestation of the disease, often triggered by events which compromise the immune system. While not completely understood, there is general agreement in the medical community that activation of the herpesvirus is triggered by some form of environmental and/or health stressor. Our product candidates, IMC-1 and IMC-2, are novel, proprietary, fixed dose combinations of anti-herpes antivirals and celecoxib. IMC-1 is a novel combination of famciclovir and celecoxib intended to synergistically suppress herpesvirus activation and replication, with the end goal of reducing a patient's viral mediated disease burden. IMC-2 is a combination of valacyclovir and celecoxib that, like IMC-1, is intended to synergistically suppress herpesvirus activation and replication with a more specific activity against the Epstein-Barr virus (herpesvirus HHV-4).

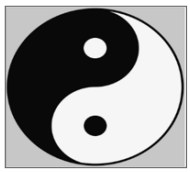
IMC-1 and IMC-2 combine two specific mechanisms of action purposely designed to inhibit herpesvirus activation and replication, thereby keeping the herpesvirus in a latent (dormant) state or "down-regulating" the herpesvirus from a lytic (active) state back to latency. The famciclovir component of IMC-1 and the valacyclovir component of IMC-2 inhibit viral DNA replication. The celecoxib component of IMC-1 and IMC-2 inhibits cyclooxegenase-2 (COX-2) and to a lesser degree cyclooxegenase-1 (COX-1) enzymes, which are used by the herpesvirus to amplify or accelerate its own replication. We are unaware of any other antivirals currently in development for the treatment of FM or related conditions. We believe this novel approach was a germane consideration in the FDA designating IMC-1 for fast-track review status for the treatment of FM. IMC-1 has also been granted a synergy patent based on the fact that neither of the individual components has proven effective in the management of FM, yet the combination therapy generated a result that is greater than the sum of its parts.

Our novel combination antiviral approach (combining viral DNA polymerase inhibitor + COX-2 inhibitor) delivers clinical benefits for patients suffering from diseases with a suspected viral mediated catalyst, including FM and LC. We have received FDA feedback on our proposal to advance IMC-1 into Phase 3 development for the treatment of FM. A recently completed open-label, exploratory trial demonstrated that patients treated with IMC-2 exhibited clinically and statistically significant improvement of their LC symptoms of fatigue, orthostatic intolerance, anxiety and pain. These encouraging results led to the Company funding a second,

phase 2 investigator-initiated study assessing two dosage strengths of IMC-2 versus placebo. The results of this study demonstrated that combination antiviral therapy could reduce fatigue symptoms in LC patients, but, with only 44 patients enrolled, the results were not statistically significant.

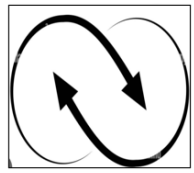
Dormant Herpesvirus is Reactivated by External Triggers and Amplifies Its Own Replication via Cyclooxygenase (COX-1 and COX-2) Enzymes

Generally Healthy Patient:
- Everyone previously infected with herpes viruses of some kind
- Virus lies dormant in nerves and a range of human cells
- Homeostasis achieved



Infection/Other Stressor:
- Reduced immune response results in activation of dormant virus
- Immune response produces inflammatory mediators, including cyclooxygenase-2 (COX-2)

Reactivated Herpes Virus:
- Replicates using viral DNA polymerase
- Further increases COX-2 production
- COX-2 accelerates viral replication

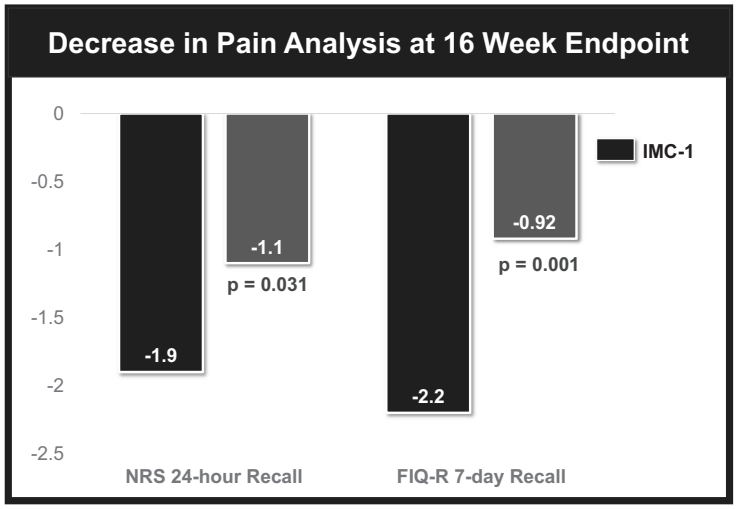


Combination Antiviral Treatment:
- DNA polymerase inhibitor reduces herpes virus replication
- Celecoxib inhibits COX-2, thus
  - Reduces inflammation
  - Inhibits viral replication
  - Blunts viral accelerant
- Synergistic combination converts virus back into a dormant state
- Delivers clinical response

Fibromyalgia Program Background

The potential of IMC-1 in FM was demonstrated by statistically significant improvement versus placebo in the primary endpoint of pain reduction in our double-blinded, placebo-controlled, randomized Phase 2a proof-of-concept study in FM patients. This proof-of-concept study generated statistically significant clinical data on the effects of IMC-1 on both primary pain assessment and secondary measures of pain reduction, reduction in fatigue and improvement in the global health status in patients diagnosed with FM. A result is considered to be statistically significant when the probability of the result occurring by random chance, rather than from the efficacy of the treatment, is sufficiently low. The conventional method for measuring the statistical significance of a result is known as the “p-value,” which represents the probability that random chance caused the result (e.g., a p-value = 0.001 means that there is a 0.1% or less probability that the difference between the control group and the treatment group is purely due to random chance). Generally, a p-value less than 0.05 is considered statistically significant and may be supportive of a finding of efficacy by regulatory authorities. However, regulatory authorities, including the FDA and European Medicines Agency (“EMA”), do not rely on strict statistical significance thresholds as criteria for marketing approval and maintain the flexibility to evaluate the overall risks and benefits of a new treatment.

The table below demonstrates the significant differences observed in the proof-of-concept study between IMC-1 and placebo in change from baseline using both the Numerical Rating Scale (NRS) 24-hour recall pain data and the Revised Fibromyalgia Impact Questionnaire (FIQ-R) with LOCF/BOCF imputation.



IMC-1 also exhibited consistent improvement across several secondary FM treatment outcomes, including 50% responder analysis, improved functional assessments, lower chronic fatigue, increased time to rescue medication and improvements in FM patient's overall global health status. One key secondary measure assessing a 30% pain reduction analysis was approaching but did not meet statistical significance (p = 0.052). In the Phase 2a study, IMC-1 demonstrated a lower discontinuation rate due to adverse events as compared with placebo.

There were no deaths during the study and only three SAEs were reported. The two SAEs in the IMC-1 group were a non-ST segment elevation myocardial infarction and a facial cellulitis and the one SAE in the placebo group was a right breast micro-metastatic ductal carcinoma. One of the 3 SAEs was considered possibly related to study treatment — the non-ST segment elevation myocardial infarction that occurred early in the study in a 47-year- old patient treated with IMC-1. The causal relationship of this SAE to treatment with IMC-1 cannot be ruled out and as such was determined to be "possibly related" to IMC-1; however, the patient's underlying coronary artery disease and strong family history of premature cardiac disease suggest that other causal factors might also have been involved.

Based on the significant unmet need in treating FM and the aforementioned Phase 2a FM data, IMC-1 has been granted FDA designation for fast-track review status. In addition, the novel mechanism of IMC-1 has enabled us to secure composition of matter intellectual property (patent) protection to 2033.

Following on from our successful Phase 2a study, we held an end of Phase 2 meeting with the FDA. In the meeting, we agreed to initiate either a Phase 2b study or a Phase 3 program after we provide animal toxicology study data, to conduct a human PK study and a clinical trial protocol that includes monitoring renal function through standard safety labs to the FDA. A human PK study with the combined tablet of IMC-1 was completed and performed as expected, with no drug-drug interactions and no adverse events. Multiple dose PK of IMC-1 was well characterized and provides additional data to better understand the PK profile of IMC-1. As a result, we have progressed development of IMC-1 from Phase 2a proof-of-concept to a larger scale Phase 2b study, known as FORTRESS (Fibromyalgia Outcome Research Trial Evaluating Synergistic Suppression of HSV-1), for the treatment of FM. The Phase 2b and chronic toxicology studies are planned components of the registration package supporting Phase 3 requirements.

In September 2022, we announced the top line results from our FORTRESS study in FM. Overall, the FORTRESS study did not achieve statistical significance on the prespecified primary efficacy endpoint of

change from baseline to Week 14 in the weekly average of daily self-reported average pain severity scores comparing IMC-1 to placebo (p=0.302). However, analysis of the data showed a bifurcation of response based on the timing of patient enrollment in the FORTRESS study. During the first half of the trial from June 2021 to November 2021, for the patients who were enrolled (n=208) (Cohort 1) when the Delta variant of COVID-19 was the dominant strain in the U.S., full vaccination rates were below 50% and some form of quarantining had been in place for over a year and was still in place in most geographies, IMC-1 demonstrated no improvement versus placebo-treated patients. Conversely, during the second half of the trial from November 2021 to April 2022, for the patients who were enrolled (n=214) (Cohort 2) when vaccination rates improved, the Omicron variant of COVID-19 became the dominant U.S. strain and quarantining restrictions were lessened, IMC-1-treated patients demonstrated a statistically significant improvement on the primary pain reduction endpoint (p=0.03) at Week 14, as well as a statistically significant improvement in the key secondary PROMIS Fatigue assessment (p=0.006) and the Fibromyalgia Impact Questionnaire-Revised (FIQR) symptoms domain score (p=0.015). We believe the likelihood of such a differential response based on the timing of patient enrollment is highly unlikely due to chance or a random occurrence, thus further analysis of the data was warranted, particularly in the context of our previous IMC-1 Phase 2a study success.

Importantly, IMC-1 displayed a first in class safety profile with excellent tolerability and with only 4.6% of IMC-1 treated patients dropping out due to adverse events, as compared with 8.1% of placebo treated patients. No adverse event category in the IMC-1 group exceeded a 4% rate with the exception of COVID-19 infection. Overall discontinuations were 18.5% in the IMC-1 treated group versus 23% in the placebo treated group. Patients in the FORTRESS trial were randomized one-to-one to either IMC-1 or placebo and patient background demographics and baseline pain scores were well matched.

In addition to potential COVID pandemic related impacts, a number of factors differed between those patients recruited during the first half versus the second half of the FORTRESS study. For example, 70% of the patients enrolled in the first half of the study were “Prior” patients who had previous relationships with their respective FORTRESS research sites and/or were participants in prior FM clinical trials. In contrast, over 50% of the FORTRESS subjects enrolled later in the study were “New”, community based patients who had not participated in prior FM clinical trials. These New patients were generally recruited through social media advertising. Based on this demographic understanding, the team assessed how New patients versus Prior treated patients responded to IMC-1 treatment, in both cases versus placebo. Encouragingly, New patients demonstrated statistically significant improvement on the primary endpoint of reduction in FM related pain versus placebo, irrespective of when they enrolled in the study. In addition, New patients demonstrated statistical improvement in key secondary measures, including reduction in fatigue, improvement on the FIQR total scores and reductions in depression, the latter of which is believed to be important given depression is associated with the increased rate of suicide amongst FM patients. Conversely, Prior patients did not show improvement in FM related pain when compared with placebo. In addition to the difference in response between Prior and New patients, we also observed differences within these groups based on timing of recruitment. We believe that recruitment early in the FORTRESS study was much more strongly impacted by pandemic related issues, as opposed to those recruited in 2022. Factors such as staffing levels, training, rates of absenteeism, and supply related issues all improved at the site level as we moved into 2022.

Based on the analysis of the FORTRESS data, we believe focusing the forward development of IMC-1 on New FM patients represents a viable and manageable path forward. The Company met with the FDA in March 2023 to discuss the most appropriate next steps in advancing IMC-1 development as a treatment for FM. The Phase 3 program agreed with FDA includes two qualifying pivotal trials demonstrating the safety and efficacy of IMC-1 treating patients with FM. One of the Phase 3 studies will be a four-arm, multifactorial design to demonstrate the relative safety and efficacy of IMC-1 as compared to celecoxib alone, famciclovir alone and placebo. The other Phase 3 study is planned as a two-arm study comparing IMC-1 to placebo. All patients from the two pivotal Phase 3 studies will be offered the opportunity to enroll into an open label safety extension study in which all patients will be treated with IMC-1. Long-term safety data is required for chronic therapy approval. We are presently exploring partnership opportunities as the primary means by which to advance IMC-1 into Phase 3 development.

Background of Fibromyalgia (FM)

FM is a widespread chronic pain disorder including severe symptoms of fatigue lasting 3 months or longer in duration. FM is also characterized by generalized aching, muscle stiffness, non-restorative sleep, chronic fatigue, depression, cognitive impairment and disturbances in bowel function. Researchers estimate that FM affects 2% to 8% of the U.S. population and is the second most common “rheumatic disorder,” second to osteoarthritis. The National Fibromyalgia & Chronic Pain Association estimates that 10 million Americans have FM.

We estimate that there are approximately 3.6 million patients in the U.S. that have been diagnosed with FM, with approximately 2 million patients being treated. Because there are no specific clinical or laboratory tests available to diagnose FM, diagnosis is established by demonstrating that a patient has widespread chronic pain in 7 or more of the 19 bodily locations for at least 3 months in duration. Additionally, these patients may also have non-restorative sleep, life altering fatigue, and cognitive impairment. The underlying cause of FM has remained elusive and frustrated treating physicians and the scientific community alike. To date, the three products approved by the FDA for the treatment of FM have the potential to cause troublesome side effects and/or deliver limited efficacy.

Our Novel Mechanism of Action (“MOA”)

Scientists and clinicians generally agree that patients with FM have a problem with central pain processing. The exact causality of the heightened pain sensitivity in FM is poorly understood. What is generally agreed is that the central sensitization seen in FM is secondary to a combination of genetic and environmental factors that render the patient susceptible to developing the widespread chronic pain and related symptoms seen in FM. We believe that, when FM patients are exposed to significant life stressors, be they physical or emotional, there is abnormal stress to the immune system allowing herpesviruses to reactivate. This reactivation event, in turn, leads to a herpesvirus associated immune response. Herpesviruses are unique in that they remain in a dormant state (latency) in differing tissue types, depending on the strain, as nonintegrated, circular DNA associated with nucleosomes, with recurrent reactivations for the life of the host. We believe it is likely that nerve resident viral herpetic reactivation is necessary for the nociceptive response seen in FM. This cyclical process of virus reactivation and lytic infection is postulated to perpetuate FM symptoms in these patients.

Our novel therapeutic is directed at interrupting the ongoing immune response by suppressing the herpesvirus, which suppresses the abnormal stress response, thereby alleviating the central pain processing abnormality and other FM symptoms. Studies have shown that neither antivirals nor COX-2/NSAIDS taken alone result in a meaningful clinical benefit. However, when administered in combination, the synergistic response was unexpected and promising. This IMC-1 synergistic response resulted from a combination of famciclovir inhibiting viral DNA polymerase and celecoxib inhibiting upregulation of COX-2 (and to a lesser extent, COX-1). There have been multiple published studies using NSAIDS/COX-2’s in the treatment of FM. According to a 2017 review published in the Cochrane Database of Systemic Reviews, NSAIDs/COX-2’s alone were shown to be no more effective than placebo in treating pain associated with FM. Products included in the review were ibuprofen 2400mg daily, naproxen 1000mg daily, tenoxicam 20mg daily and COX-2 etoricoxib 90mg daily. Antiviral monotherapy treatment of FM was studied by Dr. Sally A. Kendall and her colleagues and published in 2004 in the Journal of Rheumatology. Dr. Kendall evaluated valacyclovir 1 gram three times a day vs placebo in 60 patients with FM. The results showed no difference in change of pain between valacyclovir and placebo.

Virally induced upregulation of COX enzymes is important for efficient viral replication. An article published by Dr. Lynn W. Enquist, a professor at Princeton University, and his colleagues in the Journal of Virology (2004), demonstrated that many herpesviruses significantly up-regulate COX-2 and to a lesser degree COX-1. In an article published by Yuehong Liu and colleagues in 2014 in The Scientific World Journal, they estimated 14-fold increase in COX-2, 1.8-fold increase in COX-1 during herpesvirus infection.

Celecoxib inhibits COX-2 and to a lesser degree COX-1, both of which are critical to the replication and growth of live virions. In general, COX-2 inhibition is regarded as more important than COX-1 inhibition for the suppression of herpesvirus reactivation. COX-2 activation is involved in the induction of herpetic recurrences, and COX-2 inhibition is accompanied not only by a reduction of viral shedding, but also a reduction of viral DNA in nerve ganglia.

The anti-herpesvirus MOA of the nucleoside analogs (which include famciclovir) is well characterized, and this drug class has been used to treat viruses over decades. In its active state famciclovir is initially phosphorylated to a monophosphate form, after which it is converted to penciclovir triphosphate by cellular kinases within virus-infected cells. Penciclovir triphosphate, the active moiety, competitively inhibits viral DNA polymerase, reducing viral DNA synthesis and replication. The specificity of penciclovir for viral DNA polymerase is an important contributor to its benign safety profile. Famciclovir interrupts DNA polymerase and, in combination with celecoxib, results in synergistic viral suppression. If definitively demonstrated through pivotal clinical trials, the efficacy, safety and tolerability, along with the combined MOA, would, we believe, differentiate IMC-1 from current standard of care and near-term pipeline drugs, while providing new opportunities in the treatment of other chronic pain conditions within the Somatic Symptom Disorders.

Long-COVID (LC) Program Background

The diagnosis of LC, as defined by the Center for Disease Control (“CDC”), is new, recurring or continuation of symptoms, most notably fatigue and post exertional malaise, greater than 4 weeks after an acute COVID-19 infection. Research highlights that up to 30% of LC patients were asymptomatic during their acute COVID-19 illness. A 2022 CDC estimate revealed that 6.9% of adults had LC in 2022 and 3.4% of adults exhibited active LC sequelae at the time of the survey. As new research highlights, the majority of COVID-19 morbidity is associated not with acute COVID-19, but with LC, as evidenced by more than one in four LC adults reporting significant activity limitations. Presently, there are no approved treatments for LC illness. The only approved COVID-19 treatment, Paxlovid, failed to improve LC sequelae.

Just as in FM, we believe many of the symptoms associated with Post-Acute Sequelae of COVID-19 infection (“PASC”) are related to secondary reactivation of tissue resident herpesviruses, and that a suppressive antiviral treatment regimen may be helpful in managing these patients. Recent studies indicate reactivated herpesvirus infection lead to LC, as opposed to residual SARS-CoV-2 virus after the acute infection. Reactivated herpesviruses, such as Epstein-Barr virus (“EBV”), are associated with fatigue and cognitive dysfunction, the predominant symptoms of LC. According to Olson et al, nucleoside analogue antiviral agents are activated by EBV thymidine kinase (BXLF1) or serine/threonine protein kinase/phosphotransferase (BGLF4), which are expressed only during the lytic phase of EBV replication. Furthermore, Lin and colleagues concluded that nucleoside analogs, such as valacyclovir, have been developed with the goal of inhibiting the EBV lytic cycle by blocking DNA replication.

A multitude of studies now suggest that some of the symptoms of PASC may not be a direct result of the SARS-CoV-2 virus but may be the result of the reactivation of latent human herpesviruses. Peluso et al. at UCSF reported that EBV reactivation is associated with fatigue and neurocognitive dysfunction in patients with PASC. Reactivation of EBV has been reported among the critically ill patients suffering from PASC and EBV viremia has been correlated with COVID severity. A longitudinal multi-omic study suggested that four main risk factors for developing PASC are type-2 diabetes, SARS-CoV-2 RNAemia, specific auto-antibodies, and EBV viremia (Su, 2022). Patients with the post-COVID syndrome and reactivation of EBV and HHV-6 infections are at high risk of developing various pathologies, including rheumatologic diseases.

In July 2023, the Company received positive data from an exploratory, open-label, proof of concept study in LC funded by an unrestricted grant provided to the Bateman Horne Center (“BHC”). BHC enrolled female patients diagnosed with LC illness, otherwise known as PASC. Patients (n-22) treated with a combination of valacyclovir and celecoxib (“Val/Cel”) exhibited clinically and statistically significant improvements in fatigue, pain, and symptoms of autonomic dysfunction as well as ratings of general well-being related to LC when treated open-label for 14 weeks, as compared to a control cohort (n=17) of female LC patients matched by age

and length of illness and treated with routine care. The statistically significant improvements in PASC symptoms and general health status were particularly encouraging given that the mean duration of LC illness was two years for both the treated and control cohort prior to enrollment in this study. A summary of the results can be seen below.

Study Endpoints	P Value
H PROMIS Fatigue T-Score	0.008
NRS Fatigue 0-10 Scale	<0.001
NRS Pain 0-10 Scale	0.041
PGIC 1-7 (7 is best)	0.022
PGIC 0-10 (0 is best)	0.019
OISAS-Orthostatic Intolerance Symptoms Assessment Scale	0.002
OIDAS-Orthostatic Intolerance Daily Activity Scale	<0.001
HADS depression	0.059
HADS anxiety	0.023

Treatment with Val/Cel was generally well tolerated, with an observed safety profile consistent with the known safety profiles of valacyclovir and celecoxib. In the study, nausea was the most common adverse event. There were no serious adverse events observed in this study and only one treated patient discontinued treatment due to adverse events, possibly related to drug treatment.

In August 2023, we signed an unrestricted grant research agreement with BHC to conduct a second, investigator-initiated, randomized, double-blinded, placebo-controlled exploratory study of LC with IMC-2. The primary goal of the study was to establish the IMC-2 treatment effect versus a placebo in order to help inform the design of a larger LC Phase 2b study. In November 2024, we announced the results from this study. We enrolled 44 patients that were randomized to a high dose treatment group of 1500/750 (Val/Cel), a low dose treatment group of 750/200 (Val/Cel) and placebo. While not statistically significant given the small sample size recruited for this trial (14 to 15 patients per group), the study demonstrated that the low dose combination antiviral therapy IMC-2 exhibited clinically meaningful improvements in fatigue and sleep disruption as compared to patients treated with placebo. Overall, the IMC-2 adverse event profile was favorable in this study. The high dose IMC-2 treatment (valacyclovir 1500 mg + celecoxib 200 mg dosed twice daily) resulted in more GI related adverse events compared to the low dose and placebo cohorts. We are currently seeking external financing and partnership opportunities to continue the advancement of IMC-2.

Regulatory and Development Timeline

IMC-1

We have continued to regularly engage the FDA regarding IMC-1 for the treatment of FM. Since we are combining proprietary doses of two previously approved drugs, our fixed dose combination product candidates are eligible for submission to the FDA for approval under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("FDCA"). Under Section 505(b)(2), we are able to rely upon FDA's previous findings of safety and effectiveness, and extensively reference several sections of the United States Prescribing Information for Famvir (famciclovir) and Celebrex (celecoxib). We expect our 505(b)(2) new drug application ("NDA") filing to rely on portions of the development programs conducted for the reference drugs, as described in the FDA-approved United States Prescribing Information. In our discussions with the FDA, the FDA has agreed to our 505(b)(2) filing plan.

At the conclusion of our FORTRESS Phase 2b clinical study in 2022, we requested an end-of-phase 2 meeting with the FDA. The meeting was held in March 2023, with the Anesthesiology, Addiction Medicine and Pain Medicine division of the FDA. Based on a review of the safety and efficacy data, the FDA provided feedback that our Phase 3 proposal was acceptable. The proposed Phase 3 program will consist of four primary components: two adequate and well-controlled clinical studies, one of which would be a full factorial design with each of the individual components of IMC-1 (famciclovir and celecoxib) as separate comparator arms, a

long-term safety trial, and a pharmacokinetic/food effect study. Based on data from the recently completed FORTRESS Phase 2b trial, we proposed a Phase 3 development program targeting community-based FM patients, who have not participated in prior FM trials. The FDA was in agreement and the Company could progress to Phase 3 subject to review of the final results from our recently completed chronic toxicology program.

The chronic toxicology studies consisted of a six-month rat and a nine-month dog study. The final reports were completed in May 2023 and submitted to the FDA that month. Results were consistent with earlier studies, and all toxicities shown were consistent with known toxicities of celecoxib and famciclovir. The data were reviewed by the FDA and following their initial review of our chronic toxicology program, the FDA concluded that the chronic toxicology studies appear adequate to support the safety of IMC-1 at the dose proposed by the Company for chronic use. With completion of this initial review of the toxicology program, the FDA has now agreed to our proposed Phase 3 program for IMC-1 for treatment of fibromyalgia.

IMC-2

In September 2023, we requested a Pre-Investigational New Drug Application ("PIND") for IMC-2 for the treatment of LC with the FDA. In October, we submitted a full briefing package and by the end of December 2023, we received written communication from the Antivirals Group, Division of Infectious Diseases, on the development requirements and key endpoints associated with advancing IMC-2 into Phase 2 for treatment of LC symptoms. The FDA agreed that we could use improvement in fatigue as a primary endpoint in a Phase 2 study and agreed with our overall study design. The Phase 2 study will compare IMC-2 versus placebo in a randomized, double-blind study of LC patients for 12 weeks. We are currently seeking external financing and partnership opportunities to continue the advancement of IMC-2.

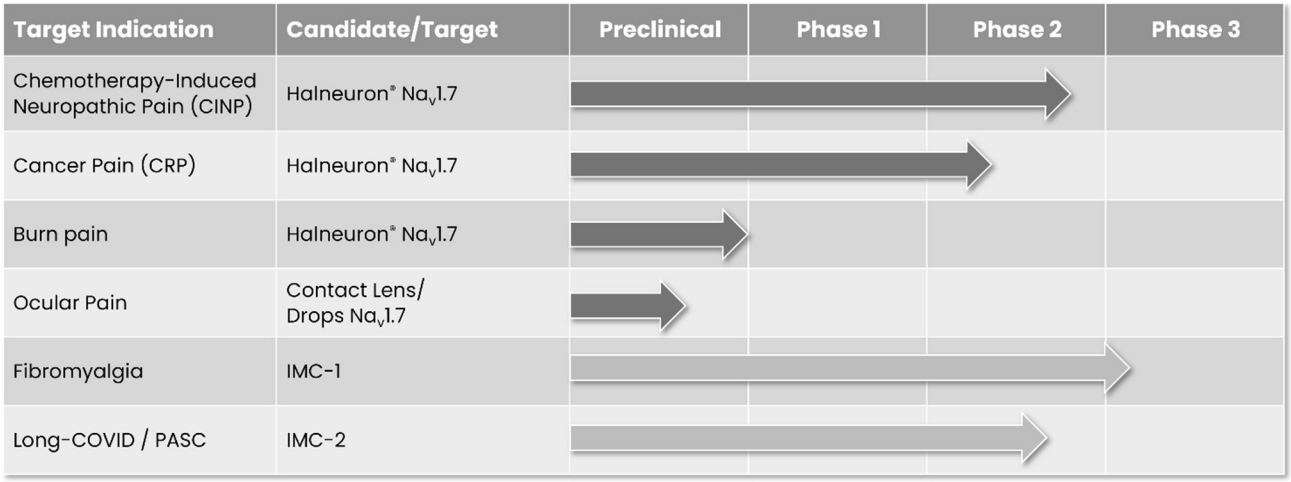
FM Market and Competition

The three pharmaceutical agents currently approved for the treatment of FM, pregabalin (Lyrica), duloxetine (Cymbalta) and milnacipran (Savella), are all associated with significant adverse events and limited clinical efficacy. Despite this, Lyrica and Cymbalta together had peak sales of approximately $10 billion across all of their approved indications, with Lyrica achieving sales of $3.6 billion in the United States in 2018, including sales related to FM. Reflecting the need for more effective and better tolerated treatments, a large number of additional products are also prescribed that are not indicated for FM. The American Academy of Rheumatology and FDA strongly recommends avoiding opioid narcotic medications for treating FM. Evidence shows these drugs are not helpful to most people with FM and will cause greater pain sensitivity or make pain persist. Despite that, research shows that FM patients are prescribed opioids as part of their treatment regimen.

According to the National Fibromyalgia & Chronic Pain Association, approximately 10 million Americans and 3% – 6% of people worldwide are afflicted with FM. Common chronic pain conditions affect approximately 116 million adults in the United States at a cost of $560 – $635 billion annually in direct medical treatment costs and lost productivity. This estimate combines the incremental cost of health care ($261-$300 billion) and the cost of lost productivity ($299 – $335 billion), more than heart disease or cancer. Competitive late-stage FM pipeline products are not disruptive to the current standard of care, nor do they appear to address the root cause of the disease.

Our Product Development Pipeline

We currently have a pipeline of candidates with significant potential for value creation.



Intellectual Property

We strive to protect and enhance the proprietary technologies, inventions and improvements that we believe are important to our business, including seeking, maintaining and defending patent rights, whether developed internally or licensed from third parties. Our policy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements, platforms and our product candidates that are important to the development and implementation of our business.

As of December 31, 2024, our portfolio of owned Halneuron®-related patents totaled 7 issued families of patents in the United States and abroad. As TTX is a natural molecule, we do not hold Composition of Matter patents. However, we do hold patents related to the manufacturing, formulation, and use of Halneuron®. Exclusivity of our issued patents expire over the period of 2027 to 2030. Once pending patents are issued, exclusivity extends to 2042 and 2045.

Issued Family of Patents

- Stable Freeze-Dried Pharmaceutical Formulation of Tetrodotoxin
    - U.S.A. (8,124,608)
- Use of Sodium Channel Blockers for The Treatment of Neuropathic Pain Developing as a Consequence of Chemotherapy
    - U.S.A. (9,018,222, 10,149,852, 10,624,896 and 11,419,873)
    - Canada (2,942,085 and 2,647,235)
    - China (101563079)
    - Germany (60 2007 055 539.6)
    - Spain (E11180427)

- France (2,394,646)
- United Kingdom (2394646)
- Italy (502018000000000)

- Sodium Channel Blocking Compounds Tetrodotoxin Galactopyranosides
  - U.S.A. (8,486,901)

Pending Patent Families

- Tetrodotoxin Liquid Formulations
  - U.S.A. (Application No. 18/556/683)
  - Australia (Application No. 2022261799)
  - Canada (Application No. 3215362)
  - China (Application No. 202280000000.00)
  - European Patent Office (Application No. 22790649.2)
  - Hong Kong SAR (Application No. 62024091184)
  - Japan (Application No. 2023-565457)
  - South Korea (Application No. 10-2023-7037918)
  - New Zealand (Application No. 804051)
- Process for the Extraction and Purification of Tetrodotoxin
  - PCT International (Application No. PCT/CA2023/050562)
  - U.S.A. (Application No. 18/880,674)
  - Australia (Application No. 2023301716)
  - Canada (Application No. 3259981)
  - China (Application No. 202380051910.X)
  - Europe (Application No. 23834327.1)
  - Japan
  - South Korea (Application No. 10-2025-7003014)
  - New Zealand (Application No. 817473)

- Use of Tetrodotoxin for Ocular Applications
    - U.S.A. (Application No. 63/652,113)
- Process for the Synthesis of Tetrodotoxin and Intermediates Thereof
    - U.S.A (Application No. 63/672,146)

As of December 31, 2024, our antiviral portfolio of owned patents totaled 21 issued patents in the United States and abroad. This includes three Composition of Matter patents, including a Synergistic Patent, and two Method of Use patents in the United States, all of which relate to IMC-1. Exclusivity with all patents extends to 2033.

Issued US IMC-1 Patents

- U.S. “Composition of Matter” Patents (US 8,809,351 & US 10,034,846) Drug-combination of famciclovir and celecoxib
- U.S. “Method-of-Use” Patent (US 9,040,546) Famciclovir + celecoxib for the treatment of FM (fibromyalgia), CFS or IBS
- U.S. “Method-of-Use” Patent (US 9,173,863) Method of dispensing famciclovir + celecoxib in a regimen to treat Functional Somatic Syndrome conditions
- U.S. “Composition of Matter” Synergistic Patent (US 10,251,853) Synergistic combination for total daily dose of famciclovir and celecoxib

Issued Foreign IMC-1 Patents

- European Patent (EP 2 811 833 & 2 965 759 – validated in 18 countries)
- Japan (JP 5855770 & 6422848)
- Australia (AU 2013217110)
- China (CN 104144606)
- Korea (KR 10-1485748)
- Canada (2,863,812)

U.S. Patents Covering Other Anti-Viral Combinations

- U.S. 9,682,051 (acyclovir/meloxicam)
- U.S. 8,623,882 (acyclovir/diclofenac)
- U.S. 9,259,405 (famciclovir/diclofenac)
- U.S. 9,642,824 (valacyclovir/diclofenac)
- U.S. 9,980,932 (valacyclovir/meloxicam)

- U.S. 10,543,184 (acyclovir/celecoxib)
- U.S. 10,632,087 (famciclovir/meloxicam)
- U.S. 11,096,912 (valacyclovir/celecoxib)

U.S. Pending Applications

- U.S. provisional application Serial No. 63/524,391 (valacyclovir/celecoxib or famciclovir/celecoxib to treat Alzheimer's disease or Long-COVID)
- PCT/US2023/032842 (valacyclovir/celecoxib or famciclovir/celecoxib to treat Alzheimer's disease or Long-COVID)

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued for regularly filed applications in the United States are granted a term of 20 years from the earliest effective non-provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a portion of the U.S. Patent and Trademark Office ("USPTO") delay in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Furthermore, we rely upon trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our collaborators, employees and consultants and invention assignment agreements with our employees. We also have confidentiality agreements or invention assignment agreements with our collaborators and selected consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

We have also been granted additional U.S. and EU patents, representing all possible combinations of targeted antivirals and non-steroidal anti-inflammatory drugs (NSAIDs/COX-2s) containing appropriate COX-2 & COX-1 inhibition. At present, we are developing only IMC-1 (famciclovir/celecoxib) with the other patents being obtained to increase the therapeutic combinations that we may explore in the future to treat other virally medicated illnesses.

Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our drugs or processes, obtain licenses or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future drugs may have an adverse impact on us. If third parties have prepared and filed patent applications prior to March 16, 2013 in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO, to determine priority of invention. For more information, please see "Risk Factors—Risks Related to Our Intellectual Property."

Material Agreements

In 2012, we entered into a Know-How License Agreement (the "License Agreement") with the University of Alabama. In consideration for the License Agreement, the University of Alabama received membership interests in the Company representing 10% of the issued membership interests at that time. The License Agreement is in effect for 25 years and will terminate on June 1, 2037. Under the License Agreement, we were granted a non-exclusive, worldwide, royalty-free license to utilize, including the right to sublicense and sell products incorporating, the know-how, technical information, and data related and pertaining to the herpesvirus biology, including herpesvirus replication mechanisms, modes of action of anti-herpesvirus medications, and sensitivity and accuracy of herpesvirus diagnostic tests, any of which were developed by the University of Alabama under the direction of Dr. Carol Duffy before the effective date of the License Agreement, all of which is defined as the Technical Information. The University of Alabama reserved the right to use the Technical Information for educational, research, clinical, and other non-commercial purposes. We may assign the license to any purchaser or transferee of substantially all of our assets.

Sales and Marketing

If Halneuron® receives regulatory approval, we plan to enter into sales and marketing agreements with one or several pharmaceutical companies to sell to anesthesiologists, oncologists, and to primary care physicians.

If IMC-1 or IMC-2 is approved, we plan to enter into sales and marketing agreements with one or several pharmaceutical companies to sell to neurologists, geriatric specialists and to primary care physicians.

Manufacturing

We rely on third-party contractors for manufacturing clinical supplies and plan to do so for commercial supply as well. For Halneuron®, we are currently working with an overseas supplier for the synthetic development of the active pharmaceutical ingredient ("API"). We are also working with a Canadian manufacturer for lyophilization and manufacturing of Halneuron®'s lyophilized fill and finish product which will be distributed to the clinical sites for reconstitution and use in clinical trials.

We are presently developing a synthetically formulated version of Halneuron® to be used for both Phase 3 development as well as for commercialization, presuming success in future development and approval by the FDA. This new process is nearing completion, as evidenced by the establishment of chemical equivalence between naturally harvested tetrodotoxin and the new synthetic formulation. We plan to engage with the FDA in the second half of 2025 to discuss their regulatory feedback regarding advancing the synthetic formulation for Phase 3 in 2026. There are several benefits to advancing a synthetically manufactured Halneuron® product, including establishment of a highly repeatable and more cost-effective manufacturing process and to garner significantly longer intellectual property protection, the latter of which we plan to file later this year.

For IMC-1 and IMC-2, presently we are working with an overseas supplier for the manufacture of the cGMP (as defined below) API and with a local supplier for storage stability, encapsulating, blister packing, blinding and distribution of the capsules or pills to the clinical sites.

Government Regulation

The FDA and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements upon companies involved in the clinical development, manufacture, marketing and distribution of drugs, such as those we are developing. These agencies and other federal, state and local entities regulate, among other things, the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion, distribution, post-approval monitoring and reporting, sampling and export and import of our product candidates.

U.S. Government Regulation of Drug Products

In the United States, the FDA regulates drugs under the FDCA and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- Completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice ("GLP") regulations.
- Submission to the FDA of an IND, which must become effective before human clinical trials may begin.
- Approval by an independent institutional review board ("IRB") at each clinical site before each trial may be initiated.
- Performance of adequate and well-controlled human clinical trials in accordance with good clinical practice ("GCP") requirements to establish the safety and efficacy of the proposed drug product for each indication.
- Submission to the FDA of an NDA.
- Satisfactory completion of an FDA advisory committee review, if applicable.
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practice ("cGMP") requirements and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity.
- Satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data.
- Payment of user fees and securing FDA approval of the NDA.
- Compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy ("REMS") and the potential requirement to conduct post-approval studies.

Preclinical Studies

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before

the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to initiate.

Clinical Trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it initiates at that institution. Information about certain clinical trials must be submitted within specific timeframes to the NIH for public dissemination on their www.clinicaltrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase 1: The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.

- Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

- Phase 3: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 studies or trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act ("PDUFA"), guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA, for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to the FDA because the FDA has approximately two months to make a "filing" decision.

In addition, under the Pediatric Research Equity Act of 2003, as amended and reauthorized, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective.

The FDA also may require submission of a REMS plan to ensure that the benefits of the drug outweigh its risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, which reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities comply with cGMP requirements and are adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, 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 and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA 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 labeling claims, are subject to further testing requirements and FDA review and approval.

Special FDA Expedited Review and Approval Programs

The FDA has various programs, including fast track designation, accelerated approval, priority review, and breakthrough therapy designation, which are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. The FDA may review sections of the NDA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

The FDA may give a priority review designation to drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Under the current PDUFA agreement, these six- and ten-month review periods are measured from the "filing" date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast track designation are also likely to be considered appropriate to receive a priority review.

In addition, products tested for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM) that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on IMM or other clinical endpoint, and the drug may be subject to accelerated withdrawal procedures.

Moreover, under the provisions of the Food and Drug Administration Safety and Innovation Act, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for our product candidates as appropriate.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug influences a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting an NDA. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will be receiving orphan product exclusivity. Orphan product exclusivity means that the FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity. Orphan exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. Further, the FDA may approve more than one product for the same orphan indication or disease if the products contain different active ingredients. Moreover, competitors may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There are continuing, annual program user fee requirements for any marketed products.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments and list their marketed drug products with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval of a drug is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- Restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls.
- Fines, warning letters or holds on post-approval clinical trials.
- Refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals.
- Product seizure or detention, or refusal to permit the import or export of products.
- Injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs or devices may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

U.S. Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of our product candidates, Halneuron®, IMC-1 and IMC-2, or any other product candidate for which we may seek regulatory approval.

Sales in the U.S. will depend in part on the availability of adequate financial coverage and reimbursement from third-party payors, which include government health programs such as Medicare, Medicaid, TRICARE and the Veterans Administration, as well as managed care organizations and private health insurers. Prices at which we or our customers seek reimbursement for our product candidates can be subject to challenge, reduction or denial by payors.

The process for determining whether a payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list or formulary, which might not include all the FDA-approved products for a particular indication. Also, third-party payors may refuse to include a branded drug on their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or another alternative is available. However, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be available. Private payors often rely on the lead of the governmental payors in rendering coverage and reimbursement determinations. Sales of Halneuron®, IMC-1, IMC-2 or any other product candidates will therefore depend substantially on the extent to which the costs of our products will be paid by third-party payors. Achieving favorable coverage and reimbursement from the Centers for Medicare and Medicaid Services ("CMS") and/or the Medicare Administrative Contractors is typically a significant gating issue for successful introduction of a new product.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved for marketing, we may need to conduct studies in order to demonstrate the medical necessity and cost-effectiveness of any products, which would be in addition to the costs expended to obtain regulatory approvals. Third-party payors may not consider our product candidates to be medically necessary or cost-effective compared to other available therapies, or the rebate percentages required to secure favorable coverage may not yield an adequate margin over cost or may not enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development.

U.S. Healthcare Fraud and Abuse Laws and Compliance Requirements

We are subject to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, our proposed sales and marketing programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our operations include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value;

- federal false claims and civil monetary penalties laws, including the federal civil False Claims Act, which prohibits anyone from, among other things, knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services that are false or fraudulent;

- provisions of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program or making false statements in connection with the delivery of or payment for healthcare benefits, items or services. In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, impose certain requirements relating to the privacy, security and transmission of individually identifiable health information; and

- the federal Physician Payment Sunshine Act requirements, under the Patient Protection and Affordable Care Act, which require manufacturers of certain drugs and biologics to track and report to CMS payments and other transfers of value they make to U.S. physicians and teaching hospitals as well as physician ownership and investment interests in the manufacturer. Many states have their own Sunshine laws governing the tracking and reporting of payments to healthcare providers.

The Hatch-Waxman Amendments and Generic Competition

Section 505(b)(2) NDAs

As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA.

Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as "the Hatch-Waxman Amendments" to the FDCA and enables the applicant to rely, in part, on the FDA's previous approval of a similar product, or published literature, in support of its application. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. If the Section 505(b)(2) applicant can establish that reliance on FDA's previous findings of safety and effectiveness is scientifically appropriate, it may eliminate the need to conduct certain preclinical studies or clinical trials of the new product. The FDA may also require companies to perform additional studies or measurements, including clinical trials, to support the change from the approved reference drug. The FDA may then approve the new product candidate for all, or some, of the label indications for which the reference drug has been approved or for any new indication sought by the Section 505(b)(2) applicant.

ANDA Approval Process

The Hatch-Waxman Amendments also established an abbreviated FDA approval process for drugs that are shown to be bioequivalent to drugs previously approved by the FDA through the NDA process. Approval to market and distribute these drugs is obtained by filing an abbreviated new drug application ("ANDA") with the FDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown to be bioequivalent to the listed drug. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. ANDAs are termed abbreviated because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, a generic applicant must demonstrate that its product is bioequivalent to the innovator drug. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

Orange Book Listing

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant's product. Upon approval, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a Section 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA, as applicable, that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or Section 505(b)(2) application refers. The applicant may also elect to submit a "section viii"

statement certifying that its proposed label does not contain (or carves out) any language regarding a patented method-of-use that is approved for the reference drug, rather than certify to a listed method-of-use patent.

If within 45 days of receipt of a Paragraph IV Notification the NDA holder for the reference drug and/or patent owners initiates a patent infringement lawsuit against the ANDA or 505(b)(2) applicant, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification (the 30-Month Stay), expiration of the patent, settlement of the lawsuit with a finding of patent invalidity or non-infringement, or a decision in the infringement case that is favorable to the applicant.

The ANDA or Section 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the reference drug has expired as described in further detail below.

Non-Patent Exclusivity

In addition to patent exclusivity, the holder of the NDA for the listed drug may be entitled to a period of non-patent exclusivity, during which the FDA cannot approve an ANDA or Section 505(b)(2) application that relies on the listed drug. For example, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon NDA approval of a new chemical entity, or NCE, which is a drug that contains an active moiety that has not been approved by the FDA in any other NDA. A fixed combination drug product may receive NCE exclusivity if one of its active ingredients is an NCE, but not if all of its active ingredients have previously been approved. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacologic action. During the five year exclusivity period, the FDA cannot accept for filing any ANDA seeking approval of a generic version of that drug or any Section 505(b)(2) NDA for the same active moiety and that relies on the FDA's findings regarding that drug, except that the FDA may accept such an application for filing after four years if the application includes a paragraph IV certification to a listed patent. In the case of such applications accepted for filing between four and five years after approval of the reference drug, a 30-Month Stay of approval triggered by a timely patent infringement lawsuit is extended by the amount of time necessary to extend the stay until 7-1/2 years after the approval of the reference drug NDA.

A drug, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical trials (other than bioavailability studies) was essential to the approval of the application and was conducted/sponsored by the applicant. Should this occur, the FDA would be precluded from approving any ANDA or Section 505(b)(2) application for the protected modification until after that three-year exclusivity period has run. However, unlike NCE exclusivity, the FDA can accept an application and begin the review process during the exclusivity period.

Regulation Outside the United States

To the extent that any of our product candidates, once approved, are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals.

To market our future products in the EEA (which is comprised of the 27 Member States of the EU plus Norway, Iceland and Liechtenstein) and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization ("MA"). There are two types of marketing authorizations:

- The Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use of the EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products and medicinal products indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-

immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU; and

- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the member countries of the EEA assess the risk-benefit balance of the product based on scientific criteria concerning its quality, safety and efficacy.

Data and Marketing Exclusivity

In the EEA, new products authorized for marketing, or reference products, qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial authorization of the reference product in the EU. The 10-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Orphan Drug Designation

In the EEA, a medicinal product can be designated as an orphan drug if its sponsor can establish that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the EU when the application is made, or that the product is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the EU and that without incentives it is unlikely that the marketing of the drug in the EU would generate sufficient return to justify the necessary investment in development. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the EU or, if such method exists, the drug will be of significant benefit to those affected by that condition.

In the EEA, an application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. During this market exclusivity period, the EMA or the member state competent authorities, cannot accept another application for a marketing authorization, or grant a marketing authorization, for a similar medicinal product for the same indication. The period of market exclusivity is extended by two years for medicines that have also complied with an agreed pediatric investigation plan.

This period may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation, for example because the product is sufficiently profitable not to justify market exclusivity. Market exclusivity can be revoked only in very selected cases, such as consent from the marketing authorization holder, inability to supply sufficient quantities of the product, demonstration of “clinical superiority” by a similar medicinal product, or, after a review by the Committee for

Orphan Medicinal Products, requested by a member state in the fifth year of the marketing exclusivity period (if the designation criteria are believed to no longer apply). Medicinal products designated as orphan drugs are eligible for incentives made available by the EU and its Member States to support research into, and the development and availability of, orphan drugs.

Human Capital Resources

As of December 31, 2024, we had twelve full-time employees and no part-time employees, four employees working in the U.S. and eight employees working in Canada. Accordingly, a high percentage of our work performed for our development projects is outsourced to qualified independent contractors. All employees and contractors are subject to contractual agreements that specify requirements for confidentiality, ownership of newly developed intellectual property and restrictions on working for competitors as well as other matters.

Facilities

Dogwood leases offices for its Canadian employees at the address 1150-1100 Melville St, Vancouver, B.C., Canada. The U.S. operations do not own or lease any offices at this time other than a "virtual office" at the address set forth on the cover page of this Annual Report.

Share Exchange Agreement and Combination

On October 7, 2024, the Company, entered into a Share Exchange Agreement (the "Exchange Agreement") with Sealbond Limited ("Sealbond") pursuant to which the Company acquired 100% of the issued and outstanding common shares of Pharmagesic (Holdings) Inc. ("Pharmagesic", and such transaction, the "Combination"). Prior to the Combination, Pharmagesic was a wholly-owned subsidiary of Sealbond and an indirect wholly-owned subsidiary of CK Life Sciences Int'l., (Holdings) Inc. ("CKLS"), a listed entity on the Main Board of the Hong Kong Stock Exchange.

Under the terms of the Exchange Agreement, upon the consummation of the Combination, in exchange for all of the outstanding common shares of Pharmagesic, the Company issued to Sealbond an aggregate of (A) 211,383 shares of the Company's common stock, par value $0.0001 per share ("Common Stock") and (B) 2,108.3854 shares of the Company's Series A Non-Voting Convertible Preferred Stock, par value $0.0001 per share ("Series A Preferred Stock"). Each share of Series A Preferred Stock is convertible into 10,000 shares of Common Stock, subject to certain conditions.

Loan Agreement

On October 7, 2024, in connection with the Exchange Agreement, the Company entered into a Loan Agreement (the "Loan Agreement") with Conjoint Inc., a Delaware corporation ("Lender"). Pursuant to the Loan Agreement, Lender agreed to make a loan to the Company in the aggregate principal amount of $19,500,000, of which (i) $16,500,000 was disbursed on October 7, 2024 and (ii) $3,000,000 was disbursed on February 18, 2025. Prior to the Debt Exchange and Cancellation Transaction described below, the Loan Agreement bore interest at the Secured Overnight Financing Rate ("SOFR"). The Loan Agreement was payable in full with principal and accrued interest on October 7, 2027.

Reverse Stock Split

On October 7, 2024, the Company effected a reverse stock split (the "Reverse Stock Split"), pursuant to which every 25 shares of the Company's issued and outstanding Common Stock was converted automatically into one issued and outstanding share of Common Stock. The Reverse Stock Split affected all stockholders uniformly and did not by itself alter any stockholder's percentage interest in the Company's equity, except to the extent that the Reverse Stock Split would result in a stockholder owning a fractional share. No fractional shares were issued in connection with the Reverse Stock Split and any stockholder who would have received any fractional shares instead received a cash payment equal to the fair market value of such fractional share.

Exchange and Cancellation Agreement

On March 12, 2025, we entered into a Debt Exchange and Cancellation Agreement (the "Exchange and Cancellation Agreement") with the Lender. Pursuant to the Exchange and Cancellation Agreement, the principal amount of all loans made to the Company under the Loan Agreement, along with accrued interest through March 12, 2025, was deemed repaid and all of the Company's obligations satisfied in full and cancelled in exchange for 284.2638 shares of the Company's Series A-1 Non-Voting Convertible Preferred Stock, par value $0.0001 per share (the "Debt Exchange and Cancellation Transaction").

March 2025 Offering

On March 12, 2025, we entered into an agreement with Maxim Group LLC as placement agent in connection with the issuance and sale by the Company in a registered direct offering of 578,950 shares of our Common Stock at a price of $8.26 per share (the "March 2025 Offering"), pursuant to an effective shelf registration statement on Form S-3 (File No. 333-263700). The March 2025 Offering closed on March 14, 2025, and the gross proceeds from the March 2025 Offering were approximately $4.78 million. The net proceeds of the March 2025 Offering were approximately $4.25 million after deducting placement agent fees and offering expenses payable by the Company.

Corporate Information

The Company was originally formed on February 28, 2012 as a limited liability company under the laws of the State of Alabama as "Innovative Med Concepts, LLC." On July 23, 2020, the Company changed its name from "Innovative Med Concepts, LLC" to "Virios Therapeutics, LLC." The Company was then incorporated under the laws of the State of Delaware on December 16, 2020 through a corporate conversion just prior to the Company's initial public offering ("IPO"). On October 7, 2024, the Company changed its name from "Virios Therapeutics, Inc." to "Dogwood Therapeutics, Inc." In addition, effective at the open of market trading on October 9, 2024, the Common Stock ceased trading under the ticker symbol "VIRI" and began trading on the Nasdaq Stock Market under the ticker symbol "DWTX".

Available Information

The Securities and Exchange Commission (the "SEC") maintains an internet site, www.sec.gov, that contains the Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments thereto, and other reports electronically filed with the SEC. The Company makes these documents that have been filed with the SEC available free of charge through the Company's website, www.dwtx.com, by clicking the Investors tab and selecting "All SEC Filings" under the "SEC Filings" tab. Information included on the Company's website is not part of this Annual Report on Form 10-K.

Item 1A. Risk Factors

An investment in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties described below and the other information contained in the Annual Report on Form 10-K. Our business, financial condition, results of operations or prospects could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our common stock could decline.

Risks Related to Our Financial Position and Need for Additional Capital

Our recurring losses from operations raise substantial doubt that we will be able to continue as a going concern and our independent registered public accounting firm has issued an audit report that includes an explanatory paragraph referring to the uncertainty regarding our ability to continue as a going concern without additional capital becoming available. This may hinder our ability to obtain future financing.

Our financial statements as of December 31, 2024 were prepared under the assumption that we will continue as a going concern for the next twelve months. Due to our recurring losses from operations, we concluded that there is substantial doubt in our ability to continue as a going concern within one year after the financial statements are issued without additional capital becoming available. Our independent registered public accounting firm has issued an audit report that includes an explanatory paragraph referring to the uncertainty regarding our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We have incurred losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We are not currently profitable, and we may never achieve or sustain profitability.

We are a development-stage biotechnology company with a limited operating history and have incurred losses since our formation. We incurred consolidated net losses of $12,349,724 and $5,296,015 for each of the years ended December 31, 2024 and 2023. As of December 31, 2024, we had an accumulated deficit of $73,818,946. We have not commercialized any products and have never generated revenue from the commercialization of any product. To date, we have devoted most of our financial resources to research and development, including our preclinical and clinical work, and to intellectual property.

We expect to incur significant additional operating losses for the next several years, at least, as we advance Halneuron®, IMC-1, IMC-2 and any other product candidates through clinical development, complete clinical trials, seek regulatory approval and commercialize the drug or any other product candidates, if approved. The costs of advancing product candidates into each clinical phase tend to increase substantially over the duration of the clinical development process. Therefore, the total costs to advance any of our product candidates to marketing approval in even a single jurisdiction will be substantial. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to begin generating revenue from the commercialization of any products or achieve or maintain profitability. Our expenses will also increase substantially if and as we:

- conduct our Phase 3 studies or conduct clinical trials for any other indications or other product candidates;
- establish sales, marketing, distribution, and compliance infrastructures to commercialize Halneuron®, IMC-1 or IMC-2, if approved, and for any other product candidates for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;

- hire additional clinical, scientific and commercial personnel;

- add operational, financial and management information systems and personnel, including personnel to support our development and planned future commercialization efforts, as well as to support our transition to a public reporting company; and

- acquire or in-license or invent other product candidates or assets.

Furthermore, our ability to successfully develop, commercialize and license any product candidates and generate product revenue is subject to substantial additional risks and uncertainties, as described below under "— Risks Related to Development, Clinical Testing, Manufacturing and Regulatory Approval" and "— Risks Related to Commercialization." As a result, we expect to continue to incur net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' (deficit) equity and working capital. The amount of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If we are unable to develop and commercialize one or more product candidates, either alone or through collaborations, or if revenues from any product that receives marketing approval are insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain profitability or meet outside expectations for our profitability. If we are unable to achieve or sustain profitability or to meet outside expectations for our profitability, the value of our common stock will be materially and adversely affected.

We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of Halneuron®, IMC-1 or IMC-2.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to advance the clinical development, launch and commercialization (if we receive regulatory approval) of Halneuron®, IMC-1 and/or IMC-2. We will require additional capital for the further development and potential commercialization of Halneuron®, IMC-1 or IMC-2. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

Our cash on hand as of December 31, 2024 is not sufficient to fund our operations and capital requirements for at least the next 12 months subsequent to the filing date of the Company's Annual Report on Form 10-K. Currently, the planned research and development activities for the next year include advancing the Halneuron® Phase 2b clinical trial for the treatment of CINP with an interim data readout in the fourth quarter of 2025; further developing the synthetic production and scale-up process of TTX; continued salaries and benefits; and maintaining operations in the U.S. and Canada. Additional capital will need to be raised to fund the second half of the Halneuron® Phase 2b for the treatment of CINP and before initiating additional research and development activities. We have based this estimate on assumptions that may prove to be wrong, and we could deploy our available capital resources sooner or for other purposes than we currently expect. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to the:

- initiation, progress, timing, costs and results of preclinical studies and clinical trials, including patient enrollment in such trials, for Halneuron®, IMC-1 or IMC-2 or any other product candidates we develop in the future;

- clinical development plans we establish for Halneuron®, IMC-1 and/or IMC-2 or any other product candidates we develop in the future;

- obligation to make royalty and non-royalty sublicense receipt payments to third-party licensors, if any, under our licensing agreements;

- number and characteristics of product candidates that we discover or in-license and develop;
- outcome, timing and cost of regulatory review by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect;
- costs of filing, prosecuting, defending and enforcing any patent claims and maintaining and enforcing other intellectual property rights;
- effects of competing technological and market developments;
- costs and timing of the implementation of commercial-scale manufacturing activities; and
- costs and timing of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval.

If we are unable to expand our operations or otherwise capitalize on our business opportunities due to a lack of capital, our ability to become profitable will be compromised.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. We do not currently have any committed external source of funds. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our common stockholder's rights as common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, intellectual property, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate product candidate development or future commercialization efforts.

Unstable global market and economic conditions may have serious adverse consequences on our business, financial condition and results of operations.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates and uncertainty about economic stability. For example, the ongoing conflict between Ukraine and Russia has created extreme volatility in the global capital markets and is expected to have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may have adverse consequences on us or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive.

We have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

We were established and began operations in 2012. Our operations to date have been limited to financing and staffing our company, conducting proof-of-concept studies for IMC-1 and IMC-2, and conducting preclinical and clinical studies of IMC-1. In October 2024, we acquired Halneuron® through the formation of Dogwood Therapeutics, Inc. and are currently conducting a Phase 2b clinical trial in CINP. Our experience includes testing IMC-1 and IMC-2 in clinical trials for safety and proof-of-concept. We have not yet demonstrated the ability to successfully obtain marketing approval, manufacture a commercial scale product, arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will eventually need to transition from a company with a research focus to a company capable of supporting commercial activities. We may not be successful in such a transition and, as a result, our business may be adversely affected.

As we continue to build our business, we expect our financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, the results of any particular quarterly or annual period should not be relied upon as indications of future operating performance.

Risks Related to Development, Clinical Testing, Manufacturing and Regulatory Approval

We are heavily dependent on the success of our product candidates, Halneuron®, IMC-1 and IMC-2, which are still under clinical development, and if these candidates do not receive regulatory approval or, if approved, our commercialization efforts are unsuccessful, our business may be harmed.

We do not have any products that have been granted regulatory approval. Currently, our product candidates include Halneuron® for the treatment of CINP, IMC-1 for the treatment of FM and IMC-2 for the treatment of LC. As a result, our business is dependent on our ability to successfully complete clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize Halneuron®, IMC-1 and/or IMC-2 in a timely manner. We cannot commercialize Halneuron®, IMC-1 or IMC-2 in the United States without first obtaining regulatory approval from the FDA; similarly, we cannot commercialize Halneuron®, IMC-1 or IMC-2 outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of Halneuron®, IMC-1 or IMC-2 for a target indication, we must demonstrate with substantial evidence gathered in preclinical studies and clinical trials and, with respect to approval in the United States, to the satisfaction of the FDA, that Halneuron®, IMC-1 or IMC-2 is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. In our most recent clinical trial involving IMC-1, the Phase 2b FORTRESS study,

IMC-1 did not achieve statistically significant efficacy outcomes. Even if IMC-1 were to successfully obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for Halneuron® IMC-1 or IMC-2 in one or more jurisdictions, or any approval we receive contains significant limitations or requirements, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of any other product candidate that we may in-license, develop or acquire in the future. Furthermore, even if we obtain regulatory approval for Halneuron®, IMC-1 or IMC-2, we will still need to develop a commercial organization, establish commercially viable pricing and obtain approval for adequate reimbursement from third-party and government payors. If we are unable to successfully commercialize Halneuron®, IMC-1 or IMC-2, we may not be able to earn sufficient revenue to continue our business.

We may face future business disruption and related risks resulting from the spread of infectious disease, which could have a material adverse effect on our business.

The development of our product candidates could be disrupted and materially adversely affected in the future by a pandemic, epidemic or outbreak of an infectious disease.

The spread of an infectious disease may also result in the inability of our suppliers to deliver components or raw materials on a timely basis or materially and adversely affect our collaborators and out-license partners' ability to perform preclinical studies and clinical trials. In addition, hospitals may reduce staffing and reduce or postpone certain treatments in response to the spread of an infectious disease. Such events may result in a period of business and manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations.

The ultimate extent of the impact of any epidemic, pandemic or other health crisis on our ability to advance the development of our product candidates, including delays in starting or completing clinical trials, or to raise financing to support the development of our product candidates, will depend on future developments, which are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the severity of such epidemic, pandemic or other health crisis and actions taken to contain or prevent their further spread, among others.

Clinical trials are expensive, time-consuming and difficult to design and implement and involve an uncertain outcome.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Because the results of preclinical studies and early clinical trials are not necessarily predictive of future results, Halneuron®, IMC-1, IMC-2 and our other compounds may not have favorable results in later preclinical and clinical studies or receive regulatory approval. We may experience delays in initiating and completing any clinical trials that we intend to conduct, and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, or at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies;
- obtaining regulatory approval to commence a trial;
- reaching an agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- obtaining Institutional Review Board, or IRB, approval at each site, or Independent Ethics Committee, or IEC, approval at sites outside the United States;

- recruiting suitable patients to participate in a trial in a timely manner and in sufficient numbers;

- having patients complete a trial or return for post-treatment follow-up;

- imposition of a clinical hold by regulatory authorities or IRBs, including as a result of unforeseen safety issues or side effects or failure of trial sites to adhere to regulatory requirements or follow trial protocols;

- clinical sites deviating from trial protocol, committing fraud or other violations of regulatory requirements, or dropping out of a trial, which can render data from that site unusable in support of regulatory approval;

- addressing patient safety concerns that arise during the course of a trial;

- adding a sufficient number of clinical trial sites; or

- manufacturing sufficient quantities of Halneuron®, IMC-1 or IMC-2 for use in clinical trials.

We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs or IECs of the institutions in which such trials are being conducted, the Data Safety Monitoring Board, or DSMB, for such trial or the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and, while we have agreements governing their committed activities, we have limited influence over their actual performance, as described in "Risks Related to Our Dependence on Third Parties."

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, expensive, and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for Halneuron®, IMC-1, IMC-2 or any other product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that we will never obtain regulatory approval for Halneuron®, IMC-1, IMC-2 or any other product candidates. We are not permitted to market any of our product candidates in the United States until we receive regulatory approval from the FDA. Our ability to successfully obtain regulatory approval from the FDA or comparable foreign regulatory authorities is subject to many risks and uncertainties, including the occurrence of one or more of the following:

- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;

- serious and unexpected treatment-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates, or other products containing the active ingredient in our product candidates;

- negative or ambiguous results from our clinical trials or results that may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;

- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

- the data collected from clinical trials of our product candidates may not be acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical trials;

- the FDA or comparable foreign authorities may disagree regarding the formulation, labeling and/or the specifications of our product candidates;

- the FDA or comparable foreign regulatory authorities may fail to approve or find deficiencies with the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;

- the FDA or comparable foreign regulatory authorities may inspect and find deficiencies at the clinical trial sites we use to conduct our clinical studies; and

- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Prior to obtaining approval to commercialize a product candidate in the United States or in a foreign jurisdiction, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities.

The FDA or comparable foreign regulatory bodies can delay, limit or deny approval of our product candidates or require us to conduct additional preclinical or clinical testing or abandon a program for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the adequacy of the design or implementation of our clinical trials;

- the FDA or comparable foreign regulatory authorities may disagree with our safety interpretation of our drug;

- the FDA or comparable foreign regulatory authorities may disagree with our efficacy interpretation of our drug; or

- the FDA or comparable foreign regulatory authorities may regard our CMC package as inadequate, and more particularly:

- if our NDA does not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof;

- if the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions;

- if the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity;

- if FDA determines that it has insufficient information to determine whether such drug is safe for use under such conditions;

- if based on information we submit and any other information before the FDA, the FDA determines there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or

- if FDA determines that our labeling is false or misleading in any particular way.

Of the large number of drugs in development, only a small percentage successfully complete the regulatory approval processes and are commercialized. This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market Halneuron®, IMC-1, IMC-2 or another product candidate, which would significantly harm our business, results of operations and prospects.

In addition, the FDA or the applicable comparable foreign regulatory agency also may approve a product candidate for a more limited indication or patient population than we originally requested, the FDA or applicable foreign regulatory agency may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate, or may require warnings, other safety-related labeling information, or impose post-market safety requirements, including distribution restrictions, that negatively impact the commercial potential of the drug. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. Patient enrollment and retention in clinical trials depends on many factors, including:

- the patient eligibility criteria defined in the protocol;

- the size of the patient population required for analysis of the trial's primary endpoints;

- the nature of the trial protocol;

- the existing body of safety and efficacy data with respect to the product candidate;

- the proximity of patients to clinical sites;

- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- competing clinical trials being conducted by other companies or institutions;
- our ability to maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

Results of preclinical studies, early clinical trials or analyses may not be indicative of results obtained in later trials.

The results of preclinical studies, early clinical trials or analyses of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. In addition, conclusions based on promising data from analyses of clinical results may be shown to be incorrect when implemented in prospective clinical trials. Even if our clinical trials for Halneuron®, IMC-1 and IMC-2 are completed as planned, we cannot be certain that their results will support the safety and efficacy sufficient to obtain regulatory approval.

From time to time, we may publish interim "top-line" or preliminary data from our clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or "top-line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Serious adverse events or undesirable side effects caused by Halneuron®, IMC-1, IMC-2 or any other product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of any clinical trial we conduct could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Patients treated with IMC-1 in our Phase 2a and Phase 2b studies discontinued their participation due to adverse events at a rate lower than patients treated with placebo. The most common adverse events IMC-1 patients experienced (other than COVID-19 infection) were gastrointestinal events and headache at rates less than 5%. There were three serious adverse events observed in the Phase 2a study, two on patients treated with IMC-1, and one for a placebo treated patient. In the larger Phase 2b study, there were three serious adverse events that occurred in two patients, both of whom were treated with placebo.

If unacceptable side effects arise in the development of our product candidates, we, the FDA or the IRBs at the institutions in which our studies are conducted, or the DSMB, if constituted for our clinical trials, could recommend a suspension or termination of our clinical trials, or the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of a product candidate for any or all targeted indications. In addition, drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete a trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing

the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label, such as a “black box” warning or contraindication;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of a product candidate, if approved, and could significantly harm our business, results of operations and prospects.

The market opportunities for Halneuron®, IMC-1 or IMC-2, if approved, may be smaller than we anticipate.

We are developing Halneuron® for the treatment of CINP, IMC-1 for the treatment of FM and IMC-2 for the treatment of LC. Our estimates of market potential have been derived from a variety of sources, including scientific literature, patient foundations and primary and secondary market research, and may prove to be incorrect. Even if we obtain significant market share for any product candidate, if approved, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional indications.

We have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any of our product candidates.

We have never obtained marketing approval for a product candidate. It is possible that the FDA may refuse to accept for substantive review any NDAs that we submit for our product candidates or may conclude after review of our data that our application is insufficient to obtain marketing approval of our product candidates. If the FDA does not accept or approve our NDAs for our product candidates, it may require that we conduct additional clinical, preclinical or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA that we submit may be delayed or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs.

Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing our product candidates, generating revenues and achieving and sustaining profitability. If any of these

outcomes occur, we may be forced to abandon our development efforts for our product candidates, which could significantly harm our business.

Even if we obtain FDA approval for Halneuron®, IMC-1, IMC-2 or any other product candidates in the United States, we may never obtain approval for or commercialize Halneuron®, IMC-1, IMC-2 or any other product candidate in any other jurisdiction, which would limit our ability to realize their full global market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary between jurisdictions and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Even if we obtain regulatory approval for Halneuron®, IMC-1, IMC-2 or any other product candidate, we will still face extensive and ongoing regulatory requirements and obligations and any product candidates, if approved, may face future development and regulatory difficulties.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with current Good Manufacturing Practice, or cGMP, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and Good Clinical Practice, or GCP, requirements for any clinical trials that we conduct post-approval.

Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product candidate may be marketed or to the conditions of approval, including a requirement to implement a REMS. If any of our product candidates receive marketing approval, the accompanying label may limit the approved indicated use of the product candidate, which could limit sales of the product candidate. The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use, and if we market our products for uses beyond their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act, or FDCA, relating to the promotion of prescription drugs may lead to FDA enforcement actions and investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on manufacturing such products;
- restrictions on the labeling or marketing of products;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Further, the FDA's policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or in foreign jurisdictions. For example, certain policies of the current presidential administration may impact our business and industry. Namely, the current presidential administration has taken several executive actions, including the issuance of a number of executive orders, which could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

We may seek a Breakthrough Therapy designation for Halneuron®, IMC-1 or IMC-2 from the FDA. However, we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process.

We may seek a Breakthrough Therapy designation for Halneuron®, IMC-1, IMC-2 or one or more of our other product candidates. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination

with one or more other drugs, to treat a serious condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for priority review if supported by clinical data at the time the NDA is submitted to the FDA.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. Even if we receive Breakthrough Therapy designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

The use of Halneuron®, IMC-1, IMC-2 or any other product candidates we may develop in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by patients, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- significant costs to defend the litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize Halneuron®, IMC-1, IMC-2 or any other product candidate;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased market demand for any product; and
- loss of revenue.

The product liability insurance coverage we plan to acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. In connection with our clinical studies, we have carried and continue to carry insurance for product liability claims in the United States. We intend to acquire insurance coverage to include larger clinical studies, different countries and sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts.

A successful product liability claim, or series of claims, brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect the results of our operations and business, including preventing or limiting the commercialization of any product candidates we develop.

Risks Related to Commercialization

We face significant competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to acquire, develop, and obtain marketing approval for new products on a cost-effective basis and to market them successfully. If either Halneuron®, IMC-1 and/or IMC-2 is approved, we will face intense competition from a variety of businesses, including large, fully integrated pharmaceutical companies, specialty pharmaceutical companies and biopharmaceutical companies in the United States and other jurisdictions. These organizations may have significantly greater resources than we do and may conduct similar research; seek patent protection; and establish collaborative arrangements for research, development, manufacturing and marketing of products that may compete with us.

Our competitors may, among other things:

- have significantly greater name recognition, financial, manufacturing, marketing, drug development, technical, and human resources than we do, and future mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors;

- develop and commercialize products that are safer, more effective, less expensive, more convenient, or easier to administer, or have fewer or less severe effects;

- obtain quicker regulatory approval;

- implement more effective approaches to sales and marketing; or

- form more advantageous strategic alliances.

Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel; establishing clinical trial sites and patient registration; and in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, or are more convenient or are less expensive. Our competitors may also obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing or strengthening their market position before we are able to enter the market.

We may face early generic competition for Halneuron®, IMC-1, IMC-2 or any other products we successfully develop and market.

Pharmaceutical companies developing novel products face intense competition from generic drug manufacturers who aggressively seek to challenge patents and non-patent exclusivities for branded products, and who are able to use much less-onerous product development and FDA approval pathways for their generic products. The active ingredient of Halneuron®, tetrodotoxin, is available for purchase in the open market today. Both of the active ingredients of IMC-1, famciclovir and celecoxib, and IMC-2, valacyclovir and celecoxib, are

marketed in numerous FDA-approved single-ingredient generic products that copy the original brand name products containing those active ingredients, indicating that numerous potential generic competitors have successfully developed formulation and manufacturing processes to make finished drug products of the individual components of IMC-1 and IMC-2 using these ingredients. Such generic competitors could apply those processes to develop equivalent generic versions of Halneuron®, IMC-1 or IMC-2. Under FDA's generic drug approval processes, described in more detail in the section titled "Hatch-Waxman and Generic Competition," we do not believe that either Halneuron®, IMC-1 or IMC-2 would be eligible for the 5-year NCE Exclusivity period, because both active ingredients have previously been approved by FDA in other branded drug products, although Halneuron®, IMC-1 or IMC-2 may qualify for a 3-year exclusivity period during which no generic version could be approved.

As discussed elsewhere herein, we have procured several patents that we believe cover IMC-1 and would be eligible for listing in FDA's Orange Book, and as such would require any proposed generic competitor to IMC-1 or IMC-2 seeking FDA approval prior to the expiration of such patents to submit a Paragraph IV Certification alleging that our patent(s) are invalid, unenforceable, or would not be infringed by the marketing of the proposed generic product. Such a Paragraph IV ANDA could be submitted to the FDA at any time after approval of the IMC-1 or IMC-2 NDA, but if we file a patent infringement action against such a generic challenger within 45 days of receiving the required notification of such Paragraph IV filing, FDA would be barred from approving the generic version for typically 30 months from the date of our receipt of the notification. This 30-Month Stay, however, may be shortened if the court earlier decides that our patents are in fact invalid, unenforceable, or would not be infringed. Even if the litigation is not concluded at the end of the 30-Month Stay, FDA may still grant final approval of the generic application, and the applicant would be able to choose to launch its product, absent a court-ordered injunction, but at the risk of becoming liable to us for monetary infringement damages, including potentially treble damages, if we ultimately prevail in the litigation.

We are presently developing a synthetically formulated version of Halneuron® to be used for both Phase 3 development as well as for commercialization, and we plan to engage with the FDA in the second half of 2025 to discuss their regulatory feedback regarding advancing the synthetic formulation for Phase 3 in 2026. However, we may fail to successfully develop and commercialize this synthetic formulation of Halneuron®, which could result in cost overruns and cause delays in Phase 3 development. Any such failure may prevent us from, or delay us in, commercializing Halneuron®, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Furthermore, delays in Phase 3 development, and therefore regulatory approval of Halneuron®, could also reduce the period of time during which we can market it under patent protection.

Even if we are successful in achieving regulatory approval to commercialize Halneuron®, we expect to eventually face generic competition, however this may occur sooner than anticipated. Given the amount of time required for the development, testing and regulatory review of Halneuron®, patents protecting Halneuron® might expire before or shortly after generic alternatives are approved and commercialized. Generic products may be significantly less costly to bring to market than Halneuron®, and companies that produce generic products are generally able to offer them at lower prices. As a result, the launch of a generic version of Halneuron® would be likely to result in a reduction in the demand for Halneuron®, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

IMC-1 uses novel dosage strengths of both famciclovir and celecoxib, and IMC-2 uses novel dosage strengths of valacyclovir and celecoxib, neither of which dosage strengths have been approved by FDA for other products. Thus, there are no currently approved single-ingredient generic products that could readily be prescribed in combination as a direct equivalent substitute for IMC-1 or IMC-2. However, physicians are lawfully able to prescribe drugs for unapproved uses and in unapproved strengths, and it is possible that some physicians could seek to prescribe separately approved generic versions of these drugs in combination as a treatment for FM, LC or other proposed indications for IMC-1 or IMC-2, in an attempt to lower the costs to their patients.

The successful commercialization of Halneuron®, IMC-1, IMC-2 and any other product candidate we develop will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels, and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as Halneuron®, IMC-1 or IMC-2, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our drug and any other product candidates we develop. Assuming we obtain coverage for our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States or elsewhere will be available for our product candidates or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar, or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and offer to reimburse patients only for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing drugs may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on our product candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

We may also be subject to extensive governmental price controls and other market regulations outside of the United States, and we believe the increasing emphasis on cost-containment initiatives in other countries have and will continue to put pressure on the pricing and usage of medical products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits.

Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

Even if Halneuron®, IMC-1, IMC-2 or any other product candidate we develop receives marketing approval, it may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

If Halneuron®, IMC-1, IMC-2 or any other product candidate we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If it does not achieve an adequate level of acceptance, we may not generate significant product revenues or become profitable. The degree of market acceptance of our product candidates, if approved, will depend on a number of factors, including but not limited to:

- the efficacy and potential advantages compared to alternative treatments;
- effectiveness of our sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- the impact of any restrictions on the use of our product together with other medications.

Because we expect sales of our product candidates, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of our product candidates to find market acceptance would harm our business and could require us to seek additional financing.

If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing Halneuron®, IMC-1 or IMC-2, if approved.

We do not have any infrastructure for the sales, marketing or distribution of Halneuron®, IMC-1 or IMC-2, or compliance functions related to such activities, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market and successfully commercialize any of our product candidates that receive regulatory approval, we must build our sales, distribution, marketing, managerial, compliance, and other non-technical capabilities or make arrangements with third parties to perform these services. We expect to build a focused sales, distribution and marketing infrastructure to market Halneuron®, IMC-1 and/or IMC-2, if approved, in the United States and potential other major markets. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, oversee the compliance of sales and marketing functions, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing, distribution and compliance capabilities could delay any product launch, which would adversely impact the commercialization of that product. For example, if the commercial launch of Halneuron®, IMC-1 and/or IMC-2 for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or attain adequate numbers of physicians to prescribe our products; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of our product candidates, if approved, in certain markets overseas. Therefore, our future success will depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator's strategic interest in a product and such collaborator's ability to successfully market and sell the product. We intend to pursue collaborative arrangements regarding the sale and marketing of our product candidates, if approved, for certain markets overseas; however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

If we are unable to build our own sales force or negotiate a collaborative relationship for the commercialization of Halneuron®, IMC-1 and/or IMC-2, we may be forced to delay the potential commercialization of the drug or reduce the scope of our sales or marketing activities. If we need to increase our expenditures to fund commercialization activities for Halneuron®, IMC-1 and/or IMC-2 we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. We may also have to enter into collaborative arrangements for Halneuron®, IMC-1 or IMC-2 at an earlier stage than otherwise would be ideal and we may be required to relinquish rights to it or otherwise agree to terms unfavorable to us. Any of these occurrences may have an adverse effect on our business, operating results and prospects.

If we are unable to establish adequate sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates and may never become profitable. We will be competing with many companies that currently have extensive and well-

funded marketing and sales operations. 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.

A variety of risks associated with operating internationally could materially adversely affect our business.

We currently have no international operations outside of North America, but our business strategy includes potentially expanding beyond North America if any of our product candidates receive regulatory approval. Doing business internationally involves a number of risks, including but not limited to:

- difficulties maintaining compliance with multiple, conflicting and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its books and records provisions, or its anti-bribery provisions.

Any of these factors could significantly harm any future international expansion and operations and, consequently, our results of operations.

Risks Related to Our Dependence on Third Parties

Our employees and independent contractors, including principal investigators, clinical trial sites, CROs, consultants, vendors, and any third parties we may engage in connection with development and commercialization, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

Our employees and independent contractors, including principal investigators, clinical trial sites, consultants, vendors and any third parties we may engage in connection with development and commercialization of our product candidates, could engage in misconduct, including intentional, reckless or negligent conduct or unauthorized activities that violate: the laws and regulations of the FDA or other similar regulatory requirements of other authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; manufacturing standards; data privacy, security, fraud and abuse and other healthcare laws and regulations; or laws that require the reporting of true, complete and accurate financial information and data. Specifically, 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. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the 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 such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

We currently rely on third-party contract manufacturing organizations, or CMOs, for the production of clinical supply of Halneuron®, IMC-1 and IMC-2 and intend to rely on CMOs for the production of commercial supply of Halneuron®, IMC-1 and IMC-2, if approved. Our dependence on CMOs may impair the development and commercialization of the drug, which would adversely impact our business and financial position.

We have limited personnel with experience in manufacturing, and we do not own facilities for manufacturing. Instead, we rely on and expect to continue to rely on CMOs for the supply of cGMP grade clinical trial materials and commercial quantities of Halneuron®, IMC-1, IMC-2 and any product candidates we develop, if approved. Reliance on CMOs may expose us to more risk than if we were to manufacture our product candidates ourselves. We intend to manufacture a sufficient clinical supply of Halneuron®, IMC-1 and IMC-2 to enable us to complete future clinical trials, and we have also engaged a CMO to provide clinical and commercial supply of the drug product.

The facilities used to manufacture our product candidates must be inspected by the FDA and comparable foreign authorities. While we provide oversight of manufacturing activities, we do not and will not control the execution of manufacturing activities by, and are or will be essentially dependent on, our CMOs for compliance with cGMP requirements for the manufacture of our product candidates. As a result, we are subject to the risk that our product candidates may have manufacturing defects that we have limited ability to prevent. If a CMO cannot successfully manufacture material that conforms to our specifications and the regulatory requirements,

we will not be able to secure or maintain regulatory approval for the use of our product candidates in clinical trials, or for commercial distribution of our product candidates, if approved. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval or finds deficiencies in the future, we may need to find alternative manufacturing facilities, which would delay our development program and significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates, if approved. In addition, any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacture of our product candidates or that obtained approvals could be revoked. Furthermore, CMOs may breach existing agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreement at a time that is costly or otherwise inconvenient for us. If we were unable to find an adequate CMO or another acceptable solution in time, our clinical trials could be delayed, or our commercial activities could be harmed.

We rely on and will continue to rely on CMOs to purchase from third-party suppliers the raw materials necessary to produce our product candidates. We do not and will not have control over the process or timing of the acquisition of these raw materials by our CMOs. Moreover, we currently do not have any agreements for the production of these raw materials. Supplies of raw material could be interrupted from time to time and we cannot be certain that alternative supplies could be obtained within a reasonable timeframe, at an acceptable cost, or at all. In addition, a disruption in the supply of raw materials could delay the commercial launch of our product candidates, if approved, or result in a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates. Growth in the costs and expenses of raw materials may also impair our ability to cost effectively manufacture our product candidates. There are a limited number of suppliers for the raw materials that we may use to manufacture our product candidates and we may need to assess alternative suppliers to prevent a possible disruption of the manufacture of our product candidates.

Finding new CMOs or third-party suppliers involves additional cost and requires our management's time and focus. In addition, there is typically a transition period when a new CMO commences work. Although we generally have not, and do not intend to, begin a clinical trial unless we believe we have on hand, or will be able to obtain, a sufficient supply of our product candidates to complete the clinical trial, any significant delay in the supply of our product candidates or the raw materials needed to produce our product candidates, could considerably delay conducting our clinical trials and potential regulatory approval of our product candidates.

As part of their manufacture of our product candidates, our CMOs and third-party suppliers are expected to comply with and respect the proprietary rights of others. If a CMO or third-party supplier fails to acquire the proper licenses or otherwise infringes the proprietary rights of others in the course of providing services to us, we may have to find alternative CMOs or third-party suppliers or defend against claims of infringement, either of which would significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates, if approved.

We intend to rely on third parties to conduct, supervise and monitor our clinical trials. If those third parties do not successfully carry out their contractual duties, or if they perform in an unsatisfactory manner, it may harm our business.

We rely, and will continue to rely, on CROs, CRO-contracted vendors and clinical trial sites to ensure the proper and timely conduct of our clinical trials. Our reliance on CROs for clinical development activities limits our control over these activities, but we remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards.

We and our CROs will be required to comply with the GLP requirements for our preclinical studies and GCP requirements for our clinical trials, which are regulations and guidelines enforced by the FDA and are also required by comparable foreign regulatory authorities. Regulatory authorities enforce GCP requirements through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs

fail to comply with GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. Accordingly, if our CROs fail to comply with these requirements, we may be required to repeat clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and we do not control whether or not they devote sufficient time and resources to our clinical trials. Our CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities, which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If our relationship with any CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects.

- the number and type of our collaborations could adversely affect our attractiveness to future collaborators or acquirers; and

- the loss of, or a disruption in our relationship with, any one or more collaborators could harm our business.

If any collaborations do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research and development funding or milestone or royalty payments under such collaborations. If we do not receive the funding we expect under these agreements, our continued development of our product candidates could be delayed, and we may need additional resources to develop additional product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report on Form 10-K also apply to the activities of any collaborators and there can be no assurance that our collaborations will produce positive results or successful products on a timely basis or at all.

In addition, subject to its contractual obligations to us, if one of our collaborators is involved in a business combination or otherwise changes its business priorities, the collaborator might deemphasize or terminate the development or commercialization of our product candidates. If a collaborator terminates its agreement with us, we may find it more difficult to attract new collaborators and the perception of our business and our stock price could be adversely affected.

We may in the future collaborate with additional pharmaceutical and biotechnology companies for development and potential commercialization of therapeutic products. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and

conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our programs, and our business may be materially and adversely affected.

Risks Related to Healthcare Laws and Other Legal Compliance Matters

Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates, if approved, and may affect the prices we may set.

In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or the ACA, substantially changed the way healthcare is financed by both the government and private insurers and continues to significantly impact the U.S. pharmaceutical industry. Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. It is unclear how future litigation or healthcare initiatives at the U.S. federal and state levels will impact our business, financial condition and results of operations. Complying with any new legislation or changes in healthcare regulation could be time consuming and expensive, resulting in a material adverse effect on our business.

In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been Congressional inquiries and proposed federal and state legislation designed to 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. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological 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 could harm our business, results of operations, financial condition 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 product candidates or put pressure on our product pricing.

In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. 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, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or certain 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 for, or the purchase, lease, order, or recommendation of, any good, facility, item, or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The U.S. federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand;

- the U.S. federal false claims and civil monetary penalties laws, including the civil False Claims Act, or FCA, which, among other things, impose criminal and civil penalties, including through civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. A claim includes “any request or demand” for money or property presented to the federal government. In addition, 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 U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program 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 a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- 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,

specified requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information. 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;

- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- the U.S. federal legislation commonly referred to as the Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics, and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members; and

- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including our consulting agreements and other relationships with physicians and other healthcare providers, some of whom receive stock or stock options as compensation for their services, could be subject to challenge under one or more of such laws. Ensuring that our current and future internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving 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 governmental laws and regulations that may apply to us, we may be subject to the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel

resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Any clinical trial programs we conduct or research collaborations we enter into in the European Economic Area may subject us to the General Data Protection Regulation.

If we conduct clinical trial programs or enter into research collaborations in the European Economic Area, we may be subject to the General Data Protection regulation, or GDPR. The GDPR applies extraterritorially and implements stringent operational requirements for processors and controllers of personal data, including, for example, high standards for obtaining consent from individuals to process their personal data, robust disclosures to individuals, a comprehensive individual data rights regime, data export restrictions governing transfers of data from the European Union, or EU, to other jurisdictions, short timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to health data, other special categories of personal data and coded data and additional obligations if we contract third-party processors in connection with the processing of personal data. The GDPR provides that EU member states may establish their own laws and regulations limiting the processing of personal data, including genetic, biometric or health data, which could limit our ability to use and share personal data or could cause our costs to increase. If our or our partners' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to €20 million or up to 4% of our total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill.

We are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.

Our operations, including our development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, the production efforts of our third-party manufacturers or our development efforts may be interrupted or delayed. Further, any new laws, rules and regulations, including changes to regulatory policy and the promulgation of new laws and regulations under the new presidential administration in the U.S. could make compliance more difficult or expensive.

If we become profitable, our ability to use our net operating loss carryforwards and other tax attributes to offset future taxable income or taxes may be subject to limitations.

As of December 31, 2024, we had U.S. federal net operating loss carryforwards, or NOLs, of approximately $36,669,000 million and Georgia and Florida state NOLs of approximately $44,443,000 million and $1,372,000 million, respectively. As of December 31, 2024, we also had Canadian non-capital loss carryforwards of approximately $25,277,000, which have a twenty year carryforward and begin expiring in 2025 and Hong Kong tax losses carryforwards or approximately $58,126,000 which have no expiry. These net operating losses can be carried forward and applied against future taxable income, if any. A full allowance for the value of the NOLs is provided for in our audited consolidated financial statements for the year of December 31, 2024 included in

this Annual Report on Form 10-K. We cannot guarantee what the ultimate outcome or amount of the benefit we may receive from the NOLs, if any, will be. If we become profitable in the future, our ability to use net operating loss carryforwards and other tax attributes to offset future taxable income or reduce taxes may be subject to limitations.

Risks Related to Our Intellectual Property

Our patents may be challenged in courts or in patent offices which could result in the invalidation, narrowing or unenforceability of our patents and our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

There is no assurance that all the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents further cover Halneuron®, IMC-1, IMC-2 or any other product candidates we develop in the future, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period during which we could market a product candidate under patent protection could be reduced.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. However, in certain instances, the laws of the United States are more restrictive than those of foreign countries. For example, a recent series of U.S. Supreme Court cases has narrowed the types of subject matter considered eligible for patenting. Accordingly, certain diagnostic methods are considered ineligible for patenting because they are directed to a “law of nature.” Further, publications of discoveries in scientific literature often lag the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated, held unenforceable, in whole or in part, or reduced in term. Such a result could limit our ability to stop others from using or commercializing similar or identical 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. While various extensions may be available, the life of a patent 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 product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may become subject to third parties' claims alleging infringement of their patents and proprietary rights, or we may need to become involved in lawsuits to protect or enforce our patents, which could be costly, time consuming, delay or prevent the development and commercialization of our product candidates or put our patents and other proprietary rights at risk.

Our commercial success depends, in part, upon our ability to develop, manufacture, market and sell our product candidates without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. Litigation relating to infringement or misappropriation of patent and other intellectual property rights in the pharmaceutical and biotechnology industries is common, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the USPTO and corresponding foreign patent offices. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, many companies in intellectual property-dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors. Numerous U.S., EU and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the intellectual property rights of third parties.

We may be subject to third-party claims including infringement, interference or derivation proceedings, post-grant review and *inter partes* review before the USPTO or similar adversarial proceedings or litigation in other jurisdictions. Even if we believe third party infringement claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize the applicable product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Proceedings challenging our patents or those that we license may also result in our patent claims being invalidated or narrowed in scope. Similarly, if our patents or patent applications are challenged during interference or derivation proceedings, a court may hold that a third-party is entitled to certain patent ownership rights instead of us. Further, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, methods of manufacture, or methods of treatment, prevention or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In addition, defending such claims would cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages, if we are found to be infringing a third party's patent rights. If we are found to have infringed such rights willfully, the damages may be enhanced and may include attorneys' fees. Further, if a patent infringement suit is brought against us or our third-party service providers, our development, manufacturing or sales activities relating to the product or product candidate that is the subject of the suit may be delayed or terminated. As a result of patent infringement claims, or in order to avoid potential infringement claims, we may choose to seek, or be required to seek, a license from the third party, which may require us to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if a license can be obtained on acceptable terms, the rights may be nonexclusive, which could give our competitors access to the same intellectual property rights. If we are unable to enter into a license on acceptable terms, we could be prevented from commercializing one or more of our product candidates, forced to modify such product candidates, or to cease some aspect of our business operations, which could harm our business significantly. Modifying our product candidates to design around third-party intellectual property rights may result in significant cost or delay to us and could prove to be technically infeasible. 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. In addition, if the breadth or strength of protection provided the patents and patent applications we own or in-license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

If we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States and in Europe, 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, for example, lack of eligibility, lack of novelty, obviousness or non-enablement. Third parties might allege unenforceability of our patents because someone connected with prosecution of the patent withheld relevant information, or made a misleading statement, during prosecution. The outcome of proceedings involving assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity of patents, for example, 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 the patent protection on our product candidates. Furthermore, our patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing on our patents or other intellectual property rights.

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 view these announcements in a negative light, the price of our common stock could be adversely affected.

Finally, 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 view these announcements in a negative light, the price of our common stock could be adversely affected. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace.

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

We cannot guarantee that any of our or our licensors' patent searches or analyses, including but not limited to 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, Europe and elsewhere that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, in the United States, certain filed applications that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States, EU and elsewhere are published 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. Therefore, patent applications covering our future product candidates, or their manufacture or use may currently be unpublished. 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 product candidates. 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 product candidates. We may incorrectly determine that our product candidates 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, the EU or elsewhere that we consider

relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

From time to time, we may identify patents or applications in the same general area as our products and product candidates. We may determine these third-party patents are irrelevant to our business based on various factors including our interpretation of the scope of the patent claims and our interpretation of when the patent expires. If the patents are asserted against us, however, a court may disagree with our determinations. Further, while we may determine that the scope of claims that will issue from a patent application does not present a risk, it is difficult to accurately predict the scope of claims that will issue from a patent application, our determination may be incorrect, and the issuing patent may be asserted against us. 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 monetary damages, we may be temporarily or permanently prohibited from commercializing our product candidates. We might, if possible, also be forced to redesign our product candidates so that we no longer infringe on 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.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical and pharmaceutical industries involve both technological complexity and legal complexity. Therefore, obtaining and enforcing biopharmaceutical and pharmaceutical patents is costly, time-consuming and inherently uncertain.

The U.S. has in recent years enacted and implemented wide ranging patent reform legislation. Additionally, 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. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the U.S. federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Similarly, the complexity and uncertainty of European patent laws has also increased in recent years. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and European and other patent agencies over the lifetime of a patent. In addition, the USPTO and European and other patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent failure to make payment of such fees or to comply with such provisions 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 such noncompliance will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors fail to maintain the patents and patent applications covering our product candidates or if we or our licensors

otherwise allow our patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize our product candidates in any indication for which they are approved.

We enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection, but enforcement is not as strong as that in the United States or the EU. These products may compete with our product candidates, and our and our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications before grant. The grant proceeding of each national or regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for and launch generic versions of our products. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and the EU, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. 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 or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of marketing exclusivity for our product candidates, our business may be materially harmed.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, we may be able to extend the term of a patent covering each product candidate under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments and similar legislation in the EU. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. The total patent term including the extension cannot exceed 14 years following regulatory approval. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially.

Further, under certain circumstances, patent terms covering our products or product candidates may be extended for time spent during the pendency of the patent application in the USPTO (referred to as Patent Term Adjustment, or PTA). The laws and regulations underlying how the USPTO calculates the PTA is subject to change and any such PTA granted by the USPTO could be challenged by a third-party. If we do not prevail under such a challenge, the PTA may be reduced or eliminated, resulting in a shorter patent term, which may negatively impact our ability to exclude competitors. Because PTA added to the term of patents covering pharmaceutical products has particular value, our business may be adversely affected if the PTA is successfully challenged by a third party and our ability to exclude competitors is reduced or eliminated.

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

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, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are similar to Halneuron®, IMC-1, IMC-2 or any other product candidates we develop in the future but that are not covered by the claims of the patents that we own or license from others;

- others may independently develop similar or alternative technologies or otherwise circumvent any of our technologies without infringing our intellectual property rights;

- we or any of our collaborators might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own, license or will own or license;

- we or any of our collaborators might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have obtained a license, or will own or will have obtained a license;

- 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 advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;

- our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- ownership of our patents or patent applications may be challenged by third parties; and

- the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that our trade secrets will be misappropriated or disclosed, and confidentiality agreements with employees and third parties may not adequately prevent disclosure of trade secrets and protect other proprietary information.

We consider proprietary trade secrets or confidential know-how and unpatented know-how to be important to our business. We may rely on trade secrets or confidential know-how to protect our technology, especially where patent protection is believed by us to be of limited value. Because we expect to rely on third parties to manufacture Halneuron®, IMC-1, IMC-2 and any other product candidates we develop in the future, and we expect to collaborate with third parties on the development of Halneuron®, IMC-1, IMC-2 and any other product candidates we develop in the future, we must, at times, share trade secrets with them. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. However, trade secrets or confidential know-how can be difficult to maintain as confidential.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with us 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. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. 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. 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 have an adverse effect on our business and results of operations. Enforcing a claim that a third party obtained illegally and is using trade secrets or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction.

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. 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 our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our unregistered trademarks or trade names. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

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

A third party may hold intellectual property, including patent rights that are important or necessary to the development or commercialization of Halneuron®, IMC-1, IMC-2 or any other product candidates we develop in the future. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize Halneuron®, IMC-1, IMC-2 or any other product candidates we develop in the future, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, which could materially harm our business. At this time, we are unaware of any intellectual property that interferes with ours or is complementary and needed to commercialize Halneuron®, IMC-1 or IMC-2.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership or right to use. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

Our proprietary information may be lost, or we may suffer security breaches.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to

employee error, malfeasance or other disruptions. Although, to our knowledge, we have not experienced any such material security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, significant regulatory penalties, disruption of our operations, damage to our reputation and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay our clinical development of our product candidates.

Risks Related to Our Employees, Managing Our Growth and Our Operations

Our future success depends on our ability to retain our key personnel and to attract, retain and motivate qualified personnel.

We are highly dependent on the development, regulatory, commercialization and business development expertise of the executive team, as well as the other principal members of our management, scientific and clinical teams. Although we have employment agreements, offer letters or consulting agreements with our executive officers, these agreements do not prevent them from terminating their services at any time.

If we lose one or more of our executive officers or key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop product candidates, gain regulatory approval, and commercialize new products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be engaged by entities other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified personnel, our ability to develop and commercialize product candidates will be limited.

We expect to expand our development, regulatory, and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities or acquire new facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We may engage in acquisitions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources.

In the future, we may enter into transactions to acquire other businesses, products or technologies. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms, or at all. Any acquisitions we make may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered

liabilities of the acquired business that are not covered by the indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and nondisruptive manner. Acquisitions may also divert management attention from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results.

Our business and operations would suffer in the event of system failures.

Our computer systems, as well as those of our CROs and other contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters (including hurricanes), 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 development programs. For example, the loss of preclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. 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 personal, confidential or proprietary information, we could incur liability and the further development of IMC-1, IMC-2 or any other product candidates we develop in the future could be delayed.

We may be materially adversely affected by currency fluctuations in the United States dollar versus the Canadian dollar.

The Canadian dollar is the functional currency for our Canadian subsidiaries and our financial results, reported in U.S. dollars, are affected by changes in the currency exchange rate. The assets, liabilities, revenues, and expenses of our Canadian subsidiaries are generally all denominated in Canadian dollars. However, the Canadian dollar financial statements of our Canadian subsidiaries are translated into U.S. dollars in our consolidated financial statements. Therefore, significant exchange rate fluctuations between the U.S. dollar and the Canadian dollar could have a material adverse effect on our financial condition and results of operations. A weaker Canadian dollar relative to the U.S. dollar would result in lower levels of assets, liabilities and operating results as translated in our U.S. dollar reporting currency financial statements. In addition, our net investment in our Canadian subsidiaries, shown as Goodwill and Intangible Assets in the consolidated balance sheets, is significantly affected by fluctuations in the exchange rate between the U.S. dollar and the Canadian dollar.

Risks Related to Our Common Stock

If we are unable to maintain listing of our common stock on the Nasdaq Capital Market or another national stock exchange, it may be more difficult for our stockholders to sell their shares of common stock.

Nasdaq requires issuers to comply with certain standards to remain listed on its exchange. On November 15, 2024, we received a letter from Nasdaq notifying us that the amount of our stockholders' equity had fallen below the $2,500,000 required minimum for continued listing under Listing Rule 5550(b) (the "Rule"). The letter also noted that we did not meet the alternatives of market value of listed securities or net income from continuing operations and, therefore, no longer comply with the Nasdaq Listing Rules. The notice had no immediate effect on the continued listing status of the Company's common stock on the Nasdaq Capital Market, and, therefore, the Company's listing remains fully effective. On December 27, 2024, we submitted to Nasdaq a plan of compliance to achieve and sustain compliance with the Rule. On February 2, 2025, we received a letter from Nasdaq granting us until May 14, 2025 to regain our compliance with the Nasdaq Listing Rules.

However, if the Company fails to regain compliance with Nasdaq's listing rules, it could be subject to suspension and delisting proceedings. If we are unable to maintain our listing on Nasdaq, it may become more difficult for our stockholders to sell our common stock in the public market. In addition, in the event the Company's securities are delisted, broker-dealers have certain regulatory burdens imposed upon them, which may discourage broker-dealers from effecting transactions in the Company's securities, further limiting the

liquidity of such securities. A determination that our common stock is a "penny stock" will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our common stock. Such delisting from The Nasdaq Capital Market and continued or further declines in the Company's share price could also greatly impair our ability to raise additional necessary capital through equity or debt financing, and could significantly increase the ownership dilution to stockholders caused by our issuing equity in financing or other transactions. Further, if we are delisted, we would also incur additional costs under state blue sky laws in connection with any sales of our securities.

The market price of our common stock is highly volatile, which could result in substantial losses for holders of our common stock.

The market price of our common stock is highly volatile and is subject to wide fluctuations in response to a variety of factors, including the following:

- delay in clinical trial enrolment and data readouts;
- material cost overruns in clinical trials;
- any delay in submitting an NDA and any adverse development or perceived adverse development with respect to the FDA's review of that NDA;
- failure to successfully develop and commercialize Halneuron®, IMC-1, IMC-2 or any other product candidates we develop in the future;
- inability to obtain additional funding;
- regulatory or legal developments in the United States and other countries applicable to Halneuron®, IMC-1, IMC-2 or any other product candidates;
- adverse regulatory decisions;
- changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for Halneuron®, IMC-1, IMC-2 or any other product candidate, or the inability to do so at acceptable prices;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- changes in the market valuations of companies similar to ours;
- market conditions in the pharmaceutical and biotechnology sectors, and the issuance of new or changed securities analysts' reports or recommendations;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- significant lawsuits, including patent or shareholder litigation, and disputes or other developments relating to our proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;

- additions or departures of key scientific or management personnel;
- sales of our common stock by us or our shareholders in the future;
- trading volume of our common stock;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, as well as general economic, political, regulatory and market conditions, may negatively affect the market price of our common stock, regardless of our actual operating performance.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against companies following a decline in the market price of their securities. This risk is especially relevant for us because biotechnology companies have experienced significant share price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management’s attention and resources, which could harm our business.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our common stock, our stock price and trading volume could decline.

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts may publish about us or our business. We do not have any control over these analysts. If our financial performance fails to meet analyst estimates or one or more of the analysts who cover us downgrade our common stock or change their opinion of our common stock, our share price would likely decline. If one or more of these analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock would be our stockholder’s sole source of gain on an investment in our common stock for the foreseeable future.

We are subject to significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we no longer qualify as an emerging growth company, we incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002 (“SOX”), the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations impose various requirements on U.S. reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance

initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations may make it more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors. In addition, these rules and regulations are often subject to varying interpretations, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Pursuant to Section 404 of SOX, we are required to furnish a report by our senior management on our internal control over financial reporting. While we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

To comply with Section 404, we are required to engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and maintain a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be reevaluated frequently. Our 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 in accordance with generally accepted accounting principles. In connection with our initial public offering, we began the process of documenting, reviewing and improving our internal controls and procedures for compliance with Section 404 of SOX, which requires annual management assessment of the effectiveness of our internal control over financial reporting.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls and any failure to maintain that adequacy or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our common share price and make it more difficult for us to effectively market and sell our service to new and existing customers.

We are an "emerging growth company," and a "smaller reporting company" and the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including exemption from compliance with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden

parachute payments not previously approved. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our IPO, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock held by non-affiliates exceeds $700 million as of the end of our prior second fiscal quarter, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 and reduced disclosure obligations regarding executive compensation.

In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We intend to take advantage of the extended transition period for adopting new or revised accounting standards under the JOBS Act as an emerging growth company. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile.

Provisions in our certificate of incorporation and bylaws and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions include those establishing:

- Advance notice bylaw provisions for proposals from stockholders for presentation at annual meetings; and

- Forum selection bylaw provisions.

Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our certificate of incorporation and our bylaws will contain exclusive forum provisions for certain claims, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our certificate of incorporation and our bylaws, to the fullest extent permitted by law, provide that the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising

pursuant to the General Corporation Law of the State of Delaware, our certificate of incorporation, or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine.

Moreover, Section 22 of the Securities Act (as defined below) creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder and our bylaws provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or a Federal Forum Provision. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While there can be no assurance that federal or state courts will follow the holding of the Delaware Supreme Court or determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court. Section 27 of the Exchange Act (as defined below) creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder and neither the exclusive forum provision nor the Federal Forum Provision applies to suits brought to enforce any duty or liability created by the Exchange Act. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder must be brought in federal court. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the regulations promulgated thereunder.

Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions, including the Federal Forum Provision. These provisions may limit our stockholders' ability to bring a claim in a judicial forum they find favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation and/or bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition.

Risks Related to the Combination

There is no guarantee that the Combination will increase stockholder value.

In October 2024, we consummated the Combination. We cannot guarantee that implementing the Combination and related transactions will not impair stockholder value or otherwise adversely affect our business. The Combination poses significant integration challenges between our businesses and employees which could result in management and business disruptions, any of which could harm our results of operation, business prospects, and impair the value of the Combination to our stockholders.

If our acquired intangible assets and goodwill become impaired, we may be required to record a significant charge to earnings.

Following the Combination, a significant amount of our total assets are related to acquired intangible assets and goodwill, which are subject to annual impairment reviews, or more frequent reviews if events or circumstances indicate that the carrying value may not be recoverable. For example, in 2024 we recorded a cumulative translation loss of $3.8 million primarily related to our acquired intangible assets located in Canada, primarily due to fluctuations in the exchange rate between the U.S. dollar and the Canadian dollar and future exchange rate fluctuations may require us to incur additional translation losses. Because of the significance of these assets, any charges for impairment as well as amortization of intangible assets could have a material adverse effect on the combined company's results of operations and financial condition.

Tetrodotoxin and Halneuron® may become subject to a contractual repurchase right in certain circumstances, which could have a material adverse effect on our results of operations, financial condition, and cash flows.

In connection with the Combination, we agreed to enter into a Repurchase Agreement with Sealbond upon the occurrence of certain circumstances, pursuant to which Sealbond has the right to acquire all of the Company's and its direct and indirect subsidiaries' intellectual property, rights, title, regulatory submissions, assignment of contracts, data and interests, as of the time of such acquisition, in and to tetrodotoxin and Halneuron® (the "Repurchase Option") in exchange for the aggregate cash settlement amount Sealbond would then be entitled to under the Certificate of Designation. In the event that the Repurchase Option is exercised, the Company may experience the loss of a key asset and product development program, and reduced long-term product development and marketing opportunities for the Company, which could have a material adverse effect on the price of our Common Stock, our results of operations and financial condition.

Pursuant to the terms of the Exchange Agreement, we are required to recommend that our stockholders approve the conversion of all outstanding shares of our Series A Non-Voting Convertible Preferred Stock into shares of our Common Stock. We cannot guarantee that our stockholders will approve this matter.

Under the terms of the Exchange Agreement, we agreed to call and hold a meeting of our stockholders to obtain, among other things, the requisite approvals for the conversion of all outstanding shares of Series A Non-Voting Convertible Preferred Stock to be issued in the Combination into shares of our Common Stock and to seek approval of a potential "change of control" under Nasdaq Listing Rules 5110 and 5635(C), in each case as required by the Nasdaq Stock Market LLC listing rules. If such approval is not obtained at that meeting, the Company agreed to seek to obtain such approvals at an annual or special stockholders meeting to be held at least every six months thereafter until such approval is obtained, which would be time consuming and costly.

The issuance of common stock upon conversion of our outstanding Series A Non-Voting Convertible Preferred Stock and Series A-1 Non-Voting Convertible Preferred Stock will cause immediate and substantial dilution to existing shareholders.

As of the date of this Annual Report on Form 10-K, we had 2,213.8044 outstanding shares of Series A Non-Voting Convertible Preferred Stock and 284.2638 outstanding shares of Series A-1 Non-Voting Convertible Preferred Stock. If the Company's stockholders approve the conversion of each series of preferred stock into Common Stock, each holder of Series A Non-Voting Convertible Preferred Stock or Series A-1 Non-Voting Convertible Preferred Stock may, at its option, convert each of its shares of preferred stock into 10,000 shares of Common Stock. The conversion of the Series A Non-Voting Convertible Preferred Stock and Series A-1 Non-Voting Convertible Preferred Stock of the Company will cause significant dilution to the then holders of our Common Stock. In addition, the Common Stock issuable upon conversion of our outstanding Series A Non-Voting Convertible Preferred Stock and Series A-1 Non-Voting Convertible Preferred Stock may represent overhang that may also adversely affect the market price of our Common Stock. Overhang occurs when there is a greater supply of a company's stock in the market than there is demand for that stock, which typically depresses a company's stock price. If we experience overhang, any additional shares which the then holders of our Common Stock attempt to sell in the market will only further decrease the market price of our Common Stock.

We may be required to settle shares of Series A Non-Voting Convertible Preferred Stock for cash, which could have a material adverse effect on our business and financial condition.

The Certificate of Designation provides that if Company fails to deliver to the holders of Series A Non-Voting Convertible Preferred Stock certificates or electronic entries representing the shares of Common Stock issuable upon the conversion of the Series A Non-Voting Convertible Preferred Stock and certain events set forth in the Exchange Agreement occur, each share of Series A Non-Voting Convertible Preferred Stock will be settled for cash at the option of the holder at a price per share equal to the then-current fair value of a share of

Common Stock. If we are required to cash settle a significant amount of Series A Preferred Stock, we may not have sufficient liquidity to satisfy our obligations, which could have a material adverse effect on our business and financial condition.

The failure to successfully integrate the businesses of the Company and Pharmagesic in the expected timeframe could adversely affect Dogwood's results of operations, financial condition, and future results.

Our ability to successfully integrate the operations of the Company and Pharmagesic will depend, in part, on our ability to realize the anticipated benefits from the Combination. If we are not able to achieve these objectives within the anticipated time frame, or at all, the anticipated benefits of the Combination may not be realized fully, or at all, or may take longer to realize than expected, and the value of our common shares may be adversely affected. In addition, the integration of the Company's and Pharmagesic's respective businesses will be a time-consuming and expensive process. Proper planning and effective and timely implementation will be critical to avoid any significant disruption to Dogwood's operations. It is possible that the integration process could result in the loss of key employees, the disruption of its ongoing business or the identification of inconsistencies in standards, controls, procedures and policies that adversely affect its ability to maintain relationships with customers, suppliers, distributors, creditors, lessors, clinical trial investigators or managers or to achieve the anticipated benefits of the Combination. Delays encountered in the integration process could have a material adverse effect on Dogwood's expenses, operating results and financial condition, including the value of shares of its Common Stock.

Our future results will suffer if we do not effectively manage our expanded operations.

As a result of the Combination, we will become a more diversified company and our business will become more complex. There can be no assurance that we will effectively manage the increased complexity without experiencing operating inefficiencies or control deficiencies. Significant management time and effort is required to effectively manage our increased complexity and our failure to successfully do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In addition, as a result of the Combination, our financial statements and results of operations for periods prior to October 7, 2024 may not provide meaningful guidance to form an assessment of the prospects or potential success of our future business operations.

We expect to incur substantial expenses related to the integration of Pharmagesic.

We have incurred, and expect to continue to incur, substantial expenses in connection with the Combination and the integration of Pharmagesic. There are a large number of processes, policies, procedures, operations, technologies and systems that must be integrated, including purchasing, accounting and finance, billing, payroll, research and development, marketing and benefits. Both the Company and Pharmagesic have incurred significant transaction expenses in connection with the drafting and negotiation of the Exchange Agreement, and the related ancillary agreements. While we have assumed that a certain level of expenses will be incurred, there are many factors beyond our control that could affect the total amount or the timing of the integration expenses. Moreover, many of the expenses that will be incurred are, by their nature, difficult to estimate accurately. These integration expenses likely will result in our taking significant charges against earnings following the completion of the Combination, and the amount and timing of such charges are uncertain at present.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Our use of information systems for using, transmitting and storing data is a vital aspect of our business operations. Information systems can be vulnerable to a range of cybersecurity threats that could potentially have a material impact on our business strategy, results of operations and financial condition.

Cybersecurity Risk Management and Strategy. The Company actively maintains a cyber-risk management program. Cybersecurity is a key category within our risk management program, and our cybersecurity risk management is intended to assist in assessing, identifying, and managing material risks from cybersecurity threats to the Company's information systems. This integration of cybersecurity into the Company's overall enterprise risk management program is to ensure that cybersecurity considerations are included in decision-making processes throughout the Company.

Our cybersecurity program is designed to safeguard against evolving and increasingly sophisticated cybersecurity threats by helping to prevent, detect, mitigate and respond to cyber-attacks. Our approach consists of, among other things, cybersecurity threat and vulnerability prevention, detection, mitigation and remediation of potential cybersecurity risks. We employ cybersecurity intrusion detection systems and continuous monitoring, in order to help defend against unauthorized access. Identity-based access management also serves an integral role of our cybersecurity strategy and involves access controls and identity authentication requirements. Access to the Company's data is monitored and controlled according to access control policies. Data protection and privacy practices, including data loss prevention, help to safeguard sensitive information.

The Audit Committee of our Board of Directors is responsible for oversight of the Company's cyber-risk management program and management's role is to assist the Audit Committee in identifying and considering material cybersecurity risks, ensure implementation of management and employee level cybersecurity practices and training and provide the Audit Committee with regular reports regarding any cybersecurity attacks or vulnerabilities. As of the date of this Annual Report on Form 10-K, the Company has not experienced any cybersecurity attacks.

The Company also requires our employees to participate in cybersecurity training and awareness programs. In particular, we have determined that the most significant cybersecurity risk to our organization is social engineering schemes such as phishing schemes. All employees receive training twice a year in identifying and stopping social engineering cyber-attacks. The Company's employees are expected to help safeguard the Company's information systems and to assist in the discovery and reporting of cybersecurity incidents. These programs are intended to decrease cybersecurity risks associated with human error and foster a culture of cybersecurity consciousness.

Our cybersecurity program is periodically evaluated against established quantifiable goals and other external benchmarks. This evaluation is carried out through periodic internal and external risk assessments and compliance audits. The third parties that the Company engages in order to conduct these evaluations, assessments and audits, including our third-party internal audit vendor, Crowe LLP, also advise us on the effectiveness of our cybersecurity processes and assist the Company in remediating any identified vulnerabilities and implementing any recommended measures to improve our cybersecurity defenses.

In addition to monitoring cybersecurity threats to the Company's information systems, the Company's vendor risk management practices are intended to help monitor, mitigate and prevent cybersecurity risks from external sources. We operate as a virtual company and maintain vital information, including financial and payroll information, on servers owned and maintained by our vendors. As such, we rely on the internal controls of our third party vendors to protect our vital information. We obtain and review reports on the internal controls of our vendors on an annual basis to ensure that we believe their cybersecurity procedures are adequate and to confirm that there have been no data breaches affecting our information. For certain third-party providers we deem critical to our operations, we also obtain and review System and Organization Controls reports at the

beginning of an engagement, as well as on an ongoing basis, in order to assess their cybersecurity preparedness.

To date, the risks from cybersecurity threats, including as a result of any previous immaterial cybersecurity incidents, have not materially affected, or are reasonably likely to materially affect, our business strategy, results of operations, or financial condition. While the Company maintains cybersecurity insurance, the costs related to cybersecurity threats or disruptions may not be fully insured. For more information regarding the risks the Company faces from cybersecurity threats, see "Risk Factors—Risks Related to Our Intellectual Property—Our proprietary information may be lost, or we may suffer security breaches."

Item 2. Properties

We do not own or lease any real property in the United States. We run a virtual model and have a mailing address in Alpharetta, Georgia. We lease office spaces in Vancouver, British Columbia, Canada located at 1150-1100 Melville St, Vancouver B.C., Canada.

Item 3. Legal Proceedings

From time to time, we may be involved in claims that arise during the ordinary course of business. Regardless of the outcome, litigation can be costly and time consuming, and it can divert management's attention from important business matters and initiatives, negatively impacting our overall operations. We do not currently have any pending litigation to which we are a party or to which our property is subject that we believe to be material. Regardless of the outcome, litigation can be costly and time consuming, and it can divert management's attention from important business matters and initiatives, negatively impacting our overall operations.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

Our common stock was listed on The Nasdaq Capital Market ("Nasdaq") under the symbol "VIRI" at our initial public offering on December 16, 2020. On October 7, 2024, in connection with the Business Combination, we changed our name to Dogwood Therapeutics and on October 9, 2024, our common stock started trading under the symbol "DWTX".

As previously reported, on November 2, 2023, the Company received a letter from the Listing Qualifications Department of The Nasdaq Stock Market, LLC ("Nasdaq") notifying the Company that, for the previous 30 consecutive business days, the bid price for the Company's Common Stock had closed below the minimum $1.00 per share requirement for continued listing on the Nasdaq (the "Minimum Bid Price Requirement"). The letter stated that the Company had 180 calendar days, or until April 30, 2024 to regain compliance such that the closing bid price for the Company's Common Stock is at least $1.00 for a minimum of 10 consecutive business days.

On May 1, 2024, the Company received another letter from Nasdaq informing it that the Company's Common Stock had failed to comply with the $1.00 minimum bid price required for continued listing and, as a result, the Company's Common Stock continues to be subject to delisting. Following receipt of the letter, the

Company requested a hearing with Nasdaq. On June 11, 2024, the Company received notice from Nasdaq that the Nasdaq Hearing Panel had granted the Company an exception until October 28, 2024 to regain compliance with the Minimum Bid Price Requirement. On October 29, 2024, the Company received a letter from Nasdaq stating that the Company had regained compliance with Minimum Bid Price Requirement because the Company's Common Stock had a closing bid price of at least $1.00 per share for more than ten consecutive business days.

On November 15, 2024, we received a letter from Nasdaq notifying us that the amount of our stockholders' equity had fallen below the $2,500,000 required minimum for continued listing under Listing Rule 5550(b) (the "Rule"). The letter also noted that we did not meet the alternatives of market value of listed securities or net income from continuing operations and, therefore, no longer comply with the Nasdaq Listing Rules. The notice had no immediate effect on the continued listing status of the Company's common stock on the Nasdaq Capital Market, and, therefore, the Company's listing remains fully effective. On December 27, 2024, we submitted to Nasdaq a plan of compliance to achieve and sustain compliance with the Rule. On February 2, 2025, we received a letter from Nasdaq granting us until May 14, 2025 to regain our compliance with the Nasdaq Listing Rules. As of March 14, 2025, after giving effect to the Exchange and Cancellation Agreement and the March 2025 Offering and the deduction of related estimated placement agent fees and estimated offering expenses payable by us, our total stockholders' equity is estimated to be more than $2.5 million.

Holders of Record

As of March 28, 2025, there were approximately 111 holders of record of shares of our common stock. This number does not reflect the beneficial holders of our common stock who hold shares in street name through brokerage accounts or other nominees.

Dividend Policy

We have never declared or paid any cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future.

Per the Certificate of Designation, holders of Series A Preferred Stock shall be entitled to receive, and the Company shall pay, payment-in-kind dividends on each share of Series A Preferred Stock, accruing at a rate equal to five percent (5.0%) per annum payable in shares of Series A Preferred Stock on the date that is 180 days after the date of the original issuance of such Series A Preferred Stock or such earlier date that such holder may convert any portion of the Series A Preferred Stock to Common Stock. Holders of Series A-1 Non-Voting Convertible Preferred Stock are not entitled to receive a dividend.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the year ended December 31, 2024.

Recent Sales of Unregistered Securities

We did not issue any equity securities during the year ended December 31, 2024 that were not registered under the Securities Act and that have not otherwise been described in a Quarterly Report on Form 10-Q or a Periodic Report on Form 8-K.

Item 6. Selected Financial Data

This item is not required.

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties, including those set forth under "Cautionary Statement About Forward-Looking Statements." Actual results and experience could differ materially from the anticipated results and other expectations expressed in our forward-looking statements as a result of a number of factors, including but not limited to those discussed in this Item and in Part I, Item 1A. "Risk Factors." Actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth under "Risk Factors" and elsewhere in this Annual Report on Form 10-K.

Summary Overview

We are a pre-revenue, development-stage biopharmaceutical company focused on developing new medicines to treat pain and fatigue-related disorders. Our pipeline is focused on two separate pillars: Na_v 1.7 modulation to treat chronic and acute pain disorders and combination antiviral therapies targeting reactivated herpes virus mediated illnesses. The proprietary non-opioid Na_V 1.7 analgesic program is centered on our lead development candidate Halneuron®, which is a voltage-gated sodium channel modulator, a mechanism known to be effective for reducing pain. The antiviral program includes IMC-1 and IMC-2, which are novel, proprietary, fixed dose combinations of nucleoside analog, anti-herpes antivirals and the anti-inflammatory agent celecoxib for the treatment of FM and LC.

Na_v 1.7 Non-Opioid Analgesic Program

Our lead product candidate, Halneuron®, is in late-stage clinical development for the treatment of CINP. The active pharmaceutical ingredient is highly purified TTX, a potent sodium channel modulator found in puffer fish and several other marine animals. Halneuron® works as an analgesic by modulating the activity of $Na_v1.7$, a key sodium channel involved in pain signal transmission. By reducing the activity of the $Na_v1.7$ channel, Halneuron® has the potential to reduce pain associated with conditions involving neuropathic pain.

In the first quarter of 2025, we commenced a HALT-CINP-203 clinical trial in the United States. HALT-CINP-203 is a double-blind, placebo controlled clinical trial to access the efficacy and safety of Halneuron® in 200 patients with moderate to severe neuropathic pain caused by previous platinum and/or taxane chemotherapy. The primary efficacy endpoint is the change from baseline at week 4 in the weekly average of daily 24-hour recall pain intensity scores, comparing Halneuron® to the placebo. The secondary endpoints are patient global impression of change, PROMIS regarding fatigue, PROMIS related to sleep, PROMIS-29, pain interference, hospital anxiety and depression scale and neuropathic pain symptom inventory. We expect to release interim data from HALF-CINP-203 in the second half of 2025.

Antiviral Program

We plan to continue development of IMC-1 and IMC-2 which are novel, proprietary, fixed dose combinations of nucleoside analog, anti-herpes antivirals and the anti-inflammatory agent celecoxib. IMC-1 is a novel combination of famciclovir and celecoxib intended to synergistically suppress herpesvirus activation and replication, with the end goal of reducing a patient's viral mediated disease burden. IMC-2 is a combination of valacyclovir and celecoxib that like IMC-1, is intended to synergistically suppress herpesvirus activation and replication with a more specific activity against the Epstein-Barr virus (herpesvirus HHV-4).

Share Exchange Agreement

On October 7, 2024, the Company, entered into the Exchange Agreement with Sealbond, pursuant to which the Company acquired 100% of the issued and outstanding common shares of Pharmagesic and the parent company of Wex Pharmaceuticals, Inc. in the Combination. Prior to the Combination, Pharmagesic was a

wholly-owned subsidiary of Sealbond and an indirect wholly-owned subsidiary of CKLS, a listed entity on the Main Board of the Hong Kong Stock Exchange.

Loan Agreement

On October 7, 2024, in connection with the Exchange Agreement, the Company entered into a Loan Agreement (the "Loan Agreement") with Conjoint Inc., a Delaware corporation ("Lender"). Pursuant to the Loan Agreement, Lender agreed to make a loan to the Company in the aggregate principal amount of $19,500,000, of which (i) $16,500,000 was disbursed on October 7, 2024 and (ii) $3,000,000 was disbursed on February 18, 2025. Prior to the Debt Exchange and Cancellation Transaction described below, the Loan Agreement bore interest at the Secured Overnight Financing Rate ("SOFR"). The Loan Agreement was payable in full with principal and accrued interest on October 7, 2027.

Contingent Value Rights Agreement

Concurrently with the closing of the Combination, the Company entered into a contingent value rights agreement (the "CVR Agreement") with a rights agent (the "Rights Agent"), pursuant to which each holder of Common Stock as of October 17, 2024, including those holders receiving shares of Common Stock in connection with the Combination, is entitled to one contractual contingent value right (each, a "CVR") issued by the Company, subject to and in accordance with the terms and conditions of the CVR Agreement, for each share of Common Stock held by such holder as of 5:00 p.m. Eastern Daylight Time on October 17, 2024. The CVR Agreement has a term of seven years.

Each contingent value right entitles the holders (the "Holders") thereof, in the aggregate, to 87.75% of any Upfront Payment (as defined in the CVR Agreement) or Milestone Payment (as defined in the CVR Agreement) received by the Company in a given calendar quarter.

The distributions in respect of the CVRs that become payable will be made on a quarterly basis and will be subject to a number of deductions, subject to certain exceptions or limitations, including but not limited to for certain taxes and certain out-of-pocket expenses incurred by the Company.

Under the CVR Agreement, the Rights Agent has, and Holders of at least 30% of the CVRs then-outstanding have, certain rights to audit and enforcement on behalf of all Holders of the CVRs. The CVRs may not be sold, assigned, transferred, pledged, encumbered or in any other manner transferred or disposed of, in whole or in part, other than as permitted pursuant to the CVR Agreement. The Holders of the CVRs do not have the rights of a shareholder and do not have the ability to vote, rights to dividends, or other interests. The CVRs also establish certain restrictions of mergers and change in control activities, as defined in the agreement.

Name Change

On October 7, 2024, the Company changed its name from "Virios Therapeutics, Inc." to "Dogwood Therapeutics, Inc." In addition, effective at the open of market trading on October 9, 2024, the Company's Common Stock ceased trading under the ticker symbol "VIRI" and began trading on the Nasdaq Stock Market under the ticker symbol "DWTX".

Reverse Stock Split

On October 7, 2024, the Company effected the Reverse Stock Split, pursuant to which every 25 shares of the Company's issued and outstanding Common Stock was converted automatically into one issued and outstanding share of Common Stock. The Reverse Stock Split affected all stockholders uniformly and did not by itself alter any stockholder's percentage interest in the Company's equity, except to the extent that the Reverse Stock Split would result in a stockholder owning a fractional share. No fractional shares were issued in connection with the Reverse Stock Split and any stockholder who would have received any fractional shares instead received a cash payment equal to the fair market value of such fractional share.

Recent Developments

On March 12, 2025, we entered into the Exchange and Cancellation Agreement with the Lender. Pursuant to the Exchange and Cancellation Agreement, the principal amount of all loans made to the Company under the Loan Agreement, along with accrued interest through March 12, 2025, was deemed repaid and all of the Company's obligations satisfied in full and cancelled in exchange for 284.2638 shares of the Company's Series A-1 Non-Voting Convertible Preferred Stock, par value $0.0001 per share.

On March 12, 2025, we entered into an agreement with Maxim Group LLC as placement agent in connection with the issuance and sale by the Company in a registered direct offering of 578,950 shares of our Common Stock at a price of $8.26 per share in the March 2025 Offering, pursuant to an effective shelf registration statement on Form S-3 (File No. 333-263700). The March 2025 Offering closed on March 14, 2025, and the gross proceeds from the March 2025 Offering were approximately $4.78 million. The net proceeds of the March 2025 Offering were approximately $4.25 million after deducting placement agent fees and offering expenses payable by the Company.

Financial Operations Overview

The following discussion sets forth certain components of our statements of operations as well as factors that impact those items.

Research and Development Expenses

Our research and development expenses consist of expenses incurred in development and clinical studies relating to our product candidates, including:

- payments to third-party contract research organizations, or CROs;
- payments to third-party contract development and manufacturing organizations, or CMOs;
- personnel-related expenses, such as salaries, benefits and stock compensation; and
- payments to contract laboratories and independent consultants.

We expense all research and development costs as incurred. Clinical development expenses for our product candidates are a significant component of our current research and development expenses. Products in later stage clinical development generally have higher research and development expenses than those in earlier stages of development, primarily due to increased size and duration of the clinical trials. We track and record information regarding research and development expenses for each study or trial we conduct. We use third-party CROs, CMOs, contractor laboratories and independent contractors. We recognize the expenses associated with third parties performing services for us in our clinical studies based on the percentage of each study completed at the end of each reporting period.

Our research and development expenses in 2024 primarily related to planning and start-up costs of the HALT-CINP-203 clinical trial; funding the grant to the Bateman Horne Center for the second investigator-sponsored study assessing IMC-2 as a treatment for symptoms associated with LC; and continued salaries and benefits.

As we advance the HALT-CINP-203 clinical trial, we expect our research and development expenses to increase. These expenditures are subject to numerous uncertainties regarding timing and cost to completion. Completion of our clinical development and clinical trials may take several years or more. Because of the numerous risks and uncertainties associated with product development, we cannot determine with certainty the duration and completion costs of the current or future studies and clinical trials or if, when, or to what extent we

will generate revenues from the commercialization and sale of our product candidates. We may never succeed in achieving regulatory approval for our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

- successful enrollment in, and completion of, clinical trials;
- successful completion of Investigational New Drug-enabling activities;
- receipt of marketing approvals from applicable regulatory authorities;
- making arrangements with third-party manufacturers or establishing our own commercial manufacturing capabilities;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity;
- launching commercial sales of Halneuron®, IMC-1 or IMC-2, if approved, whether alone or in collaboration with others;
- acceptance of Halneuron®, IMC-1 or IMC-2, if approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies and treatment options;
- a continued acceptable safety profile following approval;
- enforcing and defending intellectual property and proprietary rights and claims; and
- achieving desirable medicinal properties for the intended indications.

A change in the outcome of any of these factors could mean a significant change in the costs and timing associated with the development of our current and future product candidates. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development, or if we experience significant delays in execution of or enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. We expect our research and development expenses to increase for the foreseeable future as we continue the development of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits and other related personnel costs, including equity and stock-based compensation, for personnel serving in our executive, finance and administrative functions. General and administrative expenses also include public company costs, directors' and officers' insurance, professional fees for legal, including patent related expenses, consulting, auditing and tax services.

We anticipate that our general and administrative expenses will increase in the future to support continued research and development activities and potential commercialization of our product candidates and increased costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, lawyers and accountants, among other expenses.

Other Income/Expense

Other income/expense consists of interest income earned on cash in a money market account offset by interest expense and loan amortization costs associated with the loan from Conjoint, Inc.

Related Parties

The Company uses Gendreau Consulting, LLC ("Gendreau"), a consulting firm, for drug development, clinical trial design, and planning, implementation and execution of contracted activities with CROs. Gendreau's managing member became the Company's Chief Medical Officer ("CMO") effective January 1, 2021. The Company has and may continue to contract the services of the CMO's spouse through Gendreau to perform certain activities in connection with the Company's clinical programs.

On October 7, 2024, in connection with the Exchange Agreement, the Company entered into the Loan Agreement with Lender who is an affiliate of CKLS. Pursuant to the Loan Agreement, the Lender agreed to make a loan to the Company in the aggregate principal amount of $19,500,000, of which (i) $16,500,000 was disbursed on October 7, 2024 and (ii) $3,000,000 was disbursed on February 18, 2025. The Loan Agreement bore interest at SOFR plus 2.00%. On March 12, 2025, the principal amount of all loans made to the Company under the Loan Agreement, along with accrued interest through such date was deemed repaid and all of the Company's obligations with respect to the principal amount and accrued interest was satisfied in full and cancelled in connection with the Debt Exchange and Cancellation Transaction.

For a full discussion of related party transactions see Note 11 to the Financial Statements included in this Annual Report on Form 10-K.

Income Taxes

As of December 31, 2024, the Company has U.S. federal net operating loss carryforwards of approximately $36,669,000, which have an indefinite carryforward and Georgia and Florida state net operating loss carryforwards of approximately $44,443,000 and $1,372,000, respectively, which have a twenty-year carryforward and begin expiring in 2037. As of December 31, 2024, the Company also had Canadian non-capital loss carryforwards of approximately $25,277,000, which have a twenty year carryforward and begin expiring in 2025 and Hong Kong tax losses carryforwards or approximately $58,126,000 which have no expiry. These net operating losses can be carried forward and applied against future taxable income, if any. As the Company was incorporated in December 2020, all tax years of the Company remain open to examination by tax authorities.

The Company has provided a full valuation allowance for its deferred tax assets as of December 31, 2023 due to the uncertainty surrounding the ability to realize these assets. At December 31, 2024, the Company evaluated the realizability of its deferred tax assets and determined that the valuation allowance should be adjusted for the consideration of the acquired in-process research and development intangible assets. The ultimate realization of the deferred tax assets is dependent upon the generation of future taxable income during the periods in which these temporary differences become deductible.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as critical because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates — which also would have been reasonable — could have been used. On an ongoing basis, we evaluate our estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and other market-specific or other relevant assumptions that we believe to

be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Indefinite-Lived Intangible Assets

Indefinite-lived intangible assets consist of In-Process Research and Development ("IPR&D"). The fair values of IPR&D project assets acquired in business combinations are capitalized. The Company generally utilizes the Multi-Period Excess Earning Method to determine the estimated fair value of the IPR&D assets acquired in a business combination. The projections used in this valuation approach are based on many factors, such as relevant market size, the estimated probability of regulatory success rates, anticipated patent protection, expected pricing, expected treated population, and estimated payments (e.g., royalty). The estimated future net cash flows are then discounted to the present value using an appropriate discount rate. These assets are treated as indefinite-lived intangible assets until completion or abandonment of the projects, at which time the assets are amortized over the remaining useful life or written off, as appropriate.

Intangible assets with indefinite lives, including IPR&D, are tested for impairment if impairment indicators arise and, at a minimum, annually. However, an entity is permitted to first assess qualitative factors to determine if a quantitative impairment test is necessary. Further testing is only required if the entity determines, based on the qualitative assessment, that it is more likely than not that an indefinite-lived intangible asset's fair value is less than its carrying amount. Otherwise, no further impairment testing is required. The indefinite-lived intangible asset impairment test consists of a one-step analysis that compares the fair value of the intangible asset with its carrying amount. If the carrying amount of an intangible asset exceeds its fair value, an impairment loss is recognized in an amount equal to that excess. The Company considers many factors in evaluating whether the value of our intangible assets with indefinite lives may not be recoverable, including, but not limited to, expected growth rates, the cost of equity and debt capital, general economic conditions, outlook and market performance of the Company's industry and recent and forecasted financial performance.

Redeemable and Convertible Preferred Stock

The Company applies ASC 480 when determining the classification and measurement of its preferred stock. Preferred shares subject to mandatory redemption are classified as liability instruments and are measured at fair value. Conditionally redeemable preferred shares (including preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control) are classified as temporary equity. At all other times, preferred shares are classified as stockholders' (deficit) equity.

Research and Development

Research and development costs are expensed as incurred. The Company arranges and contracts with third-party contract research organizations ("CROs"), contract development and manufacturing organizations ("CMOs"), contractor laboratories and independent consultants. As part of the process of preparing its financial statements, the Company may be required to estimate some of its expenses resulting from its obligations under these arrangements and contracts. The financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided. The Company's objective is to reflect the appropriate expenses in its financial statements by matching those expenses with the period in which services are rendered. The Company determines any accrual estimates based on account discussions with applicable personnel and outside service providers as to the progress or state of completion. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known at that time. The Company's estimates

are dependent upon the timely and accurate reporting of CROs, CMOs and other third-party vendors. At the end of each reporting period, the Company compares the payments made to each service provider to the estimated progress towards completion of the related project. Factors that the Company considers in preparing these estimates include the number of patients enrolled in studies, milestones achieved, and other criteria related to the efforts of its vendors. These estimates will be subject to change as additional information becomes available. Depending on the timing of payments to vendors and estimated services provided, the Company will record prepaid or accrued expenses related to these costs.

Equity and Share-Based Compensation

The Company recognizes compensation expense relating to equity-based payments based on the fair value of the equity or liability instrument issued. For equity-based instruments, the expense is based upon the grant date fair value and recognized over the service period. For awards with a performance condition, compensation expense is recognized over the requisite service period if it is probable that the performance condition will be satisfied. Expense is recognized within both research and development and general and administrative expenses and forfeitures are recognized as they are incurred. For awards to non-employees, the Company recognizes compensation expense in the same manner as if the Company had paid cash for the goods or services. The Company estimates the fair value of options and warrants granted using an options pricing model.

Results of Operations

Operating expenses and other (expense) income were comprised of the following:

	Year Ended December 31,	
	2024	**2023**
Operating expenses:		
Research and development	**$ 3,530,913**	$ 1,728,078
General and administrative	**8,696,335**	3,718,841
Total operating expenses	**$ 12,227,248**	$ 5,446,919
Other (expense) income:		
Interest (expense) income, net	**(92,192)**	150,904
Exchange loss, net	**(30,787)**	—
Total other income	**(122,979)**	150,904
Loss before income taxes	**$ (12,350,227)**	$ (5,296,015)

Years Ended December 31, 2024 and 2023

Research and Development Expenses

Research and development expenses increased by $1.8 million to $3.5 million for the year ended December 31, 2024 from $1.7 million for the year ended December 31, 2023. The increase was primarily due to increases in expenses for clinical trials of $1.0 million, research and preclinical activities of $0.3 million, drug development and manufacturing costs of $0.4 million and salaries and related personnel costs of $0.3 million partially offset by a decrease in regulatory consulting of $0.2 million.

General and Administrative Expenses

General and administrative expenses increased by $5.0 million to $8.7 million for the year ended December 31, 2024 from $3.7 million for the year ended December 31, 2023. This increase was primarily due to nonrecurring transaction costs of $4.9 million related to the Combination, an increase in salaries and related

personnel costs of $0.4 million offset by a decrease of $0.3 million related to costs associated with being a public company primarily due to lower insurance expenses.

Other (Expense) Income

Other (expense) income increased by $0.3 million to $0.1 million in expense for the year ended December 31, 2024 from $0.2 million in income for the year ended December 31, 2023. The increase in other expense was due the interest and loan discount amortization on the related party loan of $0.3 million offset by interest income of $0.2 million versus $0.2 million in interest income for the year ended December 31, 2023.

Liquidity and Capital Resources

Since our inception, we have financed our operations through public offerings of common stock and proceeds from private placements of membership interests and convertible promissory notes. To date, we have not generated any revenue from the sale of products and we do not anticipate generating any revenue from the sales of products for the foreseeable future. We have incurred losses and generated negative cash flows from operations since inception. As of December 31, 2024, our principal source of liquidity was our cash, which totaled $14.8 million.

Equity Financings

On May 19, 2024, the Company entered into an agreement with Maxim Group LLC as placement agent in connection with the issuance and sale by the Company in a public offering of 340,000 shares of its Common Stock at a public offering price of $5.00 per share (the "May 2024 Offering"), pursuant to an effective shelf registration statement on Form S-3 (File No. 333-263700). The May 2024 Offering closed on May 22, 2024, and the gross proceeds from the May 2024 Offering were $1,700,000. The net proceeds of the May 2024 Offering were $1,382,170 after deducting placement agent fees and offering expenses payable by the Company.

In July 2023, we entered into a Capital on Demand™ Sales Agreement (the "Sales Agreement") with JonesTrading Institutional Services LLC ("JonesTrading") under which we could issue and sale shares of our Common Stock, from time to time, through JonesTrading, acting as sales agent or principal, up to an aggregate offering price of up to $6,700,000 in which is commonly referred to as an "at-the-market" ("ATM") program. During the three months ended September 30, 2023, we sold 25,675 shares of our Common Stock under the ATM program at a weighted-average gross sales price of approximately $52.78 per share and raised $1,355,090 of gross proceeds. The total commissions and related legal and accounting fees were approximately $198,650, and we received net proceeds of approximately $1,156,440. In August 2023, we terminated the Sales Agreement. As of December 31, 2023, there was no ATM program in place.

Debt Financings

Concurrent with the Combination with Pharmagesic, on October 7, 2024, the Company entered into the Loan Agreement with Lender and an affiliate of CKLS. Pursuant to the Loan Agreement, the Lender agreed to make a loan to the Company in the aggregate principal amount of $19,500,000, of which (i) $16,500,000 was disbursed on October 7, 2024 and (ii) $3,000,000 was disbursed on February 18, 2025. Pursuant to the terms of the Loan Agreement, the proceeds are to be used for the purpose of (1) funding operations and (2) performing clinical and research & development activities related to Halneuron®. The Loan Agreement bears interest at SOFR plus 2.00%, that increases by 1.00% in the event of default that resets on an annual basis on October 1st. On March 12, 2025, the principal amount of all loans made to the Company under the Loan Agreement, along with accrued interest through such date was deemed repaid and all of the Company's obligations with respect to the principal amount and accrued interest was satisfied in full and cancelled in connection with the Debt Exchange and Cancellation Transaction. For more information, please see "Recent Developments" above.

There were no debt financings during the year ended December 31, 2023. There was no debt outstanding at December 31, 2023.

Future Capital Requirements

We anticipate our cash on hand at December 31, 2024 of approximately $14.8 million plus the additional loan proceeds of $3 million received on February 18, 2025 and net offering proceeds of $4.25 million received on March 14, 2025, will fund operations through the first quarter of 2026. The Company will need to secure additional financing to fund its ongoing clinical trials and operations beyond the first quarter of 2026 to continue to execute its strategy. We will need to finance our cash needs through public or private equity offerings, debt financings, collaboration and licensing arrangements or other financing alternatives. To the extent that we raise additional funds by issuing equity or equity-linked securities, our shareholders will experience dilution. We can give no assurances that we will be able to secure such additional sources of funds to support our operations, or, if such funds are available to us, that such additional financing will be sufficient to meet our needs. As a result, substantial doubt exists regarding our ability to continue as a going concern 12 months from the issuance of the Annual Report on Form 10-K. Failure to secure the necessary financing in a timely manner and on favorable terms could have a material adverse effect on the Company's strategy and value and could require the delay of product development and clinical trial plans.

Cash Flows

The following table summarizes our cash flows from operating, investing and financing activities.

	Years Ended December 31,	
	2024	**2023**
Statement of Cash Flows Data:		
Net cash (used in) provided by:		
Operating activities	**$ (8,790,805)**	$ (4,870,489)
Investing activities	**3,761,936**	—
Financing activities	**16,704,464**	1,156,443
Increase (decrease) in cash	**$ 11,675,595**	$ (3,714,046)

Years ended December 31, 2024 and 2023

Operating Activities

For the year ended December 31, 2024, net cash used in operations was $8.8 million and consisted of a net loss of $12.3 million and a net change in operating assets and liabilities of $3.5 million attributable to a net decrease in accounts payable and accrued expenses of $0.1 million and an increase in prepaid expenses of $0.5 million offset by non-cash items of $3.5 million for non-cash transaction costs, $0.5 million attributable to share-based compensation and $0.1 million of depreciation, amortization and loss on foreign exchange.

For the year ended December 31, 2023, net cash used in operations was $4.9 million and consisted of a net loss of $5.3 million and a net change in operating assets and liabilities of $0.4 million attributable to a decrease in accounts payable of $0.5 million and a decrease in accrued expenses of $0.2 million offset by a decrease in prepaid expenses of $0.5 million and non-cash items of $0.6 million attributable to share-based compensation.

Investing Activities

Net cash provided by investing activities for the year ended December 31, 2024 consisted of $3.8 million in cash acquired in connection with the Combination. There were no investing activities for the year ended December 31, 2023.

Financing Activities

Net cash provided by financing activities during the year ended December 31, 2024 was $16.7 million and was attributable to loan proceeds, net of fees, of $15.3 million and cash proceeds from our public offering in May 2024, net of placement agent fees and offering costs, of $1.4 million.

Net cash provided by financing activities during the year ended December 31, 2023 was $1.2 million and was attributable to proceeds from the issuance and sale of common stock under the ATM program, net of commissions and other related expenses. In addition, there were 19,145 warrants cashless exercised. As a result, 7,718 shares of common stock were surrendered at fair value to satisfy the exercise price and 11,427 shares of common stock were issued.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements or relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities.

Recent Accounting Pronouncements

See Note 2 – Summary of Significant Accounting Policies in the accompanying notes to the financial statements elsewhere in this report for details of recently issued accounting pronouncements and their expected impact on our financial statements.

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"), was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an "emerging growth company." As an "emerging growth company," we are electing to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards.

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis), and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation. These exemptions will apply until December 31, 2025 or until we no longer meet the requirements for being an "emerging growth company," whichever occurs first.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

This item is not required.

Item 8. Financial Statements and Supplementary Data

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Report of Independent Registered Public Accounting Firm

Shareholders, Board of Directors, and Audit Committee
Dogwood Therapeutics, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Dogwood Therapeutics, Inc. (the "Company") as of December 31, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, changes in Series A non-voting convertible preferred stock and stockholders' (deficit) equity, and cash flows for each of the years in the two-year period ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt about the Company's Ability to Continue as a 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 has incurred an accumulated deficit since inception, has not generated revenue from operations and does not expect to experience positive cash flows from operating activities in the near term. These conditions, along with other matters as set forth in Note 1, raise substantial doubt about the Company's 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 audits.

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 audits 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 audits, 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 audits 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 include examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits 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 audits provide a reasonable basis for our opinion.

/s/ Forvis Mazars, LLP

We have served as the Company's auditor since 2020.

Atlanta, Georgia
March 31, 2025

DOGWOOD THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS

	2024	2023 (As Adjusted)
Assets		
Current assets:		
Cash	**$ 14,847,949**	$ 3,316,946
Prepaid expenses and other current assets	**1,696,513**	848,496
Total current assets	**16,544,462**	4,165,442
Property and equipment, net	**16,811**	—
Right-of-use assets	**205,837**	—
Prepaid expenses, long-term	**18,133**	—
Goodwill	**11,812,476**	—
Intangible assets	**65,710,527**	—
Total assets	**$ 94,308,246**	$ 4,165,442
Liabilities, Series A Non-Voting Convertible Preferred Stock, and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	**$ 1,231,805**	$ 111,913
Accrued expenses	**1,894,835**	246,635
Lease liability, current portion	**49,696**	—
Total current liabilities	**3,176,336**	358,548
Debt with related party, net of issuance costs	**15,381,077**	—
Lease liability, long-term portion	**154,885**	—
Deferred tax liability	**11,314,925**	—
Total liabilities	**30,027,223**	358,548
Commitments and contingencies (Note 12)		
Series A Non-Voting Convertible Preferred Stock, $0.0001 par value; 2,213.8044 shares authorized, issued and outstanding at December 31, 2024 and no shares authorized, issued and outstanding at December 31, 2023	**74,405,362**	—
Stockholders' (deficit) equity:		
Common stock, $0.0001 par value; 43,000,000 shares authorized; 1,339,896 and 1,332,178 shares issued and outstanding at December 31, 2024, respectively; and 778,035 and 770,317 shares issued and outstanding at December 31, 2023	**133**	77
Preferred stock, $0.0001 par value; 1,997,786 and 2,000,000 shares authorized; no shares issued and outstanding at December 31, 2024 and 2023, respectively	**—**	—
Additional paid-in capital	**67,856,589**	65,575,167
Accumulated deficit	**(73,818,946)**	(61,469,222)
Accumulated other comprehensive loss	**(3,862,987)**	—
	(9,825,211)	4,106,022
Less: Treasury stock, 7,718 shares of common stock at cost	**(299,128)**	(299,128)
Total stockholders' (deficit) equity	**(10,124,339)**	3,806,894
Total liabilities, Series A Non-Voting Convertible Preferred Stock and stockholders' (deficit) equity	**$ 94,308,246**	$ 4,165,442

See accompanying notes to the financial statements.

DOGWOOD THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Year Ended	
	December 31, 2024	December 31, 2023 (As Adjusted)
Revenue	**$ —**	$ —
Operating expenses:		
Research and development	**3,530,913**	1,728,078
General and administrative expenses	**8,696,335**	3,718,841
Total operating expenses	**12,227,248**	5,446,919
Loss from operations	**(12,227,248)**	(5,446,919)
Other (expense) income:		
Interest (expense) income, net	**(92,192)**	150,904
Exchange loss, net	**(30,787)**	—
Total other (expense) income	**(122,979)**	150,904
Loss before income taxes	**(12,350,227)**	(5,296,015)
Deferred income tax provision	**503**	—
Net loss	**(12,349,724)**	(5,296,015)
Accrual of paid-in-kind dividends on Series A Non-Voting Convertible Preferred Stock	**(514,105)**	—
Net loss attributable to common stockholders	**$ (12,863,829)**	$ (5,296,015)
Net loss per common share, basic and diluted	**$ (12.52)**	$ (7.05)
Weighted average number of shares outstanding – basic and diluted	**1,027,788**	751,071
Comprehensive loss		
Net loss	**$ (12,349,724)**	$ (5,296,015)
Foreign currency translation adjustment	**(3,862,987)**	—
Comprehensive loss	**$ (16,212,711)**	$ (5,296,015)

See accompanying notes to the financial statements.

DOGWOOD THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN SERIES A NON-VOTING CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' (DEFICIT) EQUITY

	Series A Non-Voting Convertible Preferred Stock		Common Stock		Additional	Accumulated	Accumulated Other Comprehensive	Treasury	Total Stockholders'
	Shares	Amount	Shares	Par	Paid-In Capital	Deficit	Loss	Stock	(Deficit) Equity
Balance, December 31, 2022, as adjusted	—	$ —	733,215	$ 73	$ 63,499,628	$ (56,173,207)	$ —	$ —	$ 7,326,494
Issuance of common shares under Sales Agreement, net of costs	—	—	25,675	3	1,156,440	—	—	—	1,156,443
Exercise of warrants	—	—	19,145	2	299,127	—	—	—	299,129
Shares surrendered in cashless warrant exercises	—	—	(7,718)	(1)	—	—	—	(299,128)	(299,129)
Share-based compensation expense	—	—	—	—	619,972	—	—	—	619,972
Net loss	—	—	—	—	—	(5,296,015)	—	—	(5,296,015)
Balance, December 31, 2023, as adjusted	—	$ —	770,317	$ 77	$ 65,575,167	$ (61,469,222)	$ —	$ (299,128)	$ 3,806,894
Proceeds from public offering of common stock, net of offering costs	—	—	340,000	34	1,382,136	—	—	—	1,382,170
Issuance of stock in connection with the acquisition of Pharmagesic	2,108.3854	70,372,634	211,383	21	893,072	—	—	—	893,093
Transaction costs paid through the issuance of stock	105.4190	3,518,623	10,568	1	44,649	—	—	—	44,650
Payout of fractional shares in connection with reverse stock split	—	—	(90)	—	(351)	—	—	—	(351)
Accrual of paid-in-kind dividends on Series A Non-Voting Convertible Preferred Stock	—	514,105	—	—	(514,105)	—	—	—	(514,105)
Share-based compensation expense	—	—	—	—	476,021	—	—	—	476,021
Net loss	—	—	—	—	—	(12,349,724)	—	—	(12,349,724)
Accumulated other comprehensive loss	—	—	—	—	—	—	(3,862,987)	—	(3,862,987)
Balance (deficit), December 31, 2024	**2,213.8044**	**$ 74,405,362**	**1,332,178**	**$ 133**	**$ 67,856,589**	**$ (73,818,946)**	**$ (3,862,987)**	**$ (299,128)**	**$ (10,124,339)**

See accompanying notes to the financial statements.

DOGWOOD THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2024	**2023**
Cash flows from operating activities		
Net loss	**$ (12,349,724)**	$ (5,296,015)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on foreign exchange	**30,787**	—
Amortization of loan costs	**58,432**	—
Depreciation	**12,177**	—
Non-cash transaction costs	**3,563,273**	—
Deferred tax benefit	**(503)**	—
Share-based compensation expense	**476,021**	619,972
Changes in operating assets and liabilities:		
(Increase) decrease in prepaid expenses and other current assets	**(498,717)**	490,268
Increase (decrease) in accounts payable	**219,888**	(461,251)
Decrease in accrued expenses and other liabilities	**(302,439)**	(223,463)
Net cash used in operating activities	**(8,790,805)**	(4,870,489)
Cash flows from investing activities		
Cash acquired through the acquisition of Pharmagesic	**3,761,936**	—
Net cash provided by investing activities	**3,761,936**	—
Cash flows from financing activities		
Proceeds from public offering of common stock, net of offering costs	**1,382,170**	—
Proceeds from loan with related party, net of fees	**15,322,645**	—
Payout of fractional shares with reverse stock split	**(351)**	—
Proceeds from issuance of shares on ATM, net of fees	**—**	1,156,443
Net cash provided by financing activities	**16,704,464**	1,156,443
Net increase in cash	**11,675,595**	(3,714,046)
Cash, beginning of period	**3,316,946**	7,030,992
Effect of foreign currency translation on cash	**(144,592)**	—
Cash, end of period	**$ 14,847,949**	$ 3,316,946
Supplemental disclosure of non-cash financing and investing activities:		
Preferred stock issued in connection with acquisition of Pharmagesic	**$ 70,372,634**	$ **—**
Common stock issued in connection with acquisition of Pharmagesic	**$ 893,093**	$ **—**
Accrual of paid-in-kind dividends on Series A Non-Voting Convertible Preferred Stock	**$ 514,105**	$ **—**
Reduction in equity for shares surrendered in cashless warrant exercises	**$ —**	$ 299,129

See accompanying notes to the financial statements.

DOGWOOD THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Background and Organization

Dogwood Therapeutics, Inc. ("Dogwood"), formerly known as Virios Therapeutics, Inc. (the "Company") was incorporated under the laws of the State of Delaware on December 16, 2020 through a corporate conversion (the "Corporate Conversion") just prior to the Company's initial public offering ("IPO"). The Company was originally formed on February 28, 2012 as a limited liability company ("LLC") under the laws of the State of Alabama as Innovative Med Concepts, LLC. On July 23, 2020, the Company changed its name from Innovative Med Concepts, LLC to Virios Therapeutics, LLC. On October 7, 2024, the Company acquired Pharmagesic (Holdings) Inc., a Canadian corporation ("Pharmagesic") and the parent company of Wex Pharmaceuticals, Inc. ("Wex"), and changed its name from Virios Therapeutics, Inc. to Dogwood Therapeutics, Inc. (the "Name Change") on October 9, 2024.

Dogwood operates in one segment and is a pre-revenue, development-stage biopharmaceutical company focused on developing new medicines to treat pain and fatigue-related disorders. The Dogwood research pipeline is focused on two separate mechanistic pillars; Na_v 1.7 modulation to treat chronic and acute pain disorders and combination antiviral therapies targeting reactivated herpes virus mediated illnesses. The proprietary non-opioid Na_v 1.7 analgesic program is centered on our lead development candidate Halneuron®. Halneuron® is a voltage-gated sodium channel modulator, a mechanism known to be effective for reducing pain. Halneuron® treatment has demonstrated pain reduction of both general cancer related pain and chemotherapy-induced neuropathic pain ("CINP"). The Halneuron® Phase 2b study commenced in the first quarter of 2025. The antiviral program includes IMC-1 and IMC-2, which are novel, proprietary, fixed dose combinations of nucleoside analog, anti-herpes antivirals and the anti-inflammatory agent, celecoxib for the treatment of fibromyalgia ("FM") and Long-COVID ("LC").

Going Concern

Since its founding, the Company has been engaged in research and development activities, as well as organizational activities, including raising capital. The Company has not generated any revenues to date. As such, the Company is subject to all of the risks associated with any development-stage biotechnology company that has substantial expenditures for research and development. Since inception, the Company has incurred losses and negative cash flows from operating activities. The Company has funded its losses primarily through issuance of members' interests, convertible debt instruments and issuances of equity securities. For the years ended December 31, 2024 and 2023, the Company incurred consolidated net losses of $12,349,724 and $5,296,015, respectively, and had consolidated net cash outflows used in operating activities for the years ended December 31, 2024 and 2023 of $8,790,805 and $4,870,489, respectively. As of December 31, 2024, the Company had a consolidated accumulated deficit of $73,818,946 and is expected to incur losses in the future as it continues its development activities.

Concurrent with the Combination discussed below, on October 7, 2024, the Company entered into a Loan Agreement (the "Loan Agreement") with Conjoint Inc., a Delaware corporation ("Lender") and an affiliate of CKLS. Pursuant to the Loan Agreement, the Lender agreed to make a loan to the Company in the aggregate principal amount of $19,500,000, of which (i) $16,500,000 was disbursed on October 7, 2024 and (ii) $3,000,000 was disbursed on February 18, 2025. Pursuant to the terms of the Loan Agreement, the proceeds are to be used for the purpose of (1) funding operations and (2) performing clinical and research & development activities related to Halneuron®.

During November 2024, the Company announced the results from an investigator-sponsored study conducted by the Bateman Horne Center ("BHC") in a double-blinded, placebo-controlled investigator-sponsored study ("BHC-202") assessing the combination of Val/Cel for the treatment of fatigue and related sequalae associated with Long-COVID ("LC"). The study demonstrated that the low dose combination antiviral therapy IMC-2 treated patient cohort (valacyclovir 750 mg + celecoxib dosed 200 mg twice daily) exhibited

clinically meaningful reductions in LC associated fatigue and sleep disturbance, as compared with the placebo treated cohort. The high dose IMC-2 treated cohort (valacyclovir 1500 mg + celecoxib 200 mg dosed twice daily) did not exhibit clinically meaningful differences versus placebo, believed to be related to higher levels of gastrointestinal (GI) adverse events associated with the higher dose regimen. The Company has initially applied for non-dilutive funding through the NIH's initiative to address LC called RECOVER-Treating Long-COVID ("RECOVER-TLC") which just allocated new funds for LC programs. The Company is also engaged with potential investors who are performing due diligence for funding a larger study.

Management anticipates the cash on hand at December 31, 2024 of approximately $14.8 million plus the additional loan proceeds of $3 million received on February 18, 2025 and net offering proceeds of $4.25 million received on March 14, 2025, will fund operations through the first quarter of 2026. The Company will need to secure additional financing to fund its ongoing clinical trials and operations beyond the first quarter of 2026 to continue to execute its strategy. Management plans to explore various dilutive and non-dilutive sources of funding, including equity financings, debt financings, collaboration and licensing arrangements or other financing alternatives. There can be no assurance that management will be successful in raising additional funds or on terms acceptable to the Company. Accordingly, there is substantial doubt about the Company's ability to operate as a going concern within one year after the issuance date of these consolidated financial statements. The consolidated financial statements have been prepared on a going concern basis and do not include any adjustments to reflect this uncertainty.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"). The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, Pharmagesic, including Pharmagesic's wholly owned subsidiary, Wex, and Wex's wholly owned subsidiaries, IWT Bio, Inc. ("IWT"), Wex Medical Corporation ("WMC"), and Wex Medical Limited ("WML"). All intercompany accounts and transactions have been eliminated in consolidation. The Company has determined the functional currency of Pharmagesic, Wex, IWT and WMC and WML to be the Canadian Dollar. The Company translates assets and liabilities of Pharmagesic, Wex, IWT, WMC and WML at exchange rates in effect at the balance sheet date with the resulting translation adjustments directly recorded as a separate component of accumulated other comprehensive income. Income and expense accounts are translated at average exchange rates for the period. Transactions which are not in the functional currency are remeasured into the functional currency and gains and losses resulting from the remeasurement are recorded in foreign currency exchange and other gain (loss), net.

Reverse Stock Split

On October 9, 2024, we effected a reverse stock split of 25 shares for 1 share of Common Stock ("the Reverse Stock Split"). The Reverse Stock Split reduced the number of shares of Common Stock issued (which includes outstanding shares and treasury shares) from 27,950,888 shares to 1,118,035 shares, and reduced shares outstanding from 27,757,937 shares to 1,110,317 shares. There was no change to the total number of shares of Common Stock that the Company is authorized to issue and there was no change in the par value of the Common Stock, and no fractional shares were issued. All share and per share amounts in the financial statements and footnotes have been retroactively adjusted for all periods presented to give effect to the Reverse Stock Split. As a result of the Reverse Stock Split, the exercise prices and number of shares to be issued under each of our outstanding option and warrant agreements were proportionately adjusted. As a result of the changes, there was a reclassification of $1,867 to additional paid in capital from par value of Common Stock and treasury stock as of December 31, 2023. The cash settlement of fractional shares that occurred in October 2024 was less than $1,000.

Use of Estimates

The preparation of these consolidated financial statements and accompanying notes in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. In addition, management's assessment of the Company's ability to continue as a going concern involves the estimation of the amount and timing of future cash inflows and outflows. The Company's significant estimates and assumptions include estimated work performed but not yet billed by contract manufacturers and clinical research organizations, the valuation of equity and stock-based related instruments, the valuation allowance related to deferred taxes and the estimated fair value of the net assets acquired in connection with the business combination of Pharmagesic, and the estimated fair value of the contingent value rights ("CVRs") given to common stockholders at the time of the business combination. Some of these judgments can be subjective and complex, and, consequently, actual results could differ from those estimates. Although the Company believes that its estimates and assumptions are reasonable, they are based upon information available at the time the estimates and assumptions were made. Actual results could differ from those estimates.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources in assessing performance. The Company has one reportable segment. The segment consists of the development of clinical and preclinical product candidates focused on advancing novel therapeutics for pain and fatigue illness. The Company's chief operating decision maker ("CODM") is the chief executive officer.

The accounting policies of the segment are the same as those described in the summary of significant accounting policies. The CODM assesses performance for the segment based on net loss, which is reported on the income statement as consolidated net loss. The measure of segment assets is reported on the balance sheet as total consolidated assets.

To date, the Company has not generated any product revenue. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as it advances product candidates through all stages of development and clinical trials and, ultimately, seek regulatory approval. As such, the CODM uses cash forecast models in deciding how to invest into the segment. Such cash forecast models are reviewed to assess the entity-wide operating results and performance. Net loss is used to monitor budget versus actual results. Monitoring budgeted versus actual results is used in assessing performance of the segment and in establishing management's compensation, along with cash forecast models.

The table below summarizes the significant expense categories regularly reviewed by the CODM for the years ended December 31, 2024 and 2023:

	Year Ended	
	December 31, 2024	December 31, 2023
Operating expenses:		
Clinical	**$ 1,153,345**	$ 112,196
Chemical, manufacturing and controls	**710,055**	312,691
Research and preclinical	**505,750**	267,803
Regulatory	**20,065**	186,395
Other research and development costs	**1,141,698**	848,993
Total research and development	**3,530,913**	1,728,078
General and administrative expenses	**8,696,335**	3,718,841
Total operating expenses	**$ 12,227,248**	$ 5,446,919
Interest expense (income), net	**92,192**	(150,904)
Exchange loss, net	**30,787**	—
Net loss before income taxes	**$ 12,350,227**	$ 5,296,015

Concentrations of Credit Risk

Cash is potentially subject to concentrations of credit risk. The Company believes it is not exposed to significant credit risk due to the financial strength of the depository institutions in which the cash is held.

Fair Value Measurements

ASC Topic 820, *Fair Value Measurement*, provides guidance on the development and disclosure of fair value measurements. Under this accounting guidance, 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 at the measurement date. 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 a liability.

The accounting guidance classifies fair value measurements in one of the following three categories for disclosure purposes:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Inputs other than Level 1 prices for similar assets or liabilities that are directly or indirectly observable in the marketplace.
- Level 3 — Unobservable inputs which are supported by little or no market activity and values determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

The carrying amount of the Company's consolidated financial instruments, including cash, accounts payable and accrued expenses approximate their fair values. See Notes 3, 9, and 10 below.

Business Combinations

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 to determine if 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 the screen is met, the transaction is accounted for as an asset acquisition. If the screen is not met, 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 requirements of a business. If determined to be a business combination, the Company accounts for the transaction under the acquisition method of accounting as indicated in ASU 2017-01, Business Combinations (ASC 805), which requires the acquiring entity in a business combination to recognize the fair value of all assets acquired, liabilities assumed, and any non-controlling interest in the acquiree and establishes the acquisition date as the fair value measurement point. Accordingly, the Company recognizes assets acquired and liabilities assumed in business combinations based on the fair value estimates as of the date of acquisition. In accordance with ASC 805, Business Combinations, the Company recognizes and measures goodwill as of the acquisition date, as the excess of the fair value of the consideration paid over the fair value of the identified net assets acquired.

Cash

Cash is maintained in bank deposit accounts, which exceed the federally insured limits of $250,000. The Company does not have any cash equivalents.

Property and Equipment

Property and equipment are carried at acquisition cost less accumulated depreciation, subject to review for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable as described further under the heading "Impairment of Long-Lived Assets" below.

Depreciation and amortization are computed using the straight-line method based on the estimated useful lives of the related assets. Leasehold improvements are amortized over the term of the lease. Office equipment and furniture are depreciated over five years and computer software and equipment are depreciated over two years.

When an asset is disposed of, the associated cost and accumulated depreciation is removed from the related accounts on the Company’s consolidated balance sheet with any resulting gain or loss included in the Company's consolidated statement of operations.

Indefinite-Lived Intangible Assets

Indefinite-lived intangible assets consist of In-Process Research and Development (“IPR&D”). The fair values of IPR&D project assets acquired in business combinations are capitalized. The Company generally utilizes the Multi-Period Excess Earning Method to determine the estimated fair value of the IPR&D assets acquired in a business combination. The projections used in this valuation approach are based on many factors, such as relevant market size, the estimated probability of regulatory success rates, anticipated patent protection, expected pricing, expected treated population, and estimated payments (e.g., royalty). The estimated future net cash flows are then discounted to the present value using an appropriate discount rate. These assets are treated as indefinite-lived intangible assets until completion or abandonment of the projects, at which time the assets are amortized over the remaining useful life or written off, as appropriate.

Intangible assets with indefinite lives, including IPR&D, are tested for impairment if impairment indicators arise and, at a minimum, annually. However, an entity is permitted to first assess qualitative factors to determine if a quantitative impairment test is necessary. Further testing is only required if the entity determines, based on the qualitative assessment, that it is more likely than not that an indefinite-lived intangible asset’s fair value is less than its carrying amount. Otherwise, no further impairment testing is required. The indefinite-lived intangible asset impairment test consists of a one-step analysis that compares the fair value of the intangible asset with its carrying amount. If the carrying amount of an intangible asset exceeds its fair value, an impairment loss is recognized in an amount equal to that excess. The Company considers many factors in evaluating whether the value of our intangible assets with indefinite lives may not be recoverable, including, but not limited

to, expected growth rates, the cost of equity and debt capital, general economic conditions, outlook and market performance of the Company's industry and recent and forecasted financial performance.

The Company evaluates indefinite-lived intangible assets for impairment at least annually on October 1 and whenever facts and circumstances indicate that their carrying amounts may not be recoverable. For the year ended December 31, 2024, the Company determined that there was no impairment to IPR&D.

Goodwill

Goodwill represents the amount of consideration paid in excess of the fair value of net assets acquired as a result of the Company's business acquisitions accounted for using the acquisition method of accounting. The intangible assets acquired represented the fair value of IPR&D which has been recorded on the accompanying consolidated balance sheet as indefinite-lived intangible assets. A deferred tax liability was recorded for the difference between the fair value of the acquired IPR&D and its tax basis which was recognized as goodwill in applying the purchase method of accounting. Goodwill is not amortized and is subject to impairment testing at a reporting unit level on an annual basis or when a triggering event occurs that may indicate the carrying value of the goodwill is impaired. An entity is permitted to first assess qualitative factors to determine if a quantitative impairment test is necessary. Further testing is only required if the entity determines, based on the qualitative assessment, that it is more likely than not that the fair value of the reporting units is less than its carrying amount.

The Company evaluates goodwill for impairment at least annually on October 1 and whenever facts and circumstances indicate that their carrying amounts may not be recoverable. For the year ended December 31, 2024, the Company determined that there was no impairment to goodwill.

Operating Lease Right-of-use Asset and Lease Liability

The Company accounts for leases under ASC 842, Leases. Operating leases are included in "Right-of-use assets" within the Company's consolidated balance sheets and represent the Company's right to use an underlying asset for the lease term. The Company's related obligation to make lease payments are included in "Lease liability" and "Lease liability, net of current portion" within the Company's consolidated balance sheets. Operating lease right-of-use ("ROU") assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rates, which are the rates incurred to borrow on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment. Lease expense for lease payments is recognized on a straight-line basis over the lease term. The ROU assets are tested for impairment according to ASC 360, Property, Plant, and Equipment ("ASC 360"). Leases with an initial term of 12 months or less are not recorded on the balance sheet and are recognized as lease expense on a straight-line basis over the lease term.

As of December 31, 2024, the Company's operating lease ROU assets and corresponding short-term and long-term lease liabilities primarily relate to the operating lease for an office in Vancouver, British Columbia, that was acquired as part of the Business Combination with Pharmagesic. The office lease expires on August 31, 2028.

Impairment of Long-Lived Assets

In accordance with ASC 360-10-35, Impairment or Disposal of Long-Lived Assets, the Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable (i.e., impaired). Once an impairment is determined, the actual impairment recognized is the difference between the carrying amount and the fair value (less costs to sell for assets to be disposed of) as estimated using one of the following approaches: income, cost, and/or market. Fair value using the income approach is determined primarily using a discounted cash flow model that uses the estimated cash flows associated with the asset or asset group under review, discounted at a rate commensurate

with the risk involved. Fair value utilizing the cost approach is determined based on the replacement cost of the asset reduced for, among other things, depreciation and obsolescence. Fair value, utilizing the market approach, benchmarks the fair value against the carrying amount.

Redeemable and Convertible Preferred Stock

The Company applies ASC 480 when determining the classification and measurement of its preferred stock. Preferred shares subject to mandatory redemption are classified as liability instruments and are measured at fair value. Conditionally redeemable preferred shares (including preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control) are classified as temporary equity. At all other times, preferred shares are classified as stockholders' (deficit) equity. See Note 10 to these consolidated financial statements.

Income Taxes

The Company provides for income taxes using the asset and liability approach. Deferred tax assets and liabilities are recorded based on the differences between the financial statement and tax bases of assets and liabilities and the tax rates in effect when these differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The Company operated as an Alabama limited liability company until its Corporate Conversion. Therefore, the Company passed through all income and losses to its members until this point.

The Company is subject to the provisions of ASC 740, *Income Taxes*. Under ASC 740, consideration is given to the recognition and measurement of tax positions that meet a "more-likely-than-not" threshold. A tax position is a position taken in a previously filed tax return or a position expected to be taken in a future that is reflected in measuring current or deferred income tax assets and liabilities. Tax positions include the Company's status as a pass-through entity until December 16, 2020 and as a corporation thereafter. The recognition and measurement of tax positions taken for various jurisdictions consider the amounts and probabilities of outcomes that could be realized upon settlement using the facts, circumstances, and information available at the reporting date. The Company has determined that it does not have any material unrecognized tax benefits or obligations as of December 31, 2024 and 2023. The Company recognizes interest and penalties related to uncertain tax positions, if any, in income tax expense. The Company is not currently under examination by the Internal Revenue Service or by state tax authorities and the Company's tax year remains subject to examination by the tax authorities.

Net Income (Loss) per Common Share Applicable to Common Stockholders

The Company uses the two-class method to compute net income per common share during periods the Company realizes net income and has securities outstanding (e.g., redeemable convertible preferred stock) that entitle the holder to participate in dividends and earnings of the Company. In addition, the Company analyzes the potential dilutive effect of outstanding redeemable convertible preferred stock under the "if-converted" method when calculating diluted earnings per share and reports the more dilutive of the approaches (two class or "if-converted"). The two-class method is not applicable during periods with a net loss, as the holders of the redeemable convertible preferred stock have no obligation to fund losses. The Company also analyzes the potential dilutive effect of outstanding stock options and warrants under the treasury stock method (as applicable), during periods of income.

Basic and Diluted Net Income (Loss) per Share

Basic net loss per common share ("EPS") is computed in accordance with U.S. GAAP. Basic EPS is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted EPS reflects potential dilution and is computed by dividing net loss by the weighted average

number of common shares outstanding during the period increased by the number of additional common shares that would have been outstanding if all potential common shares had been issued and were dilutive. However, potentially dilutive securities are excluded from the computation of diluted EPS to the extent that their effect is anti-dilutive. For the years ended December 31, 2024 and 2023, the Company had 92,777 and 77,745 options, respectively, 7,755 and 7,755 warrants, respectively, 22,138,044 and 0 preferred stock, respectively, to purchase or convert into common shares outstanding that were anti-dilutive.

Research and Development

Research and development costs are expensed as incurred. The Company arranges and contracts with third-party contract research organizations ("CROs"), contract development and manufacturing organizations ("CMOs"), contractor laboratories and independent consultants. As part of the process of preparing its financial statements, the Company may be required to estimate some of its expenses resulting from its obligations under these arrangements and contracts. The financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided. The Company's objective is to reflect the appropriate expenses in its financial statements by matching those expenses with the period in which services are rendered. The Company determines any accrual estimates based on account discussions with applicable personnel and outside service providers as to the progress or state of completion. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known at that time. The Company's estimates are dependent upon the timely and accurate reporting of CROs, CMOs and other third-party vendors. At the end of each reporting period, the Company compares the payments made to each service provider to the estimated progress towards completion of the related project. Factors that the Company considers in preparing these estimates include the number of patients enrolled in studies, milestones achieved, and other criteria related to the efforts of its vendors. These estimates will be subject to change as additional information becomes available. Depending on the timing of payments to vendors and estimated services provided, the Company will record prepaid or accrued expenses related to these costs.

Share-Based Compensation

The Company recognizes compensation expense relating to share-based awards to employees and directors with a performance condition over the requisite service period if it is probable that the performance condition will be satisfied. For awards to non-employees, the Company recognizes compensation expense in the same manner as if the Company had paid cash for the goods or services. The Company estimates the fair value of options and warrants granted using an options pricing model, see Note 13. Expense is recognized within both research and development and general and administrative expenses and forfeitures are recognized as they are incurred.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that is (i) no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided by the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Recently Adopted Accounting Standards

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2023-07, "Segment Reporting (ASC 280): Improvements to Reportable Segment Disclosures"

("ASU 2023-07"), which is intended to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The guidance is to be applied retrospectively to all prior periods presented in the financial statements. Upon transition, the segment expense categories and amounts disclosed in the prior periods should be based on the significant segment expense categories identified and disclosed in the period of adoption. The Company adopted ASU 2023-07 for the fiscal year ended December 31, 2024. See Segment Information above.

Recent Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-09, Improvements to Income Tax Disclosures (Topic 740), which establishes new income tax disclosure requirements in addition to modifying and eliminating certain existing requirements. The new guidance requires consistent categorization and greater disaggregation of information in the rate reconciliation, as well as further disaggregation of income taxes paid. This change is effective for annual periods beginning after December 15, 2024. This change will apply on a prospective basis to annual financial statements for periods beginning after the effective date. However, retrospective application in all prior periods presented is permitted. The Company is currently evaluating the impact of this ASU on its financial statements.

Subsequent Events

On March 13, 2025, the Board approved an exchange of the outstanding principal plus accrued interest of $19,926,891 related to the Loan Agreement into Series A-1 Non-Voting Convertible Preferred Stock ("Series A1 Preferred Stock") at the market price of the lower of the average five-day closing price of the closing price on the date the transactions completed. As such, the Company issued 284.2638 shares of Series A1 Preferred Stock.

On March 12, 2025, the Company entered into an agreement with Maxim Group LLC as placement agent in connection with the issuance and sale by the Company in a registered direct offering of 578,950 shares of its Common Stock at a price of $8.26 per share (the "March 2025 Offering"), pursuant to an effective shelf registration statement on Form S-3 (File No. 333-263700). The March 2025 Offering closed on March 14, 2025, and the gross proceeds from the March 2025 Offering were approximately $4.78 million. The net proceeds of the March 2025 Offering were approximately $4.25 million after deducting placement agent fees and offering expenses payable by the Company.

3. Business Combination

On October 7, 2024, the Company entered into a Share Exchange Agreement (the "Exchange Agreement") with Sealbond Limited, a British Virgin Islands corporation ("Sealbond"), pursuant to which the Company acquired 100% of the issued and outstanding common shares of Pharmagesic (Holdings) Inc., a Canadian corporation ("Pharmagesic") (such transaction, the "Combination"). Prior to the Combination, Pharmagesic was a wholly-owned subsidiary of Sealbond and an indirect wholly-owned subsidiary of CK Life Sciences Int'l., (Holdings) Inc. ("CKLS"), a listed entity on the Main Board of the Hong Kong Stock Exchange.

Under the terms of the Exchange Agreement, on October 7, 2024 (the "Closing"), in exchange for all of the outstanding common shares of Pharmagesic immediately prior to the Effective Time, the Company issued to Sealbond, as sole shareholder of Pharmagesic, an aggregate of (A) 211,383 shares of the Company's unregistered Common Stock, which shares shall represent a number of shares equal to no more than 19.99% of the outstanding shares of Common Stock as of immediately before the Effective Time and (B) 2,108.3854 shares of the Company's unregistered Series A Non-Voting Convertible Preferred Stock, par value $0.0001 per share ("Series A Preferred Stock") (as described below). The issuance of the shares of Common Stock and Series A Preferred Stock to Sealbond occurred on October 9, 2024. Each share of Series A Preferred Stock is

convertible into 10,000 shares of Common Stock, subject to certain conditions described in the Exchange Agreement.

The Board of Directors of the Company (the "Board") approved the Exchange Agreement and the related transactions, and the consummation of the Combination was not subject to approval of Company stockholders. Pursuant to the Exchange Agreement, the Company agreed to hold a stockholders' meeting to submit the certain matters to its stockholders for their consideration, including: (i) the approval of the conversion of shares of Series A Preferred Stock into shares of Common Stock in accordance with the rules of the Nasdaq Stock Market LLC (the "Conversion Proposal") and (ii) the approval of a "change of control" under Nasdaq Listing Rules 5110 and 5635(b) (the "Change of Control Proposal"); and together with the Conversion Proposal, the "Meeting Proposals"). In connection with these matters, the Company agreed to file a proxy statement on Schedule 14A with the SEC at any time between the interim analysis readout of the Phase 2b study for Halneuron® and June 30, 2026, or earlier, if mutually agreed upon by both parties.

The Company's transaction costs of $4.9 million were expensed as incurred and included in the General and Administration expenses in the Company's consolidated statement of operations.

The transaction was accounted for under the acquisition method of accounting. Under the acquisition method, the total purchase price of the acquisition is allocated to the net tangible and identifiable intangible assets acquired and liabilities assumed based on the fair values as of the date of the acquisition. Consideration paid is comprised of the estimated fair value of various securities issued including the Series A Preferred Stock and Common Stock issued to Sealbond, the sole shareholder of Pharmagesic. In the fourth quarter of fiscal 2024, the preliminary purchase price allocation was updated, including the related determination of fair value of these securities issued as consideration, the allocation of consideration to the specific in-process research and development programs acquired and the related tax implications for the updates to the purchase price allocation.

The fair value of the consideration totaled approximately $71.3 million, summarized as follows:

Fair value of common stock issued	$ 893,093
Fair value of preferred stock issued	70,372,634
Total Consideration Paid	$ 71,265,727

The Company recorded the assets acquired and liabilities assumed as of the date of the Combination based on the information available at that date. The following table presents the allocation of the purchase price to the estimated fair values of the assets acquired and liabilities assumed as of the Combination date:

Assets acquired:	
Cash	$ 3,762,000
Prepaid expenses and other current assets	380,000
Property and equipment	19,000
In-process research and development assets	69,500,000
Goodwill	12,493,727
Right-of-use asset - operating leases	230,000
Total assets acquired	$ 86,384,727
Liabilities assumed:	
Accounts payable	$ 904,000
Accrued expenses and other current liabilities	2,017,000
Deferred tax liability	11,968,000
Operating lease liabilities	230,000
Total liabilities assumed	$ 15,119,000
Net assets acquired	$ 71,265,727

The fair value of IPR&D was capitalized as of the Combination date and accounted for as indefinite-lived intangible assets until completion or disposition of the assets or abandonment of the associated research and development efforts. Upon successful completion of the development efforts, the useful lives of the IPR&D assets will be determined based on the anticipated period of regulatory exclusivity and will be amortized within operating expenses. Until that time, the IPR&D assets will be subject to impairment testing and will not be amortized. The goodwill recorded related to the acquisition is the excess of the fair value of the consideration transferred by the acquirer over the fair value of the net identifiable assets acquired and liabilities assumed at the date of the Combination. The goodwill recorded is not deductible for tax purposes.

The following summarizes the Company's intangible assets and goodwill acquired in connection with the Combination and their carrying value as of December 31, 2024.

	Combination Date Fair Value	Impairment	Translation Adj	Carrying Value as of December 31, 2024
Halneuron® for Cancer Related Pain	$ 59,900,000	$ —	$ (3,266,035)	$ 56,633,965
Halneuron® for Chemotherapy Induced Neuropathic Pain	9,600,000	—	(523,438)	9,076,562
Total in-process research and development (IPR&D)	$ 69,500,000	$ —	$ (3,789,473)	$ 65,710,527
Goodwill	$ 12,493,727	$ —	$ (681,291)	$ 11,812,436

Intangible asset fair values for the two IPR&D programs were determined using the Multi-Period Excess Earnings Method ("MPEEM") which is a form of the income approach. Under the MPEEM, the fair value of an intangible asset is equal to the present value of the asset's incremental after-tax cash flows (excess earnings) remaining after deducting the market rates of return on the estimated value of contributory assets (contributory charge) over its remaining useful life. To calculate fair value of acquired IPR&D programs under the MPEEM, the Company uses probability-weighted cash flows discounted at a rate considered appropriate given the significant inherent risks associated with drug development by development-stage companies. Cash flows were calculated based on estimated projections of revenues and expenses related to each program and then reduced by a contributory charge on requisite assets employed. Contributory assets included debt-free working capital, net fixed assets and assembled workforce. Rates of return on the contributory assets were based on rates used for comparable market participants. Cash flows were assumed to extend through the market exclusivity period estimated to be provided by trade-secrets and patents for the synthetic manufacture of drug product. The resultant cash flows were then discounted to present value using a weighted-average cost of equity capital for companies with profiles substantially similar to that of each acquired IPR&D program, which the Company believes represents the rate that market participants would use to value the assets. The Company compensated for the phase of development of each program by probability-adjusting its estimation of the expected future cash flows. The projected cash flows were based on significant assumptions, such as the time and resources needed to complete the development and approval of each IPR&D program, estimates of revenue and operating profit related to the program considering its stage of development, the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in drug development, such as obtaining marketing approval from the FDA and other regulatory agencies, and risks related to the viability of and potential alternative treatments in any future target markets.

Unaudited Pro Forma Financial Information

The following unaudited pro forma financial information reflects the consolidated results of operations of the Company as if the Combination had taken place on January 1, 2023. The unaudited pro forma financial

information is not necessarily indicative of the results of operations as they would have been had the transactions been effected on the assumed date.

(In thousands)	December 31, 2024	2023
Net revenues	**$ —**	$ —
Net loss before taxes	**$ (19,649)**	$ (11,388)

Nonrecurring pro forma transaction costs directly attributable to the Combination was $4.9 million for the year ended December 31, 2024. There were no such costs for the year ending December 31, 2023. The costs deducted included success fees of $3.6 million in the aggregate incurred with financial advisors in connection with the Combination.

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	December 31, 2024	December 31, 2023
Prepaid insurance	**$ 667,257**	$ 702,352
Prepaid clinical research costs	**835,603**	133,819
Prepaid travel	**96,749**	—
Prepaid accounting fees	**55,525**	—
Prepaid services	**13,373**	8,766
Other miscellaneous current assets	**28,006**	3,559
	1,696,513	848,496
Long-term		
Security deposit on leased premises	**18,133**	—
	$ 1,714,646	$ 848,496

5. Property and Equipment

In connection with the Combination, the Company acquired certain property and equipment that was revalued at the date of the Combination. At December 31, 2024, net property and equipment at cost consisted of the following:

	December 31, 2024
Computer equipment	**$ 5,952**
Office furniture and equipment	**12,435**
Total property and equipment, at cost	**18,387**
Less: Accumulated depreciation and amortization	**(1,576)**
Property and equipment, net	**$ 16,811**

6. License Agreement

The Company entered into a Know-How License Agreement (the “Agreement”) with the University of Alabama (“UA”) in 2012. In consideration for the Agreement, UA received a 10% non-voting membership interest in the Company. Upon the adoption of the May 1, 2020 Second Amended and Restated Operating Agreement, the non-voting membership interest converted to a voting membership interest. Upon the Corporate Conversion, voting membership interest was converted into shares of common stock. The Agreement is in effect for 25 years and will terminate on June 1, 2037.

7. Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2024	December 31, 2023
Accrued interest on preferred members' interests and related party loan	**$ 417,539**	$ 188,085
Accrued compensation	**737,281**	**—**
Accrued clinical research costs	**611,741**	**—**
Accrued professional fees	**97,093**	27,550
Accrued director fees	**30,054**	31,000
Other miscellaneous accrued expenses	**1,127**	**—**
	$ 1,894,835	$ 246,635

8. Leases

In connection with the Combination, the Company acquired a right-of-use asset which was revalued at the date of the Combination. Pharmagesic has obtained the right to control the use of office premises for a period of time through a lease arrangement. The lease arrangement was negotiated on an individual basis and contains a wide range of different terms and conditions including lease payments and remaining lease terms to August 31, 2028. The lease arrangement does not impose any covenants other than the security interests in the leased asset that is held by the lessor. The Company maintains a security deposit totaling $18,133 as of December 31, 2024.

There were no additions or extensions to the right-of-use asset during the period from the Combination date to December 31, 2024. Total cash outflows for the lease were $31,940 for the period from the Combination date to December 31, 2024 and these costs were included in net cash used in operating activities.

The following table presents the components of the lease costs included in general and administrative expenses in the statements of operations for the period ended December 31, 2024:

	December 31, 2024
Component of lease cost	
Operating lease cost	**$ 17,772**
Variable lease cost	**14,167**
Total lease expense	**$ 31,939**

Future minimum annual commitments under the operating leases are as follows:

Year ending December 31:	
2025	$ 63,467
2026	63,879
2027	65,012
2028	41,829
Total lease payments	234,187
Less: amount representing interest	(29,606)
Present value of net minimum lease payments	$ 204,581
Less: current obligations	(49,696)
Long-term obligations under leases	$ 154,885

Other information related to this operating lease and the calculation of related right-of-use assets and operating lease liabilities consists of the following:

	2024
Cash paid for amounts included in the measurement of lease liabilities	$ 31,939
Weighted-average remaining lease term (in years) - operating leases	3.7
Weighted-average discount rate - operating leases	7.82%

9. Promissory Note with Related Party

On October 7, 2024, in connection with the Exchange Agreement, the Company entered into a Loan Agreement (the "Loan Agreement") with Conjoint Inc., a Delaware corporation ("Lender") and an affiliate of CKLS. Pursuant to the Loan Agreement, Lender agreed to make a loan to the Company in the aggregate principal amount of $19,500,000, of which (i) $16,500,000 was disbursed on October 7, 2024 and (ii) $3,000,000 was disbursed on February 18, 2025. Pursuant to the terms of the Loan Agreement, the proceeds are to be used for the purpose of (1) funding operations and (2) performing clinical and research & development activities related to Halneuron®. The Loan Agreement bears interest at the Secured Overnight Financing Rate ("SOFR") plus 2.00%, that increases by 1.00% in the event of default that resets on an annual basis on October 1st. The Loan Agreement is payable in full with principal and accrued interest on October 7, 2027. The promissory note was recorded net of issuance costs of $1,177,355. The issuance costs are being amortized to interest expense using an effective interest rate of 7.82%. As of the year ended December 31, 2024, the Company recognized interest expense of $229,454 and amortization of issuance costs of $58,432 in the accompanying consolidated income statements.

The Company evaluated the fair value of its related party note payable by analyzing the terms of the instrument in comparison to a synthetic credit rating and implied market cost of debt rate. Based on this evaluation, which included consideration of current rates and other terms available to the Company for similar debt instruments, the Company believes the fair value of the note is approximately $15.7 million as of December 31, 2024.

There were no outstanding promissory notes for the year ended December 31, 2023.

10. Stockholders' Deficit

Preferred Stock

The restated certificate of incorporation, as amended, of the Company permits its Board of Directors to issue up to 2,000,000 shares of preferred stock, par value of $0.0001 per share, in one or more series, to designate the number of shares constituting such series, and fix by resolution, the powers, privileges, preferences and relative, option or special rights thereof, including liquidation preferences and dividends, and conversion and redemption rights of each such series.

In October 2024, the Board of Directors designated 2,213.8044 of the 2,000,000 shares of preferred stock to be Series A Non-Voting Convertible Preferred Stock ("Series A Preferred Stock"). As of December 31, 2024, the Company has authorized, issued and outstanding 2,213.8044 shares of Series A Preferred Stock and 1,997,786 authorized and no issued and outstanding shares of preferred stock .

Holders of Series A Preferred Stock shall be entitled to receive, and the Company shall pay, payment-in-kind dividends on each share of Series A Preferred Stock, accruing at a rate equal to five percent (5.0%) per annum payable in shares of Series A Preferred Stock on the date that is 180 days after the date of the original issuance of such Series A Preferred Stock or such earlier date that that such holder may convert any portion of the Series A Preferred Stock to Common Stock.

Except as otherwise required by law, the Series A Preferred Stock does not have voting rights. However, as long as any shares of Series A Preferred Stock are outstanding, the Company may not, without the affirmative vote of the holders of a majority of the then-outstanding shares of the Series A Preferred Stock, (i) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock or alter or amend the Certificate of Designation, amend or repeal any provision of, or add any provision to, the Charter or Amended and Restated Bylaws of the Company, or file any articles of amendment, certificate of designations, preferences, limitations and relative rights of any series of Preferred Stock, if such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of the Series A Preferred Stock, regardless of whether any of the foregoing actions shall be by means of amendment to the Charter or by merger, consolidation, recapitalization, reclassification, conversion or otherwise, (ii) issue further shares of Series A Preferred Stock, or increase or decrease (other than by conversion) the number of authorized shares of Series A Preferred Stock (iii) prior to the Stockholder Approval (as defined in the Certificate of Designation) or at any time while at least 30% of the originally issued Series A Preferred Stock remains issued and outstanding, consummate either: (A) any Fundamental Transaction (as defined in the Certificate of Designation) or (B) any merger or consolidation of the Company with or into another entity or any stock sale to, or other business combination in which the stockholders of the Company immediately before such transaction do not hold at least a majority of the capital stock of the Company immediately after such transaction, or (iv) enter into any agreement with respect to any of the foregoing.

The Series A Preferred Stock shall rank on parity with the Common Stock as to distributions of assets upon liquidation, dissolution or winding-up of the Company, whether voluntarily or involuntarily.

Following stockholder approval of the Conversion Proposal, each share of Series A Preferred Stock will automatically convert into 10,000 shares of Common Stock, subject to certain limitations provided in the Certificate of Designation, including that the Company shall not affect any conversion of Series A Preferred Stock into shares of Common Stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than a specified percentage of the total number of shares of Common Stock issued and outstanding immediately after giving effect to such conversion (the "Beneficial Ownership Limitation"); provided, however, that the Beneficial Ownership Limitation will not apply after the stockholder approval of the Change of Control Proposal and upon the occurrence of certain other events as set forth in the Certificate of Designation. If at any time following the earliest of (a) Stockholder Approval (as defined in the Certificate of Designation), (b) the interim analysis of the Phase 2b study for Halneuron® proves futile, (c) Dogwood is delisted from Nasdaq, (d) the interim analysis of the Phase 2b study for Halneuron® is not completed by December 31, 2025, or (e) June 30, 2026, the Company fails to deliver to a Holder certificates representing shares of Common Stock or electronically deliver such shares, the Series A Preferred Stock is redeemable for cash at the option of the holder thereof at a price per share equal to the then-current Fair Value (as defined and described in the Certificate of Designation) of the Series A Preferred Stock for any undeliverable shares.

Form of Repurchase Agreement

The terms of the Exchange Agreement provides that Sealbond has the right to exercise an option, but not an obligation, after the Closing and upon the occurrence of certain conditional events including continued listing requirements, to acquire all of the Company's and its direct and indirect subsidiaries' intellectual property, rights, title, regulatory submissions, assignment of contracts, data and interests, as of the time of such acquisition, in and to tetrodotoxin and Halneuron®, in accordance with the terms and conditions of the form of Repurchase Agreement for a cash settlement value as defined in the agreement.

Contingent Value Rights Agreement

Concurrently with the Closing of the Combination, the Company entered into a contingent value rights agreement (the "CVR Agreement") with a rights agent (the "Rights Agent"), pursuant to which each holder of Common Stock as of October 17, 2024, including those holders receiving shares of Common Stock in connection with the Combination, was entitled to one contractual contingent value right (each, a "CVR") issued by the Company, subject to and in accordance with the terms and conditions of the CVR Agreement, for each

share of Common Stock held by such holder as of 5:00 p.m. Eastern Daylight Time on October 17, 2024. The CVR Agreement has a term of seven years.

Each contingent value right entitles the holders (the "Holders") thereof, in the aggregate, to 87.75% of any Upfront Payment (as defined in the CVR Agreement) or Milestone Payment (as defined in the CVR Agreement) received by the Company in a given calendar quarter.

The distributions in respect of the CVRs that become payable will be made on a quarterly basis and will be subject to a number of deductions, subject to certain exceptions or limitations, including but not limited to for certain taxes and certain out-of-pocket expenses incurred by the Company.

Under the CVR Agreement, the Rights Agent has, and Holders of at least 30% of the CVRs then-outstanding have, certain rights to audit and enforcement on behalf of all Holders of the CVRs. The CVRs may not be sold, assigned, transferred, pledged, encumbered or in any other manner transferred or disposed of, in whole or in part, other than as permitted pursuant to the CVR Agreement. The Holders of the CVRs do not have the rights of a shareholder and do not have the ability to vote, rights to dividends, or other interests. The CVRs also establish certain restrictions of mergers and change in control activities, as defined in the agreement.

The Company determined that the fair value of the CVRs were immaterial on the date of issuance as there were no imminent transactions to indicate value. The Company will evaluate the fair value of the CVRs at least annually on October 1 and whenever facts and circumstances indicate that their carrying amounts may have changed.

The Company's certificate of incorporation adopted on December 16, 2020, authorizes the issuance of two classes of stock to be designated, respectively, "Common Stock" and "Preferred Stock". The total number of shares which the Company is authorized to issue is 45,000,000, each with a par value of $0.0001 per share. Of these shares, 43,000,000 shall be Common Stock and 2,000,000 shall be Preferred Stock.

Common Stock

As of December 31, 2024, the Company had 43,000,000 shares of common stock authorized, of which 22,359,995 shares of common stock were reserved for the issuance upon the conversion of the Series A Preferred Stock.

Dividends

Subject to the rights of holders of all classes of Company stock outstanding having rights that are senior to or equivalent to holders of the Common Stock are entitled to receive dividends when and as declared by the Board.

Liquidation

Subject to the rights of holders of all classes of stock outstanding having rights that are senior to or equivalent to the holders of Common Stock as to liquidation, upon liquidation, dissolution or winding up of the Company, the assets of the Company will be distributed to the holders of the Common Stock.

Voting

The holders of the Common Stock are entitled to one vote for each share of Common Stock held. There is no cumulative voting.

At-the-market Offering

On July 14, 2023, the Company entered into a Capital on Demand™ Sales Agreement (the "Sales Agreement") with JonesTrading Institutional Services LLC ("JonesTrading") relating to shares of Common Stock, par value $0.0001 per share. In accordance with the terms of the Sales Agreement, the Company could offer and sell shares of Common Stock having an aggregate offering price of up to $6,700,000 from time to time through JonesTrading, acting as sales agent or principal, in which is commonly referred to as an "at-the-market" ("ATM") program. On August 14, 2023, the Company announced a halt to sales under the Sales Agreement and on September 18, 2023, the Company announced the termination of the Sales Agreement with JonesTrading effective September 28, 2023. Before the termination of the Sales Agreement, the Company sold 25,675 shares of Common Stock under the ATM program at a weighted-average gross sales price of approximately $52.78 per share and raised $1,355,090 of gross proceeds. The total commissions and related legal and accounting fees were approximately $198,650, and the Company received net proceeds of approximately $1,156,440.

Public Offering

On May 19, 2024, the Company entered into an agreement with Maxim Group LLC as placement agent in connection with the issuance and sale by the Company in a public offering of 340,000 shares of its Common Stock at a public offering price of $5.00 per share (the "May 2024 Offering"), pursuant to an effective shelf registration statement on Form S-3 (File No. 333-263700). The May 2024 Offering closed on May 22, 2024, and the gross proceeds from the May 2024 Offering were $1,700,000. The net proceeds of the May 2024 Offering were $1,382,170 after deducting placement agent fees and offering expenses payable by the Company.

11. Related Parties

The Company uses Gendreau Consulting, LLC, a consulting firm ("Gendreau"), for drug development, clinical trial design and planning, implementation and execution of contracted activities with the clinical research organization. Gendreau's managing member is the Company's Chief Medical Officer ("CMO"). The Company may continue to contract the services of the CMO's spouse through Gendreau to serve as the Company's Medical Director and to perform certain activities in connection with the Company's ongoing clinical development of its product candidates. During the years ended December 31, 2024 and 2023, the Company paid Gendreau $56,141 and $103,624, respectively, and had accounts payable of $21,260 and $0 to Gendreau as of December 31, 2024 and 2023, respectively. See also Note 9 – "Promissory Note with Related Party" and Note 2 under "Subsequent Events".

12. Commitments and Contingencies

Litigation

The Company is subject, from time to time, to claims by third parties under various legal disputes. The defense of such claims, or any adverse outcome relating to any such claims, could have a material adverse effect on the Company's liquidity, financial condition and cash flows.

Employment Agreement and Deferred Compensation Plan

The Company has employment agreements with its CEO, CFO, SVP of Operations (the "Executives"), as well as its CMO. Per the terms of the agreements, each Executive and the CMO are entitled to receive a cash bonus with a target amount of no less than 50% for the CEO, 35% for the CMO and 20% for the CFO and SVP of Operations, of the then-current base salary. The bonuses are subject to achievement of annual bonus metrics set by the Board. The employment agreements will continue in effect until terminated by either party pursuant to its terms. Upon termination of the agreement by the Company for any reason other than for cause, death or disability or by one of the Executives or CMO for good reason, the Company shall pay to an Executive a "Severance Payment" equal to the aggregate of the Executive's then-current annual base salary plus an amount equal to a prorated portion of the Executive's cash bonus for the year in which the termination occurs. The Severance Payment to an Executive is payable in cash over a period of one year. The Company shall pay to the CMO a Severance Payment equal to 25% of the then-current annual base salary plus a prorated portion of the CMO's cash bonus for the year in which the termination occurs over a period of three months and health benefits for a period of 12 months unless the CMO becomes eligible for health benefits under another employer. If the termination of the agreement is related to a change of control, the Company shall pay to the Executives and the CMO a "Change of Control Termination Payment" equal to the aggregate of 1.0 times the then-current annual base salary plus an amount equal to 1.0 times the Executives' and CMO's cash bonus for year in which the termination occurs. The Change of Control Termination Payments are payable in a single cash lump sum no later than 45 days after the triggering event.

13. Share-Based Compensation

Equity Incentive Plan

On June 16, 2022, the stockholders of the Company approved the Amended and Restated 2020 Equity Incentive Plan (the "Plan") to increase the total number of shares of common stock reserved for issuance under the Plan by 50,000 shares to 82,500 total shares issuable under the Plan. As of December 31, 2024 and 2023, 1,423 and 16,454 shares, respectively, were available for future grants.

The Plan provides for grants to employees, members of the Board, consultants and advisors to the Company, in the form of stock awards, options, and other equity-based awards. The amount and terms of grants are determined by the Board. Stock options have a maximum term of 10 years after date of grant and are exercisable in cash or as otherwise determined by the Board. The maximum aggregate number of shares subject to grant under the Plan to any individual, with the exception of any non-employee director, during any calendar year is limited to 20,000 shares. With respect to any non-employee director, the maximum aggregate number of shares subject to grant under the Plan to any individual during any calendar year is limited to 8,000 shares.

The table below sets forth the outstanding options to purchase common shares under the Plan:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Outstanding at December 31, 2022	65,276	$ 121.20	9.04
Granted	1,260	46.25	—
Forfeited	(490)	168.75	—
Outstanding at December 31, 2023	66,046	$ 119.42	8.08
Granted	15,031	8.93	—
Forfeited	—	—	—
Outstanding at December 31, 2024	81,077	$ 98.93	7.39
Exercisable at December 31, 2024	56,096	$ 136.88	6.83

As of December 31, 2024, the aggregate intrinsic value of options outstanding and exercisable was $0. As of December 31, 2023, the aggregate intrinsic value of options outstanding and exercisable was $192,465 and $64,155, respectively.

During the year ended December 31, 2024, the Company granted certain individuals options to purchase 15,031 shares of the Company's Common Stock with an average exercise price of $8.925 per share, contractual terms of 10 years and a vesting period of one year. The options had an aggregate grant date fair value of $105,931 that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model included: (1) discount rate of 4.2975% based on the daily par yield curve rates for U.S. Treasury obligations, (2) expected life of 5.5 years based on the simplified method (vesting plus contractual term divided by two), (3) expected volatility of 100.76% based on the average historical volatility of comparable companies' stock, (4) no expected dividends and (5) fair market value of the Company's stock of $8.925 per share.

During the year ended December 31, 2023, the Company granted certain individuals options to purchase 1,260 shares of the Company's common stock with an average exercise price of $46.25 per share, contractual terms of 10 years and a vesting period of one year. The options had an aggregate grant date fair value of $45,360 that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model included: (1) discount rate of 3.89% based on the daily par yield curve rates for U.S. Treasury obligations, (2) expected life of 5.5 years based on the simplified method (vesting plus contractual term divided by two), (3) expected volatility of 98.66% based on the average historical volatility of comparable companies' stock, (4) no expected dividends and (5) fair market value of the Company's stock of $46.25 per share.

For the years ended December 31, 2024 and 2023, the Company recognized share-based compensation expense related to stock options of $476,021 and $619,972, respectively. The unrecognized compensation expense for stock options at December 31, 2024 and 2023 was $168,741 and $539,461, respectively.

Stock Options for Unregistered Securities

In addition to the stock options issued under the Plan, and in conjunction with the IPO, the Company granted non-qualified stock options to purchase 11,700 shares of common stock as provided for in the President's employment agreement (the "President Options"). The President Options are exercisable within 10 years of the date of grant at $10.00 per share, were 100% vested at the grant date and have a remaining contractual term of 5.96 years. As of December 31, 2024, there was no unrecognized compensation expense related to these options as they were 100% vested upon issuance. The shares of common stock issuable upon exercise of the President Options will be unregistered, and the option agreement does not include any obligation on the part of the Company to register such shares of common stock. Consequently, the Company has not recognized a contingent liability associated with registering the securities for the arrangement. As of December 31, 2024, the aggregate intrinsic value of the President Options was $0.

Underwriters Warrants

In conjunction with the IPO, the Company granted the underwriters warrants to purchase 6,900 shares of common stock at an exercise price of $312.50 per share. The warrants have a five-year contractual term and became 100% exercisable on December 21, 2021.

In conjunction with the offering in September 2022, the Company granted the underwriter warrants to purchase 20,000 shares of common stock at an exercise price of $15.625 per share (the "Representative

Warrants"). The Representative Warrants have a five-year contractual term and became 100% exercisable on March 18, 2023.

For the year ended December 31, 2023, there were 19,145 Representative Warrants exercised. As a result, 7,718 shares of common stock were surrendered at fair value to satisfy the exercise price and 11,427 shares of common stock were issued. The surrendered shares are shown as treasury stock at a cost of $299,128 in stockholders' (deficit) equity.

There were no warrant exercises for the year ended December 31, 2024.

There is no unrecognized compensation expense for these awards as of December 31, 2024. The table below sets forth the outstanding warrants to purchase common shares:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Outstanding at December 31, 2022	26,900	$ 91.75	4.27
Granted	—	—	—
Exercised	(19,145)	15.63	—
Outstanding at December 31, 2023	7,755	$ 279.77	2.16
Granted	—	—	—
Outstanding at December 31, 2024	7,755	$ 279.77	1.15
Exercisable at December 31, 2024	7,755	$ 279.77	1.15

As of December 31, 2024, the aggregate intrinsic value of the warrants outstanding was $0.

14. Income Taxes

As of December 31, 2024, the Company has U.S. federal net operating loss carryforwards of approximately $36,669,000, which have an indefinite carryforward and Georgia and Florida state net operating loss carryforwards of approximately $44,443,000 and $1,372,000, respectively, which have a twenty-year carryforward and begin expiring in 2037. As of December 31, 2024, the Company had Canadian non-capital loss carryforwards of approximately $25,277,000, which have a twenty year carryforward and begin expiring in 2025 and Hong Kong tax losses carryforwards or approximately $58,126,000 which have no expiry.

A reconciliation of the worldwide consolidated income tax rate to the Company's effective tax rate is as follows:

	Year Ended December 31,	
	2024	2023
U.S. federal statutory income tax rate	**21.00 %**	21.00 %
Permanent differences	**(2.60)%**	(2.01)%
State taxes, net of federal benefit	**2.60 %**	4.30 %
Foreign exchange	**0.43 %**	— %
Other adjustments	**— %**	0.20 %
Change in valuation allowance	**(21.43)%**	(23.49)%
Effective Income Tax rate	**— %**	— %

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company's deferred tax assets are comprised of the following:

	As of December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	**$ 26,081,361**	$ 7,132,019
Research and development tax credits	**8,765,999**	—
Capitalized research and development expenditures	**1,627,842**	1,524,035
Stock compensation	**1,434,890**	1,441,652
Depreciation and amortization	**275,412**	14,049
Lease liabilities	**58,227**	—
Investment in partnership	**30,035**	30,639
Gross deferred tax assets	**38,273,766**	10,142,394
Valuation allowance	**(31,370,027)**	(9,926,772)
Net deferred tax assets	**6,903,739**	215,622
Deferred tax liabilities:		
Right-of-use asset	**(55,341)**	—
In-process research and development intangible assets	**(17,741,842)**	—
Prepaid expenses	**(421,481)**	(215,622)
Deferred tax liabilities	**(18,218,664)**	(215,622)
Net deferred taxes	**$ (11,314,925)**	$ —

For tax years beginning on or after January 1, 2022, the 2017 Tax Cuts and Jobs Act amended Section 174 of the code to eliminate current-year deductibility of research and development expenses and requires taxpayers to capitalize and amortize them over five years for research activities performed in the United States and fifteen years for research activities performed outside of the United States. For the 2024 and 2023 tax years, the Company has capitalized $2,810,785 and $1,728,078 of research and development expenses, respectively.

The Company has provided a full valuation allowance for its deferred tax asset as of December 31, 2023 due to the uncertainty surrounding the ability to realize these assets. At December 31, 2024, the Company evaluated the realizability of its deferred tax assets and determined that the valuation allowance should be adjusted for the consideration of the acquired in-process research and development intangible assets. An income tax benefit for the year ended December 31, 2024 is reflected in the consolidated statement of operations.

The Company experienced a net change in valuation allowance of $21,443,255 and $1,244,274 for the years ended December 31, 2024 and 2023, respectively. The large valuation adjustment for the year ended December 31, 2024, primarily related to the Combination of Pharmagesic and acquired in-process research and development intangible assets.

The components of the income tax benefit are as follows:

	As of December 31,	
	2024	2023
Current:		
Federal	$ —	$ —
State	—	—
Foreign	—	—
	$ —	$ —
Deferred:		
Federal	$ —	—
State	—	—
Foreign	(503)	—
	$ (503)	$ —
Total income tax benefit	$ (503)	$ —

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures.

Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures were effective to ensure that the information required to be disclosed by us in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in rules, regulations and forms of the SEC, including ensuring that such material information is accumulated by and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our 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 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 because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management utilized the criteria established in the Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) to conduct an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2023. Based on the assessment, management has concluded that, as of December 31, 2024, our internal control over financial reporting was effective.

As an emerging growth company, management's assessment of internal control over financial reporting was not subject to attestation by our independent registered public accounting firm.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(f) of the Exchange Act that occurred during the quarter ended December 31, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. However, we are in the process of integrating Legacy Pharmagesic into our system of internal control over financial reporting which may result in future changes to our internal control environment.

Item 9B. Other Information

Rule 10b5-1 Trading Arrangements

During the fiscal quarter ended December 31, 2024, no director or "officer" (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated any "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

We incorporate the information required by this Item 10 by reference to the definitive proxy statement for our 2024 annual meeting of shareholders, to be filed with the SEC.

The following is a list of our executive officers as of the date of this Annual Report.

Name	Position
Greg Duncan	Chairman and Chief Executive Officer
R. Michael Gendreau, M.D., Ph.D.	Chief Medical Officer
Ralph Grosswald	Senior Vice President of Operations
Angela Walsh	Chief Financial Officer, Corporate Secretary and Treasurer

Item 11. Executive Compensation

We incorporate the information required by this Item 11 by reference to the definitive proxy statement for our 2025 annual meeting of shareholders, to be filed with the SEC.

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

We incorporate the information required by this Item 12 by reference to the definitive proxy statement for our 2025 annual meeting of shareholders, to be filed with the SEC.

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

We incorporate the information required by this Item 13 by reference to the definitive proxy statement for our 2025 annual meeting of shareholders, to be filed with the SEC.

Item 14. Principal Accountant's Fees and Services

The Independent Registered Public Accounting Firm is Forvis Mazars, LLP (PCAOB Firm ID No. 686) located in Atlanta, Georgia. We incorporate the remaining information required by this Item 14 by reference to the definitive proxy statement for our 2025 annual meeting of shareholders, to be filed with the SEC.

Part IV

Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed or furnished as part of this Annual Report on Form 10-K:

1. Financial Statements

Reference is made to the Index to Financial Statements under Part II, Item 8 hereof.

2. Financial Statement Schedules

The Financial Statement Schedules have been omitted because they are not applicable, not required, or the information is shown in the financial statements or related notes.

3. Exhibits

EXHIBIT INDEX

Exhibit Number	Description
2.1	Plan of Conversion (incorporated by reference herein from Exhibit 2.1 to the Company's Registration Statement on Form S-1, filed with the SEC on August 28, 2020)
2.2	Certificate of Conversion of Virios Therapeutics, LLC (incorporated by reference herein from Exhibit 2.2 to the Company's Registration Statement on Form S-1, filed with the SEC on August 28, 2020)
2.3	Share Exchange Agreement, dated October 7, 2024, relating to Pharmagesic (Holdings) Inc., by and between Virios Therapeutics, Inc. and Sealbond Limited (incorporated by reference herein from Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the SEC on October 7, 2024)
3.1	Certificate of Incorporation of Virios Therapeutics, Inc. (incorporated by reference herein from Exhibit 3.1 to the Company's Registration Statement on Form S-1, filed with the SEC on August 28, 2020)
3.2	Certificate of Amendment of Certificate of Incorporation of Virios Therapeutics, Inc., as amended, dated October 7, 2024 (incorporated by reference herein from Exhibit 3.2 to the Company's Current Report on Form 8-K, filed with the SEC on October 7, 2024)
3.3	Certificate of Designation of Series A Non-Voting Convertible Preferred Stock of Virios Therapeutics, Inc., dated October 7, 2024 (incorporated by reference herein from Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on October 7, 2024)
3.4	Certificate of Designation of Series A-1 Non-Voting Convertible Preferred Stock of Dogwood Therapeutics, Inc. (incorporated by reference herein from Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on March 12, 2025)
3.5	Amended and Restated By-Laws of Dogwood Therapeutics, Inc. (incorporated by reference herein from Exhibit 3.3 to the Company's Current Report on Form 8-K, filed with the SEC on October 7, 2024)
4.1	Specimen Certificate evidencing shares of the Registrant's common stock. (incorporated by reference herein from Exhibit 4.1 to the Company's Registration Statement on Form S-1, filed with the SEC on October 16, 2020)
4.2	Description of Registrant's Securities (incorporated by reference herein from Exhibit 4.2 to the Company's Annual Report on Form 10-K, filed with the SEC on March 23, 2021)
10.2+	Employment Agreement, dated April 5, 2020, by and between Greg Duncan and Innovative Med Concepts, LLC, as amended. (incorporated by reference herein from Exhibit 10.3 to the Company's Registration Statement on Form S-1, filed with the SEC on August 28, 2020)
10.3+	Employment Agreement, dated April 5, 2020, by and between Angela Walsh and Innovative Med Concepts, LLC, as amended. (incorporated by reference herein from Exhibit 10.4 to the Company's Registration Statement on Form S-1, filed with the SEC on August 28, 2020)
10.4+	Employment Agreement, dated April 5, 2020, by and between Ralph Grosswald and Innovative Med Concepts, LLC, as amended. (incorporated by reference herein from Exhibit 10.5 to the Company's Registration Statement on Form S-1, filed with the SEC on August 28, 2020)

10.5+	Virios Therapeutics, Inc. Amended and Restated 2020 Equity Incentive Plan. (incorporated by reference herein from Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed June 17, 2022)
10.6+	Form of Stock Option Award Agreement (incorporated by reference herein from Exhibit 10.6 to the Registrant's Annual Report on Form 10-K filed March 14, 2023)
10.7	University of Alabama Know-How License Agreement, dated June 1, 2012, by and between The Board of Trustees of The University of Alabama for and on behalf of its component institution The University of Alabama and Innovative Med Concepts, LLC. (incorporated by reference herein from Exhibit 10.7 to the Company's Registration Statement on Form S-1, filed with the SEC on August 28, 2020)
10.8+	Employment Agreement, dated September 10, 2020, by and between R. Michael Gendreau and Virios Therapeutics, LLC. (incorporated by reference herein from Exhibit 10.8 to the Company's Registration Statement on Form S-1, filed with the SEC on September 16, 2020)
10.9	Loan Agreement, dated October 7, 2024, by and between Virios Therapeutics, Inc. and Sealbond Limited (incorporated by reference herein from Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on October 7, 2024)
10.10	Registration Rights Agreement, Dated October 7, 2024, by and between Virios Therapeutics, Inc. and Sealbond Limited (incorporated by reference herein from Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on October 7, 2024)
10.11	Letter Agreement, dated October 7, 2024, by and between Virios Therapeutics, Inc. and CK Life Sciences Int'l (Holdings) Inc. (incorporated by reference herein from Exhibit 10.3 to the Company's Current Report on Form 8-K, filed with the SEC on October 7, 2024)
19.1*	Dogwood Therapeutics, Inc. Insider Trading Policy
21.1*	Subsidiaries
23.1*	Consent of Forvis Mazars, LLP
31.1*	Certification of Chief Executive Officer Pursuant to Rule 13a-15(e) or Rule 15d-15(e)
31.2*	Certification of Chief Financial Officer Pursuant to Rule 13a-15(e) or Rule 15d-15(e)
32.1*	Certification of Chief Executive Officer and Chief Financial Officer of Periodic Report Pursuant to 18 U.S.C. Section 1350
97.1+	Virios Therapeutics, Inc. Incentive Compensation Recoupment Policy (previously filed as Exhibit 97.1 to the Registrant's Annual Report on Form 10-K filed March 1, 2024)
101.INS*	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	XBRL Schema Document.
101.CAL*	XBRL Calculation Linkbase Document.
101.DEF*	XBRL Definition Linkbase Document.
101.LAB*	XBRL Label Linkbase Document.
101.PRE*	XBRL Presentation Linkbase Document.
104*	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101).

***** Filed with this Annual Report on Form 10-K.

\+ Indicates management contract or compensatory plan.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 31, 2025.

DOGWOOD THERAPEUTICS, INC.

By: /s/ Greg Duncan
Greg Duncan
Chairman of the Board of Directors, and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below on March 31, 2025 by the following persons on behalf of the registrant and in the capacities indicated:

Signature	Title
/s/ Greg Duncan Greg Duncan	Chairman of the Board of Directors, and Chief Executive Officer (Principal Executive Officer)
/s/ Angela Walsh Angela Walsh	Chief Financial Officer, Corporate Secretary and Treasurer (Principal Financial and Accounting Officer)
/s/ Alan Yu Alan Yu	Director
/s/ Abel De La Rosa Abel De La Rosa	Director
/s/ David Keefer David Keefer	Director
/s/ Melvin Toh, MD Melvin Toh, M.D.	Director
/s/ John C. Thomas, Jr. John C. Thomas, Jr.	Director
/s/ Richard J. Whitley, MD Richard J. Whitley, M.D.	Director