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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, 2025

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, 2025, 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 $8,092,720 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 10, 2026 was 33,401,553.

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 2026 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, 2025, 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.
- Unstable global market and economic conditions may have serious adverse consequences on our business, financial condition and results of operations.

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

- We are heavily dependent on the success of our product candidates 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 any 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 any of our product candidates 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 an approved product.

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 our product candidates and intend to rely on CMOs for the production of commercial supply.
- 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.

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 neuropathy. 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 treating chronic neuropathic pain and neuropathy. Our Halneuron® $Na_V1.7$ modulation program is intended to treat chronic and acute pain disorders. Our recently licensed SP16 program is centered on a cell signaling molecule that has shown early promise in treating neuropathy and nerve damage. The Halneuron® program is a proprietary non-opioid $Na_V1.7$ analgesic program centered on voltage-gated sodium channel modulation, a mechanism known to be effective for reducing pain. SP16 is the focus of a planned Phase 1b study that is fully funded through a research grant supplied by the National Cancer Institute, with patient enrollment projected to start in mid-2026.

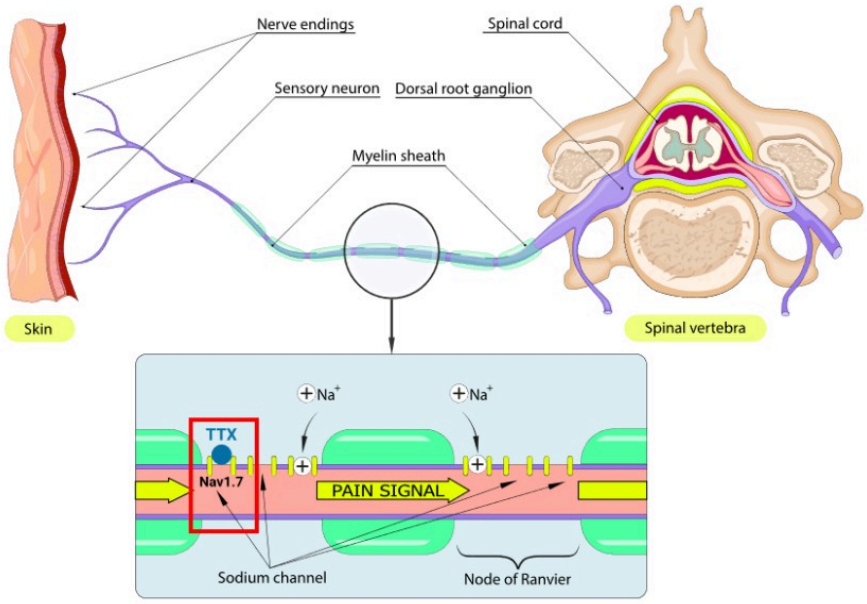
$Na_V1.7$ Non-Opioid Analgesic Program

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 CINP.

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 over 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 $2.8 billion annually according to DelveInsight 2018. Allied Market Research estimates the larger cancer related pain market reaching approximately $7.5 billion in yearly sales by 2027. 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; and
- the Halneuron® QD dose group exhibited a mean reduction of -0.4 points versus placebo on NRS pain recall assessment.

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 HAL-CINP-203 Phase 2b clinical trial in the United States. HAL-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 approximately 240 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 HAL-CINP-203 Phase 2b primary efficacy endpoint is pain improvement over 4 weeks 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. An interim analysis conducted in December 2025 confirmed that Halneuron was separating from placebo in the 97 patient subset included in the analysis, and that a sample size of 210-240 was expected to provide 80+% power to see a statistically significant result. This preliminary evidence of a Halneuron® treatment effect is noteworthy as patients in the interim analysis population present an average duration of CINP of 5 years and 67% of patients that met entry criteria were also being treated with stable doses of other chronic pain medicines, including pregabalin, gabapentin, duloxetine, and opioids. In addition, the overall study dropout rate of approximately 4.4% is far below rates typically observed with other FDA approved chronic pain medicines. While still blinded, we believe these findings reaffirm the encouraging safety and tolerability profile of Halneuron® observed in previous clinical trials.

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 Programs

While our primary focus is on advancing development of Halneuron® and SP16, we continue to explore partnership opportunities to advance our novel antiviral therapies to treat diseases associated with a viral triggered abnormal immune response such as fibromyalgia (“FM”) and Long-COVID (“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.

IMC-1

IMC-1 is a combination of famciclovir and celecoxib that is intended to synergistically suppress herpesvirus activation and replication. Based on the analysis of the IMC-1 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 currently seeking external opportunities to continue the advancement of IMC-1.

IMC-2

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). 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 opportunities to continue the advancement of IMC-2.

Serpin Peptide 16 (SP16)

Chemotherapy induced peripheral neuropathy ("CIPN") is a prevalent and debilitating complication of cancer treatment, affecting an estimated 68% of patients within the first month after therapy and persisting in approximately 30% of survivors beyond six months. Taxanes and platinum agents are among the most neurotoxic chemotherapeutics, frequently resulting in dose-limiting neuropathy that compromises treatment efficacy and long-term survivorship. Despite its clinical significance, no FDA-approved therapies exist to prevent or treat CIPN, and current off-label interventions such as duloxetine provide only marginal benefit with notable side effects.

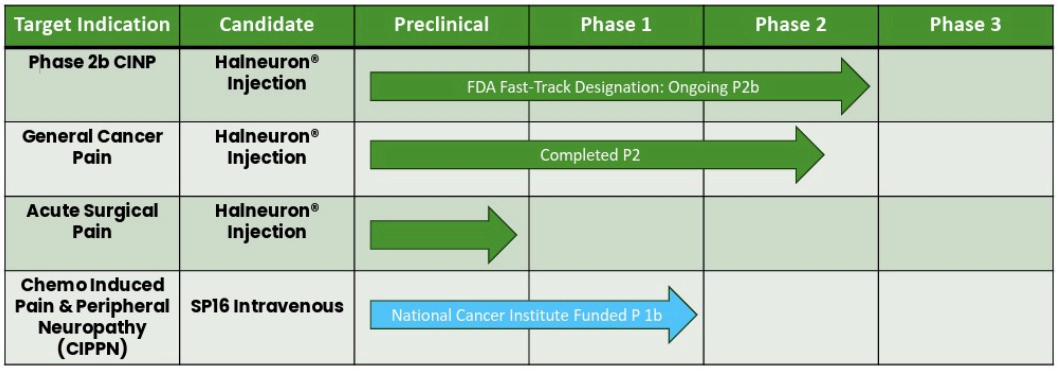
SP16 is a synthetic anti-inflammatory peptide developed to replicate the cytoprotective and anti-inflammatory signaling properties of Serine Protease Inhibitors (SERPINs), such as α1-Antitrypsin (AAT), without exerting protease inhibitory activity. Upon protease binding and enzymatic inactivation, SERPINs undergo a conformational change that exposes a conserved peptide motif (typically 5–11 amino acids), which engages the low-density lipoprotein receptor-related protein 1 ("LRP1"). LRP1 mediates clearance of plasma proteins and initiates downstream anti-inflammatory and cytoprotective signaling. SP16 retains this LRP1-binding motif while eliminating protease inhibition, resulting in a 17-amino acid peptide with enhanced plasma stability and potency. In vitro binding studies confirm selective engagement of LRP1 without meaningful affinity for other receptor classes.

Through LRP1 activation, SP16 mitigates damaging inflammation, rebalances immune signaling, and promotes neuronal survival and regeneration. Preclinical studies demonstrate that SP16 alleviates paclitaxel-induced cold and mechanical allodynia, reduces neuroinflammatory cytokine expression, and promotes neuronal repair via p-AKT signaling. Importantly, SP16 does not interfere with the anticancer activity of taxanes or other chemotherapeutic classes, a critical safeguard for its use in combination with chemotherapy.

The SP16 program is in early Phase 1 development with a National Cancer Institute funded grant and is expected to start in mid-2026. The first in-human studies are anticipated to involve administration of SP16 to breast cancer patients to investigate the potential for SP16 to reduce neuropathy secondary to treatment with chemotherapeutic agents that are also neurotoxic.

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, 2025, 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 expires 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
    - PCT International (PCT/EP2007/002662)
    - 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
  - PCT International (PCT/CA2022/050623)
  - U.S.A. (Application No. 18/556,683)
  - Australia (Application No. 2022261799)
  - Canada (Application No. 3,215,362)
  - China (Application No. 202280030118.1)
  - European Patent Office (Application No. 22790649.2)
  - Hong Kong SAR (Application No. 62024091183.9)
  - 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. 3,259,981)
  - China (Application No. 202380051910.X)
  - Europe (Application No. 23834327.1)
  - Hong Kong SAR (Application No. 62025104240.9)
  - Japan (Application No. 2024-576699)

  - South Korea (Application No. 10-2025-7003014)
  - New Zealand (Application No. 817473)

- Process for the Synthesis of Tetrodotoxin and Intermediates Thereof
  - U.S.A. (Application No. 63/926,858)

- Intermediates and Process for the Synthesis of Tetrodotoxin
  - U.S.A. (Application No, 63/926.859)

As of December 31, 2025, our licensed SP16 portfolio includes two patent families which include one issued U.S. patent and eight foreign patents. The licensed patent families also include patent applications pending in the U.S. and abroad. The licensed families cover methods of using SP16. Issued patent and patents issuing from the pending applications of the two licensed families are expected to expire in 2036 and 2042.

Issued SP16 Family 1 Patents

- U.S. (US 11020462)
- Australia (AU2016317726)
- Canada (CA2996975)
- China (ZL201680063220.6, ZL202010764749.9, ZL202110597016.5)
- Europe (EP3340974; validated in Belgium, Switzerland, Germany, France, United Kingdom, Luxembourg, Monaco, Malta, Netherlands and Sweden)
- Hong Kong (1258994, 40039746, 40056903)
- Israel (IL257764)
- Japan (JP6929272)

Pending SP16 Family 1 Patent Applications

- China (App. No. 2021105971420)
- Hong Kong (App. No. 420220463921)
- US (App. No. 18/899,798)

Pending SP16 Family 2 Patent Applications

- U.S. (App. Nos. 18/148,942 and 18/726,945)
- Australia (App. No. 2022431253)
- Canada (App. No. 3247129)

- China (App. No. 2022800922844)
- Europe (App. No. 229192620)
- Hong Kong (App. Nos. 620251060641 and 620240999214)
- Israel (App. No. 314135)
- Japan (App. No. 2024540848)
- New Zealand (App. No. 812913)

As of December 31, 2025, our antiviral portfolio of owned patents totaled 14 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. 11,096,912 (valacyclovir/celecoxib)

U.S. Pending Applications

- PCT/US2023/032842 (valacyclovir/celecoxib or famciclovir/celecoxib to treat Alzheimer's disease or Long-COVID): Nationalized in Australia, Canada, Europe, Japan and U.S.

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.

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.

On September 29, 2025, we entered into an Exclusive Licensing Agreement (the "Licensing Agreement") with Serpin Pharma Inc. ("Serpin Pharma") and Rejuvenation Labs, Inc. ("Rejuvenation" and, together with Serpin Pharma, "Serpin"), pursuant to which Serpin Pharma granted the Company a royalty-free, sublicensable global license to develop Serpin Pharma's intravenous formulation of SP16.

Sales and Marketing

If Halneuron®, SP16, IMC-1 or IMC-2 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.

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 2026 to discuss their regulatory feedback regarding advancing the synthetic formulation for Phase 3 in 2027. 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.

We are working with Serpin Pharma and their contract manufacturer to supply SP16 for development research and may do so for commercialization, presuming continued successful clinical development.

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 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 any approved products 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, 2025, we had eight full-time employees and no part-time employees with five employees working in the U.S. and three 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. At this time, the Company does not own or lease any location in the United States 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 was 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.

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 ("Series A-1 Preferred Stock") (the "Debt Exchange and Cancellation Transaction").

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.

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.

Serpin Licensing Agreement

On September 29, 2025, we entered into the Licensing Agreement with Serpin, pursuant to which Serpin granted the Company a royalty-free, sublicensable global license to develop Serpin Pharma's intravenous formulation of SP16. SP16 is a first-in-class low density LRP1 agonist which has demonstrated both anti-inflammatory, immunomodulatory and neural repair activity that has the potential to treat chemotherapy-induced peripheral neuropathy. In consideration of the Licensing Agreement, we issued 191,017 shares of Common Stock and 89.5939 shares of Series A-2 Non-Voting Convertible Preferred Stock, par value $0.0001 per share ("Series A-2 Preferred Stock") to Serpin Pharma and (ii) 191,017 shares of Common Stock and 89.5939 shares of Series A-2 Preferred Stock to Rejuvenation, as further described under "Serpin Equity Issuance and Registration Rights Agreement" below.

Tungsten Advisors (through its Broker-Dealer, Finalis Securities LLC) (together with its affiliates, "Tungsten") acted as the financial advisor to the Company in connection with the Licensing Agreement. As compensation for services rendered by Tungsten, the Company issued to Tungsten and its affiliates and designees an aggregate of 10.8694 shares of Series A-2 Preferred Stock.

Serpin Equity Issuance and Registration Rights Agreement

On September 29, 2025, in connection with the Licensing Agreement, we also entered into an Equity Issuance and Registration Rights Agreement (the "Serpin Registration Rights Agreement") with Serpin.

Pursuant to the Serpin Registration Rights Agreement, we filed a Form S-3 registration statement registering the shares issued under the Serpin Registration Rights Agreement. The Form S-3 registration statement became effective on November 5, 2025. We also granted Serpin customary demand registration and indemnification rights and entered into customary issuer covenants.

Conversion of Preferred Stock to Common Stock

On November 21, 2025, we held a Special Meeting of our stockholders. At the Special Meeting, our stockholders approved for purposes of complying with the applicable provisions of Nasdaq Listing Rule 5635, the potential issuance of our Common Stock upon the conversion of the Company's Series A Preferred Stock, Series A-1 Preferred Stock, and Series A-2 Preferred Stock. As a result, on November 21, 2025, all outstanding shares of Series A Preferred Stock, Series A-1 Preferred Stock and Series A-2 Preferred Stock converted into Common Stock at a ratio of one preferred stock to 10,000 shares of Common Stock.

Equity Distribution Agreement

On November 28, 2025, the Company entered into an Equity Distribution Agreement (the "Northland Agreement") with Northland Securities, Inc., as sales agent, relating to the issuance and sale from time to time by the Company (the "ATM Program") of shares of the Company's common stock having an aggregate offering price of up to $8,558,712. We sold shares of Common Stock for gross proceeds of $89,762 pursuant to the Northland Agreement during the fourth quarter of 2025.

On January 9, 2026, the Company provided notice of its termination, effective January 9, 2026, of the Northland Agreement. The Company is not subject to any termination penalties related to the termination of the Northland Agreement.

Registered Offering and Private Placement

Subsequent to year end, on January 11, 2026, 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 2,338,948 shares of its Common Stock (the "Registered Offering"), pursuant to an effective shelf registration statement on Form S-3 (File No. 333-287575). In a concurrent private placement (together with the Registered Offering, the "January 2026 Offering"), the Company agreed to sell (i) unregistered pre-funded warrants to purchase up to 2,047,089 shares of Common Stock (the "Pre-funded Warrants") and (ii) unregistered common stock warrants to purchase up to 4,386,037 shares of Common Stock (the "Common Stock Warrants") at a combined offering price of $2.85 per share of Common Stock and accompanying Common Stock Warrant and $2.8499 per Pre-funded Warrant and accompanying Common Stock Warrant. The January 2026 Offering closed on January 13, 2026, and the gross proceeds to the Company were approximately $12.5 million. The net proceeds of the January 2026 Offering were approximately $11.4 million after deducting placement agent fees and offering expenses payable by the Company.

On January 15, 2026, the Company filed a Form S-3 Registration Statement for the resale of up to 6,433,126 shares of the Company's Common Stock consisting of (i) 2,047,089 shares of Common Stock underlying the Pre-Funded Warrants at an exercise price of $0.0001 per share; and (ii) 4,386,037 shares of Common Stock underlying the Common Stock Warrants to purchase shares of Common Stock at an exercise price of $3.28 per share. The Form S-3 Registration Statement was declared effective by the SEC on January 29, 2026.

Subsequent to year end, the Company received notification and payment for the exercise of 1,319,089 Pre-Funded Warrants at an exercise price of $0.0001 per share and 1,319,089 shares of Common Stock were issued. As of March 10, 2026, there are 728,000 Pre-Funded Warrants outstanding.

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. Certain of the risk factors described below include references to past events as examples. These examples, or the absence of other examples, should not be viewed as a representation as to whether or not the events, factors or contingencies described in our risk factors have or have not occurred. Instead, the disclosures in this section reflect our beliefs and opinions as to the factors, events or contingencies that could materially and adversely affect us in the future.

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, 2025 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 $34,257,370 and $12,349,724 for each of the years ended December 31, 2025 and 2024. As of December 31, 2025, we had an accumulated deficit of $108,076,316. 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 our product candidates through clinical development, complete clinical trials, seek regulatory approval and commercialize the drug or any other product candidates we develop in the future, 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 products for which we 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' equity (deficit) 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 our product candidates.

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 our development product candidates. We will require additional capital for the further development and potential commercialization of our product candidates. 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 and cash equivalents on hand as of December 31, 2025 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 top-line data readout in the third quarter of 2026. The capital raised in January of 2026 funds the ongoing Halneuron® Phase 2b CINP study through completion; the commencement of a Phase 2b extension study; further development of the synthetic production and scale-up process of Halneuron®; continued salaries and benefits; and continued operations in the U.S. and Canada. 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;
- clinical development plans we establish for 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 Russia-Ukraine conflict and the conflict between U.S., Israel and Iran have created extreme volatility in the global capital markets and may continue 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 geopolitical 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. SP16 is the focus of a planned Phase 1b study that is fully funded through a research grant supplied by the National Cancer Institute, with patient enrollment projected to start in mid-2026. 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 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 under active development include Halneuron® for the treatment of CINP and SP16 for the treatment of neuropathy and nerve damage. 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 these candidates in a timely manner. We cannot commercialize these candidates in the United States without first obtaining regulatory approval from the FDA; similarly, we cannot commercialize these candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of these candidates 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 our product candidates are safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. If we are unable to obtain regulatory approval for our product candidates 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, 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 approved products, we may not be able to earn sufficient revenue to continue our business.

Approved products are subject to continuing obligations regarding manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, post-marketing studies, and submission of safety and efficacy data under U.S. federal and state laws and comparable foreign regulations. Holders of Biologics License Applications (BLAs) or New Drug Applications (NDAs), as well as manufacturing facilities, must comply with current Good Manufacturing Practice (cGMP) requirements and are subject to ongoing inspections by the FDA and foreign authorities. Compliance requires significant time, resources, and investment in manufacturing, quality control, and regulatory oversight.

Promotional activities are strictly regulated and must align with approved labeling; “off-label” promotion is prohibited. Changes to an approved product, its labeling, or manufacturing process generally require prior regulatory approval. Regulatory authorities may also mandate post-marketing studies to confirm safety and efficacy. Failure to complete such studies or negative outcomes could result in withdrawal of marketing approval.

If regulators identify previously unknown safety issues, manufacturing deficiencies, or improper marketing practices, they may impose restrictions or require product withdrawal. Noncompliance with regulatory requirements could result in:

- Warning letters;
- Civil or criminal penalties;
- Suspension or withdrawal of approvals;
- Clinical trial holds;
- Refusal to approve pending applications;
- Operational restrictions, including closure of manufacturing facilities; or
- Product seizures or recalls.

Government investigations of alleged violations could require significant resources and generate negative publicity. Any sanctions or loss of approval would adversely affect commercialization and revenue generation, and materially harm our business.

Regulatory policies may change, and new requirements may be introduced that delay or prevent approval of products derived from our candidates. We cannot predict future legislative or administrative actions in the United States, Europe, or other jurisdictions. If such actions limit regulatory operations, our business could be negatively impacted. Failure to adapt to evolving requirements or maintain compliance could result in loss of marketing approvals and prevent us from achieving or sustaining profitability.

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, our product candidates 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 our product candidates 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®, SP16 or any other product candidates we develop in the future, 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 any 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 charges drug and biologic product manufacturers user fees, which are adjusted on an annual basis in accordance with the Prescription Drug User Fee Act, or PDUFA. The fee for the submission of an NDA for which clinical data is substantial (for example, for the fiscal year 2025 this application fee exceeds $4.1 million), and the sponsor of an approved NDA is also subject to an annual program fee, currently more than $400,000 per program. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

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 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 any of our product candidates, 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 any of our product candidates 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 any of our 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.

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. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patent registries. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without a REMS, if required. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, many 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;

- 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® and/or SP16, if approved, may be smaller than we anticipate.

We are developing Halneuron® for the treatment of CINP and neuropathic pain and SP16 for neuropathy. 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®, SP16 or any other product candidate we develop in the future in the United States, we may never obtain approval for or commercialize those product candidates 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®, SP16 or any other product candidate we develop in the future, 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® 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®, SP16 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®, SP16 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 or unanticipated manufacturing defects. 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®, SP16 or any other product candidate we develop in the future;
- 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 Halneuron®, SP16 or other development products are 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.

Our products may be subject to certain legal and regulatory requirements regarding the packaging, distribution, sale, and labeling of medical products in the United States.

If our products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

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

The failure to comply with any of these laws or regulatory requirements subjects' firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

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

We may face early generic competition for Halneuron®, SP16 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. Under FDA's generic drug approval processes, described in more detail in the section titled "Hatch-Waxman and Generic Competition," we believe that Halneuron® would still be eligible for the 5 year NCE Exclusivity period, because Halneuron has not previously been approved for any indication by FDA.

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.

The successful commercialization of Halneuron® or any other product candidate we develop in the future 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. 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 any of our product candidates 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 any 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 any product candidate that receives regulatory approval.

We do not have any infrastructure for the sales, marketing or distribution of any products, 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 may choose to build a focused sales, distribution and marketing infrastructure to market an approved product 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. 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 our approved product(s), 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, 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 product candidates 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® and SP16 and intend to rely on CMOs for the production of commercial supplies. 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. 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® and SP16 to enable us to complete future clinical trials, and we have also engaged a CMO to provide clinical and commercial supply of 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 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;

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

- federal government price reporting laws, which require us to calculate and report complex pricing metrics to government programs and which may be used in the calculation of reimbursement and/or discounts on marketed products;

- the Foreign Corrupt Practices Act, a United States law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals);

- the national anti-bribery laws and laws governing interactions with healthcare professionals of European Union Member States;

- the U.K. Bribery Act 2010; 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, 2025, we had U.S. federal net operating loss carryforwards, or NOLs, of approximately $45,410,000 and Georgia and Florida state NOLs of approximately $58,689,000 and $1,750,000, respectively. As of December 31, 2025, we also had Canadian non-capital loss carryforwards of approximately $22,024,000, which have a twenty-year carryforward and begin expiring in 2026 and Hong Kong tax losses carryforwards of approximately $58,026,000, 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, 2025 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®, SP16 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®, SP16, 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 any of our product candidates, and we expect to collaborate with third parties on the development of any of our 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 any of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our 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® or SP16.

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 any product candidates we develop 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. We have received a delisting notice from Nasdaq as a result of the closing bid price of our common stock being below $1.00 per share for 30 consecutive business days. Our common stock may be involuntarily delisted from Nasdaq if we fail to regain compliance with the minimum closing bid price requirement of $1.00 per share.

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, and the price of our common stock may be adversely affected due to the likelihood of decreasing liquidity resulting from delisting. In addition, it may inhibit or preclude our ability to raise additional funding.

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®, SP16 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®, SP16 or any other product candidate we develop in the future;
- adverse regulatory decisions;
- changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for Halneuron®, SP16 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 a "smaller reporting company" and the reduced reporting requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We no longer qualify as an emerging growth company, but we still qualify as a "smaller reporting company," which allows 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.

We cannot predict if investors will find our common stock less attractive because we may rely on this exemption. 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

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 2025 and 2024 we recorded a cumulative translation gain of $3.3 million and a translation loss of $3.8 million, respectively, 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.

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.

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 was estimated to be more than $2.5 million. As of December 31, 2025, our total stockholders' equity is $74.9 million.

Holders of Record

As of March 10, 2026, there were approximately 100 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 were entitled to receive, and the Company paid, payment-in-kind dividends on each share of Series A Preferred Stock, which accrued 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 and the Series A-2 Non-Voting Convertible Preferred Stock were 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, 2025.

Recent Sales of Unregistered Securities

We did not issue any equity securities during the year ended December 31, 2025 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 with a pipeline focused on developing new medicines to treat pain and neuropathy. Our Halneuron® $Na_v1.7$ modulation program is intended to treat chronic neuropathic pain and acute pain disorders. Our recently licensed SP16 program is centered on a cell signaling molecule that has shown early promise in treating neuropathy and nerve damage.

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 HAL-CINP-203 clinical trial in the United States. HAL-CINP-203 is a double-blind, placebo controlled clinical trial to access the efficacy and safety of Halneuron® in approximately 240 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 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 released interim data from HAL-CINP-203 in December 2025 and expect to have top-line results available during the third quarter of 2026.

SP16 Program

SP16 is currently at the Phase 1 stage with studies in breast cancer patients scheduled to begin in mid-2026. These initial investigational studies are supported by a National Cancer Institute grant to investigate the potential for SP16 to reduce neuropathy secondary to treatment with chemotherapeutic agents that are also neurotoxic. SP16 is the focus of a planned Phase 1b study that is fully funded through a research grant supplied by the National Cancer Institute, with patient enrollment projected to start in mid-2026.

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.

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.

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.

Registered Direct 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, pursuant to an effective shelf registration statement on Form S-3 (File No. 333-263700) (the "March 2025 Offering"). The March 2025 Offering closed on March 14, 2025, and the gross proceeds 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.

Serpin License Agreement

On September 29, 2025, the Company entered into the Licensing Agreement with Serpin, pursuant to which Serpin granted the Company an exclusive royalty-free, sublicensable global license to develop Serpin Pharma's intravenous formulation of SP16. SP16 is a first-in-class low density LRP1 agonist which has demonstrated both anti-inflammatory, immunomodulatory and neural repair activity that has the potential to treat chemotherapy-induced peripheral neuropathy. In consideration of the Licensing Agreement, the Company issued shares of common stock and Series A-2 Non-Voting Convertible Preferred Stock to Serpin Pharma and Rejuvenation.

Conversion of Preferred Stock to Common Stock

On November 21, 2025, we held a Special Meeting of our stockholders. At the Special Meeting, our stockholders approved for purposes of complying with the applicable provisions of Nasdaq Listing Rule 5635, the potential issuance of our Common Stock upon the conversion of the Company's Series A Preferred Stock, Series A-1 Preferred Stock, and Series A-2 Preferred Stock. As a result, on November 21, 2025, all outstanding shares of Series A Preferred Stock, Series A-1 Preferred Stock and Series A-2 Preferred Stock converted into Common Stock at a ratio of one preferred stock to 10,000 shares of Common Stock.

Equity Distribution Agreement

On November 28, 2025, the Company entered into an Equity Distribution Agreement (the "Northland Agreement") with Northland Securities, Inc., as sales agent, relating to the issuance and sale from time to time by the Company (the "ATM Program") of shares of the Company's common stock having an aggregate offering price of up to $8,558,712. We have sold shares of Common Stock for gross proceeds of $89,762 pursuant to the Northland Agreement during the fourth quarter of 2025.

Recent Developments

On January 9, 2026, the Company provided notice of its termination, effective January 9, 2026, of the Northland Agreement. The Company is not subject to any termination penalties related to the termination of the Northland Agreement.

Subsequent to year end, on January 11, 2026, 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 2,338,948 shares of its Common Stock (the "Registered Offering"), pursuant to an effective shelf registration statement on Form S-3 (File No. 333-287575). In a concurrent private placement (together with the Registered Offering, the "January 2026 Offering"), the Company agreed to sell (i) unregistered pre-funded warrants to purchase up to 2,047,089 shares of Common Stock (the "Pre-funded Warrants") and (ii) unregistered common stock warrants to purchase up to 4,386,037 shares of Common Stock (the "Common Stock Warrants") at a

combined offering price of $2.85 per share of Common Stock and accompanying Common Stock Warrant and $2.8499 per Pre-funded Warrant and accompanying Common Stock Warrant. The January 2026 Offering closed on January 13, 2026, and the gross proceeds to the Company were approximately $12.5 million. The net proceeds of the January 2026 Offering were approximately $11.4 million after deducting placement agent fees and offering expenses payable by the Company.

On January 15, 2026, the Company filed a Form S-3 Registration Statement for the resale of up to 6,433,126 shares of the Company's Common Stock consisting of (i) 2,047,089 shares of Common Stock underlying the Pre-Funded Warrants at an exercise price of $0.0001 per share; and (ii) 4,386,037 shares of Common Stock underlying the Common Stock Warrants to purchase shares of Common Stock at an exercise price of $3.28 per share. The Form S-3 Registration Statement was declared effective by the SEC on January 29, 2026.

Subsequent to year end, the Company received notification and payment for the exercise of 1,319,089 Pre-Funded Warrants at an exercise price of $0.0001 per share and 1,319,089 shares of Common Stock were issued. As of March 10, 2026, there are 728,000 Pre-Funded Warrants outstanding.

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 2025 included approximately $12.0 million of acquired In-Process Research and Development ("IPR&D") related to the Licensing Agreement with Serpin and approximately $9.8 million on the development of Halneuron® including costs associated with the HAL-CINP-203 clinical trial and development related activities associated with the synthetic manufacture of Halneuron®.

As we advance the HAL-CINP-203 clinical trial, we expect our research and development expenses related to the development of Halneuron® 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® or SP16, if approved, whether alone or in collaboration with others;
- acceptance of our product candidates, 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 a $6.1 million loss on debt conversion with a related party related to the Exchange and Cancellation Agreement with the Lender offset by interest income of $0.1 million earned on cash in a money market account.

Related Parties

The Company uses Gendreau Consulting, LLC, a consulting firm ("Gendreau"), for drug development, clinical trial design and the planning, implementation and execution of contracted activities with the clinical research organization. Gendreau's managing member is the Company's Chief Medical Officer ("CMO"). From time to time, the Company contracts the services of immediate family members of the Company's CMO through Gendreau to perform certain activities in connection with the Company's ongoing clinical development of its product candidates. Such services have included service as the Company's Medical Monitor and currently include service by immediate family members of the CMO as the Company's Chief Safety Officer for the HAL-CINP-203 clinical trial and as an assistant in connection with various clinical site related activities.

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, 2025, the Company has U.S. federal net operating loss carryforwards of approximately $45,410,000, which have an indefinite carryforward and Georgia and Florida state net operating loss carryforwards of approximately $58,689,000 and $1,750,000, respectively, which have a twenty-year carryforward and begin expiring in 2037. As of December 31, 2025, the Company also had Canadian non-capital loss carryforwards of approximately $22,024,000, which have a twenty-year carryforward and begin expiring in 2026 and Hong Kong tax losses carryforwards of approximately $58,026,000, 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.

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 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 and for subsequent annual impairment testing. 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. 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, recent clinical data, 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 years ended December 31, 2025 and 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 its carrying amount may not be recoverable. When conducting our annual

impairment test, we elected to perform a quantitative assessment. As the Company consists of one reporting unit, we compare the estimated fair value of our reporting unit to its carrying value. If the fair value exceeds the carrying value, no further evaluation is required, and no impairment exists. If the carrying amount exceeds the fair value, the difference between the carrying value and the fair value is recorded as an impairment loss, the amount of which may not exceed the total amount of goodwill. We determined the fair value of our reporting unit based upon the quoted market price and related market capitalization of the Company's common stock, adjusted for an estimated control premium. For the years ended December 31, 2025 and 2024, the Company determined that there was no impairment to goodwill.

Redeemable and Convertible Preferred Stock

The Company applies ASC 480, *Distinguishing Liabilities from Equity*, 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' equity (deficit).

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 were comprised of the following:

	Year Ended December 31,	
	2025	2024
Operating expenses:		
Research and development	**$ 21,866,071**	$ 3,530,913
General and administrative	**6,102,374**	8,696,335
Total operating expenses	**$ 27,968,445**	$ 12,227,248
Other expense:		
Loss on debt conversion with related party	**(6,134,120)**	—
Loss on fixed asset disposal	**(2,731)**	—
Interest income (expense), net	**96,938**	(92,192)
Exchange loss, net	**(27,916)**	(30,787)
Total other expense	**(6,067,829)**	(122,979)
Loss before income taxes	**$ (34,036,274)**	$ (12,350,227)

Years Ended December 31, 2025 and 2024

Research and Development Expenses

Research and development expenses increased by $18.3 million to $21.8 million for the year ended December 31, 2025 from $3.5 million for the year ended December 31, 2024. The increase was primarily due to $12.0 million of acquired In-Process Research and Development ("IPR&D") related to the Licensing Agreement with Serpin and the impact of the Combination, including increases in expenses for clinical trials of $6.1 million related to the HAL-CINP-203 study, drug development and manufacturing costs of $0.3 million and salaries and related personnel costs of $0.3 million offset by a decrease in research and preclinical costs of $0.4 million.

General and Administrative Expenses

General and administrative expenses decreased by $2.6 million to $6.1 million for the year ended December 31, 2025 from $8.7 million for the year ended December 31, 2024. This decrease was primarily due to a decrease in nonrecurring transaction costs of $3.9 million related to the Combination with Pharmagesic in October 2024 and a decrease in expenses associated with being a pubic company of $0.2 million offset by increases in salaries and related personnel costs of $0.5 million, legal and professional fees of $0.6 million, franchise tax fees of $0.2 million and other general and administrative costs of $0.2 million.

Other Expense

Other expense increased by $6.0 million to $6.1 million in expense for the year ended December 31, 2025 from $0.1 million in expense for the year ended December 31, 2024. The increase in other expense was primarily due to a $6.1 million loss on debt conversion with a related party related to the Exchange and Cancellation Agreement with the Lender offset by interest income of $0.1 million.

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, 2025, our principal source of liquidity was our cash, which totaled $6.5 million.

Equity Financings

Subsequent to year end, on January 11, 2026, 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 2,338,948 shares of its Common Stock (the "Registered Offering"), pursuant to an effective shelf registration statement on Form S-3 (File No. 333-287575). In a concurrent private placement (together with the Registered Offering, the "January 2026 Offering"), the Company agreed to sell (i) unregistered pre-funded warrants to purchase up to 2,047,089 shares of Common Stock (the "Pre-funded Warrants") and (ii) unregistered common stock warrants to purchase up to 4,386,037 shares of Common Stock (the "Common Stock Warrants") at a combined offering price of $2.85 per share of Common Stock and accompanying Common Stock Warrant and $2.8499 per Pre-funded Warrant and accompanying Common Stock Warrant. The January 2026 Offering closed on January 13, 2026, and the gross proceeds to the Company were approximately $12.5 million. The net proceeds of the January 2026 Offering were approximately $11.4 million after deducting placement agent fees and offering expenses payable by the Company.

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.

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 $1.7 million. The net proceeds of the May 2024 Offering were approximately $1.4 million after deducting placement agent fees and offering expenses payable by the Company.

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 was no debt outstanding at December 31, 2025.

Future Capital Requirements

We anticipate our cash and cash equivalents on hand at December 31, 2025 of approximately $6.5 million, plus the additional net proceeds of approximately $11.4 million received from the January 2026 Offering, will fund operations through the third quarter of 2026. The Company will need to secure additional financing to fund its ongoing clinical trials and operations beyond the third 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,	
	2025	**2024**
Statement of Cash Flows Data:		
Net cash (used in) provided by:		
Operating activities	**$ (15,618,651)**	$ (8,790,805)
Investing activities	**—**	3,761,936
Financing activities	**7,284,806**	16,704,464
Increase (decrease) in cash	**$ (8,333,845)**	$ 11,675,595

Years ended December 31, 2025 and 2024

Operating Activities

For the year ended December 31, 2025, net cash used in operations was $15.7 million and consisted of a net loss of $34.3 million and a net change in operating assets and liabilities of $0.2 million attributable to an increase in prepaid expenses of $0.2 million offset by non-cash items of $11.9 million for non-cash costs related to the Serpin License Agreement, $6.1 million loss on debt conversion with Conjoint, $0.4 million attributable to share-based compensation, $0.2 million related to deferred tax expense and $0.2 million of depreciation, amortization, loss on foreign exchange, reduction in carrying amount of right-of-use asset and loss on fixed asset disposal.

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.

Investing Activities

There were no investing activities for the year ended December 31, 2025. 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.

Financing Activities

Net cash provided by financing activities during the year ended December 31, 2025 was $7.3 million and was attributable to cash proceeds from the Loan Agreement of $3.0 million, cash proceeds from our registered direct offering in March 2025, net of placement agent fees and offering costs, of $4.2 million, and cash proceeds from the sale of Common Stock under the ATM program, net of fees, of $0.1 million.

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.

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.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

This item is not required.

Item 8. Financial Statements and Supplementary Data

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the 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, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, changes in Series A non-voting convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2025 and 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, 2025 and 2024, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2025, 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.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current-period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Critical Audit Matter – Impairment of indefinite-lived assets

As disclosed in Note 2, 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. The projections used in this valuation approach are based upon the relevant market size, the estimated probability of regulatory success rates, anticipated patent protection, expected pricing, expected treated population, and estimated payments. The estimated future net cash flows are then discounted to the present value using an appropriate discount rate.

We identified the quantitative impairment test of intangible assets as a critical audit matter. The principal considerations for that determination included the judgment involved in assessing management's impairment test of intangibles due to the measurement uncertainty involved in determining the fair value of the identified-lived assets, specifically as it relates to evaluating the appropriateness of the model used and the sensitivity to changes in key assumptions such as the relevant market size and estimated probability of regulatory success rates. This required a high degree of auditor effort, including specialized skills and knowledge, and significant auditor judgment.

The primary procedures we performed to address this critical audit matter included:

- We obtained an understanding of management's process for assessing intangible asset impairment testing, including management's process for developing these assumptions used in determining forecasted cash flows.
- We tested the quantitative impairment tests, including management's process for these developing assumptions used in the fair value calculation.
- We evaluated reasonableness of these assumptions based upon industry and published medical data, and actual performance based upon changes in the status of clinical trials.
- With the assistance of our valuation professionals with specialized skills and knowledge, we evaluated the reasonableness of the model and assumption of estimated probability of regulatory success rates in management's fair value calculations.

Critical Audit Matter – The Classification and Valuation of the Convertible Preferred Stock

As disclosed in Notes 2 and 10, 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.

As disclosed in Notes 6 and 10, the Company issued shares of common stock and Series A-2 Non-Voting Convertible Preferred Stock to acquire a Licensing Agreement, which was treated as an asset acquisition and expensed in research and development expense during the year. The fair value assigned to the asset was the fair value of the common stock, preferred stock, and direction transaction costs incurred.

We identified the classification and the valuation of the preferred stock as a critical audit matter. The principal considerations for that determination included the complexity and audit effort required in identifying and evaluating embedded features for the instruments against the criteria for classification, specifically as it relates to evaluating the redemption features and the determination of whether such features meet the criteria for permanent or mezzanine equity presentation. In addition, the valuation of the preferred stock issued included judgment involved in assessing the reasonableness of management's model for determining the fair value. These procedures required a high degree of auditor effort, including specialized skills and knowledge, and significant auditor judgment in evaluating the appropriateness of the model used.

The primary procedures we performed to address this critical audit matter included:

- We obtained an understanding of management's process for identifying and evaluating the critical terms of the preferred stock agreements in determining the classification.
- With the assistance of professionals in our firm that have specialized skills and knowledge in accounting for debt and equity instruments:
    - We evaluated management's analysis and conclusions regarding the relevant provisions and features of the preferred stock and the criteria for classification.
    - We read the preferred stock agreements to identify the relevant features and settlement provisions for our evaluation.
    - We independently evaluated the relevant features and settlement provisions of the preferred stock and assessed the criteria for liability-classification.
- With the assistance of our valuation professionals with specialized skills and knowledge:
- We evaluated the reasonableness of model and assumptions used in management's fair value calculations.

/s/ Forvis Mazars, LLP

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

Atlanta, Georgia
March 18, 2026

DOGWOOD THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS

	2025	2024
Assets		
Current assets:		
Cash and cash equivalents	**$ 6,524,744**	$ 14,847,949
Prepaid expenses and other current assets	**1,906,462**	1,696,513
Total current assets	**8,431,206**	16,544,462
Property and equipment, net	**12,754**	16,811
Right-of-use assets	**163,140**	205,837
Prepaid expenses, long-term	**19,037**	18,133
Goodwill	**12,401,118**	11,812,476
Intangible assets	**68,985,026**	65,710,527
Deferred issuance costs	**158,956**	—
Total assets	**$ 90,171,237**	$ 94,308,246
Liabilities, Series A Non-Voting Convertible Preferred Stock, and Stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	**$ 760,945**	$ 1,231,805
Accrued expenses	**2,241,417**	1,894,835
Lease liability, current portion	**56,841**	49,696
Total current liabilities	**3,059,203**	3,176,336
Debt with related party, net of issuance costs	**—**	15,381,077
Lease liability, long-term portion	**105,763**	154,885
Deferred tax liability	**12,109,404**	11,314,925
Total liabilities	**15,274,370**	30,027,223
Commitments and contingencies (Note 12)		
Series A Non-Voting Convertible Preferred Stock, $0.0001 par value; 2,104 shares authorized and 2,103.1494 shares issued and no shares outstanding at December 31, 2025 and 2,270 shares authorized and 2,213.8044 shares issued and outstanding at December 31, 2024	**—**	74,405,362
Stockholders' equity (deficit):		
Common stock, $0.0001 par value; 43,000,000 shares authorized; 29,751,234 and 29,743,516 shares issued and outstanding at December 31, 2025, respectively; and 1,339,896 and 1,332,178 shares issued and outstanding at December 31, 2024, respectively	**2,974**	133
Series A Non-Voting Convertible Preferred Stock, $0.0001 par value; 166 shares authorized and issued and no shares outstanding at December 31, 2025 and no shares authorized, issued and outstanding at December 31, 2024	**—**	**—**
Series A-1 Non-Voting Convertible Preferred Stock, $0.0001 par value; 285 shares authorized and 284.2638 issued and no shares outstanding at December 31, 2025 and no shares authorized, issued and outstanding at December 31, 2024	**—**	**—**
Series A-2 Non-Voting Convertible Preferred Stock, $0.0001 par value; 190.0572 shares authorized and issued and no shares outstanding at December 31, 2025 and no shares authorized, issued and outstanding at December 31, 2024	**—**	**—**
Preferred stock, $0.0001 par value; 1,997,254 and 1,997,730 shares authorized; no shares issued and outstanding at December 31, 2025 and 2024, respectively	**—**	—
Additional paid-in capital	**183,856,376**	67,856,589
Accumulated deficit	**(108,076,316)**	(73,818,946)
Accumulated other comprehensive loss	**(587,039)**	(3,862,987)
	75,195,995	(9,825,211)
Less: Treasury stock, 7,718 shares of common stock at cost	**(299,128)**	(299,128)
Total stockholders' equity (deficit)	**74,896,867**	(10,124,339)
Total liabilities, Series A Non-Voting Convertible Preferred Stock and stockholders' equity (deficit)	**$ 90,171,237**	$ 94,308,246

See accompanying notes to the consolidated financial statements.

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

	Year Ended	
	December 31, 2025	December 31, 2024
Revenue	**$ —**	$ —
Operating expenses:		
Research and development	**21,866,071**	3,530,913
General and administrative expenses	**6,102,374**	8,696,335
Total operating expenses	**27,968,445**	12,227,248
Loss from operations	**(27,968,445)**	(12,227,248)
Other expense:		
Loss on debt conversion with related party	**(6,134,120)**	—
Loss on fixed asset disposal	**(2,731)**	—
Interest income (expense), net	**96,938**	(92,192)
Exchange loss, net	**(27,916)**	(30,787)
Total other expense	**(6,067,829)**	(122,979)
Loss before income taxes	**(34,036,274)**	(12,350,227)
Deferred income tax (expense) benefit	**(221,096)**	503
Net loss	**(34,257,370)**	(12,349,724)
Accrual of paid-in-kind dividends on Series A Non-Voting Convertible Preferred Stock	**(1,256,662)**	(514,105)
Net loss attributable to common stockholders	**$ (35,514,032)**	$ (12,863,829)
Net loss per common share, basic and diluted	**$ (7.13)**	$ (12.52)
Weighted average number of shares outstanding – basic and diluted	**4,977,446**	1,027,788
Comprehensive loss		
Net loss	**$ (34,257,370)**	$ (12,349,724)
Foreign currency translation adjustment	**3,275,948**	(3,862,987)
Comprehensive loss	**$ (30,981,422)**	$ (16,212,711)

See accompanying notes to the consolidated financial statements.

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

	Series A Non-Voting Convertible Preferred Stock		Series A Non-Voting Convertible Preferred Stock		Series A-1 Non-Voting Convertible Preferred Stock		Series A-2 Non-Voting Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Treasury Stock	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Par					
Balance, December 31, 2023	—	$ —	—	$ —	—	$ —	—	$ —	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)
Conversion of loan payable plus interest into Series A-1 Non-Voting Convertible Preferred Stock	—	—	—	—	284.2638	24,994,461	—	—	—	—	—	—	—	—	24,994,461
Proceeds from registered direct offering of common stock, net of offering costs	—	—	—	—	—	—	—	—	578,950	58	4,252,187	—	—	—	4,252,245
Accrual of paid-in-kind dividends on Series A Non-Voting Convertible Preferred Stock	—	1,256,662	—	—	—	—	—	—	—	—	(1,256,662)	—	—	—	(1,256,662)
Issuance of paid-in-kind dividends on Series A Non-Voting Convertible Preferred Stock	55.3450	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Issuance of stock in connection with the License Agreement with Serpin	—	—	—	—	—	—	179.1878	9,240,328	382,034	38	2,108,790	—	—	—	11,349,156
License Agreement transaction costs paid through the issuance of stock	—	—	—	—	—	—	10.8694	560,511	—	—	—	—	—	—	560,511
Tungsten waiver of Series A Non-Voting Convertible Preferred Stock	(16.0000)	(533,500)	16.0000	533,500	—	—	—	—	—	—	—	—	—	—	533,500
Sealbond waiver of Series A Non-Voting Convertible Preferred Stock	(150.0000)	(5,001,567)	150.0000	5,001,567	—	—	—	—	—	—	—	—	—	—	5,001,567
Conversion of preferred stock into common stock	(2,103.1494)	(70,126,957)	(166.0000)	(5,535,067)	(284.2638)	(24,994,461)	(190.0572)	(9,800,839)	27,434,704	2,743	110,454,581	—	—	—	70,126,957
Proceeds from issuance of shares on ATM, net of fees	—	—	—	—	—	—	—	—	15,650	2	85,249	—	—	—	85,251
Share-based compensation expense	—	—	—	—	—	—	—	—	—	—	355,642	—	—	—	355,642
Net Loss	—	—	—	—	—	—	—	—	—	—	—	(34,257,370)	—	—	(34,257,370)
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	—	—	—	3,275,948	—	3,275,948
Balance, December 31, 2025	—	$ —	—	$ —	—	$ —	—	$ —	29,743,516	$2,974	$ 183,856,376	$(108,076,316)	$ (587,039)	$(299,128)	$ 74,896,867

See accompanying notes to the consolidated financial statements.

DOGWOOD THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2025	**2024**
Cash flows from operating activities		
Net loss	**$ (34,257,370)**	$ (12,349,724)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on foreign exchange	**27,916**	30,787
Loss on fixed asset disposal	**2,731**	—
Amortization of loan costs	**52,373**	58,432
Depreciation	**2,063**	12,177
Reduction in carrying amount of right-of-use asset	**66,115**	—
Loss on debt conversion with related party	**6,134,120**	—
Acquisition of license for research and development	**11,909,667**	—
Non-cash transaction costs	**—**	3,563,273
Deferred tax expense (benefit)	**221,096**	(503)
Share-based compensation expense	**355,642**	476,021
Changes in operating assets and liabilities:		
Increase in prepaid expenses and other current assets	**(208,687)**	(498,717)
(Decrease) increase in accounts payable	**(532,607)**	219,888
Increase (decrease) in accrued expenses and other liabilities	**608,290**	(302,439)
Net cash used in operating activities	**(15,618,651)**	(8,790,805)
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	**4,252,245**	1,382,170
Proceeds from loan with related party, net of fees	**3,000,000**	15,322,645
Payout of fractional shares with reverse stock split	**—**	(351)
Proceeds from issuance of shares on ATM, net of cash fees paid	**86,366**	—
Cash payment of issuance costs	**(53,805)**	—
Net cash provided by financing activities	**7,284,806**	16,704,464
Net (decrease) increase in cash	**(8,333,845)**	11,675,595
Cash and cash equivalents, beginning of period	**14,847,949**	3,316,946
Effect of foreign currency translation on cash and cash equivalents	**10,640**	(144,592)
Cash and cash equivalents, end of period	**$ 6,524,744**	$ 14,847,949
Supplemental disclosure of non-cash financing and investing activities:		
Issuance costs included in accounts payable and accrued expenses	**$ 106,266**	$ —
Conversion of debt with related party into Series A-1 Non-Voting Convertible Preferred Stock	**$ 19,500,000**	$ —
Conversion of accrued interest on debt with related party into Series A-1 Non-Voting Convertible Preferred Stock	**$ 426,891**	$ —
Conversion of Series A Non-Voting Convertible Preferred Stock from temporary equity to permanent equity	**$ 5,535,067**	$ —
Accrual of paid-in-kind dividends on Series A Non-Voting Convertible Preferred Stock	**$ 1,256,662**	$ 514,105
Preferred stock issued in connection with License Agreement	**$ 9,800,839**	$ —
Common stock issued in connection with License Agreement	**$ 2,108,828**	$ —
Conversion of preferred stock into common stock	**$ 110,457,324**	$ —
Preferred stock issued in connection with acquisition of Pharmagesic	**$ —**	$ 70,372,634
Common stock issued in connection with acquisition of Pharmagesic	**$ —**	$ 893,093

See accompanying notes to the consolidated financial statements.

DOGWOOD THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Background and Organization

Dogwood Therapeutics, Inc. (the "Company"), formerly known as Virios Therapeutics, Inc., 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. Prior to the business combination, Pharmagesic was a wholly-owned subsidiary of Sealbond Limited 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.

The Company operates in one segment and is a pre-revenue, development-stage biopharmaceutical company focused on developing new medicines to treat pain and peripheral neuropathy associated with cancer. The Company's drug candidates include Halneuron® and SP16. Halneuron® is a voltage gated sodium channel inhibitor (Nav 1.7 modulation) presently in Phase 2b development to treat the chronic pain resulting from cancer chemotherapy ("CINP"), with potential to expand into non-neuropathic cancer pain and acute post-surgical pain. Halneuron® has demonstrated effectiveness in reducing both cancer related pain, as well as CINP in prior phase 2 clinical. The Halneuron® Phase 2b CINP study ("HAL-CINP-203") commenced in the first quarter of 2025. Interim data from HAL-CINP-203 was released in December 2025 and top-line results are expected during the third quarter of 2026. SP16 is a proprietary peptide drug that exhibits immunomodulatory and anti-inflammatory properties and is expected to enter Phase 1 development to treat peripheral neuropathy resulting from cancer chemotherapy ("CIPN"). The neurotrophic effects of SP16 as demonstrated in preclinical research shows potential neuroprotective effects by activating neurite survival and growth in the presence of paclitaxel, highlighting potential to preserve a patient's full chemotherapy regimen.

Additionally, our pipeline includes IMC-1, a novel, proprietary, fixed dose combination of a nucleoside analog and the anti-inflammatory agent celecoxib for the treatment of fibromyalgia.

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, 2025 and 2024, the Company incurred consolidated net losses of $34,257,370 and $12,349,724, respectively, and had consolidated net cash outflows used in operating activities for the years ended December 31, 2025 and 2024 of $15,618,651 and $8,790,805, respectively. As of December 31, 2025, the Company had a consolidated accumulated deficit of $108,076,316 and is expected to incur losses in the future as it continues its development activities.

Subsequent to year end, on January 11, 2026, 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 2,338,948 shares of its Common Stock (the "Registered Offering"), pursuant to an effective shelf registration statement on Form S-3 (File No. 333-287575). In a concurrent private placement (together with the Registered Offering, the "January 2026 Offering"), the Company agreed to sell (i) unregistered pre-funded warrants to purchase up to 2,047,089 shares of Common Stock (the "Pre-funded Warrants") and (ii) unregistered common

stock warrants to purchase up to 4,386,037 shares of Common Stock (the "Common Stock Warrants") at a combined offering price of $2.85 per share of Common Stock and accompanying Common Stock Warrant and $2.8499 per Pre-funded Warrant and accompanying Common Stock Warrant. The January 2026 Offering closed on January 13, 2026, and the gross proceeds to the Company were approximately $12.5 million. The net proceeds of the January 2026 Offering were approximately $11.4 million after deducting placement agent fees and offering expenses payable by the Company.

Management anticipates the cash and cash equivalents on hand at December 31, 2025 of approximately $6.5 million plus the additional net proceeds of approximately $11.4 million received from the January 2026 Offering, will fund operations through the third quarter of 2026. The Company will need to secure additional financing to fund its ongoing clinical trials and operations beyond the third 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 continue 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. 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, the estimated fair value of the net assets acquired in connection with the business combination of Pharmagesic, including impairment of In-Process Research and Development and discount for lack of marketability, the estimated fair value of the contingent value rights ("CVRs") given to common stockholders at the time of the business combination and recurring reporting period assessments, impairment considerations of intangible assets, the fair value of the preferred stock modification, and the fair value of the consideration provided in connection with the license agreement with Serpin Pharma. 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, 2025 and 2024:

	Year Ended	
	December 31, 2025	December 31, 2024
Operating expenses:		
Acquired in-process research and development	**$ 12,030,389**	$ —
Clinical	**7,251,179**	1,153,345
Chemical, manufacturing and controls	**1,027,799**	710,055
Research and preclinical	**58,198**	505,750
Regulatory	**43,477**	20,065
Other research and development costs	**1,455,029**	1,141,698
Total research and development	**21,866,071**	3,530,913
General and administrative expenses	**6,102,374**	8,696,335
Total operating expenses	**$ 27,968,445**	$ 12,227,248
Loss on debt conversion with related party	**6,134,120**	—
Interest (income) expense, net	**(96,938)**	92,192
Loss on fixed asset disposal	**2,731**	—
Exchange loss, net	**27,916**	30,787
Net loss before income taxes	**$ 34,036,274**	$ 12,350,227

Concentrations of Credit Risk

Cash and cash equivalents are 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 and cash equivalents are 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 and cash equivalents, accounts payable and accrued expenses approximate their fair values. The Company determined that the fair value of the CVRs were immaterial on the date of issuance as well as at December 31, 2025 and

December 31, 2024, as there were no imminent transactions to indicate value. The fair values of the Company's debt at December 31, 2024 were estimated using market rates the Company believes would be available for similar types of financial instruments and represent level 2 measurements. See Note 9 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. If determined to be an asset acquisition, the Company accounts for the transaction in accordance with ASC 805, *Business Combinations*, and ASC Subtopic 730-10, *Research and Development*. If the assets acquired are in-process research and development assets that are to be used in a particular research and development project and have no alternative future use, under ASC Subtopic, 730-10, *Research and Development*, these costs along with direct transaction costs are expensed immediately.

Cash and Cash Equivalents

Cash and cash equivalents are maintained in bank deposit accounts and money market funds that are readily convertible into cash, which exceed the federally insured limits of $250,000.

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 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 and for subsequent annual impairment testing. 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. 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, recent clinical data, 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 years ended December 31, 2025 and 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 its carrying amount may not be recoverable. When conducting our annual impairment test, we elected to perform a quantitative assessment. As the Company consists of one reporting unit, the Company compares the estimated fair value of our reporting unit to its carrying value. If the fair value exceeds the carrying value, no further evaluation is required, and no impairment exists. If the carrying amount exceeds the fair value, the difference between the carrying value and the fair value is recorded as an impairment loss, the amount of which may not exceed the total amount of goodwill. The Company determined the fair value of the reporting unit based upon the quoted market price and related market capitalization of the Company's common stock, adjusted for an estimated control premium. For the years ended December 31, 2025 and 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 the Company's lease does not provide an implicit rate, the Company uses its incremental borrowing rate, which is the rate 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, 2025 and 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, *Distinguishing Liabilities from Equity*, 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' equity (deficit). 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* ("ASC 740"). 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 has tax expense of $221,096 and a tax benefit of $503 as of December 31, 2025 and 2024, respectively, and does not have any material unrecognized tax benefits or obligations as of December 31, 2025 and 2024. 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 that entitle the holder to participate in dividends and earnings of the Company. In addition, the Company analyzes the potential dilutive effect of outstanding participating securities 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 participating securities have no obligation to fund losses.

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, 2025 and 2024, the Company had options to purchase 1,117,278 and 92,777 shares of Common Stock, respectively, warrants to purchase 855 and 7,755 shares of Common Stock, respectively, and preferred stock which was convertible into 0 and 22,138,044 shares of Common Stock, respectively, 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.

Recently Adopted Accounting Standards

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. The guidance is to be applied on either a prospective or a retrospective basis to annual financial statements for periods beginning after the effective date. The Company adopted ASU 2023-09 on a prospective basis for the fiscal year ended December 31, 2025. See added disclosures in Note 14.

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 November 2024, the FASB issued ASU 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which improves disclosures about an entity's expenses and addresses requests from investors for more detailed information about types of expenses including purchases of inventory, employee compensation, depreciation, amortization, and depletion, commonly presented in cost of sales, research and development and general and administrative expenses. In January 2025, the FASB issued ASU 2025-01 which revises the effective date of ASU 2024-03. Adoption of these new disclosure requirements are effective for public entities for annual reporting periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027 and early adoption is permitted. The Company is currently evaluating the impact of this ASU on its consolidated financial statements.

In May 2025, the FASB issued ASU 2025-03, *Business Combinations (Topic 805) and Consolidation (Topic 810): Determining the Accounting Acquirer in the Acquisition of a Variable Interest Entity*, to improve the requirements for identifying the accounting acquirer in Topic 805, *Business Combinations*. The amendments in ASU 2025-03 revise current guidance for determining the accounting acquirer for a transaction effected primarily by exchanging equity interests in which the legal acquiree is a variable interest entity ("VIE") that meets the definition of a business. The amendments require that an entity consider the same factors that are currently required for determining which entity is the accounting acquirer in other acquisition transactions. Entities will be required to apply the new guidance prospectively to any acquisition transaction that occurs after the initial application date. Adoption of this guidance is effective for all entities for annual reporting periods beginning after December 15, 2026, and interim reporting periods within those annual reporting periods and early adoption is permitted as of the beginning of an interim or annual reporting period. The Company is currently evaluating the impact of this ASU on its consolidated financial statements.

Subsequent Events

On January 9, 2026, the Company provided notice of its termination, effective January 9, 2026, of the Northland Agreement. The Company is not subject to any termination penalties related to the termination of the Northland Agreement.

Subsequent to year end, on January 11, 2026, 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 2,338,948 shares of its Common Stock (the "Registered Offering"), pursuant to an effective shelf registration statement on Form S-3 (File No. 333-287575). In a concurrent private placement (together with the Registered Offering, the "January 2026 Offering"), the Company agreed to sell (i) unregistered pre-funded warrants to purchase up to 2,047,089 shares of Common Stock (the "Pre-funded Warrants") and (ii) unregistered common stock warrants to purchase up to 4,386,037 shares of Common Stock (the "Common Stock Warrants") at a combined offering price of $2.85 per share of Common Stock and accompanying Common Stock Warrant and $2.8499 per Pre-funded Warrant and accompanying Common Stock Warrant. The January 2026 Offering closed on January 13, 2026, and the gross proceeds to the Company were approximately $12.5 million. The net proceeds of the January 2026 Offering were approximately $11.4 million after deducting placement agent fees and offering expenses payable by the Company.

On January 15, 2026 the Company filed a Form S-3 Registration Statement for the resale of up to 6,433,126 shares of the Company's Common Stock consisting of (i) 2,047,089 shares of Common Stock underlying the Pre-Funded Warrants at an exercise price of $0.0001 per share; and (ii) 4,386,037 shares of Common Stock underlying the Common Stock Warrants to purchase shares of Common Stock at an exercise price of $3.28 per share. The Form S-3 Registration Statement was declared effective on January 29, 2026.

Subsequent to year end, the Company received notification and payment for the exercise of 1,319,089 Pre-Funded Warrants at an exercise price of $0.0001 per share and 1,319,089 shares of Common Stock were issued. As of March 10, 2026, there are 728,000 Pre-Funded Warrants outstanding.

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"). At a special meeting of stockholders on November 21, 2025, the Meeting Proposals were approved.

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, 2025 and 2024.

	Combination Date Fair Value	Impairment	Translation Adj	Carrying Value as of December 31, 2024	Impairment	Translation Adj	Carrying Value as of December 31, 2025
Halneuron® for Cancer Related Pain	$ 59,900,000	$ —	$ (3,266,035)	$ 56,633,965	$ —	$ 2,822,194	$ 59,456,159
Halneuron® for Chemotherapy Induced Neuropathic Pain	9,600,000	—	(523,438)	9,076,562	—	452,305	9,528,867
Total in-process research and development (IPR&D)	$ 69,500,000	$ —	$ (3,789,473)	$ 65,710,527	$ —	$ 3,274,499	$ 68,985,026
Goodwill	$ 12,493,727	$ —	$ (681,251)	$ 11,812,476	$ —	$ 588,642	$ 12,401,118

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, 2024. 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
Net revenues	$ —
Net loss before taxes	$ (19,649)

Nonrecurring pro forma transaction costs directly attributable to the Combination were $4.9 million for the year ended December 31, 2024. 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, 2025	December 31, 2024
Prepaid insurance	$ 512,523	$ 667,257
Prepaid clinical research costs	1,153,417	835,603
Prepaid franchise taxes	161,400	—
Prepaid travel	1,394	96,749
Prepaid accounting fees	40,563	55,525
Prepaid services	32,289	13,373
Other miscellaneous current assets	4,876	28,006
	1,906,462	1,696,513
Long-term		
Security deposit on leased premises	19,037	18,133
	$ 1,925,499	$ 1,714,646

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. Net property and equipment at cost consist of the following:

	December 31, 2025	December 31, 2024
Computer equipment	$ —	$ 5,952
Office furniture and equipment	12,754	12,435
Total property and equipment, at cost	12,754	18,387
Less: Accumulated depreciation and amortization	—	(1,576)
Property and equipment, net	$ 12,754	$ 16,811

6. License Agreements

On September 29, 2025, the Company entered into an Exclusive Licensing Agreement (the “Licensing Agreement”) with Serpin Pharma Inc. (“Serpin Pharma”) and Rejuvenation Labs, Inc. (“Rejuvenation” and, together with Serpin Pharma, “Serpin”), pursuant to which Serpin granted the Company a royalty-free, sublicensable global license to develop Serpin Pharma’s intravenous formulation of SP16. SP16 is a first-in-class low density lipoprotein receptor-related protein-1 (LRP1) agonist which has demonstrated both anti-inflammatory, immunomodulatory and neural repair activity that has the potential to treat chemotherapy-induced peripheral neuropathy. In consideration of the Licensing Agreement, the Company issued shares of common

stock and Series A-2 Non-Voting Convertible Preferred Stock to Serpin Pharma and Rejuvenation. The Licensing Agreement was treated as an asset acquisition and expensed in research and development expense during the current period as acquired IPR&D. Consideration paid is comprised of the estimated fair value of various securities issued including the Series A-2 Preferred Stock and Common Stock issued to Serpin Pharma and Rejuvenation. See Note 10 – "Stockholders' Equity."

The fair value of the consideration totaled approximately $12.0 million, summarized as follows:

Fair value of common stock issued	$ 2,108,828
Fair value of preferred stock issued	9,800,839
Direct transaction costs	120,722
Total consideration paid	$ 12,030,389

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, 2025	December 31, 2024
Accrued interest on preferred members' interests and related party loan	**$ 188,085**	$ 417,539
Accrued compensation	**745,080**	737,281
Accrued clinical research costs	**889,066**	611,741
Accrued professional fees	**360,733**	97,093
Accrued director fees	**32,209**	30,054
Other miscellaneous accrued expenses	**26,244**	1,127
	$ 2,241,417	$ 1,894,835

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 $19,037 as of December 31, 2025.

There were no additions or extensions to the right-of-use asset during the year ended December 31, 2025 or during the period from the Combination date to December 31, 2024. Total cash outflows for the lease were $121,351 for the year ended December 31, 2025 and were $31,939 for the period from the Combination date to December 31, 2024. 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 years ended December 31, 2025 and 2024:

Component of lease cost	Year Ended December 31, 2025	December 31, 2024
Operating lease cost	**$ 66,115**	$ 17,772
Variable lease cost	**50,727**	14,167
Total lease expense	**$ 116,842**	$ 31,939

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

Year ending December 31:	
2026	$ 67,062
2027	68,252
2028	43,915
Total lease payments	179,229
Less: amount representing interest	(16,625)
Present value of net minimum lease payments	$ 162,604
Less: current obligations	(56,841)
Long-term obligations under leases	$ 105,763

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

	2025	2024
Cash paid for amounts included in the measurement of lease liabilities	**$ 121,351**	$ 31,939
Weighted-average remaining lease term (in years) - operating leases	**2.7**	3.7
Weighted-average discount rate - operating leases	**7.82%**	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 were to be used for the purpose of (1) funding operations and (2) performing clinical and research & development activities related to Halneuron®. The Loan Agreement bore 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 was 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 were being amortized to interest expense using an effective interest rate of 7.82%. For the year ended December 31, 2025, the Company recognized interest expense of $197,437 and amortization of issuance costs of $52,373 in the accompanying consolidated statement of operations and comprehensive loss. 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 statements of operations.

On March 12, 2025, the Company 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 (as of such date, an aggregate of $19,926,891), 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 "Series A-1 Preferred Stock"), based on a price per underlying share of common stock

of $7.01. The price was determined by reference to the average Nasdaq Official Closing Price of the Company's common stock for the five trading days immediately prior to the signing of the Exchange and Cancellation Agreement. Each share of Series A-1 Preferred Stock was convertible into 10,000 shares of common stock, subject to certain conditions set forth in the Series A-1 Preferred Stock Certificate of Designation ("Series A-1 Certificate of Designation"), as discussed below.

The Company evaluated the transaction in accordance with ASC 470-50-40, *Debt Modifications and Extinguishment*. As such, the Company recognized a loss on the debt extinguishment of $6,134,120 that was charged to other expense in the accompanying consolidated statements of operations and comprehensive income for the year ended December 31, 2025. The loss was determined by the difference between the closing price of the Company's common stock of $11.13 on the transaction date to the price per share used to determine the conversion price of the debt, discounted for lack of marketability.

As of December 31, 2024, 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 was approximately $15.7 million.

There were no outstanding promissory notes as of December 31, 2025.

10. Stockholders' Equity (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.

After giving effect to the designation of Series A Preferred Stock, Series A-1 Preferred Stock and Series A-2 Preferred Stock discussed below, the Company had 1,997,254 and 1,997,730 authorized and remaining to be issued shares of preferred stock at December 31, 2025 and 2024, respectively.

Series A Preferred Stock

In October 2024, the Board of Directors designated 2,270 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, 2025, the Company had 2,270 authorized and 2,269.1494 issued and no shares outstanding of Series A Preferred Stock and as of December 31, 2024, the Company had 2,270 authorized and 2,213.8044 issued and outstanding shares of Series A Preferred Stock.

Following stockholder approval of the Conversion Proposal at a special meeting of stockholders held on November 21, 2025, each share of Series A Preferred Stock automatically converted into 10,000 shares of Common Stock. In accordance with ASC 805-50-25-4, the Company has the option to apply pushdown accounting to its financial statements related to the conversion of the Series A Preferred Stock but does not believe that such an election would be meaningful or informative to readers of the financial statements. The original issuance of the Series A Preferred Stock has been disclosed since the transaction was completed, including disclosures related to its expected conversion to shares of Common Stock at a future special meeting of stockholders, and the conversion followed the original terms of the Exchange Agreement. Accordingly, the conversion was treated as an exchange of securities by an investor with the conversion completed at the carrying amount of the Series A Preferred Stock.

Except as otherwise required by law, the Series A Preferred Stock did not have voting rights. However, as long as any shares of Series A Preferred Stock were outstanding, the Company could 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 ranked on parity with the Common Stock as to distributions of assets upon liquidation, dissolution or winding-up of the Company, whether voluntarily or involuntarily. The Series A Preferred Stock were entitled to receive on an as-converted basis dividends equal to and in the same form, and in the same manner, as dividends paid to shares of Common Stock. If, prior to conversion of the Series A Preferred Stock into Common Stock, the Company effected any Fundamental Transaction (as defined in the Series A Certificate of Designation) then upon conversion of the Series A Preferred Stock, the holders of the Series A Preferred Stock would have been entitled to receive, in lieu of shares of Common Stock, the consideration that would have been issuable upon such Common Stock had the conversion occurred prior to such Fundamental Transaction.

In accordance with ASC 480-10-S99-3A, the Company had classified the Series A Preferred Stock outside of permanent equity, in the mezzanine section of the consolidated balance sheet. In addition, this guidance requires that redeemable equity securities be accreted to their redemption value if it becomes probable that the security will become redeemable. The guidance further clarifies that accretion is required when redemption is likely to occur, and that the assessment of probability should be updated at each reporting period. The term “probable” is defined in ASC 450, *Contingencies*, subparagraph 450-20-20 as “the future event or events are likely to occur.” With this framework in mind, the Company has evaluated each conditional repurchase (as described below under “Form of Repurchase Agreement and Modification”) and redemption right embedded in the Series A Preferred Stock to determine whether exercise of any right is probable for purposes of accretion to redemption value. Based on the facts and circumstances, none of the conditional repurchase or redemption rights were considered probable prior to the conversion of the Series A Preferred Stock and there has been no accretion to redemption value included in the consolidated financial statements.

Per the Series A Certificate of Designation, holders of Series A Preferred Stock were entitled to receive a PIK dividend accruing at a rate equal to five percent (5.0%) per annum payable in shares of Series A Preferred Stock on the date that was 180 days after the original issue date of the Series A Preferred Stock. As of March 31, 2025, the Company had accrued the full value of the dividend payable of $1,770,767. On April 7, 2025, 180 days after the original issue date, the Company issued an aggregate of 55.345 shares of Series A Preferred stock as a PIK dividend to the holders of Series A Preferred Stock.

Form of Repurchase Agreement and Modifications

The terms of the Exchange Agreement provides that Sealbond had 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.

In September 2025, holders of certain Series A Preferred Stock irrevocably waived the cash settlement and related repurchase rights for 166 shares of Series A Preferred Stock. As such, the Company reclassified approximately $5.5 million and 166 shares from temporary equity to permanent equity as the shares no longer qualified for temporary equity classification under ASC 480-10-S99-3A. In addition, the Company considered under ASC 470, *Debt*, whether or not the Series A Preferred Stock underlying the waivers should be treated as a modification or as an extinguishment for financial reporting purposes. The Company used the fair value method and determined that the fair value of the Series A Preferred Stock before the waiver was not significantly different (e.g. less than 10%) than the fair value of the Series A Preferred Stock immediately after the waiver and thus the waiver was considered a modification. Accordingly, there was no impact to net income or earnings per share, and any directly related fees were expensed as incurred.

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 evaluates the fair value of the CVRs at each reporting period or whenever facts and circumstances indicate that their carrying amounts may have changed. The Company determined that the fair value of the CVRs were immaterial as of December 31, 2025 and 2024.

Series A-1 Preferred Stock

In March 2025, the Board of Directors designated 285 shares of the preferred stock to be Series A-1 Preferred Stock. As of December 31, 2025, the Company had 285 shares authorized, 284.2638 shares issued and no shares outstanding of Series A-1 Preferred Stock. There were no authorized, issued and outstanding shares of Series A-1 Preferred stock at December 31, 2024.

Following stockholder approval at a special meeting of stockholders held on November 21, 2025, each share of Series A-1 Preferred Stock automatically converted into 10,000 shares of Common Stock. The

conversion was treated as an exchange of securities by an investor with the conversion completed at the carrying amount of the Series A-1 Preferred Stock.

The Series A-1 Preferred Stock ranked on parity with the Common Stock as to distributions of assets upon liquidation, dissolution or winding-up of the Company, whether voluntarily or involuntarily. The Series A-1 Preferred Stock were entitled to receive on an as-converted basis dividends equal to and in the same form, and in the same manner, as dividends paid to shares of Common Stock. If, prior to conversion of the Series A Preferred Stock into Common Stock, the Company effects any Fundamental Transaction (as defined in the Series A-1 Certificate of Designation) then upon conversion of the Series A-1 Preferred Stock, the holders of the Series A-1 Preferred Stock shall be entitled to receive, in lieu of shares of Common Stock, the consideration that would have been issuable upon such Common Stock had the conversion occurred prior to such Fundamental Transaction.

Except as otherwise required by law, the Series A-1 Preferred Stock did not have voting rights. However, as long as any shares of Series A-1 Preferred Stock were outstanding, the Company could not, without the affirmative vote of the holders of a majority of the then-outstanding shares of the Series A-1 Preferred Stock, (i) alter or change adversely the powers, preferences or rights given to the Series A-1 Preferred Stock or alter or amend the Series A-1 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-1 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-1 Preferred Stock, or increase or decrease (other than by conversion) the number of authorized shares of Series A-1 Preferred Stock, (iii) prior to the Stockholder Approval (as defined in the Series A-1 Certificate of Designation) or at any time while at least 30% of the originally issued Series A-1 Preferred Stock remains issued and outstanding, consummate either: (A) any Fundamental Transaction (as defined in the Series A-1 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.

Series A-2 Preferred Stock

In September 2025, the Board of Directors designated 190.0572 shares of the preferred stock to be Series A-2 Preferred Stock. As of December 31, 2025, the Company has 190.0572 shares authorized and issued and no shares outstanding of Series A-2 Preferred Stock. There were no authorized, issued and outstanding shares of Series A-2 Preferred stock at December 31, 2024.

Following stockholder approval at a special meeting of stockholders held on November 21, 2025, each share of Series A-2 Preferred Stock automatically converted into 10,000 shares of Common Stock. The conversion was treated as an exchange of securities by an investor with the conversion completed at the carrying amount of the Series A-2 Preferred Stock.

The Series A-2 Preferred Stock ranked on parity with the Common Stock as to distributions of assets upon liquidation, dissolution or winding-up of the Company, whether voluntarily or involuntarily. The Series A-2 Preferred Stock were entitled to receive on an as-converted basis dividends equal to and in the same form, and in the same manner, as dividends paid to shares of Common Stock. If, prior to conversion of the Series A-2 Preferred Stock into Common Stock, the Company effects any Fundamental Transaction (as defined in the Series A-2 Certificate of Designation) then upon conversion of the Series A-2 Preferred Stock, the holders of the Series A-2 Preferred Stock shall be entitled to receive, in lieu of shares of Common Stock, the consideration that would have been issuable upon such Common Stock had the conversion occurred prior to such Fundamental Transaction.

Except as otherwise required by law, the Series A-2 Preferred Stock did not have voting rights. However, as long as any shares of Series A-2 Preferred Stock were outstanding, the Company could not, without the affirmative vote of the holders of a majority of the then-outstanding shares of the Series A-2 Preferred Stock, (i) alter or change adversely the powers, preferences or rights given to the Series A-2 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-2 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-2 Preferred Stock, or increase or decrease (other than by conversion) the number of authorized shares of Series A-2 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-2 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.

On September 29, 2025, in consideration of the Licensing Agreement with Serpin, pursuant to which Serpin granted the Company a royalty-free, sublicensable global license to develop Serpin Pharma's intravenous formulation of SP16, the Company issued 191,017 shares of common stock, par value $0.0001 per share ("Common Stock") and 89.5939 shares of Series A-2 Non-Voting Convertible Preferred Stock, par value $0.0001 per share ("Series A-2 Preferred Stock") to Serpin Pharma and (ii) 191,017 shares of Common Stock and 89.5939 shares of Series A-2 Preferred Stock to Rejuvenation, as further described under "Serpin Equity Issuance and Registration Rights Agreement" below.

Tungsten Advisors (through its Broker-Dealer, Finalis Securities LLC) (together with its affiliates, "Tungsten") acted as the financial advisor to the Company in connection with the License Agreement. As compensation for services rendered by Tungsten, the Company issued to Tungsten and its affiliates and designees an aggregate of 10.8694 shares of Series A-2 Preferred Stock.

Serpin Equity Issuance and Registration Rights Agreement

On September 29, 2025, in connection with the Licensing Agreement, the Company also entered into an Equity Issuance and Registration Rights Agreement (the "Serpin Registration Rights Agreement") with Serpin.

Pursuant to the Serpin Registration Rights Agreement, the Company filed a Form S-3 registration statement registering the shares issued under the Serpin Registration Rights Agreement. The registration statement became effective on November 5, 2025. The Company also granted Serpin customary demand registration and indemnification rights and entered into customary issuer covenants.

Support Agreements

On September 29, 2025, in connection with the execution of the Licensing Agreement and the Serpin Registration Rights Agreement, the Company entered into stockholder support agreements with (i) Serpin Pharma and Rejuvenation Labs, Inc. (the "Serpin Support Agreement") and (ii) each affiliate of Tungsten holding shares of Common Stock (the "Tungsten Support Agreements"). Pursuant to the Serpin Support Agreement, among other things, each Serpin party agreed to vote or cause to be voted all of the shares of Common Stock owned by each of them in favor of the approval of the following matters: (i) for the purposes of complying with the applicable provisions of Nasdaq Listing Rule 5635 ("Rule 5635"), the potential issuance of our Common Stock upon conversion of the Series A Non-Voting Convertible Preferred Stock ("Series A Preferred Stock"), par value $0.0001 per share ("Series A Issuance Proposal"), (ii) for the purposes of complying with the applicable provisions of Rule 5635, the potential issuance of our Common Stock upon conversion of

the Series A-1 Non-Voting Convertible Preferred Stock ("Series A-1 Preferred Stock"), par value $0.0001 per share (the "Series A-1 Issuance Proposal"), and (iii) the adjournment of the stockholder meeting where the foregoing proposals are being voted upon to a later date or dates, if necessary or appropriate ("Adjournment Proposal"). Pursuant to the Tungsten Support Agreements, among other things, Tungsten agreed to vote or cause to be voted all of the shares of Common Stock owned by each of them in favor of the approval of the following matters: (i) the Series A-1 Issuance Proposal, (ii) for the purposes of complying with the applicable provisions of Rule 5635, the potential issuance of our Common Stock upon conversion of the Series A-2 Preferred Stock (the "Series A-2 Issuance Proposal"), (iii) if an amendment and restatement of the Company's current Amended and Restated 2020 Equity Incentive Plan is contemplated ("Plan Proposal") at the stockholder meeting where the foregoing proposals are being voted upon, such Plan Proposal and (iv) the Adjournment Proposal.

On September 29, 2025, the Company also entered into a support agreement with Sealbond Limited (the "Sealbond Support Agreement") whereby Sealbond Limited agreed to, among other things, vote or cause to be voted all of the shares of Common Stock owned by Sealbond Limited and its affiliates in favor of the approval of the matters contemplated by the Series A-1 Issuance Proposal, the Series A-2 Issuance Proposal, the Plan Proposal, and the Adjournment Proposal.

Common Stock

The Company's certificate of incorporation, adopted on December 16, 2020, and subsequently amended, authorizes the issuance of 43,000,000 shares of Common Stock with a par value of $0.0001 per share.

As of December 31, 2025, the Company had 43,000,000 shares of common stock authorized, of which 13,248,766 shares of common stock are available for future issuance and not otherwise reserved.

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.

Registered Direct Offering

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 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.

Equity Distribution Agreement

On November 28, 2025, the Company entered into an Equity Distribution Agreement (the "Northland Agreement") with Northland Securities, Inc., as sales agent, relating to the issuance and sale from time to time by the Company (the "ATM Program") of shares of the Company's common stock having an aggregate offering price of up to $8,558,712. We have sold shares of Common Stock for gross proceeds of $89,762 pursuant to the Northland Agreement during the fourth quarter of 2025.

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 $1.7 million. The net proceeds of the May 2024 Offering were $1.4 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"). From time to time, the Company contracts the services of the CMO's spouse through Gendreau to perform certain activities in connection with the Company's ongoing clinical development of its product candidates. In the past, the Company has contracted the CMO's spouse to serve as the Company's Medical Monitor. Currently, the Company has contracted the services of the CMO's spouse to serve as the Company's Chief Safety Officer for the HAL-CINP-203 clinical trial. In addition, the Company has contracted the services of the CMO's daughter to serve as an assistant for various clinical site related activities. During the years ended December 31, 2025 and 2024, the Company paid Gendreau $376,063 and $56,141, respectively, and had accounts payable of $14,335 and $21,260 to Gendreau as of December 31, 2025 and 2024, respectively.

See also Note 9 – "Promissory Note with Related Party" for discussion of related party promissory note with Conjoint Inc.

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. Although the results of litigation and claims cannot be predicted with certainty, we do not currently have any pending or ongoing litigation to which we are a party or to which our property is subject that we believe to be material.

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 and the Controller. 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 55% for the CEO, 40% for the CMO and CFO, 33% for SVP of Operations and 15% for the Controller, 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 and Controller 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. The Company shall pay the Controller an amount equal to three months' base salary plus accrued and unused vacation. 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 18, 2025, the stockholders of the Company approved Amendment No. 2 to the Amended and Restated 2020 Equity Incentive Plan (the "Prior Plan") to increase the total number of shares of Common Stock reserved for issuance under the Prior Plan by 108,612 shares to 191,112 total shares issuable under the Prior Plan. On June 27, 2025, the Board approved a further amendment to the Prior Plan which removed the annual individual grant limit of 20,000 shares.

On November 21, 2025, the stockholders of the Company approved the Second Amended and Restated 2020 Equity Incentive Plan (the "Plan"), which amends and restates the Prior Plan, to increase the total number of shares of Common Stock reserved for issuance under the Plan to 2,972,787 total shares. On November 21, 2025, the stockholders of the Company also approved a further amendment to the Plan which re-established annual individual grant limits as discussed below. As of December 31, 2025 and 2024, 1,867,209 and 1,423 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 500,000 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 200,000 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, 2023	66,046	$ 119.42	8.08
Granted	15,031	8.93	—
Forfeited	—	—	—
Outstanding at December 31, 2024	81,077	$ 98.93	7.39
Granted	1,039,853	5.99	—
Forfeited or expired	(15,352)	9.93	—
Outstanding at December 31, 2025	1,105,578	$ 12.80	9.64
Exercisable at December 31, 2025	80,225	$ 99.57	6.46

As of December 31, 2025 and 2024, the aggregate intrinsic value of options outstanding and exercisable was $0.

During the year ended December 31, 2025, the Company granted certain individuals options to purchase 1,039,853 shares of the Company's Common Stock with an average exercise price of $5.99 per share, contractual terms of 10 years and a vesting periods ranging from 100% after one year to 33.333% after one year and the remaining 66.667% in 24 equal monthly installments, thereafter. The options had an aggregate grant date fair value of $4,961,557 that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model included: (1) discount rates ranging from of 3.775% to 4.0275% based on the daily par yield curve rates for U.S. Treasury obligations, (2) expected lives of 5.5 years to 6.0 years based on the simplified method (vesting plus contractual term divided by two), (3) expected volatility ranging from 96.92% to 99.57% based on the average historical volatility of comparable companies' stock, (4) no expected dividends and (5) fair market value of the Company's stock ranging from $4.71 to $6.14 per share.

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 $8.93 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.

For the years ended December 31, 2025 and 2024, the Company recognized share-based compensation expense related to stock options of $355,642 and $476,021, respectively. The unrecognized compensation expense for stock options at December 31, 2025 and 2024 was $4,719,830 and $168,741, 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 employment agreement of our former President, Richard Burch (the "President Options"). The President Options are exercisable within 10 years of the date of grant at $250.00 per share, were 100% vested at the grant date and have a remaining contractual term of 4.96 years. As of December 31, 2025, 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, 2025, 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 had a five-year contractual term and became 100% exercisable on December 21, 2021 and expired on December 21, 2025.

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"), of which 855 warrants remain outstanding as of December 31, 2025. The Representative Warrants have a five-year contractual term and became 100% exercisable on March 18, 2023.

There were no warrant exercises for the years ended December 31, 2025 and 2024 and there is no unrecognized compensation expense for these awards as of December 31, 2025.

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, 2023	7,755	$ 279.77	2.16
Granted	—	—	—
Outstanding at December 31, 2024	7,755	$ 279.77	1.15
Forfeited	(6,900)	312.50	—
Outstanding at December 31, 2025	855	$ 15.63	1.72
Exercisable at December 31, 2025	855	$ 15.63	1.72

As of December 31, 2025, the aggregate intrinsic value of the warrants outstanding was $0.

14. Income Taxes

As of December 31, 2025, the Company has U.S. federal net operating loss carryforwards of approximately $45,410,000, which have an indefinite carryforward and Georgia and Florida state net operating loss carryforwards of approximately $58,689,000 and $1,750,000, respectively, which have a twenty-year carryforward and begin expiring in 2037. As of December 31, 2025, the Company had Canadian non-capital loss carryforwards of approximately $22,024,000, which have a twenty year carryforward and begin expiring in 2026 and Hong Kong tax losses carryforwards of approximately $58,026,000 which have no expiry. These net operating loss carryforwards may be limited under Section 382 of the internal revenue code. The Company will need to perform a formal Section 382 study to determine how the equity transactions discussed above impact the limitation on the utilization of its net operating loss carryforwards.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted. The OBBBA did not change the US federal corporate income-tax rate and did not materially affect Dogwood's US income-tax position. The OBBBA did reinstate the immediate expensing of domestic research and development ("R&D") expenditures under Section 174A, effective for tax years beginning after December 31, 2024. This change reverses the prior requirement to capitalize and amortize R&D costs over five years. The Company has elected to continue to capitalize R&D expenditures under Section 174A and amortize these costs over 60-months. Therefore there was no remeasurement of deferred tax assets due to the OBBBA's enactment and there was no impact on the Company's income tax provision for the year ended December 31, 2025. The Company maintains a full

valuation allowance against its deferred tax assets, including those related to net operating loss carryforwards and R&D credits.

The Company adopted ASU 2023-09 effective January 1, 2025, applying the guidance prospectively, as permitted by the standard. Comparative prior-year disclosures have not been restated. The adoption of ASU 2023-09 did not affect the Company's recognition or measurement of income tax amounts, as the ASU amends disclosure requirements only and does not modify the underlying accounting guidance in ASC 740.

Income taxes paid by the Company are as follows:

	Year Ended December 31,	
	2025	2024
Federal	$ —	$ —
State	—	—
Foreign	—	—
Total income taxes paid	$ —	$ —

A reconciliation of the worldwide consolidated income tax rate to the Company's effective tax rate as of December 31, 2025 is as follows:

	Year Ended December 31, 2025	
Pretax Income	(7,147,720)	21.00 %
Domestic state and local income taxes, net of federal effect (a)	—	— %
Foreign tax effects:		
Canada		
Other	368,275	(1.08)%
Other Adjustment - NOLs	1,639,371	(4.82)%
Change in valuation allowance	(1,442,061)	4.24 %
Other	896	— %
Effect of cross-border tax laws	—	— %
Tax credits	—	— %
Nontaxable or Nondeductible Items, net		
Debt conversion	1,288,165	(3.79)%
Other	75,693	(0.22)%
Other adjustments	224	— %
Change in valuation allowance	5,438,253	(15.98)%
Effective Income Tax rate	221,096	(0.65)%

A reconciliation of the worldwide consolidated income tax rate to the Company's effective tax rate as of December 31, 2024 is as follows:

	Year Ended December 31, 2024
U.S. federal statutory income tax rate	21.00 %
Permanent differences	(2.60)%
State taxes, net of federal benefit	2.60 %
Foreign exchange	0.43 %
Other adjustments	— %
Change in valuation allowance	(21.43)%
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,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	**$ 27,632,096**	$ 26,081,361
Research and development tax credits	**2,484,004**	8,765,999
Capitalized research and development expenditures	**2,814,581**	1,627,842
Stock compensation	**1,440,022**	1,434,890
Depreciation and amortization	**3,023,531**	275,412
Lease liabilities	**43,381**	58,227
Other	**50**	—
Investment in partnership	**—**	30,035
Gross deferred tax assets	**37,437,665**	38,273,766
Valuation allowance	**(36,952,112)**	(31,370,027)
Net deferred tax assets	**485,553**	6,903,739
Deferred tax liabilities:		
Right-of-use asset	**(42,187)**	(55,341)
In-process research and development intangible assets	**(12,112,367)**	(17,741,842)
Prepaid expenses	**(440,403)**	(421,481)
Deferred tax liabilities	**(12,594,957)**	(18,218,664)
Net deferred taxes	**$ (12,109,404)**	$ (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 2025 and 2024 tax years, the Company has capitalized $8,871,522 and $2,810,785 of research and development expenses, respectively.

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, 2025 is reflected in the consolidated statement of operations.

The Company experienced a net change in valuation allowance of $5,582,085 and $21,443,255 for the years ended December 31, 2025 and 2024, 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 expense (benefit) are as follows:

	As of December 31,	
	2025	2024
Current:		
Federal	$ —	$ —
State	—	—
Foreign	—	—
	$ —	$ —
Deferred:		
Federal	$ —	—
State	—	—
Foreign	221,096	(503)
	$ 221,096	$ (503)
Total income tax expense (benefit)	$ 221,096	$ (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, 2025. Based on the assessment, management has concluded that, as of December 31, 2025, our internal control over financial reporting was effective.

As a smaller reporting, 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, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Rule 10b5-1 Trading Arrangements

During the fiscal quarter ended December 31, 2025, 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 2026 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 2026 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 2026 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 2026 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 2026 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)
3.6	Certificate of Designation of Series A-2 Non-Voting Convertible Preferred Stock of Dogwood Therapeutics, Inc., dated September 29, 2025 (incorporated by reference herein from Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on September 29, 2025)
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)
10.12	Form of Stock Purchase Agreement (incorporated by reference herein from Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on March 14, 2025)
10.13	Exclusive License Agreement, dated September 29, 2025, by and between Dogwood Therapeutics, Inc. and Serpin Pharma, Inc. (incorporated by reference herein from Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on September 29, 2025)
10.14	Equity Issuance and Registration Rights Agreement, dated September 29, 2025, by and between Dogwood Therapeutics, Inc., Serpin Pharma, Inc. and Rejuvenation Labs, Inc. (incorporated by reference herein from Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on September 29, 2025)
10.15	Serpin Support Agreement (incorporated by reference herein from Exhibit 10.3 to the Company's Current Report on Form 8-K, filed with the SEC on September 29, 2025)
10.16	Form of Tungsten Support Agreement (incorporated by reference herein from Exhibit 10.4 to the Company's Current Report on Form 8-K, filed with the SEC on September 29, 2025)
10.17	Sealbond Support Agreement (incorporated by reference herein from Exhibit 10.5 to the Company's Current Report on Form 8-K, filed with the SEC on September 29, 2025)
10.18+	Dogwood Therapeutics, Inc. Second Amended and Restated 2020 Equity Incentive Plan (incorporated by reference herein from Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on November 21, 2025)
10.19	Equity Distribution Agreement, dated November 28, 2025, by and between Dogwood Therapeutics, Inc. and Northland Capital Markets (incorporated by reference herein from Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on November 28, 2025)
19.1	Dogwood Therapeutics, Inc. Insider Trading Policy (incorporated by reference from Exhibit 19.1 to the Company's Annual Report on Form 10-K, filed with the SEC on March 31, 2025)
21.1	Subsidiaries (incorporated by reference from Exhibit 21.1 to the Company's Annual Report on Form 10-K, filed with the SEC on March 31, 2025)
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 (incorporated by reference from Exhibit 97.1 to the Company's Annual Report on Form 10-K, filed with the SEC on 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 18, 2026.

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 18, 2026 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

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements on Forms S-3 and S-8 (Nos. 333-265757, 333-251544, 333-287575, 333-288344, 333-290658, 333-292618, 333-292750) of our report dated March 18, 2026, with respect to the consolidated financial statements of Dogwood Therapeutics, Inc., included in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ Forvis Mazars, LLP
Atlanta, Georgia
March 18, 2026

Exhibit 31.1

CERTIFICATIONS

I, Greg Duncan, certify that:

1. I have reviewed this annual report on Form 10-K of Dogwood Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present, in all material respects, the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors:

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 18, 2026

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

Exhibit 31.2

CERTIFICATIONS

I, Angela Walsh, certify that:

1. I have reviewed this annual report on Form 10-K of Dogwood Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present, in all material respects, the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors:

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 18, 2026

/s/Angela Walsh
Angela Walsh
Chief Financial Officer, Corporate Secretary and Treasurer
(Principal Financial and Accounting Officer)

Exhibit 32.1

STATEMENT PURSUANT TO
18 U.S.C. SECTION 1350
AS REQUIRED BY
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Dogwood Therapeutics, Inc. (the "Company") on Form 10-K for the period ending December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify that to the best of our knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 18, 2026	*/s/* Greg Duncan Greg Duncan	Chief Executive Officer and Chairman of the Board (Principal Executive Officer)
March 18, 2026	*/s/* Angela Walsh Angela Walsh	Chief Financial Officer, Corporate Secretary and Treasurer (Principal Financial and Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to Dogwood Therapeutics, Inc. and will be retained by Dogwood Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.