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

FORM 10-K

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

For the fiscal year ended December 31, 2024

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

For the transition period from _____ to _____

Commission file number 001-41210

THARIMMUNE, INC.
(Exact name of registrant as specified in charter)

Delaware	**84-2642541**
(State or jurisdiction of Incorporation or organization)	I.R.S. Employer Identification No.
1200 Route 22 East, Suite 2000, Bridgewater, NJ	**08807**
(Address of principal executive offices)	(Zip code)

(908) 270-8260
(Registrant's telephone number, including area code)

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	THAR	The Nasdaq Stock Market LLC

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 (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definition 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 §240.10D-1(b). ☐

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

The aggregate market value of the voting stock and non-voting common equity held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter ended June 30, 2024 was $1.7 million based upon the closing price of the registrant's common stock of $1.53 on The Nasdaq Capital Market as of that date.

Number of common shares outstanding as of March 21, 2025 was 2,108,753.

Documents Incorporated by Reference: None.

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CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements may be identified by such forward-looking terminology as "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. Our forward-looking statements are based on a series of expectations, assumptions, estimates and projections about our company, are not guarantees of future results or performance and involve substantial risks and uncertainty. We may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements. Our business and our forward-looking statements involve substantial known and unknown risks and uncertainties, including the risks and uncertainties inherent in our statements regarding:

- our projected financial position and estimated cash burn rate;
- our estimates regarding expenses, future revenues and capital requirements;
- our ability to continue as a going concern;
- our need to raise substantial additional capital to fund our operation;
- the success, cost and timing of our clinical trials;
- our dependence on third parties in the conduct of our clinical trials;
- our ability to obtain the necessary regulatory approvals to market and commercialize our product candidates;
- the impact of the COVID-19 pandemic, or any other health epidemic, on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole;
- the potential that results of pre-clinical and clinical trials indicate our current product candidates or any future product candidates we may seek to develop are unsafe or ineffective;
- the results of market research conducted by us or others;
- our ability to obtain and maintain intellectual property protection for our current and future product candidates;
- our ability to protect our intellectual property rights and the potential for us to incur substantial costs from lawsuits to enforce or protect our intellectual property rights;

- the possibility that a third party may claim we or our third-party licensors have infringed, misappropriated or otherwise violated their intellectual property rights and that we may incur substantial costs and be required to devote substantial time defending against claims against us;
- our reliance on third-party suppliers and manufacturers;
- the success of competing therapies and products that are or become available;
- our ability to expand our organization to accommodate potential growth and our ability to retain and attract key personnel;
- the potential for us to incur substantial costs resulting from product liability lawsuits against us and the potential for these product liability lawsuits to cause us to limit our commercialization of our product candidates;
- market acceptance of our product candidates, the size and growth of the potential markets for our current product candidates and any future product candidates we may seek to develop, and our ability to serve those markets; and
- the successful development of our commercialization capabilities, including sales and marketing capabilities.

All of our forward-looking statements are as of the date of this Annual Report on Form 10-K only. In each case, actual results may differ materially from such forward-looking information. We can give no assurance that such expectations or forward-looking statements will prove to be correct. An occurrence of, or any material adverse change in, one or more of the risk factors or risks and uncertainties referred to in this Annual Report on Form 10-K or included in our other public disclosures or our other periodic reports or other documents or filings filed with or furnished to the U.S. Securities and Exchange Commission (the "SEC") could materially and adversely affect our business, prospects, financial condition and results of operations. Except as required by law, we do not undertake or plan to update or revise any such forward-looking statements to reflect actual results, changes in plans, assumptions, estimates or projections or other circumstances affecting such forward-looking statements occurring after the date of this Annual Report on Form 10-K, even if such results, changes or circumstances make it clear that any forward-looking information will not be realized. Any public statements or disclosures by us following this Annual Report on Form 10-K that modify or impact any of the forward-looking statements contained in this Annual Report on Form 10-K will be deemed to modify or supersede such statements in this Annual Report on Form 10-K.

This Annual Report on Form 10-K may include market data and certain industry data and forecasts, which we may obtain from internal company surveys, market research, consultant surveys, publicly available information, reports of governmental agencies and industry publications, articles and surveys. Industry surveys, publications, consultant surveys and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable, but the accuracy and completeness of such information is not guaranteed. While we believe that such studies and publications are reliable, we have not independently verified market and industry data from third-party sources.

"QUATRAMER" and "QUATRABODY" are pending trademarks of Tharimmune, Inc. in the United States. All other brand names or trademarks appearing in this Annual Report on Form 10-K are the property of their respective holders. Solely for convenience, the trademarks and trade names contained herein may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

RISK FACTOR SUMMARY

Our business is subject to significant risks and uncertainties that make an investment in us speculative and risky. Below we summarize what we believe are the principal risk factors but these risks are not the only ones we face, and you should carefully review and consider the full discussion of our risk factors in the section titled "Risk Factors," together with the other information in this Annual Report on Form 10-K. If any of the following risks actually occurs (or if any of those listed elsewhere in this Annual Report on Form 10-K occur), our business, reputation, financial condition, results of operations, revenue, and future prospects could be seriously harmed. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business.

Risks Related to Our Financial Position and Need for Additional Capital

- We have a limited operating history, and we have not initiated, conducted or completed any clinical trials, and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and viability.
- We have incurred significant losses since inception, we expect to incur losses in the future and we may not be able to generate sufficient revenue to achieve and maintain profitability.
- We will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to curtail, delay or discontinue one or more of development programs or future commercialization efforts.
- Management has performed an analysis and concluded that there is a substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing on terms acceptable to us, if at all.

Risks Related to the Discovery and Development of Our Product Candidates

- Our business depends on the successful clinical development, regulatory approval, and commercialization of our therapeutic compounds, including our lead asset TH104.
- There are substantial risks inherent in drug development, and, as a result, we may not be able to successfully develop TH104, or other candidates in our pipeline
- We depend on license agreements with partners, including Avior Bio, LLC, Intract Pharma, Ltd, Minotaur Therapeutics, Applied Biomedical Sciences Institute, and Enkefalos Biosciences and rely on the use of their patents and patent applications. Termination of these rights or the failure to comply with obligations under certain license agreements could materially harm our business and prevents us from developing our lead candidate, TH104, and other candidates in our pipeline.
- We are substantially dependent on the success of our product candidates. If we are unable to complete development of, obtain approval for and commercialize our product candidates in a timely manner, our business may be harmed.
- We expect that our operations and development of TH104 and pipeline candidates will require substantially more capital than we currently have, and we can not guarantee when or if we will be able to secure additional funding.
- Any delays in the commencement or completion, or termination or suspension, of our ongoing, planned or future clinical trials including a hepatic impairment trial prior to a Phase 2 trial, including delays to clinical trials involving TH104 which are being planned in 2025, could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.
- The outcome of pre-clinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the U.S. Food and Drug Administration or other comparable foreign regulatory authorities.
- If we experience delays or difficulties in enrolling patients in our ongoing or planned clinical trials, our receipt of necessary regulatory approval could be delayed or prevented.
- We may be required to perform additional or unanticipated clinical trials to obtain approval or be subject to post-marketing testing requirements to maintain regulatory approval. If our candidates prove to be ineffective, unsafe or commercially unviable, our entire technology platform and pipeline would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

- Adverse side effects or other safety risks associated with our drug candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials or abandon further development, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

- Our products may never achieve market acceptance.

- We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the products we develop, our commercial opportunities will be negatively impacted.

Risks Related to Our Reliance on Third Parties

- We rely on third parties to manufacture our product candidates and conduct our pre-clinical studies and clinical trials. If these third parties do not successfully perform their contractual and regulatory duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.

- We currently depend on sole source suppliers and manufacturers for certain ingredients, and the inability to obtain such ingredients as required could harm our business.

  We anticipate relying on third-party Contract Research Organizations ("CROs") and other third parties to conduct and oversee our clinical trials. If these third parties do not meet our requirements or otherwise conduct the trials as required, we may not be able to satisfy our contractual obligations or obtain regulatory approval for, or commercialize, our product candidates.

  We expect to rely on collaborations with third parties for the successful development and commercialization of our product candidates.

  We anticipate relying completely on third-party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates.

Risks Related to Commercialization of Our Drug Candidates

- Even if we are successful in completing all pre-clinical studies and clinical trials, we may not be successful in commercializing one or more of our drug candidates.

- The development and commercialization of pharmaceutical products are subject to extensive regulation, and we may not obtain regulatory approvals for our drug candidates on a timely basis, or at all.

Risks Related to Our Intellectual Property

- Our inability to protect our intellectual property and proprietary rights may have a material adverse effect on our business.

Risks Related to Managing Our Business and Operations

- We may encounter difficulties in managing our growth, which could adversely affect our operations.

- Our employees, independent contractors, consultants, commercial partners, collaborators and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

- Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

  We may choose to discontinue developing or commercializing any of our product candidates, or may choose not to commercialize product candidates in approved indications, at any time during development or after approval, which could adversely affect us and our operations.

  Our inability to successfully in-license, acquire, develop and market additional product candidates or approved products could impair our ability to grow our business.

Risks Related to Our Common Stock

- We are currently listed on The Nasdaq Capital Market. If we are unable to maintain listing of our securities on Nasdaq or any stock exchange, our stock price could be adversely affected and the liquidity of our stock and our ability to obtain financing could be impaired and it may be more difficult for our stockholders to sell their securities.

- 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

Throughout this Annual Report on Form 10-K, references to "we," "our," "us," the "Company," or "Tharimmune," refer to Tharimmune, Inc., individually, or as the context requires, collectively with its subsidiaries.

ITEM 1. BUSINESS

Overview

Tharimmune is a clinical-stage biotechnology company developing therapeutic candidates in inflammatory and immunologic conditions with high unmet need. On November 3, 2023, we entered into a patent license agreement (the "Avior Patent License Agreement") with Avior, Inc. d/b/a Avior Bio, LLC ("Avior") pursuant to which we received an exclusive sublicensable right and license to Licensed Patent Rights and Licensed Technology to, among other things, Develop, have Developed, make, have made, use, sell, import, export and commercialize TH104 and TH103 and to practice the Licensed Technology in connection with the foregoing, throughout the world, each as defined in the Avior Patent License Agreement. In February 2023, the U.S. Food and Drug Administration ("FDA") approved an investigational new drug ("IND") application for TH104.

TH104 is a proprietary transmucosal buccal film embedded with the active compound nalmefene onto a thin film which easily adheres inside of the mouth on the cheek and biodegrades within minutes. This provides key features making TH104 an ideal product candidate for multiple liver-related and other pruritogenic inflammatory conditions. The molecule has a dual mechanism of action affecting both the μ-opioid and kappa opioid receptors. These well-known opioid receptors when stimulated and/or inhibited by the body's endogenous ligands have been shown to be involved in the body's itch circuitry for certain conditions, including cholestatic or dysregulated bile acid-related liver conditions.

TH104 has a dual mechanism of action by affecting multiple receptors, known to suppress chronic, debilitating pruritus or "uncontrollable itching" With respect to TH104, we intend to first seek approval for the treatment of moderate-to-severe chronic pruritus in patients with primary biliary cholangitis ("PBC"), an orphan rare form of liver disease with no known cure in which more than 70% of patients suffer from debilitating chronic pruritus. A Phase 2 proof-of-concept ("POC") trial with TH104 is ready to be initiated and the Company intends to conduct a hepatic impairment trial prior and expects to develop TH103 and potentially file an IND at some point in the future, depending on discussions with the FDA.

TH104, administered via a transmucosal buccal delivery system applied to the inside of the mouth by adhering to the cheek, is anticipated to demonstrate a favorable safety profile in a dedicated hepatic impairment study. This expectation is supported by data from nalmefene tablets (Selincro®), a product available in Europe and not in the United States with relevant pharmacokinetic considerations. Selincro studies, using a single 18.06 mg dose, revealed that patients with mild hepatic impairment experienced a 1.5-fold increase in exposure (AUC) and a 35% decrease in oral clearance compared to healthy subjects. In patients with moderate hepatic impairment, the impact was even more pronounced: exposure (AUC) increased 2.9-fold, Cmax increased 1.7-fold, and oral clearance was reduced by approximately 60%. Critically, despite these significant changes in exposure and clearance, no clinically relevant alterations were observed in either Cmax or the elimination half-life in either the mild or moderate hepatic impairment groups. This data provides a potential foundation for predicting TH104 behavior and we intend to acknowledge that pharmacokinetic data for nalmefene in patients with severe hepatic impairment is not yet available, and that there are existing contraindications and precautions. Therefore, while the nalmefene data suggests a reduced risk profile for TH104, we planto begin a hepatic impairment study in 2025 to fully evaluate the pharmacokinetic profile and safety in certain stages of liver impairment, beginning with mild and moderate, and potentially severe impairment prior to launching the phase 2 study to ensure we have potential suitable precautions in place if necessary.

On September 11, 2024, we entered into a Patent License Agreement (the "Intract Agreement") with Intract Pharma Limited ("Intract"), pursuant to which, we exclusively licensed INT-023/TH023, an oral anti-Tumor Necrosis Factor-alpha (TNF-a) monoclonal antibody infliximab. Infliximab is a purified recombinant DNA-derived chimeric IgG monocloncal antibody protein that contains both murine and human components that inhibit tumor TNF-a. Under the terms of the Intract Agreement, we licensed global development and commercialization rights (outside of South Korea) to Intract's Soteria® and Phloral® delivery platform along with an existing supply agreement for infliximab to be used in the oral product development program.

We are also developing an early-stage pipeline of novel therapeutic candidates targeting validated high value immuno-oncology ("IO") targets including human epidermal growth factor ("EGF") receptor 2 ("HER2"), human EGF receptor 3 ("HER3") and programmed cell death protein ("PD-1") and vascular endothelial growth factor ("VEGF"). We are developing antibodies including bispecific antibodies, antibody drug conjugates ("ADCs") and small molecular weight bovine- derived "knob" domains which have the potential to target and bind more tightly to "undruggable" epitopes with conceivably improved characteristics compared to full sized antibodies. We are developing HS1940, a novel multispecific biologic targeting both PD-1 and VEGF. We are advancing HS3215, a bispecific against both HER2 and HER3 antibody which targets a novel "bridging epitope" encompassing multiple domains of the HER2 extracellular domain ("ECD") as well as ligand-dependent and independent blocking of the ECD of HER3. HS1940

PD-1 is an immunosuppressive checkpoint and seen in macrophages, B lymphocytes, dendritic cells, monocytes, tumor-specific activated T cells, myeloid cells and natural killer cells in circumstances of chronic antigen contact. PD-L1 is one of the PD-1 ligands. PD-L1 expression has been shown to be a valuable biomarker for the prognosis and prediction of the sensitivity of PD-1/PD-L1 inhibitors. The expression of PD-L1 is mainly expressed in tumor cells, tumor-infiltrating cells and antigen-presenting cells in many cancers. Despite the noteworthy efficacy of PD-1/PD-L1 immune checkpoint inhibitors ("ICI") in the treatment of tumors, some problems remain such as drug resistance and adverse events. Acquired drug resistance may present despite resuming or continuing treatment with anti-PD-1/PD-L1 immunotherapy. The presence of drug resistance significantly reduces the efficacy of anti-PD-1/PD-L1 immunotherapy. We believe exploring the mechanisms of PD-1/PD-L1 ICI resistance may assist with the discovery of new immunotherapeutic strategies to control disease progression and provide a more sustainable survival benefit for patients. As such, we aim to further improve on PD-1 as a breakthrough technology by developing, HS1940, a proprietary PD-1 Picobody with unique binding affinity differently than currently available PD-1 drugs. We believe this unique binding difference allows for novel therapeutic possibilities both as a stand-alone agent and in combination and that our tumor immunotherapy based on PD-1 inhibition may become a future strategy for human cancers.

The EGF subset known as the epidermal growth factor receptor (“ErbB”) family of receptors are a validated set of targets preferentially overexpressed on certain solid tumors which can be clinically exploited for the treatment of drug resistant cancers. The ErbB family is encompassed of four members that belong to the transmembrane tyrosine kinase receptors (“TKR”), including EGFR (“HER1”), HER2, HER3 and HER4. The most well-known member, HER2, encodes a transmembrane TKR which is comprised of three domains: an ECD, a transmembrane domain and an intracellular tyrosine kinase domain. Ligand binding results in heterodimerization or homodimerization between the ErbB receptors leading to excitation of the intracellular tyrosine kinase domain which then activates downstream signaling pathways concerning cellular proliferation, differentiation, migration and apoptosis.

HER2 is an orphan receptor lacking a unique endogenous ligand and preserves an active conformation, making it continuously available to dimerize and preferred as a partner for neighboring member receptors. Juxtaposed to this distinct HER2 characterization, HER3 has several ligands yet it lacks intrinsic tyrosine kinase activity.

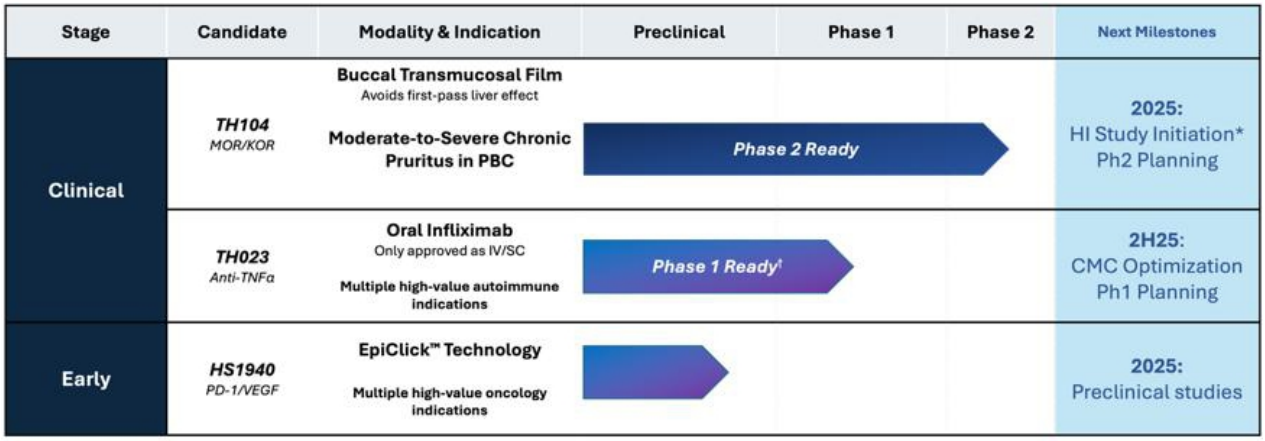
Furthermore, HER2-HER3 pairing exhibits a favorable and more potent signaling, suggesting a corresponding action between both receptors.

HER2 is a known oncogene recognized in numerous cancer types and dysregulation of HER2 signaling can be caused by mutation, amplification and overexpression. Numerous cancers exhibit high levels of HER2 compared to normal tissue, specifically tumors of the breast, colorectal, bladder, gastric, esophageal, endometrial, and ovarian cancers, signifying that HER2 may be connected to the progression of these tumors. Additionally, following the discovery of HER2 in breast cancer, antibody drugs targeting HER2 were introduced into the clinic. HERCEPTIN® (trastuzumab), the first monoclonal antibody developed by Genentech/Roche was approved for the treatment of HER2-positive metastatic breast cancer in 1998. Subsequently, tyrosine kinase inhibitors (“TKIs”) and ADCs targeting HER2 have been approved. Another antibody, PERJETA® (pertuzumab) also developed by Genentech/Roche, used in combination with trastuzumab, and docetaxel was approved in 2012, indicated for the treatment of patients with HER2-positive metastatic breast cancer. The FDA subsequently also approved a third biologic from Genentech/Roche in 2013, KADCYLA® (trastuzumab emtansine or T-DM1), for the treatment of patients with HER2-positive metastatic breast cancer in patients previously treated with trastuzumab and a taxane. T-DM1 not only retains the target-selective benefit of trastuzumab, but also kills tumor cells by delivering a potent toxin which inhibits microtubule function and has become a classic example of a targeted ADC treatment. Another ADC, ENHERTU® (trastuzumab deruxtecan), developed by Daiichi Sankyo and AstraZeneca and approved in December 2019 for the treatment of unresectable or metastatic HER2-positive breast cancer has shown anti-tumor activity in HER2-positive cancers that were resistant or insensitive to T-DM1. We believe this development history of multiple approved drugs with different modalities and novel epitopes targeting HER2 has paved a de-risked regulatory pathway as well left significant room for continued innovation in this class of therapies. According to the Fierce Pharma, in 2022, Roche/Genentech had worldwide sales of over $8 billion with respect to their HER2 targeted therapies (Herceptin and Perjeta) as well as more than $500 million in worldwide sales of ENHERTU® in the first half of 2023 alone according to AstraZeneca.

The function of HER3 in tumor biology is multidimensional. Abundant HER3 expression is identified in various solid tumor types, with a proven role in disease progression. Overexpression of HER3 signaling is thought to be involved in resistance to other targeted therapies used for treating several cancers, including anti-EGFR therapies gefitinib and cetuximab. One of the many genomic changes known to be implicated in acquired resistance to anti-EGFR TKIs in patients with EGFR-mutated advanced non-small-cell lung cancer is HER3 up-regulation promulgated by osimertinib. Therefore, blocking HER3/EGFR dimerization complex is thought to prevent or slow down both acquired and primary resistance to EGFR inhibitors. We believe combining anti-HER2 with an anti-HER3 strategy as a bispecific multifunctional agent without a toxin (HS3215) as well as with a toxin (HS0059) could capitalize on some of the findings described in the literature to take advantage of precise tumor-killing through two important targets with different mechanisms of action.

Our Portfolio

We currently have an IND-approved transmucosal film product, TH104, a Phase 2 ready clinical candidate and an oral biologic as well as two bispecific biologics in pre-clinical development. The following table summarizes our development candidate pipeline:



MOR = mu opioid receptor; KOR = kappa opioid receptor; TNFα = tumor necrosis factor-alpha;

*CMC completed; HI = hepatic impairment; TH104 ready to go into Phase 2 in the EU and US with FDA and EMA feedback received

† trial initiation ex-US; Celltrion has right-of-first refusal post clinical study

Our Strategy

Our goal is to become a leading biotechnology company developing novel treatments in inflammatory and immunologic conditions with high unmet needs. Our business strategy comprises the following components:

1. Develop TH104 as a transmucosal buccal film product for the treatment of chronic pruritus in PBC and other inflammatory diseases.

2. Develop TH023 by optimizing the CMC pathway and planning a Phase 1 first-in-human clinical trial through feedback from a non-US regulatory authority

3. Create a preclinical and clinical path forward for our early stage product candidate, HS1940, a novel PD-1/VEGF with binding differentiation compared to full length antibodies for IO vulnerable tumors.

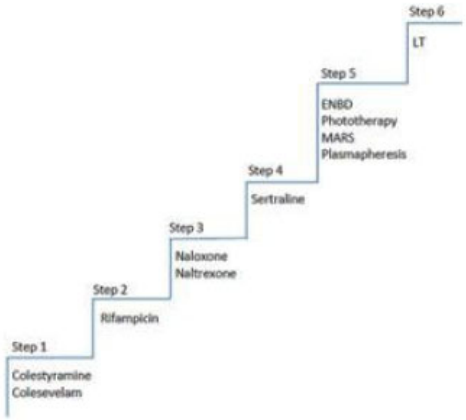
4. Hasten the discovery and development of next generation multi-specific (bi- and tri) antibodies with binding capabilities to novel epitopes of combinations of HER2, HER3, PD-1 and other validated targets with and without toxin delivery capacity to multiple high unmet need rare cancers.

5. Pursue strategic collaboration opportunities to maximize the value of our pipeline to bring novel therapies to patients suffering from high unmet need conditions.

TH104 and moderate-to-severe chronic pruritus

According to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), part of the National Institutes of Health, PBC, is a chronic disease in where the bile ducts in the liver eventually become dysfunctional and cause the buildup of bile which causes liver damage. The disease, believed to be an autoimmune condition, affects both men and women with a rate higher in women, estimated at 1 out of every 1,000 women over 40. Pruritus is one of the most common conditions associated with PBC affecting up to 75% of individuals at some point during their disease course. It has a negative impact on health-related quality of life with limited treatment options. In an on-line survey focusing on certain features of patients' itch respondents described their itch as "bugs crawling" as well as more than 65% of participants reporting that the itch was worse at night, known as nocturnal pruritus.

Treatment Ladder for Pruritus in Primary Biliary Cholangitis

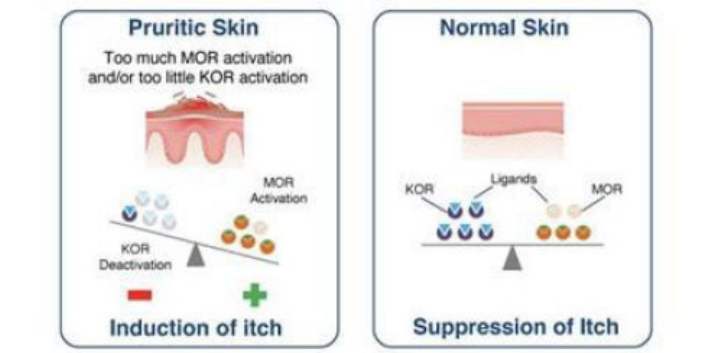


Source: Hegade VS, Bolier R, Oude Elferink RPJ, et. al. Frontline Gastroenterology 2016;7:158–166

ENBD, endobiliary nasal drainage; MARS, molecular adsorbent recirculating system; LT, liver transplantation

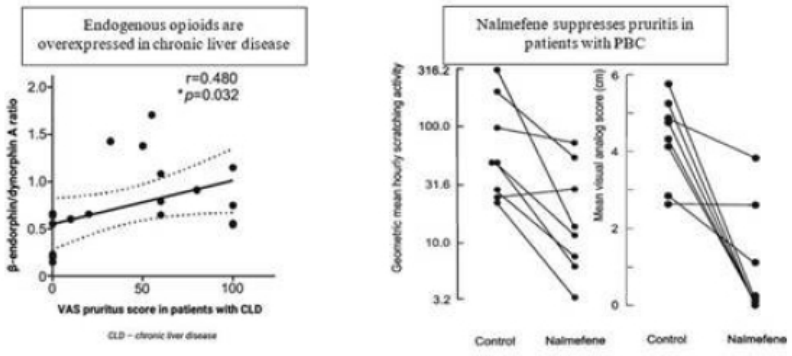
The current treatment ladder in pruritus for PBC shown above is the paradigm of therapy and if there is no response with one category of drugs, typically patients “move up” the ladder. A patient may need a combination of treatments to achieve and/or maintain symptom remission.

Endogenous opioid peptides are commonly believed to play a role in the modulation of cholestatic itch. In the late 1980s, data documented that nalmefene induced opiate-like withdrawal symptoms in individuals with cholestasis. Following this, research noted heightened levels of Met-enkephalin in the plasma of cholestatic patients. In animal experiments, the activation of μ-opioid receptors by agonists induced scratching behavior, while κ-opioid receptor agonists, on the contrary, reduced the sensation of itch.



Source: Kim BS, Inan S, Ständer S, Sciascia T,Szepietowski JC, Yosipovitch G. Role of kappa-opioid and mu-opioid receptors in pruritus: Peripheral and central itchcircuits. Exp Dermatol. 2022; 31:1900-1907. doi:10.1111/exd.14669

TH104 is a product which has been developed by embedding drug onto a proprietary transmucosal buccal film which adheres to the inside of the mouth. TH104 has key features which we believe make it an ideal product candidate for multiple liver-related and other pruritogenic inflammatory conditions. The active molecule, nalmefene, has a dual mechanism of action by affecting both the μ-opioid receptor and the kappa opioid receptor as well as inhibiting IL-17 inflammatory cytokine expression, a cytokine known to be overexpressed in PBC patient liver tissue and serum.

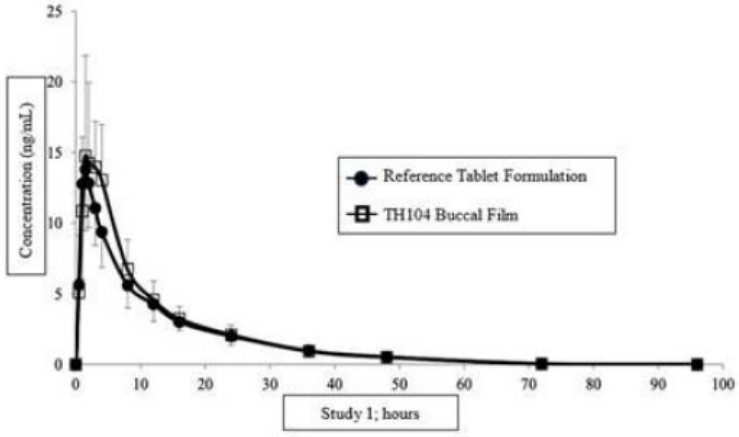


Sources: Moniaga CS, et. al. Plasma dynorphin A concentration reflects the degree of pruritus in CLD Acta Derm Venereol. 2019 Apr 1;99(4):442-443. doi: 10.2340/00015555-3139; Bergasa N et. al. Oral nalmefene therapy reduces scratching activity due to the pruritus of cholestasis: a controlled study J Am Acad Dermatol 1999;41:431-4

Previous data by *Bergasa et. al*, reported a study utilizing oral doses of nalmefene ranging from 40 to 240 mg twice-daily for 12 weeks in PBC patients. Eight patients who received at least 1 course of nalmefene were available for comparison with corresponding control data (a course of placebo and/or at baseline). Nalmefene therapy was associated with a 75% reduction in hourly scratching activity ($P < .01$). The study also achieved a decrease in the mean of a visual analogue score of the perception of pruritus in all 8 patients (mean decrease 77%, $P < .01$).

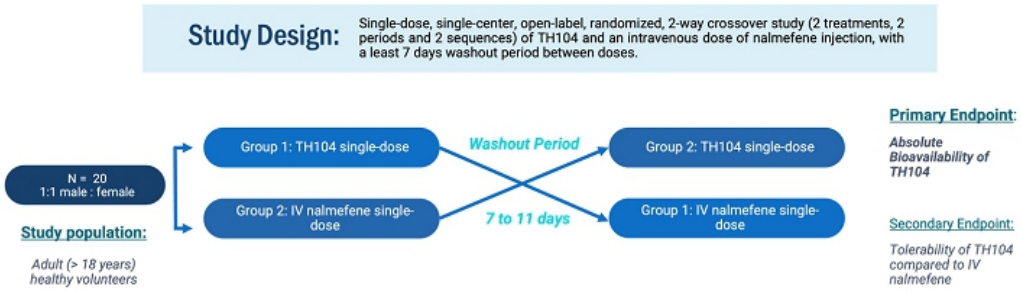
When the itch circuitry is imbalanced in diseased conditions, pharmacological intervention can help suppress this phenomenon which occurs in patients suffering from chronic pruritus. Nalmefene crosses into the circulation via a proprietary buccal delivery by adhering the drug-coated film inside the cheek where the film biodegrades in minutes and the drug is absorbed. The buccal delivery of the drug bypasses the liver's first-pass metabolism thus creating high drug concentrations in the skin, an added benefit for treating conditions in which the liver may be impaired.

TH104 data from multiple phase 1 ex-US trials achieved the primary objective of predictable pharmacokinetic profiling with favorable safety and tolerability. The first human phase 1 trial was a single-dose, single-center, open-label, randomized, 2-way crossover study of TH104 transmucosal buccal film compared to a tablet formulation marketed in Europe and not the United States, with a 14-day washout period involving 12 normal healthy volunteers under fasting conditions. The primary outcome measure was to determine the pharmacokinetics of a buccal dose of TH104, while secondary objectives included establishing the relative bioavailability of TH104 and evaluating its' tolerability for potential value in clinical efficacy studies. These data were also consistent with the comprehensive pre-clinical data package submitted to the FDA as an IND which was approved in February 2023, including pharmacokinetic profiling in beagle dog studies confirming once-daily dosing, fast or rapid onset and high bioavailability when comparing TH104 to intravenous nalmefene.



In this study, the pharmacokinetic evaluation of TH104 transmucosal film compared to an oral tablet marketed in Europe but not the United States, given as an equal-labelled dose in normal healthy volunteers under fasting conditions, was consistent and similar in comparison with results from the literature. The C_{max} and $AUC_{0-\infty}$ of TH104 was observed to be higher than the tablet product because of a possible reduced presystemic metabolism in the lower GI and liver, which is potentially advantageous for patients with an impaired liver. The half-life and T_{max} was observed to be similar for both products. There were no deaths, other serious adverse events, or other significant adverse events reported during the entire study with events consistent with the safety profile of the marketed tablet in the literature including mild dizziness, headache and somnolence, nausea and vomiting.

We launched a phase 1 pharmacokinetic trial for TH104 in early 2024 and completed the study with a topline readout in 2Q24. The clinical data package is strengthened by the phase 1 clinical trials previously conducted outside of the U.S., which showed reliable bioavailability of the active ingredient in TH104 via transmucosal film technology in healthy volunteers.



The Phase 1 trial was a single-dose, single-center, open-label, randomized 2-way crossover study comparing 16mg of TH104 with 1mg intravenous nalmefene administered under fasting conditions, with a 7-day washout period between doses. Twenty healthy subjects were enrolled to complete both doses of the crossover design. All 20 subjects completed TH104 buccal dosing, while 19 of 20 subjects also completed the intravenous dosing. The primary objective was to evaluate the absolute bioavailability of TH104, as well as to assess safety and tolerability.

Findings from the study indicate that the primary endpoint of the absolute bioavailability (F) of TH104, or fraction (or percentage) of the administered dose absorbed into the systemic circulation compared to an equivalent intravenous dose of nalmefene, was 0.459 (45.9%). The median time to maximum concentration (C_{max}) of TH104 was 2.0 hours, with rising concentrations beginning within minutes of dosing. The mean half-life ($T_{1/2}$) as measured in the blood of subjects was 14 hours after a single buccal administration of TH104, compared to 9 hours for the 1mg intravenous dose of nalmefene.

These data are consistent and within range of published findings of population PK data of nine Phase 1 studies of 243 subjects with extensive blood sampling.[1.] Furthermore, in the same analysis, receptor occupancy of oral dosing of nalmefene using a robust PK model for nalmefene was developed where a single 20mg dose showed μ-opioid receptor occupancy was simulated to be within or above 60-90% for up to 22-24 hours.

The Company believes PK results from this Phase 1 trial show proportional kinetics consistent with published findings of oral and intravenous formulations of nalmefene including F, C_{max}, $T_{1/2}$ and potential receptor occupancy time, suggest TH104 could be developed for once-daily dosing in a target population of moderate-to-severe chronic pruritus in PBC patients.

Based on the Phase 1 data, Type C meeting feedback from the U.S. Food and Drug Administration (FDA) was received and reported by the Company in June of 2024 for its planned Phase 2 clinical trial with TH104. The feedback received as Type C feedback from the FDA confirmed the Company's plan to pursue a 505(b)(2) approval pathway for TH104, which permits inclusion of data from external studies when the active ingredient is already approved in the United States. The FDA also agreed that the nonclinical studies submitted to the FDA in advance of the meeting appear sufficient to support the proposed Phase 2 clinical trial. In addition, the FDA provided feedback on study design and certain recommendations regarding PBC patient inclusion, the primary endpoint to assess pruritus in these patients, and considerations for monitoring for adverse events in this patient population. Based on this interaction, we plan to conduct a hepatic impairment study in 2025 to fully evaluate the pharmacokinetic profile and safety in certain stages of liver impairment, beginning with mild and moderate, and potentially severe impairment. We also began some start up activities for the Phase 2 trial with TH104 in moderate-to-severe chronic pruritus in PBC patients in early 2025 and have incorporated feedback from the FDA into its clinical protocol. The Company also received positive feedback from a Scientific Advice meeting with the European Medicines Agency (EMA) that included guidance on the planned Phase 2 trial to advance TH104. The EMA interactions specifically focused on both the Phase 2 and Phase 3 clinical program of TH104. Overall, the Agency noted that using Article 10(3), hybrid application, is acceptable and could enable referring to non-clinical and some safety data from the approved products. Regarding non-clinical information provided, the Agency endorsed the strategy presented by the Company and noted that there is no need to conduct additional animal studies and considered human exposure to be adequate to move forward. The Agency found the design and main features of the proposed Phase 2 study overall acceptable with some comments which were addressed by the Company subsequently. The Agency also provided general guidance for the design of a future Phase 3 study.

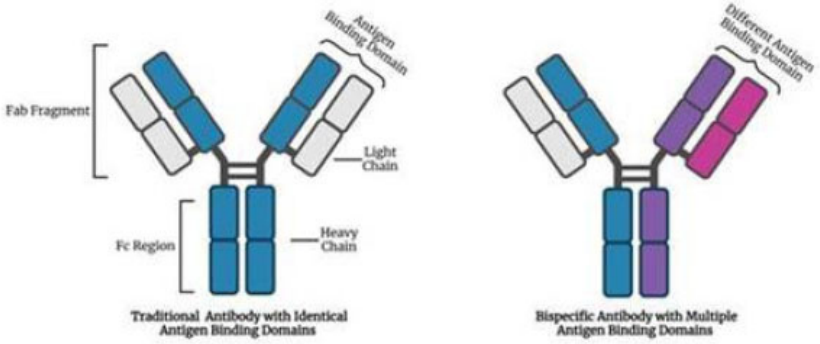
According to the Centers for Disease control and Prevention Summary Health Statistics National Health Survey, more than 4 million patients suffer from liver disease in the U.S. and about 1.7 million suffer from pruritus, where PBC has the highest rate of prevalence. We believe TH104 may also be used for treating chronic pruritogenic conditions associated with cholestatic liver disease as well as other liver related and non-liver related diseases including fatty and alcoholic liver, non-alcoholic liver disease and certain types of hepatitis. Chronic pruritus is significant in liver diseases (40% chronic pruritus; 1.7 million patients affected) as well as chronic kidney diseases (24% chronic pruritus; 1.3 million patients affected), hemodialysis as well as atopic dermatitis (40% pruritus; 2.7 million patients affected).

Furthermore, we expect TH104 to be manufactured with a high speed of manufacturing with several features including very high content uniformity, prepared using scalable manufacturing methods and appropriate cost-of-goods. We intend to be able to create a highly reproducible product using a small manufacturing footprint with few contract drug manufacturing organizations in the marketplace which may allow limited entrants.

Background on Antibodies

Full-length human antibodies play a crucial role in drug development as therapeutic agents. Antibodies are large Y-shaped proteins produced by the immune system to identify and neutralize extraneous elements such as bacteria, viruses, and additional pathogens. Their capability to target particular molecules with high specificity and affinity are valuable tools in pharmaceutical therapeutics. For drug development, much research has enabled the generation of full-length human antibodies targeting a variety of pathophysiological agents, anomalous cells, or malfunctioning proteins associated in different diseases. Using an array of methodologies, these antibodies can be developed using different approaches, including phage display, hybridoma technology, and techniques involving novel antibody engineering focused on structural diversity. The realization of numerous therapeutic antibodies has considerably affected the treatment of diverse diseases, including cancer, autoimmune disorders, infectious, and inflammatory conditions. Their promising therapeutic properties, including decreased toxicity and augmented specificity compared to small molecules and other modalities with off-target effects, make them appealing candidates for human therapeutic development.

A large number of traditional antibodies are composed of immunoglobin G (IgG) format in a Y-shape molecule consisting of two heavy chains which are identical as well as two light chains also identical. A heavy chain pairs with a light chain to form two variable regions, or antibody binding fragment (Fab) which binds to antigens of the target. The constant region includes a region referred to as the fragment crystallizable (Fc) which binds to receptors present on cells in the immune system known as effector cells. In traditional full length monoclonal antibodies, the variable regions are identical and bind to the same target.



Bispecific antibodies are a specialized class of therapeutic antibodies designed to concurrently target two dissimilar antigens. Unlike traditional monoclonal antibodies that bind to a single target, bispecific antibodies can employ multi-specific targeting, offering distinctive benefits in drug development. By targeting two separate molecules involved in a disease process, bispecific antibodies enhance therapeutic efficacy, improve target specificity, and potentially overcome certain treatment resistance mechanisms. The development of bispecific antibodies involves different engineering strategies including quadroma technology, chemical conjugation-based methods and more recent technologies including Dual Variable Domain Immunoglobulin and two-in-one models can be employed to generate bispecific antibodies. These bispecific agents can target a diversity of disease-related pathways, creating adaptable molecules for numerous medical ailments, including cancer. Ongoing research and improvements over the last decade in antibody engineering allow for the design, optimization and scale-up of bispecific antibodies for human therapeutics development.

Our Pipeline Candidates

TH104

TH104 is a product which has been developed by embedding drug onto a proprietary transmucosal buccal film which adheres to the inside of the mouth. TH104 has key features which we believe make it an ideal product candidate for multiple liver-related and other pruritogenic inflammatory conditions. The active molecule, nalmefene, has a dual mechanism of action by affecting both the μ-opioid receptor and the kappa opioid receptor as well as inhibiting IL-17 inflammatory cytokine expression. We intend to complete a phase 1 pharmacokinetic trial for TH104 in second quarter 2024 as well as a phase 2 proof-of-concept in PBC patients over approximately 12 months after aligning with FDA on trial design by late 2024/early 2025. We believe TH104 may also be used for treating chronic pruritogenic conditions associated with cholestatic liver disease as well as other liver related and non-liver related diseases including fatty and alcoholic liver, non-alcoholic liver disease and certain types of hepatitis. Chronic pruritus is significant in liver diseases as well as chronic kidney diseases, hemodialysis and atopic dermatitis.

TH023

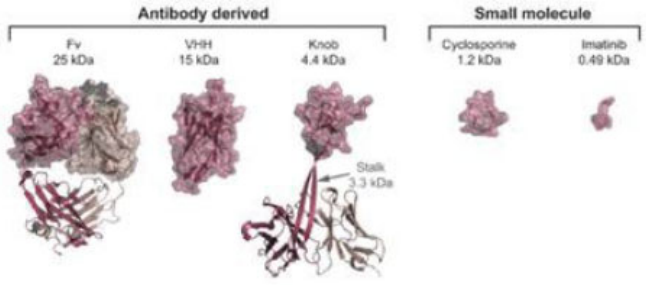
INT-023/TH023, is an oral anti-tumor necrosis factor-alpha (TNF-α) monoclonal antibody, infliximab. The product uses Intract Pharma's Soteria® and Phloral®delivery platform to deleiver infliximab as an oral product.

Infliximab is a purified, recombinant DNA-derived chimeric IgG monoclonal antibody protein that contains both murine and human components that inhibit TNF-α. Tumor necrosis factor-alpha is a signaling protein involved in acute phase reactions and systemic inflammation. Infliximab is sold by Janssen Biotech under the Remicade® brand for numerous indications including Crohn's disease, ulcerative colitis, rheumatoid diseases and plaque psoriasis. Traditionally administered through intravenous infusions, oral delivery of antibodies such as infliximab is challenging due to the complexity of navigating such large molecules through the gastrointestinal tract. TH023 aims to overcome these challenges using Intract's delivery platform, making it possible to administer infliximab in a pill form. TH023 enables the targeted delivery of infliximab directly to the colon or small intestine and the Company intends to pursue the CMC plan in 2025; subsequent to adequate formulation development analyses the Company intends to begin planning a human phase 1 trial to be conducted outside the United States as an initial proof-of-concept.

HS1940

Our early-stage lead product candidate, HS1940, is a proprietary IO biologic, in development targeting PD-1 and VEGF. On November 21, 2022, we entered into a research collaboration and product license agreement with Minotaur and a commercial license agreement with Taurus for use of certain technology, including OmniAb antibodies, to advance Picobodies against novel, unreachable and undruggable epitopes in high-value validated targets starting with PD-1. The research and collaboration agreement and product license agreement are for the development of proprietary targeted biologics, including TH 1940, against PD-1 and VEGF. It is anticipated that we will collaborate with Minotaur under the license from Taurus to discover, develop and advance biotherapeutics against high-value validated IO targets starting with PD-1. We extended this agreement in July of 2023 with an additional target (HER3) and an oncology target.

Picobodies are bovine-derived antibody "knob" domains comprised of cysteine-rich ultralong complementary determining region H3 sequences of 30-40 amino acids weighing ~3-4 KDa, which have the potential to access challenging undruggable epitopes better than full size antibodies can. By extending the half-life of knobs to create HS1940, we believe we can more efficiently target novel epitopes with greater binding affinity than approved anti-PD-1 antibodies. We further believe that the development of HS1940 is a step toward enabling us to enter the rapidly growing IO market with additional targets thereafter.



Source: Proceedings of the National Academy of Sciences of the United States of America “The smallest functional antibody fragment: Ultralong CDR H3 antibody knob regions potently neutralize SARS-CoV-2”

HS3215

HS3215, is an anti-HER2/HER3 bispecific antibody candidate. The ErbB or HER family of cell surface proteins are some of the most well-known and validated oncology drug targets including ErbB2 or HER2 and Erb3 or HER3. Our antibodies against HER2 and HER3 bind to different domains of the extracellular portion of the proteins or epitopes with trastuzumab primarily binding the ECD IV of HER2. HER2 is a validated tumor antigen for antibody drug conjugates to treat HER2 positive cancers with two approved antibodies, Roche/Genentech’s KADCYLA® and Daiichi Sankyo/AstraZeneca’s ENHERTU®. Areas of interest for the development of HS3215 are as a treatment of solid tumors in which HER2 is overexpressed including breast cancer, colorectal cancer, endometrial cancer and gastroesophageal cancer.

The ErbB family of receptor tyrosine kinases, also known as Human Epidermal Growth Factor Receptor (“HER”) family, comprises four transmembrane receptors: HER1 (EGFR/ErbB1), HER2 (Neu/ErbB2), HER3 (ErbB3), and HER4 (ErbB4). These receptors play crucial roles in the regulation of cell proliferation, survival, differentiation, and migration. The ErbB family members are activated upon binding to specific ligands, including EGF, transforming growth factor-alpha (TGF-α), amphiregulin (“AR”), and others, resulting in receptor dimerization and autophosphorylation of specific tyrosine residues within their intracellular domains.

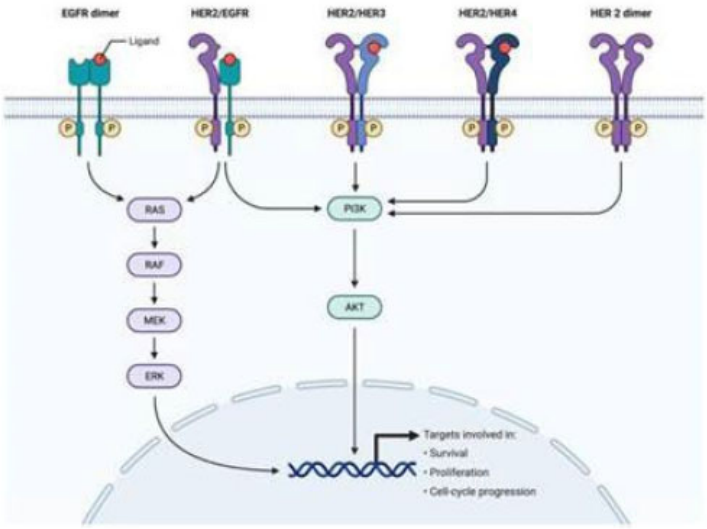
HER1, also known as EGFR, is the prototypical member of the ErbB family and is widely expressed in various tissues. Its activation initiates a downstream signaling cascade that involves the activation of the mitogen-activated protein kinase (“MAPK”) and phosphoinositide 3-kinase (“PI3K”)/AKT pathways, leading to cell proliferation and survival. HER1 dysregulation has been implicated in various cancers, making it an important therapeutic target.

HER2, also known as Neu or ErbB2, lacks a ligand-binding domain, and its activation is predominantly through heterodimerization with other ErbB family members. It is a key partner in heterodimerization with HER3, forming the most potent signaling complex among the ErbB receptors. This heterodimerization is thought to cause an oncogenic signal into cells overexpressing these receptors and cause tumorigenesis. HER2 is amplified and overexpressed in certain cancers, particularly breast cancer, contributing to aggressive tumor behavior and poor prognosis.

HER3, or ErbB3, possesses impaired tyrosine kinase activity, but its dimerization with other ErbB receptors, particularly HER2, leads to the activation of downstream signaling pathways. HER3 is a critical regulator of PI3K signaling, which is crucial for cell survival and proliferation. HER3 overexpression is associated with resistance to HER2-targeted therapies, making it an attractive target for cancer treatment. Furthermore, agents that may block both HER2 and HER3 signaling, in both ligand-dependent and independent pathways could be highly attractive strategies for human therapeutic development.

HER4, or ErbB4, exists in various isoforms and exhibits diverse functions depending on tissue context. HER4 activation can result in the activation of both the MAPK and PI3K/AKT pathways, but its signaling outcomes are complex and context-dependent. HER4 plays important roles in heart development, neural development, and breast tissue differentiation.

The ErbB family of receptor tyrosine kinases represent a closely synchronized signaling system that controls central cellular activities. Dysregulation of these receptors, either through mutations, amplifications, or overexpression, provides to the development and evolution of several cancers. Elucidating the elaborate signaling pathways and communications within the ErbB family is fundamental for developing targeted therapies to efficiently treat cancer and other diseases associated with aberrant ErbB signaling. Ongoing research continues to unveil the complexities of ErbB signaling, opening new avenues for innovative therapeutic strategies and personalized medicine approaches.



On July 5, 2023 (the "ABSI Effective Date"), we entered into a Research and Development Collaboration and License Agreement (the "ABSI Agreement") with Applied Biomedical Science Institute ("ABSI"), pursuant to which ABSI granted us an exclusive royalty-bearing, sublicensable license to the ABSI Patents and a non-exclusive, royalty-bearing, sublicensable license to the ABSI Know-How to Exploit the ABSI Products for the treatment, diagnosis, prediction, detection or prevention of disease in humans and animals worldwide (the "Territory"). Pursuant to the ABSI Agreement, the parties shall form a committee to manage the preclinical, IND-enabling studies and such other activities as shall lead to the initiation of a Phase 1 clinical trial of the ABSI Product. The parties will collaborate on a Target-by-Target basis to identify and evaluate ABSI Products directed against such Target with a view to identifying or generating suitable Products for our Company to Exploit. "Target" means ErB2 (Her2) and ErB3. Upon completion of the Discovery Timeline for a Target, subject to the terms and conditions of ABSI Agreement, we shall exclusively own any ABSI Products against such Target. In the event the committee determines that the discovery activities are unsuccessful with respect to a Target, we may propose an additional target, which, upon approval by ABSI, shall replace a failed Target, each such capitalized term as defined in the BASI Agreement.

As part of the ABSI Agreement, on July 26, 2023, we issued 1,674 shares of our common stock with a per share value of $149.34, representing total compensation expense of $250,000.

On March 11, 2024, we entered into an addendum to the ABSI Agreement to fund research services with quarterly payments of $50,000 beginning March 18, 2024 with subsequent payments due on the 18th of each calendar quarter.

In the past decade, cancer therapy has seen significant innovations, and one class of therapeutics gaining significant attention is bispecific antibodies. These specialized molecules are engineered to target two distinct antigens boosting their specificity and therapeutic potential. Among the most promising targets in oncology are HER2 and HER3 receptors, which play crucial roles in cell signaling and proliferation.

HER2 and HER3 are members of the ErbB family of receptor tyrosine kinases, and their dysregulation is associated with the development and progression of various cancers, including breast, ovarian, gastric, and lung cancers. HER2, also known as ErbB2, is overexpressed in approximately 20-30% of breast cancers and is linked to aggressive tumor behavior and poor prognosis. HER3, on the other hand, lacks intrinsic kinase activity but forms heterodimers with other ErbB family members, particularly HER2, leading to potent signaling through the PI3K/AKT pathway.

Traditional monoclonal antibodies targeting either HER2 or HER3 have shown promising clinical outcomes in some cancer patients; however, cancer cells often develop resistance mechanisms, leading to treatment failure. To overcome this challenge, researchers have turned to bispecific antibodies as a more effective approach to disrupt multiple signaling pathways simultaneously and prevent the emergence of resistance.

Bispecific antibodies that target both HER2 and HER3 receptors offer several advantages over traditional therapies. By simultaneously binding to both receptors, these antibodies can block the formation of heterodimers between HER2 and HER3, effectively inhibiting downstream signaling cascades that drive tumor growth and survival. Additionally, bispecific antibodies can also engage immune cells, such as T cells and natural killer cells, through their Fc region, promoting the destruction of cancer cells via antibody-dependent cell-mediated cytotoxicity and antibody-dependent cellular phagocytosis.

Our Other Product Candidates

HS0059, is a bispecific anti-HER2/anti-HER3 monoclonal ADC candidate. Research studies elucidating the biology of HER3 reveal that triggering of HER3 signaling stimulates tumor progression via augmentation of metastatic potential and induces treatment failure in human tumors. Mounting evidence supports HER3 as an important target and its activation is considered to be required to overcome therapeutic resistance, enhance efficacy, and increase patient survival. To date, to our knowledge, there is no FDA-approved HER3-targeted therapy for cancer treatment. Targeting both HER2 and HER3 with a blocking antibody is a strategy we intend to explore as we progress our pipeline.

We intend to further develop our pipeline with novel bispecific monoclonal antibodies. These bispecific antibodies are planned to simultaneously bind to two different antigens or to two different epitopes on the same antigen. Whether two different antigens or two epitopes on the same antigen, the bispecific antibody could bind its targets either on the same cell (*cis*) or on to different cells (*trans*). Our strategy involves targeting PD-1 combined with a known, validated undisclosed antigen or using HER2 instead of PD-1 while naturally occurring antibodies typically only target one epitope on one antigen.

Recent Developments

On June 17, 2024, we entered into a securities purchase agreement with certain accredited investors for the issuance and sale in a private placement (the "June PIPE Offering"), consisting of an offering of shares of our common stock and/or pre-funded warrants to acquire shares of our common stock and warrants to acquire shares of our common stock, with net proceeds of approximately $1.8 million. See Note 3 to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for details regarding these offerings.

We signed a manufacturing agreement for clinical trial supply with regards to TH104 and the upcoming Phase 2 clinical trial on July 25, 2024 with a contract manufacturing organization located in North Carolina. The development work includes both TH104 active product and corresponding placebo batches expected to be released for clinical packaging by the end of the year.

On September 30, 2024, we entered into a nonbinding, exclusive letter of intent (the "LOI") with Intract pursuant to which we will acquire all outstanding shares of common stock of the privately-held Intract for newly issued restricted common stock. Intract is a biopharmaceutical company incorporated in England and Wales developing disruptive delivery solutions for oral biologics. Under the terms of the LOI, following the execution of a definitive agreement and the closing of the merger, Intract shareholders will own 49% of the total equity in the combined entity, which will be named Tharimmune, Inc., with Intract becoming a wholly owned subsidiary. We believed the merger and business combination will form a best-in-class, transformative oral biologics company and the synergies between our clinical-stage assets and Intract's delivery platform will drive pipeline growth. During the year ended December 31, 2024, we paid $0.3 million in fees pursuant to the LOI agreement prior to cancellation.

On November 30, 2024, the Company provided notice to Intract that it has terminated the non-binding, exclusive LOI to merge with Intract.

On December 5, 2024, we entered into a securities purchase agreement with certain accredited investors for the issuance and sale in a private placement (the "December PIPE Offering"), consisting of an offering of shares of our common stock and/or pre-funded warrants to acquire shares of our common stock and warrants to acquire shares of our common stock, with gross proceeds of approximately $2.02 million and net proceeds of approximately $1.83 million. See Note 3 to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for details regarding these offerings.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products and intellectual property. We face competition from major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, emerging and start-up companies, universities and other research institutions both in the United States and internationally. Any drug candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Earlier stage companies, such as smaller discovery phase biotechnology companies, may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. We anticipate some of our competitors for TH104 will include Mirum Pharma, Ipsen Pharma, Cara Therapeutics, Moonlake Therapeutics, Apogee Therapetuics, and Regeneron. In addition, some of our competitors for our early-stage pipeline include Bayer AG, Moderna Inc., Roche/Genentech, Daiichi Sankyo/Astra Zeneca, Merck, Bristol-Myers Squibb and Takeda Pharmaceutical Company.

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, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. In addition, our ability to compete may be affected in many cases by insurers or other third-party payers seeking to encourage the use of generic products. Generic products are currently on the market, including the active ingredients which may be used for the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If our drug candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive generic products.

The most common methods of treating patients with cancer are surgery, radiation and drug therapy, including chemotherapy and targeted drug therapy. There are a variety of available drug therapies marketed for solid tumors. In many cases, these drugs are administered in combination to enhance efficacy. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis, including drugs in the same therapeutic class as the payloads in product candidates contained in our pipeline.

Many of these approved drugs are well established therapies and are widely accepted by physicians, patients and third-party payers. In general, although there has been considerable progress over the past few decades in the treatment of solid tumors and the currently marketed therapies provide benefits to many patients, these therapies all are limited to some extent in their efficacy and frequency of adverse events, and none of them are successful in treating all patients. As a result, the level of morbidity and mortality from solid tumor cancers remains high.

There are also a number of products in clinical development to treat solid tumors including, but not limited to, Loxo Oncology (LOXO-292), Bristol-Myers Squibb (BMS-986016 and nivolumab) Mersana / GlaxoSmithKline (XMT-2056), Zymeworks (zenidatamab) and Eli Lilly & Co (sintilimab) in addition to those products already on the market such as Merck & Co Inc. (Keytruda), Bristol-Myers Squibb Co. (Opdivo), AbbVie Inc. (Imbruvica), Roche Group (Tecentiq), Regeneron Pharmaceuticals, Inc. (Libtayo). The products in development may provide efficacy, safety, convenience and other benefits that are not provided by currently marketed therapies. As a result, they may provide significant competition for our product candidates for which we obtain marketing approval.

Manufacturing

We do not own or operate any facilities in which we can formulate or manufacture our product candidates. We intend to rely on contract manufacturers to produce all materials required to conduct pre-clinical studies and clinical trials under current good manufacturing practice ("cGMP"), with oversight of these activities by our management team. We have identified alternate sources of supply and other contract manufacturers that can produce materials for our pre-clinical and clinical trial requirements on a timely basis. However, if an existing or future contract manufacturer fails to deliver on schedule, or at all, it may delay or interrupt the development process for our product candidates, which may have an adverse effect on our operating results and estimated timelines.

Intellectual Property

The intellectual property that is available to us is important for our business, and we strive to protect it, including by obtaining, maintaining, defending, and enforcing patent protection in the United States and internationally for our proprietary technology, improvements, platforms, products and components thereof, novel biological discoveries, new therapeutic approaches and potential indications, and other inventions that are important to our business. For our product candidates, generally we initially pursue patent protection covering compositions of matter, methods of production, and methods of use. Throughout the development of our product candidates and technologies, we will seek to identify additional means of obtaining patent protection.

Our patent portfolio includes 3 patent families with 2 issued U.S. patents and 14 pending applications related generally to treatment of pruritus. The claims of these patents and applications cover devices and their method of manufacture, as well as methods of treating. Specifically, our patent portfolio currently includes two issued U.S. patents, as well as a pending application in the U.S. and 13 pending applications abroad. Patent protection is expected to expire in 2039, absent any applicable patent term adjustments or extensions. We may file other patent applications in the future.

We also have issued patents and pending applications related generally to our polymeric nanoparticle technologies, methods of making our polymeric nanoparticle technologies, and methods of using our polymeric nanoparticles therapeutically (*e.g.*, for delivery of therapeutic compounds). Patent protection for the earliest-filed family is expected to expire in 2033, absent any applicable patent term adjustments or extensions, with more recently filed families expiring approximately between 2033 and 2042. We have collaborations with Minotaur Therapeutics, Inc. and Applied Biomedical Science Institute regarding applications of this technology with a variety of multispecific binders including binders for HER2 and HER3, as well as an anti-PD-1 binder. These collaborations will likely lead to filing of additional patent applications in the future.

The term of individual patents depends upon the legal term for patents in the countries in which they are obtained. In most countries, including the U.S., the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the U.S., the term of a patent may be lengthened by patent term adjustment ("PTA"), which compensates a patentee for administrative delays by the USPTO in examining and granting a patent or the term of a patent may be shortened if a patent is terminally disclaimed over an earlier filed patent. The term of a patent that covers a drug or biological product may also be eligible for patent term extension ("PTE") after FDA approval for a portion of the term effectively lost as a result of the FDA regulatory review period, subject to certain limitations and provided statutory and regulatory requirements are met. PTE can be for no more than five years, typically only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. In addition, the length of the adjustment or extension granted could be less than that requested, and we may not receive the full PTA or PTE available if we fail to exercise due diligence during the testing phase or regulatory review process, fails to apply within applicable deadlines, fails to apply prior to expiration of relevant patents, or otherwise fails to satisfy applicable requirements.

As with many biotechnology and pharmaceutical companies, our ability to maintain and solidify our proprietary and intellectual property position for our products will depend on our success in obtaining effective patent claims and enforcing those patent claims. However, our owned pending patent applications, and any patent applications that may be filed in the future or licensed from third parties, may not result in issuance. The breadth of claims that may be allowed or enforced in our patents also cannot be predicted. Any of our issued patents or patents obtained in the future may be challenged, invalidated, infringed or circumvented. In addition, because of the extensive time required for clinical development and regulatory review of a therapeutic product that may be developed, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting the protection such patent would afford the respective product and any competitive advantage such patent may provide. Further, the collaborations we have entered into may not result in patentable subject matter or potential licensing agreements may not be successfully negotiated.

We intend to file an intent-to-use U.S. trademark application for "THARIMMUNE INC" (for "Pharmaceutical preparations for use in cancer treatment and therapies") in International class 5.

Minotaur Research and Collaboration Agreement and Taurus License Agreement

We entered into a research collaboration and product license agreement with Minotaur Therapeutics, Inc. ("Minotaur") and a commercial license agreement with Taurus Biosciences, LLC ("Taurus") for use of certain technology, including OmniAb antibodies, to advance Picobodies against novel, unreachable and undruggable epitopes in high-value validated targets starting with PD-1. The research and collaboration agreement and product license agreement are for the development of proprietary targeted biologics, including HS1940, against PD-1.

The research collaboration between us and Minotaur will be executed under the license from Taurus to discover, develop and advance biotherapeutics against high-value validated IO targets. Picobodies are bovine-derived antibody "knob" domains comprised of cysteine-rich ultralong complementary determining region H3 sequences of 30-40 amino acids weighing ~3-4KDa, which have the potential to access challenging epitopes better than full size antibodies can.

By combining non-proprietary half-life extending methods which are linked to a PD-1 Picobody™ to create HS1940, we believe we could more efficiently target novel epitopes with greater binding affinity than currently approved anti-PD-1 antibodies. We further believe that the development of HS1940 is a step toward enabling us to enter the rapidly growing immune-oncology market with additional targets thereafter.

Applied Biomedical Research Institute Research and Development Collaboration and License Agreement

On July 5, 2023 (the "ABSI Effective Date"), we entered into a Research and Development Collaboration and License Agreement (the "ABSI Agreement") with Applied Biomedical Science Institute ("ABSI") pursuant to which ABSI granted us an exclusive royalty-bearing, sublicensable license to the ABSI Patents and a non-exclusive, royalty-bearing, sublicensable license to the ABSI Know-How to Exploit the ABSI Products for the treatment, diagnosis, prediction, detection or prevention of disease in humans and animals worldwide (the "Territory"). Pursuant to the ABSI Agreement, the parties shall form a committee to manage the preclinical, IND- enabling studies and such other activities as shall lead to the initiation of a Phase 1 clinical trial of the ABSI Product. The parties will collaborate on a Target-by-Target basis to identify and evaluate ABSI Products directed against such Target with a view to identifying or generating suitable Products for our Company to Exploit. "Target" means ErB2 (Her2) and ErbB3. Upon completion of the Discovery Timeline for a Target, subject to the terms and conditions of ABSI Agreement, we shall exclusively own any ABSI Products against such Target. In the event the committee determines that the discovery activities are unsuccessful with respect to a Target, we may propose an additional target, which, upon approval by ABSI, shall replace a failed Target, each capitalized term as defined in the ABSI Agreement.

As part of the ABSI Agreement, on July 26, 2023, we issued 1,674 shares of our common stock with a per share value of $149.34, representing total compensation expense of $250,000.

On March 11, 2024, we entered into an addendum to the ABSI Agreement to fund research services with quarterly payments of $50,000 beginning March 18, 2024 with subsequent payments due on the 18th of each calendar quarter.

Avior Patent License Agreement

On November 3, 2023 (the "Avior Effective Date"), we entered into the Avior Patent License Agreement with Avior pursuant to which we received an exclusive sublicensable right and license to Licensed Patent Rights and Licensed Technology to, among other things, develop, have developed, make, have made, use, sell, import, export and commercialize TH104 and TH103 and to practice the Licensed Technology in connection with the foregoing throughout the world. Pursuant to the Avior Patent License Agreement, we paid Avior an up front license fee of $400,000 within ten days of the Avior Effective Date and an additional mid-six digit license fee which shall be paid in four equal installments within ten days of the end of each fiscal quarter following the Avior Effective Date. In addition, we shall pay Avior a high single digit percentage of any upfront payments received by us as a result of the grant of any sublicenses with respect to TH104. We shall also pay Avior milestone payments in the aggregate amount of $24.25 million upon the occurrence of various development milestones (the "Development Milestone Payments"). Furthermore, we shall pay Avior certain fees based upon sales milestones. The payments for such sales milestones range from the low seven digits to the low eight digits with higher sales being subject to higher fees. Finally, we shall pay Avior royalties based on net sales. Such royalties range from low single digit percentages to mid-single digit percentages with higher sales being subject to lower percentages. The Avior Patent License Agreement shall expire upon the expiration of the final payment obligation due to Avior as set forth in such agreement. Upon the expiration of the Avior Patent License Agreement, we shall have a fully paid-up, irrevocable, freely transferable and sublicensable worldwide license to the Licensed Patent Rights and Licensed Technology to Develop, have Developed, make, have made, use, have used sell, offer for sale, have sold, import, have imported, export, have exported, commercialize or have commercialized any and all Licensed Products and to practice the Licensed Technology worldwide. Pursuant to the Avior Patent License Agreement, we may terminate the agreement at any time without cause, upon 30 days' prior written notice to Avior along with payment of the next unpaid Development Milestone Payment, if any. Furthermore, either we or Avior may terminate the Avior Patent License Agreement (i) on written notice to the other party if the other party materially breaches any provision of the Avior Patent License Agreement and fails to cure such breach within 30 days after the breaching party receives written notice thereof or (ii) on written notice in the event that either party (A) becomes insolvent or admits its inability to pay its debts generally as they become due; (B) becomes subject, voluntarily or involuntarily, to any proceeding under any domestic or foreign bankruptcy or insolvency law, which is not fully dismissed or vacated within 60 days; (C) is dissolved or liquidated or takes any corporate action for such purpose; (D) makes a general assignment for the benefit of creditors; or (E) has a receiver, trustee, custodian or similar agent appointed by order of any court of competent jurisdiction to take charge of or sell any material portion of its property or business. Upon termination of the Avior Patent License Agreement, the license granted pursuant to such agreement shall terminate and all rights in the Licensed Patent Rights and Licensed Products shall revert back to Avior.

Enkefalos License Agreement

On June 17, 2024 (the "Enkefalos Effective Date"), we signed a letter of intent (the "Enkefelos LOI") to enter into the Enkefalos License Agreement with Enkefalos Biosciences Inc. pursuant to which we are licensing the global rights in all fields of use for the products related to the compounds knows as cyclotides to deliver HER2 antibodies across the blood-brain barrier and all associated know-how, technology, intellectual property and related information and constructs, and any associated authorized generic rights and all related assets (collectively, the "Products" referred to in this letter as ENBI-01) from Enkefalos Biosciences, Inc. Pursuant to the Enkefalos License Agreement, we paid Enkefalos an upfront license fee of $150,000 upon signing of the Enkefalos LOI and an additional $150,000 license fee to be paid 6 months after the Enkefalos Effective Date. In addition, we shall pay Enkefalos a $50,000 annual license fee and milestone payments in the aggregate amount of up to $8,500,000 upon the occurrence of various development milestones (the "Enkefalos Development Milestone Payments"). Furthermore, we shall pay Enkefalos royalties based on net sales. Such royalties range from low-single digit percentages to mid-single digit percentages with higher sales being subject to lower percentages. The Enkefalos License Agreement shall expire upon the expiration of the final payment obligation due to Enkefalos as set forth in such agreement. Upon the expiration of the Enkefalos Patent License Agreement, we shall have a fully paid, irrevocable, freely transferable and sublicensable worldwide license to the Licensed Patent Rights and Licensed Technology to Develop, have Developed, make, have made, use, have used sell, offer for sale, have sold, import, have imported, export, have exported, commercialize or have commercialized any and all Licensed Products and to practice the Licensed Technology worldwide. Pursuant to the Enkefalos License Agreement, either the Company or Enkefalos may terminate the Enkefalos License Agreement on written notice to the other party. Upon termination of the Enkefalos License Agreement, the license granted pursuant to such agreement shall terminate and all rights in the Licensed Patent Rights and Licensed Products shall revert back to Enkefalos.

Intract Patent License Agreement

On September 11, 2024 (the "Intract Effective Date"), we entered into a Patent License Agreement (the "Intract Agreement") with Intract Pharma Limited, ("Intract"), pursuant to which the Company exclusively licensed INT-023/TH023, an oral anti-Tumor Necrosis Factor-alpha (TNF-α) monoclonal antibody infliximab. Under the terms of the Intract Agreement, we licensed global development and commercialization rights (outside of South Korea) to Intract's Soteria® and Phloral® delivery platform along with an existing supply agreement for infliximab to be used in the oral product development program. Pursuant to the Intract Agreement, Intract recieved an upfront license fee of $400,000 and is eligible to receive additional payments upon an equity financing of the Company and for future development, regulatory and commercial milestones, as well as mid-single digit royalties based on net product sales. Under the terms of the Intract Agreement, we retain a right of first refusal to continue development and commercialization after a Phase 2 clinical trial and have the option to exercise the license to Intract's platform for up to four additional targets. The term of the Intract Agreement expires upon the final payment obligation of the Company under the Intract Agreement. In addition, the Intract Agreement may be terminated by us at any time upon 90 days written notice to Intract. Either party may terminate the Intract Agreement if the other party materially breaches any provision of the Intract Agreement and fails to cure such breach within thirty (30) days after the breaching party receives written notice thereof. In addition, either party may terminate the Intract Agreement on written notice in the event that either party declare: (a) becomes insolvent or admits inability to pay its debts generally as they become due; (b) becomes subject, voluntarily or involuntarily, to any proceeding under any domestic or foreign bankruptcy or insolvency law, which is not fully dismissed or vacated within sixty (60) days; (c) is dissolved or liquidated or takes any corporate action for such purpose; (d) makes a general assignment for the benefit of creditors; or (e) has a receiver, trustee, custodian or similar agent appointed by order of any court of competent jurisdiction to take charge of or sell any material portion of its property or business.

Government Regulations

Governmental authorities in the U.S. and other countries extensively regulate the research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing of pharmaceutical products such as those being developed by us. In the U.S., the FDA regulates such products under the FDCA and its implementing regulations. Failure to comply with applicable FDA requirements, both before and after approval, may subject us to administrative and judicial sanctions, such as a delay in approving or refusal by the FDA to approve pending applications, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution.

U.S. Food and Drug Administration Regulation

United States Drug Development

In the United States, the FDA regulates drugs, medical devices and combinations of drugs and devices, or combination products, under the FDCA and its implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate 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 administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning or untitled letters, requests for voluntary product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

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

- completion of extensive pre-clinical laboratory tests, animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials in accordance with an applicable IND and clinical study related regulations, referred to as GCP, to establish the safety and efficacy of the proposed drug for its proposed indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with the FDA's cGMP requirements;
- potential FDA audit of the clinical trial sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA prior to any commercial marketing or sale.

Once a pharmaceutical product candidate is identified for development, it enters the pre-clinical testing stage. Pre-clinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. An IND sponsor must submit the results of the pre-clinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. The sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the initial clinical trial lends itself to an efficacy evaluation. Some pre-clinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions related to a proposed clinical trial and places the trial on a clinical hold within that 30-day period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns or non-compliance and may be imposed on all drug products within a certain class of drugs. The FDA also can impose partial clinical holds, for example, prohibiting the initiation of clinical trials of a certain duration or for a certain dose.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. These regulations include the requirement that all research subjects provide informed consent in writing before their participation in any clinical trial. Further, an IRB must review and approve the plan for any clinical trial before it commences at any institution, and the IRB must conduct continuing review and reapprove the study at least annually. An IRB considers, among other things, whether the risks to individuals participating in the clinical trial are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information regarding the clinical trial and the consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval. Protocols detail, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety.

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

- Phase 1. The product is initially introduced into a small number of healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product is suspected or known to be unavoidably toxic, the initial human testing may be conducted in patients.

- Phase 2. Involves clinical trials in 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 and schedule.

- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit relationship of the product and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 trials. Companies that conduct certain clinical trials also are required to register them and post the results of completed clinical trials on a government-sponsored database, *www.clinicaltrials.gov*, in the United States, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events, findings from other studies that suggest a significant risk to humans exposed to the product, findings from animal or in vitro testing that suggest a significant risk to human subjects, and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients 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 product has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the study. The clinical trial sponsor may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

NDA and FDA Review Process

The results of product development, pre-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the drug, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA, which request approval to market a new drug product. The submission of an NDA is subject to the payment of a substantial user fee, and the sponsor of an approved NDA is also subject to an annual program user fee; although a waiver of such fee may be obtained under certain limited circumstances. For example, the agency will waive the application fee for the first human drug application that a small business or its affiliate submits for review.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. The FDA typically makes a decision on accepting an NDA for filing within 60 days of receipt. The decision to accept the NDA for filing means that the FDA has made a threshold determination that the application is sufficiently complete to permit a substantive review. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act ("PDUFA"), the FDA's goal to complete its substantive review of a standard NDA and respond to the applicant is ten months from the receipt of the NDA. The FDA does not always meet its PDUFA goal dates, and the review process is often significantly extended by FDA requests for additional information or clarification and may go through multiple review cycles.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel drug products or drug products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and 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. The FDA will likely re-analyze the clinical trial data, which could result in extensive discussions between the FDA and us during the review process. The review and evaluation of an NDA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving an NDA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter describes specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive, and the FDA may interpret data differently than we interpret the same data.

There is no assurance that the FDA will ultimately approve a product for marketing in the United States, and we may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products. For example, the FDA may require Phase 4 clinical trials to further assess drug safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also place other conditions on approvals, including the requirement for a REMS to assure the safe use of the drug. If the FDA concludes a Risk Evaluation and Mitigation Strategy ("REMS") is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory requirements or if problems occur following initial marketing.

Orange Book Listing and Paragraph IV Certification

For NDA submissions, including those under Section 505(b)(2), applicants are required to list with the FDA certain patents with claims that cover the applicant's product. Upon approval, each of the patents listed in the application is published in *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the Orange Book. Any applicant who subsequently files an abbreviated new drug application ("ANDA") or 505(b)(2) NDA that references a drug listed in the Orange Book must certify to the FDA 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.

If an applicant has provided a Paragraph IV Certification to the FDA, the applicant must also send notice of the Paragraph IV Certification to the holder of the NDA for the approved drug and the patent owner once the application has been accepted for filing by the FDA. The NDA holder or patent owner may then initiate a patent infringement lawsuit in response to notice of the Paragraph IV Certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV Certification prevents the FDA from approving the ANDA or 505(b)(2) application until the earlier of 30 months from the date of the lawsuit, the applicant's successful defense of the suit, or expiration of the patent.

Reimbursement

Potential sales of any of our product candidates, if approved, will depend, at least in part, on the extent to which such products will be covered by third-party payors, such as government health care programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly limiting coverage and/or reducing reimbursements for medical products and services. A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our future revenues and results of operations. Decreases in third-party reimbursement or a decision by a third-party payor to not cover a product candidate, if approved, or any future approved products could reduce physician usage of our products, and have a material adverse effect on our sales, results of operations and financial condition.

In the United States, the Medicare Part D program provides a voluntary outpatient drug benefit to Medicare beneficiaries for certain products. We do not know whether our product candidates, if approved, will be eligible for coverage under Medicare Part D, but individual Medicare Part D plans offer coverage subject to various factors such as those described above. Furthermore, private payors often follow Medicare coverage policies and payment limitations in setting their own coverage policies.

Healthcare Laws and Regulations

Sales of our product candidates, if approved, or any other future product candidate will be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we might conduct our business. The healthcare industry is highly regulated under both state and federal laws and regulations. Our operations and relationships with healthcare plans and providers are subject to extensive and increasing regulation by numerous federal, state, and local government agencies including the FDA, the Office of Inspector General ("OIG"), the DOJ, the CMS, the Office of Civil Rights, and various state authorities.

The healthcare laws and regulations that may affect our ability to operate include the following:

False Claims Acts

We will be subject to numerous federal and state laws that prohibit the presentation of false information, or the failure to disclose information, in connection with the submission and payment of medical claims for reimbursement.

The federal civil and criminal false claims laws and civil monetary penalties laws, such as the federal False Claims Act, 31 U.S.C. §§ 3729-3733, impose civil liability on individuals or entities that submit false or fraudulent claims for payment to the federal government. The False Claims Act provides, in part, that the federal government may bring a lawsuit against any person whom it believes has knowingly or recklessly: presented, or caused to be presented, a false or fraudulent claim for payment or approval to the federal government; made, used or caused to be made or used a false statement or a false record to get a claim for payment approved, including a false or fraudulent claim; concealed, or knowingly and improperly avoided or decreased, an obligation to pay or transmit money or property to the federal government; or conspired to commit any of the foregoing.

The federal government has used the False Claims Act to prosecute a wide variety of alleged false claims and fraud allegedly perpetrated against Medicare and state healthcare programs. The federal government, including as a result of the passage of the ACA, and a number of courts have taken the position that claims presented in violation of certain other statutes, including the federal Anti-Kickback Statute ("AKS") or the federal physician referral law, 42 U.S.C. 1395nn (the "Stark Law"), can also be considered a violation of the False Claims Act.

A number of states have enacted laws that are similar to the federal False Claims Act. Under Section 6031 of the Deficit Reduction Act of 2005, as amended, if a state enacts a false claims act that is at least as stringent as the federal statute and that also meets certain other requirements, the state will be eligible to receive a greater share of any monetary recovery obtained pursuant to certain actions brought under the state's false claims act. As a result, many states have enacted laws that are similar to the federal False Claims Act and there has been a concomitant increase in state false claims enforcement efforts. Violations of federal and state fraud and abuse laws may be punishable by criminal and/or civil sanctions, including significant penalties, fines, disgorgement, additional reporting requirements and oversight under a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, and/or exclusion or suspension from federal healthcare programs, such as Medicare, and debarment from contracting with the U.S. government. Penalties for False Claims Act violations include fines ranging from $13,508 to $27,018 for each false claim adjusted each year for inflation, plus up to three times the amount of damages sustained by the government. In addition to the provisions of the False Claims Act, which provide for civil enforcement, the federal government also can use several criminal statutes to prosecute persons who are alleged to have submitted false or fraudulent claims to the government for payments. Additionally, private parties may initiate *qui tam* whistleblower lawsuits against any person or entity under the False Claims Act in the name of the federal government, as well as under the false claims laws of several states, and may share in the proceeds of a successful suit. Generally, federal and state governments have made investigating and prosecuting healthcare fraud and abuse a priority.

The Federal "Stark" Law

The Federal Stark Law (42 U.S.C. § 1395nn) prohibits referrals or ordering by a physician of "designated health services," which include pharmaceuticals and drugs that are payable, in whole or in part, by Medicare or Medicaid, to an entity in which the physician or the physician's immediate family member has an investment interest or other financial relationship, subject to several exceptions. Financial relationships that are implicated by the Stark Law can include arrangements ranging from marketing arrangements and consulting agreements to medical director agreements with physicians who order our products. The Stark Law also prohibits billing for services rendered pursuant to a prohibited referral. Several states have enacted laws similar to the Stark Law. These state laws may cover all (not just Medicare and Medicaid) patients. Many federal healthcare reform proposals in the past few years have attempted to expand the Stark Law to cover all patients as well. If we violate the Stark Law, our financial results and operations could be adversely affected. Penalties for violations include denial of payment for the services, significant civil monetary penalties, and exclusion from the Medicare and Medicaid programs.

Federal and State Anti-Kickback Statutes

The AKS, set forth in Section 1128B of the Social Security Act, prohibits the knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for, or to induce, (i) the referral of a person for items or services reimbursable under federal healthcare programs, (ii) the furnishing or arranging for the furnishing of items or services reimbursable under federal healthcare programs or (iii) the purchase, lease or order or arranging or recommending purchasing, leasing or ordering of any item or service reimbursable under federal healthcare programs.

The core of a violation of the AKS is an "inducement" to refer patients for services or items that are reimbursed under a federal healthcare program, such as Medicare, Medicaid, or Tricare (which covers military personnel). The ACA amended the AKS to make it clear that a person need not have actual knowledge of the statute, or specific intent to violate the statute, as a predicate for a violation. Court cases have resulted in the interpretation that a violation may occur where even one purpose of the remuneration is to induce or reward referrals, and the OIG, which has the authority to impose administrative sanctions for violation of the statute, has adopted a similar standard.

There are certain AKS "safe harbors" which, if the respective requirements are met, would afford protection from the AKS. Failure to meet all requirements of an AKS safe harbor does not necessarily mean the arrangement violates the AKS, but it may be subject to scrutiny by legal authorities, in light of the parties' intent and arrangements. In other words, if an arrangement does not fit within a safe harbor, it does not necessarily mean that the arrangement is *per se* illegal-only that it is not shielded from regulatory scrutiny. The federal AKS provides criminal penalties for individuals or entities that knowingly and willfully solicit or receive any remuneration. A violation of the AKS is punishable by imprisonment of up to ten years, fines of up to $100,000 per offense, or both. Violation can also give rise to federal healthcare program exclusion, liability under the False Claims Act and civil penalties, which may include monetary penalties of up to $100,000 per offense, repayments of up to three times the total payments between the parties to the arrangement and suspension from future participation in Medicare and Medicaid.

Additionally, some states have enacted statutes and regulations similar to the AKS, but which may be applicable regardless of the payor source for the patient. These state laws may contain exceptions and safe harbors that are different from and/or more limited than those of federal law and that may vary from state to state.

Health Care Fraud Statute

The Health Care Fraud Statute, 18 U.S.C. § 1347, prohibits any person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, which can be either a government or private payor plan. Violation of this statute, even in the absence of actual knowledge of or specific intent to violate the statute, may be charged as a felony offense and may result in fines, imprisonment or both. The Health Care False Statement Statute, 18 U.S.C. § 1035, prohibits, in any matter involving a federal healthcare program, anyone from knowingly and willfully falsifying, concealing or covering up, by any trick, scheme or device, a material fact, or making any materially false, fictitious, or fraudulent statement or representation, or making or using any materially false writing or document knowing that it contains a materially false or fraudulent statement. A violation of this statute may be charged as a felony offense and may result in fines, imprisonment, or both.

Civil Monetary Penalties Statute

The CMPL, 42 U.S.C. § 1320a-7a, authorizes the imposition of civil monetary penalties, assessments, and exclusions against an individual or entity based on a variety of prohibited conduct, including, but not limited to: (i) presenting, or causing to be presented, claims for payment to Medicare, Medicaid, or other third-party payors that the individual or entity knows or should know are for an item or service that was not provided as claimed or is false or fraudulent; (ii) offering remuneration to a federal healthcare program beneficiary that the individual or entity knows or should know is likely to influence the beneficiary to order or receive healthcare items or services from a particular provider; (iii) arranging contracts with an entity or individual excluded from participation in a federal healthcare program; (iv) violating the federal AKS; (v) making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a federal healthcare program; (vi) making, using, or causing to be made any false statement, omission, or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider of services or a supplier under a federal healthcare program; and (vii) failing to report and return an overpayment owed to the federal government. We could be exposed to a wide range of allegations to which the federal CMPL would apply. We cannot foreclose the possibility that we will face allegations subject to the CMPL with the potential for a material adverse impact on our business, results of operations and financial condition. Substantial civil monetary penalties may be imposed under the federal Civil Monetary Penalty Statute and may vary, depending on the underlying violation. In addition, an assessment of not more than three times the total amount claimed for each item or service may also apply, and a violator may be subject to exclusion from federal and state healthcare programs.

Additionally, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws.

Employees

As of March 1, 2025, we employed 2 full-time employees and 1 part-time employee. We are not a party to any collective bargaining agreements, and we believe that we maintain good relations with our employees.

Our human capital resources objectives include identifying, recruiting, retaining and incentivizing our existing and future employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through granting of equity-based compensation awards and cash-based compensation awards, in order to increase stockholder value and support success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Facilities

Our corporate headquarters are located at 1200 Route 22 East, Suite 2000, Bridgewater, NJ 08807 pursuant to a monthly rental agreement. We believe this to be sufficient to meet our needs for the foreseeable future and that any additional space we may require will be available on commercially reasonable terms.

Legal Proceedings

From time to time, we may become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. Litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. We are currently not aware of any such legal proceedings or claims that will have, individually or in the aggregate, a material adverse effect on our business, financial condition or operating results.

Our Corporate History

We were incorporated under the laws of the State of Delaware on March 28, 2017 under the name Hillstream BioPharma Inc. ("HBI"). On July 16, 2019, Hillstream BioPharma Holdings, Inc. ("Holdco") was formed as a Delaware C-corporation. On July 24, 2019, Holdco entered into a Contribution and Exchange Agreement with Nanoproteagen LLC ("Nanoproteagen") whereby the members of Nanoproteagen exchanged 100% of their membership interests in Nanoproteagen for shares of Holdco common stock. Also on July 24, 2019, the stockholders of HBI exchanged 100% of their shares of common stock for shares of common stock of Holdco. HBI and Nanoproteagen became wholly-owned subsidiaries of Holdco. On August 7, 2019, pursuant to a certificate of amendment, Holdco's name was changed to Hillstream BioPharma, Inc. and HBI's name was changed to HB Pharma Corp. On November 12, 2020, Hillstream BioPharma, Inc. entered into a Share Exchange Agreement with Farrington Therapeutics LLC ("Farrington"), whereby the members of Farrington exchanged their membership interest in Farrington for shares of common stock of Hillstream BioPharma, Inc., and Farrington became a wholly-owned subsidiary of Hillstream BioPharma, Inc. On September 21, 2023, the Company filed a Certificate of Amendment to its Certificate of Incorporation with the Secretary of State of the State of Delaware pursuant to which it changed its name to Tharimmune, Inc. effective as of September 25, 2023.

On November 17, 2023, we filed a Certificate of Amendment to our Certificate of Incorporation, as amended, with the Delaware Secretary of State to effectuate a 1-for-25 reverse stock split of our issued and outstanding shares of common stock. The reverse stock split became effective at 4:01 p.m. Eastern time on November 20, 2023. All share data, per share data, and related information contained in this Annual Report on Form 10-K has been retrospectively adjusted to reflect the effect of the reverse stock split.

On May 22, 2024, we filed a Certificate of Amendment to our Certificate of Incorporation, as amended, with the Delaware Secretary of State to effectuate a 1-for-15 reverse stock split of our issued and outstanding shares of common stock. The reverse stock split became effective at 4:01 p.m. Eastern time on May 24, 2024. All share data, per share data, and related information contained in this Annual Report on Form 10-K has been retrospectively adjusted to reflect the effect of the reverse stock split.

As of December 31, 2024, the Company had one wholly-owned subsidiary, HB Pharma Corp.

Available Information

Our website address is *www.tharimmune.com*. The contents of, or information accessible through, our website are not part of this Annual Report on Form 10-K, and our website address is included in this document as an inactive textual reference only. We make our filings with the SEC, including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports, available free of charge on our website as soon as reasonably practicable after we file such reports with, or furnish such reports to, the SEC. The public may read and copy the materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Additionally, the SEC maintains an internet site that contains reports, proxy and information statements and other information. The address of the SEC's website is *www.sec.gov*. The information contained in the SEC's website is not intended to be a part of this filing.

ITEM 1A. RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the following risk factors and the other information in this Annual Report on Form 10-K before investing in our common stock. Our business and results of operations could be seriously harmed by any of the following risks. The risks set out below are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. If any of the following events occur, our business, financial condition and results of operations could be materially adversely affected. In such case, the value and trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Financial Position and Need for Additional Capital

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

We are a clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We commenced operations in 2017, have no products approved for commercial sale and have not generated any revenue. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. Since our inception, we have spent the first three years developing and refining our technology, and since 2019, we have focused our efforts on advancing the development of our product candidate, HSB-1216, which we recently deprioritized, as well as HS3215, HS0059 and HS1940. In November 2023, we entered into the Avior Patent License Agreement for a clinical-stage asset, TH104, and TH103, a compound which we intend to potentially file an IND for.

We have not yet commenced human clinical trials for any of our product candidates, nor have we demonstrated an ability to initiate or successfully complete any large-scale or pivotal clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to accurately predict our likelihood of success and viability than it could be if we had a longer operating history.

We plan to initiate a hepatic impairment study in 2025 prior to starting the Phase 2 clinical trial in TH104. In addition, we intend to submit INDs to the FDA for our early-stage pre-clinical programs to gain approval to initiate clinical studies in 2025 for both HS3215 and HS1940; however, no assurance can be provided that our Phase 2 trial will be completed or that our INDs will be accepted by the FDA based on our anticipated timeline, if at all. Our early-stage programs are in pre-clinical discovery and research stages. As a result, we expect that it will take several years, if ever, before we have a commercialized product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to discover, develop and market additional potential products.

Finding appropriate biomarkers for our potential drug candidates could limit our commercialization prospects and cause our losses to continue.

Any biomarker discovery or drug development that we are conducting may not be successful in identifying biomarkers that have commercial value for our products or therapeutic utility. Platforms may initially show promise in identifying potential biomarkers for our drug candidates, yet fail to stratify patients for clinical development or commercialization for a number of reasons, including, but not limited to:

- research programs to identify new biomarkers will require substantial technical, financial and human resources, and we may be unsuccessful in our efforts to identify biomarkers. If we are unable to identify suitable biomarkers for pre-clinical and clinical development, our ability to stratify patients could be compromised, which could result in significant harm to our financial position and adversely impact our stock price;
- identified biomarkers may not demonstrate correlation to efficacy, safety or tolerability;
- available data that seeks to correlate genomic or biomarker signatures with certain diseases may be influenced by the race of the patient which may limit the efficacy of our drug candidates;
- the regulatory pathway for the biomarkers may be too complex, expensive or otherwise difficult to navigate successfully; and
- competitors may develop alternative approaches that render our potential biomarkers non-competitive or less attractive.

We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, and begin to commercialize approved drugs, if any. Typically, it takes many years to develop a new drug from the time it is discovered to when it is available for treating patients. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may increase our expenses and adversely affect our ability to generate revenue. The size of our future net losses will depend, in part, on our ability to manage these aspects of our business.

We have incurred significant losses since inception, we expect to incur losses in the future and we may not be able to generate sufficient revenue to achieve and maintain profitability.

We have never been profitable and have incurred significant losses in each year since inception. For the years ended December 31, 2024 and 2023 we reported a net loss of $12.2 million and $9.3 million, respectively. As of December 31, 2024, we had an accumulated deficit of $36.9 million. We have funded our operations primarily with proceeds from the sale of our equity and debt securities.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital, our ability to achieve and maintain profitability and the performance of our stock.

Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several milestones relating to the discovery, development and commercialization of our product candidates.

Our financial condition and operating results have varied significantly in the past and are expected to continue to fluctuate significantly due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include:

- our ability to continue our current research and development programs, including conducting laboratory, pre-clinical studies for product candidates;
- our ability to initiate clinical trials for product candidates;
- the success of our clinical trials through all phases of clinical development;
- delays in the commencement, enrollment and timing of clinical trials;
- our ability to secure and maintain collaborations, licensing or other arrangements for the future development and/or commercialization of our product candidates, as well as the terms of those arrangements;
- our ability to obtain, as well as the timeliness of obtaining, additional funding to develop our product candidates;
- the results of clinical trials or marketing applications for product candidates that may compete with our product candidates;
- competition from existing products or new products that may receive marketing approval;
- potential side effects of our product candidates that could delay or prevent approval or cause an approved drug to be taken off the market;
- any delays in regulatory review and approval of our product candidates;
- our ability to identify and develop additional product candidates;
- the ability of patients or healthcare providers to obtain coverage or sufficient reimbursement for our products;
- our ability, and the ability of third parties such as Clinical Research Organizations (“CROs”) to adhere to clinical study and other regulatory requirements;

- the ability of third-party manufacturers to manufacture our product candidates and key ingredients needed to conduct clinical trials and, if approved, successfully commercialize our products;
- the costs to us, and our ability as well as the ability of any third-party collaborators, to obtain, maintain and protect our intellectual property rights;
- costs related to and outcomes of potential intellectual property litigation;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively; and
- our ability to build our finance infrastructure and, to the extent required, improve our accounting systems and controls.

Developing new products and services is a speculative and risky endeavor. Products or services that initially show promise may fail to achieve the desired results or may not achieve acceptable levels of analytical accuracy or clinical utility. We may need to alter our products in development and repeat clinical studies before we identify a potentially successful product or service. Product development is expensive, may take years to complete and can have uncertain outcomes. Failure can occur at any stage of the development. If, after development, a product or service appears successful, we may, depending on the nature of the product or service, still need to obtain FDA and other regulatory clearances, authorizations or approvals before we can market it. The FDA's clearance, authorization or approval pathways are likely to involve significant time, as well as additional research, development and clinical study expenditures. The FDA may not clear, authorize or approve any future product or service we develop. Even if we develop a product or service that receives regulatory clearance, authorization or approval, we would need to commit substantial resources to commercialize, sell and market it before it could be profitable, and the product or service may never be commercially successful. Additionally, development of any product or service may be disrupted or made less viable by the development of competing products or services.

New potential products and services may fail any stage of development or commercialization and if we determine that any of our current or future products or services are unlikely to succeed, we may abandon them without any return on our investment. If we are unsuccessful in developing additional products or services, our potential for growth may be impaired.

In cases where we are successful in obtaining regulatory approval to market one or more of our drug candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

We expect our research and development expenses to continue to be significant in connection with our continued investment in our ongoing and planned clinical trials for our current product candidates and any future product candidates we may develop. Furthermore, if we obtain regulatory approval for our product candidates, we expect to incur increased sales and marketing expenses. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have a material adverse effect on our stockholders' equity, financial position, cash flows and working capital.

We will require substantial additional funding. If we are unable to raise capital on favorable terms when needed, we could be forced to curtail, delay or discontinue our research or drug development programs or any future commercialization efforts.

We intend to advance TH104, a clinical stage asset, as well as our early-stage candidates, HS3215, HS0059 and HS1940, through development. Developing drugs is expensive and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance our product candidates through clinical studies.

As of December 31, 2024, we had cash of $3.6 million; however, we will require additional capital to obtain regulatory approval for, and to commercialize, our product candidates. Raising funds may present challenges. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities may dilute our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to make certain dividends, incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable, and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidates or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Management has performed an analysis and concluded that there exists a substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing on terms acceptable to us, if at all.

Our financial statements as of December 31, 2024 have been prepared under the assumption that we will continue as a going concern for the next twelve months. Management has performed an analysis and concluded that there exists a substantial doubt about our ability to continue as a going concern. Separately, our independent registered public accounting firm included in its opinion for the year ended December 31, 2024 an explanatory paragraph referring to our recurring losses from operations and expressing substantial doubt in 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, obtain government grants, reduce expenditures and generate significant revenue. Our financial statements as of December 31, 2024 did not include any adjustments that might result from the outcome of this uncertainty. The reaction of investors to the inclusion of a goingconcern statement in the accompanying financial statement, and our potential inability to continue as a going concern, in future years could materially adversely affect our share price and our ability to raise new capital or enter into strategic alliances.

Risks Related to the Discovery and Development of Our Product Candidates

We are substantially dependent on the success of our product candidates. If we are unable to complete development of, obtain approval for and commercialize our product candidates for one or more indications in a timely manner, our business may be harmed.

Our future success is dependent on our ability to timely and successfully complete clinical trials, obtain marketing approval for and successfully commercialize our product candidates. We currently have no products approved for sale. The success of our business, including our ability to finance our Company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of our product candidates, which may never occur.

In the future, we may also become dependent on other product candidates that we may develop or acquire; however, no product candidates based on our technology have been tested in humans and given our early stage of development, it may be many years, if at all, before we may be able to demonstrate the safety and efficacy of our product candidates to warrant approval for commercialization.

The clinical and commercial success of our current and any future product candidates will depend on a number of factors, including the following:

- our ability to raise any additional required capital on acceptable terms, or at all;
- our ability to complete IND-enabling studies and successfully submit an IND to the FDA;
- timely completion of our pre-clinical studies and clinical trials, which may be slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;

- requirements by the FDA or similar foreign regulatory agencies to conduct additional clinical trials or other studies beyond those planned to support approval of our product candidates;
- acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;
- our ability to consistently manufacture our product candidates on a timely basis;
- our ability, and the ability of any third parties with whom we contract, to remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practice ("cGMP");
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, efficacy and acceptable risk-benefit profile of our product candidates;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future approved products, if any;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our current and future product candidates or approved products, if any;
- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates in the United States and internationally, if approved for marketing, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- the availability of coverage and adequate reimbursement from managed care plans, private insurers, government payors (such as Medicare and Medicaid) and other third-party payors for any of our product candidates that may be approved;
- the convenience of our treatment or dosing regimen;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our product candidates, if approved, including relative to alternative and competing treatments;
- the willingness of physicians, operators of hospitals and clinics and patients to utilize or adopt our therapeutic approaches;
- patient demand for our current or future product candidates, if approved;
- our ability to establish and enforce intellectual property rights in and to our product candidates; and
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize our current or future product candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize our product candidates. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of our product candidates to continue our business or achieve profitability.

Our pipeline is based on novel ideas and technologies that are unproven and may not result in marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval.

We are using our technology to develop product candidates to treat rare diseases, inflammatory disorders and cancer. Our foundational science and product development approach are based on our ability to deliver our drug candidates to target receptors and specified cells or tissues at the site of disease to boost efficacy while abating adverse effects on healthy tissue. We believe that this approach may offer an improved therapeutic effect by delivering drug candidates to areas which may alleviate symptoms and/or treat diseased tissue. However, this approach to treating these diseases is novel and the clinical research that results in a product candidate has had limited testing in humans. For our early-stage, preclinical compounds, we are in the process of validating different tumor-specific therapeutic product candidates. We may spend substantial funds attempting to develop these products with our approach and never succeed in developing a marketable therapeutic.

As such, we cannot assure you that even if we are able to develop product candidates to treat the diseases we are targeting, such therapies would safely and effectively treat such diseases. We may spend substantial funds attempting to develop this approach and never succeed in developing a marketable therapeutic. We are unable to predict when or if our drug candidates will prove effective or safe in humans or if we will obtain marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we must complete pre-clinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to the outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of pre-clinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim or preliminary results of a clinical trial do not necessarily predict final results. In particular, the small number of patients in our early clinical trials may make the results of these trials less predictive of the outcome of later clinical trials.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to obtain marketing approval or commercialize our drug candidates, including:

- regulators or institutional review boards ("IRBs")/ethics committees ("ECs") may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials for our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials, delay clinical trials or abandon product development programs;
- the number of patients required for clinical trials for our drug candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or the duration of these clinical trials may be longer than we anticipate;
- competition for clinical trial participants from investigational and approved therapies may make it more difficult to enroll patients in our clinical trials;
- we or third-party collaborators may fail to obtain the clearance or approval of companion diagnostic tests, if required, on a timely basis, or at all;
- our third-party contractors may fail to meet their contractual obligations to us in a timely manner, or at all, or may fail to comply with regulatory requirements;
- we may have to suspend or terminate clinical trials for our drug candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- our drug candidates may have undesirable or unexpected side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs/ECs to suspend or terminate the trials;
- the cost of clinical trials for our drug candidates may be greater than we anticipate;
- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials for our drug candidates may be insufficient or inadequate and result in delays or suspension of our clinical trials; and
- we or a diagnostic development partner may fail to receive regulatory approval of a companion diagnostic for use with a marketed product.

Our product development costs will increase if we experience delays in pre-clinical studies or clinical trials or in obtaining marketing approvals. We do not know whether any of our planned pre-clinical studies or clinical trials will begin on a timely basis or at all, will need to be restructured or will be completed on schedule, or at all. For example, the FDA may place a partial or full clinical hold on any of our clinical trials for a variety of reasons.

Significant pre-clinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our drug candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our drug candidates and may harm our business and results of operations.

Any delays in the commencement or completion, or termination or suspension, of our ongoing, planned or future clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Before we can initiate clinical trials of a drug candidate in any indication, we must submit the results of pre-clinical studies to the FDA along with other information, including information about the drug candidate's chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory filing.

Before obtaining marketing approval from the FDA for the sale of our product candidate in any indication, we must conduct extensive clinical studies to demonstrate safety and efficacy. Clinical testing is expensive, time consuming and uncertain as to outcome. In addition, we expect to rely in part on pre-clinical, clinical and quality data generated by our CROs and other third parties for regulatory submissions for our drug candidates. While we have or will have agreements governing these third parties' services, we have limited influence over their actual performance. If these third parties do not make data available to us, or, if applicable, make regulatory submissions in a timely manner, in each case pursuant to our agreements with them, our development programs may be significantly delayed and we may need to conduct additional studies or collect additional data independently. In either case, our development costs would increase. In addition, we will need to initiate clinical trials for TH104. In addition, we will need to receive FDA clearance of our IND for HS3215, HS0059 and HS1940 before we can begin clinical trials and would require the same acceptance by the FDA prior to initiating any clinical trials in the United States for any of our other drug candidates. The FDA may require us to conduct additional pre-clinical studies for any drug candidate before it allows us to initiate clinical trials under any IND, which may lead to additional delays and increase the costs of our pre-clinical development programs.

Any delays in the commencement or completion of our ongoing, planned or future clinical trials could significantly affect our product development costs. We do not know whether our planned trials will begin on time or at all, or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- the FDA disagreeing as to the design or implementation of our clinical trials or with our recommended dose for any of our pipeline programs;
- obtaining FDA authorization to commence a trial or reaching a consensus with the FDA on trial design;
- failing to obtain regulatory clearance or approval of companion diagnostics we may use to identify patients for enrollment in our clinical trials;
- any failure or delay in reaching an agreement with 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 approval from one or more IRBs/ECs;
- IRBs/ECs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- failing to manufacture or obtain sufficient quantities of drug candidate or, if applicable, combination therapies for use in clinical trials;
- patients failing to enroll or remain enrolled in our trials at the rates we expect, or failing to return for post-treatment follow-ups;
- patients choosing an alternative treatment, or participating in competing clinical trials;
- lack of adequate funding to continue clinical trials;

- patients experiencing severe or unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selecting or being required to use clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our drug candidates or any of their components being ordered by the FDA to temporarily or permanently shut down due to violations of cGMP regulations or other applicable requirements, or infections or cross-contaminations of drug candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol Good Clinical Practice ("GCP") or other regulatory requirements;
- us, or our third-party contractors not performing data collection or analysis in a timely or accurate manner or improperly disclosing data prematurely or otherwise in violation of a clinical trial protocol; or
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs/ECs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA. 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 resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a pharmaceutical, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs/ECs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Certain of our scientific advisors or consultants who receive compensation from us are investigators for our clinical trial. Under certain circumstances, we may be required to report some of these relationships to the FDA. Although we believe our existing relationships are within the FDA's guidelines, the FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of our product candidates. If we experience delays in the completion of, or termination of, any clinical trial of our drug candidates, the commercial prospects of such drug candidate will be harmed, and our ability to generate product revenues will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues which may harm our business, financial condition, results of operations and prospects significantly.

The outcome of pre-clinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, European Medicines Agency ("EMA") or other comparable foreign regulatory authorities.

We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale. Success in pre-clinical studies and early-stage clinical trials does not mean that future clinical trials will be successful. Product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA, EMA and other comparable foreign regulatory authorities despite having progressed through pre-clinical studies and early-stage clinical trials. Regulatory authorities may also limit the scope of later-stage trials until we have demonstrated satisfactory safety, which could delay regulatory approval, limit the size of the patient population to which we may market our product candidates, or prevent regulatory approval.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dose and dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidates. As a result, assessments of efficacy can vary widely for a particular patient and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes.

We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain approval to market any of our product candidates.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available, and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary, interim or topline data from our clinical trials, such as the interim data from clinical trials related to TH104, or preclinical data for HS3215, HS0059 or HS1940. These interim updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. For example, we may report responses in certain patients that are unconfirmed at the time and which do not ultimately result in confirmed responses to treatment after follow-up evaluations. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline 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, topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. 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. Adverse changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock.

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. You or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the preliminary or topline data that we report differs from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

If we experience delays or difficulties in enrolling patients in our ongoing or planned clinical trials, our receipt of necessary regulatory approval could be delayed or prevented.

We may not be able to initiate or continue our ongoing or planned clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA. Even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. Patient enrollment is a significant factor in the timing of clinical trials. Our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate.

Patient enrollment may be affected if our competitors have ongoing clinical trials for programs that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' programs. Patient enrollment for our current or any future clinical trials may be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- the design of the trial and the complexity for patients and clinical sites;

- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved or other product candidates being investigated for the indications we are investigating;
- clinicians' willingness to screen their patients for biomarkers to indicate which patients may be eligible for enrollment in our clinical trials;
- the ability to obtain and maintain patient consents;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion or, because they may be late-stage disease patients and will not survive the full terms of the clinical trials.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Any negative results we may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining participation in our clinical trials through the treatment and any follow-up periods.

We may never receive approval to market and commercialize any product candidate. Even if we obtain regulatory approval, the approval may be for targets, disease indications, lines of therapy or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings.

We have not previously submitted an NDA to the FDA or similar regulatory approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that our product candidates will be successful in clinical trials or receive regulatory approval. Further, any future product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market a product candidate, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets or patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval to commercialize our product candidates both in the United States and in selected foreign countries. While the scope of regulatory approval generally is similar in other countries, in order to obtain separate regulatory approval in other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy. Other countries also have their own regulations governing, among other things, clinical trials and commercial sales, as well as pricing and distribution of our product candidates, and we may be required to expend significant resources to obtain regulatory approval and to comply with ongoing regulations in these jurisdictions.

We may be required to perform additional or unanticipated clinical trials to obtain approval or be subject to post-marketing testing requirements to maintain regulatory approval. If our candidates prove to be ineffective, unsafe or commercially unviable, our pipeline would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

TH104, HS3215, HS0059 and HS1940 are novel product candidates, making it difficult to predict the time, cost and potential success of these product candidates. We have not yet been able to assess the safety and efficacy of any product candidates in humans. Our success depends on our ability to develop and commercialize product candidates. The novel nature of some of our technology makes it difficult to accurately predict the developmental challenges we may face for product candidates as they proceed through research, pre-clinical or greenhouse studies and clinical or field trials.

Because our pre-clinical research programs are all research or pre-clinical stages, we have not yet been able to assess the safety or efficacy of any product candidates in humans. If our product candidates do not achieve projected development milestones or commercialization in the announced or expected timeframes, the further development or commercialization of such product candidates may be delayed, and our business may be harmed. Current or future product candidates may not meet safety and efficacy requirements for continued development or ultimate approval in humans and may cause significant adverse events or toxicities.

Adverse side effects or other safety risks associated with our drug candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials or abandon further development, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Results of our planned clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our drug candidates could result in the delay, suspension or termination of clinical trials by us or the FDA for a number of reasons. If we elect or are required to delay, suspend or terminate any clinical trial, the commercial prospects of our drug candidates will be harmed and our ability to generate product revenues from this drug candidate will be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of our drug candidates. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Moreover, if our drug candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for our drug candidates, if approved. We may also be required to modify our study plans based on findings in our clinical trials. Many drugs that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations.

It is possible that as we test our drug candidates in larger, longer and more extensive clinical trials, including with different dosing regimens, or as the use of our drug candidates becomes more widespread following any regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition, results of operations and prospects significantly.

In addition, if any of our drug candidates receive marketing approval, and we or others later identify undesirable side effects caused by treatment with such drug, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approval of the drug;
- we may be required to recall a product, change the dosage of a product, or change the way the drug is administered to patients;
- regulatory authorities may require additional warnings on the label, such as a “black box” warning or a contraindication, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients;
- additional restrictions may be imposed on the marketing or promotion of the particular product or the manufacturing processes for the product or any component thereof;
- we could be sued and held liable for harm caused to patients;
- the drug could become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our drug candidates, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

We sometimes estimate, or may in the future estimate, the timing of the accomplishment of various scientific, clinical, manufacturing, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies or clinical trials, the submission of regulatory filings, the receipt of marketing approval or the realization of other commercialization objectives.

The achievement of milestones such as the timing of the accomplishment of various scientific, clinical, manufacturing, regulatory and other product development objectives may be outside of our control. All of these milestones are based on a variety of assumptions, including assumptions regarding capital resources, constraints and priorities, progress of and results from development activities and the receipt of key regulatory approvals or actions, any of which may cause the timing of achievement of the milestones to vary considerably from our estimates. If we or our collaborators fail to achieve announced milestones in the expected timeframes, the commercialization of our product candidates may be delayed, our credibility may be undermined, our business and results of operations may be harmed, and the price of our common stock may decline.

If a product liability claim is successfully brought against us for uninsured liabilities, or such claim exceeds our insurance coverage, we could be forced to pay substantial damage awards that could materially harm our business.

The use of any of our existing or future product candidates in clinical trials and the sale of any approved pharmaceutical products may expose us to significant product liability claims. We currently do not have product liability insurance coverage but we intend to obtain such insurance. Such insurance coverage may not protect us against any or all of the product liability claims that may be brought against us in the future. We may not be able to acquire or maintain adequate product liability insurance coverage at a commercially reasonable cost or in sufficient amounts or scope to protect us against potential losses. In the event a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim, as well as uncovered damage awards resulting from a claim brought successfully against us. In the event our product candidate is approved for sale by the FDA or other regulatory agency and commercialized, we may need to substantially increase the amount of our product liability coverage. Defending any product liability claim or claims could require us to expend significant financial and managerial resources, which could have an adverse effect on our business.

Our current and future products may never achieve significant commercial market acceptance.

Our success depends on the market's confidence that we can provide therapeutic products that improve clinical outcomes, lower healthcare costs and enable better biopharmaceutical development. Failure of our products, or those jointly developed with our collaborators, to perform as expected could significantly impair our operating results and our reputation. We believe patients, clinicians, academic institutions and biopharmaceutical companies are likely to be particularly sensitive to defects, errors, inaccuracies, delays and toxicities in or associated with our products. Furthermore, inadequate performance of these products may result in lower confidence in our pipeline in general.

We may not succeed in achieving significant commercial market acceptance for our current or future products due to a number of factors, including:

- our ability to demonstrate the clinical utility of our pipeline and related products and their potential advantages over existing drug products to academic institutions, biopharmaceutical companies and the medical community;
- our ability, and that of our collaborators, to secure and maintain FDA and other regulatory clearance, authorization or approval for our products;
- the agreement by third-party payors to reimburse our products, the scope and extent of which will affect patients' willingness or ability to pay for our products and will likely heavily influence physicians' decisions to recommend our products;
- the rate of adoption of our pipeline and related products by academic institutions, clinicians, key opinion leaders, advocacy groups and biopharmaceutical companies; and
- the impact of our investments in product innovation and commercial growth.

Additionally, our customers and collaborators may decide to decrease or discontinue their use of our products due to changes in their research and development plans, failures in their clinical trials, financial constraints, the regulatory environment, negative publicity about our products, competing products or the reimbursement landscape, all of which are circumstances outside of our control. We may not be successful in addressing these or other factors that might affect the market acceptance of our products. Failure to achieve widespread market acceptance of our pipeline and related products would materially harm our business, financial condition and results of operations.

Pandemics, such as COVID-19, may adversely impact our business, results of operations, financial condition, liquidity and cash flows and that of our clients.

The COVID-19 pandemic and efforts to control its spread had an impact on our operations. For example, as a result of COVID-19, we previously experienced delays from our manufacturers with respect to the shipping of our materials as well as delays in completion of analytical testing as a result of the shelter-in-place order restrictions. Pandemics, such as COVID-19, may have a material economic effect on our business because our research and development may be affected as a result of delays in study monitoring and data analysis; some participants and clinical investigators may not be able to comply with clinical trial protocols; any quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, resulting in our inability to conduct our research activities, including our clinical trials; and infections and deaths related to a pandemic may disrupt the United States' healthcare and healthcare regulatory systems which could divert healthcare resources away from, or materially delay FDA review and/or approval of our product candidates. While the potential economic impact brought by such pandemics may be difficult to assess or predict, it has caused, and may result in further significant disruption of global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from a health pandemic could materially and adversely affect our business and the value of our common stock.

We may expend our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and drug candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and drug candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate.

We may not be successful in our efforts to design additional potential drug candidates.

The therapeutic design and development activities that we are conducting may not be successful in developing drug candidates that are useful in treating rare diseases, inflammatory conditions, cancer or other diseases. Our research programs may initially show promise in identifying potential drug candidates, yet fail to yield drug candidates for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential drug candidates;
- potential drug candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will obtain marketing approval or achieve market acceptance; or
- potential drug candidates may not be effective in treating their targeted diseases.

Research programs to identify and design new drug candidates require substantial technical, financial and human resources. We may choose to focus our efforts and resources on a potential drug candidate that ultimately proves to be unsuccessful. If we are unable to identify and design suitable drug candidates for pre-clinical and clinical development, we will not be able to obtain revenues from the sale of products in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price.

We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the products we develop, our commercial opportunities will be negatively impacted.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products, product candidates and processes competitive with ours. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may attempt to develop product candidates. In addition, our products may need to compete with drugs physicians use off-label to treat the indications for which we seek approval. This may make it difficult for us to replace existing therapies with our products.

In particular, there is intense competition in the fields of rare diseases, inflammatory conditions and oncology. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, emerging and start-up companies, universities and other research institutions. We also compete with these organizations to recruit management, scientists and clinical development personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling subjects for clinical trials and in identifying and in-licensing new product candidates.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects, are more convenient, have a broader label, are marketed more effectively, are more widely reimbursed or are less expensive than any products that we may develop. Our competitors also may obtain marketing approval from the FDA, EMA or other comparable foreign regulatory authorities for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Even if the product candidates we develop achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we develop may be adversely affected.

We are subject to healthcare laws and regulations.

Sales of our product candidates, if approved, or any other future product candidate will be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we might conduct our business. The healthcare laws and regulations that may affect our ability to operate include the following:

- The federal Anti-Kickback Statute makes it illegal for any person or entity to knowingly and willfully, directly or indirectly, solicit, receive, offer, or pay any remuneration that is in exchange for or to induce the referral of business, including the purchase, order, lease of any good, facility, item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term “remuneration” has been broadly interpreted to include anything of value.

- Federal false claims and false statement laws, including the federal civil False Claims Act and the Civil Monetary Penalties Law (“CMPL”), prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent.

- Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors or making any false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their implementing regulations, impose obligations on certain types of individuals and entities regarding the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information.

- The Federal Food, Drug and Cosmetic Act, which governs the production, sale, distribution, promotion and sampling of drugs, biologics and medical devices and prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices including marketing drug products for off-label use;

- The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations.

Also, many states have similar laws and regulations, such as anti-kickback and false claims laws that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, we may be subject to state laws that require pharmaceutical companies to comply with the federal government's and/or pharmaceutical industry's voluntary compliance guidelines, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and state laws requiring the registration of sales representatives, as well as state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA.

The laws and regulations applicable to our business are complex, changing and often subject to varying interpretations. As a result, we may not be able to adhere to all applicable laws and regulations. Any violation or alleged violation of any of these laws or regulations by us could have a material adverse effect on our business, financial condition, cash flows and results of operations. We may be a party to various lawsuits, demands, claims, *qui tam* suits, third-party complaints to the FDA, government investigations and audits, of which any could result in, among other things, substantial financial penalties or awards against us, reputational harm, termination of relationships or contracts related to our business, mandated refunds, substantial payments made by us, required changes to our business practices, exclusion from future participation in Medicare and other healthcare programs and possible criminal penalties.

If we are found in violation of applicable laws or regulations, we could suffer severe consequences that would have a material adverse effect on our business, results of operations, financial condition, cash flows, reputation and stock price, including:

- suspension or termination of our participation in federal healthcare programs;

- criminal or civil liability, fines, damages or monetary penalties for violations of healthcare fraud and abuse laws, including the federal False Claims Act, CMPL, and Anti-Kickback Statute;

- enforcement actions by governmental agencies or claims for monetary damages by patients under federal or state patient privacy laws, including HIPAA;

- repayment of amounts received in violation of law or applicable payment program requirements, and related monetary penalties;

- mandated changes to our practices or procedures that materially increase operating expenses;

- imposition of corporate integrity agreements that could subject us to ongoing audits and reporting requirements as well as increased scrutiny of our business practices;

- termination of various relationships or contracts related to our business; and

- harm to our reputation which could negatively affect our business relationships, decrease our ability to attract or retain patients and physicians, decrease access to new business opportunities and impact our ability to obtain financing, among other things.

Responding to lawsuits and other proceedings as well as defending ourselves in such matters will continue to require management's attention and cause us to incur significant legal expense. It is also possible that criminal proceedings may be initiated against us or individuals in our business in connection with investigations by the federal government.

Furthermore, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws.

If we are unable to effectively adapt to changes in the healthcare industry, including changes to laws and regulations regarding or affecting the U.S. healthcare reform, our business may be harmed.

Federal, state and local legislative bodies frequently pass legislation and promulgate regulations relating to healthcare reform or that affect the healthcare industry. We anticipate that there will continue to be increased government oversight and regulation of the healthcare industry in the future. We cannot predict the ultimate content, timing or effect of any new healthcare legislation or regulations, nor is it possible at this time to estimate the impact of potential new legislation or regulations on our business. It is possible that future legislation enacted by Congress or state legislatures, or regulations promulgated by regulatory authorities at the federal or state level, could adversely affect our business. We also cannot predict the outcome of any current or future litigation that may affect interpretation of, or deference to, agency regulations and guidance.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and if we are found to have improperly promoted off-label uses of our drugs or drug candidates, if approved, we may become subject to significant liability.

If we are found to have improperly promoted off-label uses of our drugs or drug candidates, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription drug products, such as our drug candidates. In particular, a drug may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the drug's approved labeling, including a different dosage, delivery or patient population than is contained in the label. If we receive marketing approval for our drug candidates for our proposed indications, physicians may nevertheless use our drugs for their patients in a manner that is inconsistent with the approved label. However, if we are found to have promoted our drugs for any off-label uses, the federal government could levy civil, criminal and/or administrative penalties, and seek fines against us. The FDA or other regulatory authorities could also request that we enter into a consent decree or a corporate integrity agreement, or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of our drug candidates, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

We may not be able to obtain or maintain Fast Track designation or accelerated approval for our drug candidates.

If a drug is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a drug sponsor may apply for FDA Fast Track designation. If there are therapies already available for the condition, a fast track drug must show an advantage over the available therapy including superior efficacy, lessening or avoidance of side effects, improving the diagnosis of a serious condition, decreasing a clinical significant toxicity of an available therapy or ability to address an emerging or anticipated public health need. If we seek Fast Track designation for a drug candidate, we may not receive it from the FDA. However, even if we receive Fast Track designation, Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular time frame. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

We may not be able to obtain or maintain orphan drug designation or exclusivity for our drug candidates.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as "orphan drugs." Under the Orphan Drug Act, the FDA may designate a drug candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or if the disease or condition affects more than 200,000 individuals in the United States and there is no reasonable expectation that the cost of developing and making a drug product available in the United States for the type of disease or condition will be recovered from sales of the product.

Orphan drug designation entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. Additionally, if a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity. This means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in certain circumstances, including proving clinical superiority (i.e., another product is safer, more effective or makes a major contribution to patient care) to the product with orphan exclusivity. Competitors, however, 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 than that for which the orphan product has exclusivity. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective.

A Breakthrough Therapy designation by the FDA for our drug candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our drug candidates will receive marketing approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our drug 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 drug candidate may not result in a faster development process, review or approval 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 drug candidates qualify as breakthrough therapies, the FDA may later decide that the drugs no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may seek a breakthrough therapy designation for some of our drug 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 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. For drugs and biologics 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 are also eligible for accelerated approval.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our pre-clinical studies and clinical trials. If these third parties do not successfully perform their contractual and regulatory duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.

We do not have the ability to independently conduct all aspects of our pre-clinical testing or clinical trials. As a result, we have relied upon and plan to continue to rely upon third-party medical institutions, clinical investigators, contract laboratories and other third party CROs to monitor and manage data for our ongoing pre-clinical and clinical programs. We rely on these parties for the execution of our pre-clinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with current GCP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for all of our drugs in clinical development.

Regulatory authorities enforce these current GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced under cGMP. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going clinical, nonclinical and pre-clinical or clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our results of operations and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Many of the third parties with whom we contract 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 that could harm our competitive position. If the third parties conducting our pre-clinical studies or our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical trial protocols or to GCP, or for any other reason, we may need to enter into new arrangements with alternative third parties. Switching or adding additional CROs involves additional cost and requires management 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 carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

Manufacturing pharmaceutical products is complex and subject to product loss for a variety of reasons. We contract with third parties for the manufacture of our drug candidates for pre-clinical testing and clinical trials and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities. We produce very small quantities of small molecules for evaluation in our research programs in our laboratory. We rely, and expect to continue to rely, on third parties for the manufacture of our drug candidates for pre-clinical and clinical testing, as well as for commercial manufacture if any of our drug candidates obtain marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We may be unable to establish any agreements with third-party manufacturers or to do so on favorable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory, compliance and quality assurance;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or the issuance of an FDA Form 483 notice or warning letter;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know how;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our drugs under specified storage conditions and in a timely manner.

We have only limited supply arrangements in place with respect to our drug candidates, and these arrangements do not extend to commercial supply. We acquire many key materials on a purchase order basis. As a result, we do not have long-term committed arrangements with respect to our drug candidates and other materials. If we obtain marketing approval for any of our drug candidates, we will need to establish an agreement for commercial manufacture with a third party; however, no assurance can be provided that we will be able to enter into a commercial manufacture agreement on reasonable terms, if at all.

Third-party manufacturers may not be able to comply with cGMP or similar regulatory requirements outside of the United States. Our failure, or the failure of our third-party manufacturers and suppliers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of drug candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, our third-party manufacturers and suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of waste products, and failure to comply with such laws and regulations could result in significant costs associated with civil or criminal fines and penalties for such third parties. Based on the severity of regulatory actions that may be brought against these third parties in the future, our clinical or commercial supply of drug and packaging and other services could be interrupted or limited, which could harm our business.

Our drug candidates and any products that we may develop may compete with other drug candidates and products for access to manufacturing facilities. As a result, we may not obtain access to these facilities on a priority basis or at all. There are a limited number of manufacturers that operate under cGMP and that may be capable of manufacturing our product candidates.

As we prepare for later-stage clinical trials and potential commercialization, we will need to take steps to increase the scale of production of our drug candidates. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our drug candidates or in the manufacturing facilities in which our drug candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If our current contract manufacturers for pre-clinical and clinical testing cannot perform as agreed, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our drug candidates, we may incur added costs and delays in identifying and qualifying any such replacement manufacturer or be able to reach agreement with any alternative manufacturer.

Our current and anticipated future dependence upon others for the manufacture of our drug candidates or products may adversely affect our future profit margins and our ability to commercialize any products that obtain marketing approval on a timely and competitive basis.

We currently depend on a sole source supplier and manufacturer for the active ingredient in our product candidates and the inability to obtain the active ingredient for our product candidates as required could harm our business.

We currently source the active ingredient for HS1940, HS3215 and HS0059 from sole suppliers/manufacturers. In addition, we anticipate that we will also source the active ingredient in TH104 from a sole supplier/manufacturer. Although we believe that we can obtain the active ingredient for HS1940, HS3215, HS0059 and TH104 from other suppliers, supply shortages for these particular raw material may delay our clinical trials. If we are unable to procure the active ingredient for our product candidates as needed, our business may be harmed.

Our failure to find third party collaborators to assist or share in the costs of drug development could materially harm our business, financial condition and results of operations.

Our strategy for the development and commercialization of our proprietary drug candidates may include the execution of collaborative arrangements with third parties. Existing and future collaborators have significant discretion in determining the efforts and resources they apply and may not perform their obligations as expected. Potential third-party collaborators include biopharmaceutical, pharmaceutical and biotechnology companies, academic institutions and other entities. Third-party collaborators may assist us in:

- funding research, pre-clinical development, clinical trials and manufacturing;
- seeking and obtaining regulatory approvals; and
- successfully commercializing any future drug candidates.

If we are not able to establish further collaboration agreements, we may be required to undertake drug development and commercialization at our own expense. Such an undertaking may limit the number of drug candidates that we will be able to develop, significantly increase our capital requirements and place additional strain on our internal resources. Our failure to enter into additional collaborations could materially harm our business, financial condition and results of operations.

In addition, our dependence on licensing, collaboration and other agreements with third parties may subject us to a number of risks. These agreements may not be on terms that prove favorable to us and may require us to relinquish certain rights in our drug candidates. To the extent we agree to work exclusively with one collaborator in a given area, our opportunities to collaborate with other entities could be curtailed. Lengthy negotiations with potential new collaborators may lead to delays in the research, development or commercialization of drug candidates. The decision by our collaborators to pursue alternative technologies or the failure of our collaborators to develop or commercialize successfully any drug candidate to which they have obtained rights from us could materially harm our business, financial condition and results of operations.

Risks Related to Commercialization of Our Drug Candidates

Even if we are successful in completing all pre-clinical studies and clinical trials, we may not be successful in commercializing one or more of our drug candidates.

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

Our drug candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, export and import are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA and similar regulatory authorities outside of the United States. Failure to obtain marketing approval for a drug candidate will prevent us from commercializing the drug candidate. We have not submitted an application for or received marketing approval for any of our drug candidates in the United States or in any other jurisdiction.

We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party clinical research organizations or other third-party consultants or vendors to assist us in this process. Securing marketing approval requires the submission of extensive pre-clinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the drug candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our drug candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. New therapeutics frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed. If any of our drug candidates receives marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the drug.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the drug candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted drug application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional pre-clinical, clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical studies and clinical trials could delay, limit or prevent marketing approval of a drug candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved drug not commercially viable.

If we are unable to develop satisfactory sales and marketing capabilities, we may not succeed in commercializing our drug candidates.

We have no experience in marketing and selling drug products. We have not entered into arrangements for the sale and marketing of any of our drug candidates.

There are risks involved with establishing our own sales and marketing capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a drug candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. These efforts are expected to be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We may seek to collaborate with a third party to market our drugs or may seek to market and sell our drugs by ourselves. If we seek to collaborate with a third party, we cannot be sure that a collaborative agreement can be reached on terms acceptable to us.

We cannot be sure that we will be able to acquire, or establish third party relationships to provide, any or all of these marketing and sales capabilities. The establishment of a direct sales force or a contract sales force or a combination direct and contract sales force to market our drugs will be expensive and time-consuming and could delay any drug launch. Further, we can give no assurances that we may be able to maintain a direct and/or contract sales force for any period of time or that our sales efforts will be sufficient to generate or to grow our revenues or that our sales efforts will ever lead to profits.

The development and commercialization of pharmaceutical products are subject to extensive regulation, and we may not obtain regulatory approvals for our drug candidates on a timely basis, or at all.

The time required to obtain approval or other marketing authorizations by the FDA is unpredictable, and it 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, and 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 may never obtain regulatory approval for any product candidates we may seek to develop in the future. Neither we nor any current or future collaborator is permitted to market any drug product candidates in the United States until we receive regulatory approval from the FDA.

Prior to obtaining approval to commercialize any drug product candidate in the United States, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA, that such product candidates are safe, pure and effective for their intended uses. Results from pre-clinical studies and clinical trials can be interpreted in different ways. Even if we believe the pre-clinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA. The FDA may also require us to conduct additional pre-clinical studies or clinical trials for our product candidates either prior to or after approval, or it may object to elements of our clinical development programs.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of products in development, only a small percentage successfully complete the FDA approval processes and are commercialized. The lengthy approval and marketing authorization process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval and marketing authorization to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

We have invested a significant portion of our time and financial resources in the development of our pre-clinical product candidates. Our business is dependent on our ability to successfully complete pre-clinical and clinical development, obtain regulatory approval for, and, if approved, successfully commercialize our product candidates in a timely manner.

Even if we eventually complete clinical testing and receive approval for our product candidates, the FDA, may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-marketing clinical trials. The FDA, also may approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally request, and the FDA may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

In addition, the FDA may change their policies, issue additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

Failure to obtain marketing approval in foreign jurisdictions would prevent our drug candidates from being marketed abroad.

In order to market and sell our drugs in the European Union and many other foreign jurisdictions, we or our potential third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA marketing approval. The regulatory approval process outside of the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside of the United States, it is required that the drug be approved for reimbursement before the drug can be approved for sale in that country. We or our potential third-party collaborators may not obtain approvals from regulatory authorities outside of the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside of the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our drugs in any market.

Any drug candidate that we obtain marketing approval for could be subject to post-marketing restrictions or withdrawal from the market and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our drugs, when and if any of them are approved.

While it is possible that one or more of our drug candidates may require a companion diagnostic to select the patients who will likely respond to a therapy involving one of our drug candidates as a condition of approval, it is too early in our drug candidates development to identify which drug candidate, if any, would require a companion diagnostic. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic drug or indication, the FDA generally will not approve the therapeutic drug or new therapeutic drug indication if the companion diagnostic is not also approved or cleared for that indication. Under the Federal Food, Drug and Cosmetic Act ("FDCA"), companion diagnostics are regulated as medical devices, and the FDA has generally required companion diagnostics intended to select the patients who will respond to treatment to obtain Premarket Approval ("PMA") for the diagnostic. The PMA process, including the gathering of clinical and pre-clinical data and the submission to and review by the FDA, involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. A PMA is not guaranteed and may take considerable time, and the FDA may ultimately respond to a PMA submission with a "not approvable" determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval. As a result, if we are required by the FDA to obtain approval of a companion diagnostic for a therapeutic drug candidate, and we do not obtain or there are delays in obtaining FDA approval of a diagnostic device, we may not be able to commercialize the drug candidate on a timely basis or at all and our ability to generate revenue will be materially impaired.

Any drug candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such drug, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, 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. Even if marketing approval of a drug candidate is granted, the approval may be subject to limitations on the indicated uses for which the drug may be marketed or to the conditions of approval, including the requirement to implement a REMS. New drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed. If any of our drug candidates receives marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the drug.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the drug, including the adoption and implementation of REMS. The FDA and other agencies, including the Department of Justice ("DOJ"), closely regulate and monitor the post-approval marketing and promotion of drugs to ensure they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off-label use, and if we do not market our drugs for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations and enforcement actions 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 drugs, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may have various consequences, including:

- restrictions on such drugs, manufacturers or manufacturing processes;
- restrictions and warnings on the labeling or marketing of a drug;
- restrictions on drug distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the drugs from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of drugs;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our drugs;
- drug seizure;
- injunctions or the imposition of civil or criminal penalties; or
- litigation involving patients using our drugs.

Healthcare reform initiatives in the United States may impact our business and results of operations.

In the United States, there have been, and continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect the future results of pharmaceutical manufactures' operations. In particular, there have been and continue to be a number of initiatives at the federal and state levels that seek to reduce healthcare and prescription drug costs. On the federal level, the Affordable Care Act ("ACA") was enacted in March 2010, and included measures to significantly change the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA that have been of greatest importance to the pharmaceutical and biotechnology industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;

- implementation of the federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act";
- a licensure framework for follow-on biologic products;
- creation of Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price;
- adoption of methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted or injected;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- creation of a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and
- expansion of the entities eligible for discounts under the Public Health program.

Although there have been legal and political challenges to certain aspects of the ACA, the Biden Administration has affirmed support for the law, entered its own executive orders to enforce and strengthen it, and committed to examining and, where appropriate, reversing contrary Trump Administration policies. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate."

Because of the volatility surrounding the implementation and enforcement of the ACA since its passage, the full effect that the ACA would have on a pharmaceutical manufacturer remains unclear. This uncertainty is heightened by President Biden's January 28, 2021 Executive Order on Strengthening Medicaid and the ACA which indicates that the Biden Administration may significantly modify the ACA and further reform the ACA and other federal programs in manner that may impact our operations. The Biden Administration has indicated that a goal of its administration is to expand and support Medicaid and the ACA and to make high-quality healthcare accessible and affordable. The potential increase in patients covered by government funded insurance may impact our pricing. Further, it is possible that the Biden Administration may further increase scrutiny of drug pricing.

Additionally, in December 2019, a federal appeals court held that the individual mandate portion of the ACA was unconstitutional and left open the question whether the remaining provisions of the ACA would be valid without the individual mandate. However, on appeal, the Supreme Court ruled, in June 2021, that the parties challenging the law lacked standing, leaving the ACA in place. It is unclear how any other potential litigation challenging the ACA and the healthcare reform measures of the Biden administration will impact the ACA. We 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 abroad. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services.

Moreover, prescription drug pricing and transparency has been a recent focus of federal policymaking. The Inflation Reduction Act, signed into law in August 2022, contained multiple provisions aimed at lowering the cost of prescription drugs. The law allows Medicare to negotiate the price of certain high-cost drugs with pharmaceutical manufacturers and puts a limit on out-of-pocked costs for Medicare Part D members. Pharmaceutical manufacturers will also have to pay rebates to Medicare if the prices of their drugs under Medicare increase fast than the rate of inflation. The Biden Administration also issued an executive order in October 2022 aimed at evaluating new health care payment and delivery models that would lower costs for prescription drugs and promote access to emerging therapies.

Further, there is uncertainty surrounding the applicability of the biosimilars provisions under the ACA. The FDA has issued several guidance documents, but no implementing regulations, on biosimilars. A number of biosimilar applications have been approved over the past few years. The regulations that are ultimately promulgated and their implementation are likely to have considerable impact on the way pharmaceutical manufacturers conduct their business and may require changes to current strategies. A biosimilar is a biological product that is highly similar to an approved drug notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biological product and the approved drug in terms of the safety, purity, and potency of the product.

Individual states have 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 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 a pharmaceutical manufacturer's 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 ultimate demand for certain products or put pressure product pricing, which could negatively affect a pharmaceutical manufacturer's business, results of operations, financial condition and prospects.

In addition, given recent federal and state government initiatives directed at lowering the total cost of healthcare, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and biologics and the reform of the Medicare and Medicaid programs. While no one cannot predict the full outcome of any such legislation, it may result in decreased reimbursement for drugs and biologics, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm a pharmaceutical manufacturer's ability to generate revenue. Increases in importation or re-importation of pharmaceutical products from foreign countries into the United States could put competitive pressure on a pharmaceutical manufacturer's ability to profitably price products, which, in turn, could adversely affect business, results of operations, financial condition and prospects. A pharmaceutical manufacturer might elect not to seek approval for or market products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue generated from product sales. It is also possible that other legislative proposals having similar effects will be adopted.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects. For example, average review times at the FDA for marketing approval applications can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous foreign, federal, state and local environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources, including any available insurance.

In addition, our leasing and operation of real property may subject us to liability pursuant to certain of these laws or regulations. Under existing U.S. environmental laws and regulations, current or previous owners or operators of real property and entities that disposed or arranged for the disposal of hazardous substances may be held strictly, jointly and severally liable for the cost of investigating or remediating contamination caused by hazardous substance releases, even if they did not know of and were not responsible for the releases.

We could incur significant costs and liabilities which may adversely affect our financial condition and operating results for failure to comply with such laws and regulations, including, among other things, civil or criminal fines and penalties, property damage and personal injury claims, costs associated with upgrades to our facilities or changes to our operating procedures, or injunctions limiting or altering our operations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations, which are becoming increasingly more stringent, may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to Our Intellectual Property

If we do not obtain patent term extension for any drug candidates we may develop, our business may be materially harmed.

In the United States, depending upon the timing, duration, and specifics of any FDA marketing approval of a drug candidate, the patent term of a patent that covers an FDA-approved drug may be eligible for limited patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval, and only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and other non-United States jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, if and when our drug candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those drug candidates, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. We may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of the relevant patents, or otherwise failing to satisfy applicable requirements. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing drugs following the expiration of our patent rights, and our business, financial condition, results of operations, and prospects could be materially harmed.

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

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the Leahy-Smith Act) signed into law in September 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. For example, the Leahy-Smith Act allows third-party submission of prior art to the U.S. Patent and Trademark Office ("USPTO") during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter parties review, and derivation proceedings. In addition, the Leahy-Smith Act has transformed the U.S. patent system from a "first-to-invent" system to a "first-to-file" system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court and Federal Circuit rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future.

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

Competitors and other third parties may infringe, misappropriate or otherwise violate our or our future licensors' issued patents or other intellectual property. As a result, we or our licensors may need to file infringement, misappropriation or other intellectual property related claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke such parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property. In addition, in a patent infringement proceeding, such parties could counterclaim that the patents we or our licensors have asserted are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may institute such claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter parties review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings).

An adverse result in any such proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly, and could put any of our owned or in-licensed patent applications at risk of not yielding an issued patent. A court may also refuse to stop the third party from using the technology at issue in a proceeding on the grounds that our owned or in-licensed patents do not cover such technology. 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 or trade secrets could be compromised by disclosure during this type of litigation. Any of the foregoing could allow such third parties to develop and commercialize competing technologies and products and have a material adverse impact on our business, financial condition, results of operations, and prospects.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our drug candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. There is considerable patent and other intellectual property litigation in the pharmaceutical and biotechnology industries. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and drug candidates, including interference proceedings, post grant review, inter parties review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions such as oppositions before the European Patent Office.

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. The risks of being involved in such litigation and proceedings may increase if and as our drug candidates near commercialization and as we gain the greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of merit. We may not be aware of all such intellectual property rights potentially relating to our technology and drug candidates and their uses. Thus, we do not know with certainty that our technology and drug candidates, or our development and commercialization thereof, do not and will not infringe, misappropriate or otherwise violate any third party's intellectual property.

Even if we believe that third party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of misappropriation, infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold these third-party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any technology or drug candidate covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent.

If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our drug candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive; thereby giving our competitors and other third parties access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or drug. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right and could be forced to indemnify our collaborators or others. A finding of infringement could prevent us from commercializing our drug candidates or force us to cease some of our business operations, which could materially harm our business. In addition, we may be forced to redesign our drug candidates, seek new regulatory approvals and indemnify third parties pursuant to contractual agreements. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations, and prospects.

Intellectual property litigation or other legal proceedings relating to intellectual property could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and may also have an advantage in such proceedings due to their more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could compromise our ability to compete in the marketplace.

If we fail to comply with our obligations in our future intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business.

We may be party to license and funding agreements that impose diligence, development and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with such obligations, our counterparties may have the right to terminate our agreements or require us to grant them certain rights. Such an occurrence could materially adversely affect the value of any drug candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

Additionally, these and other license agreements may not provide exclusive rights to use the licensed intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and drugs in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products and technology in fields of use and territories not included in such agreements. In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we may license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our drugs that are the subject of such licensed rights could be adversely affected.

We may need to obtain additional licenses from others to advance our research or allow commercialization of our drug candidates. It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all, or such licenses may be non-exclusive. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all.

If we are unable to obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, drug candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and drug candidates, which could harm our business, financial condition, results of operations, and prospects significantly.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, any agreements under which we license intellectual property or technology from third parties may be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected technology and drug candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

Our future licensors may rely on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents and patent applications we in-licensed. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

In spite of our best efforts, our future licensors might conclude that we have materially breached our license agreements and might therefore terminate our license agreements, thereby removing our ability to develop and commercialize drug candidates and technology covered by such agreements. If these in-licenses are terminated, or if the underlying intellectual property fails to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products and technologies identical to ours. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting, and defending patents on drug candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our 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 have patent protection or licenses but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign 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, particularly those relating to pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions 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, could put 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 and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many 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, and our business, financial condition, results of operations, and prospects may be adversely affected.

Risks Related to Managing Our Business and Operations

We may encounter difficulties in managing our growth, which could adversely affect our operations.

As of March 1, 2025, we had 2 full-time employees and 1 part-time employee. As our clinical development and commercialization plans and strategies develop, we will need to expand our managerial, clinical, regulatory, sales, marketing, financial, development, manufacturing and legal capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Our future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our development and commercialization efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our ability to continue to develop and, if approved, commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including contract manufacturers and companies focused on research and development and discovery activities. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality, accuracy or quantity of the services provided is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain, or may be substantially delayed in obtaining, regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

We may acquire additional technology and complementary businesses in the future. Acquisitions involve many risks, any of which could materially harm our business, including the diversion of management's attention from core business concerns, failure to effectively exploit acquired technologies, failure to successfully integrate the acquired business or realize expected synergies or the loss of key employees from either our business or the acquired businesses.

Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from future clinical 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 confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and study subjects, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. We may experience threats to our data and systems, including malicious codes and viruses, phishing and other cyberattack. The number and complexity of these threats continue to increase over time. If a material breach of, or accidental or intentional loss of data from, our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems or those of our third-party contractors, or our consultants' efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm.

Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

Our business is increasingly dependent on critical, complex, and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. These systems are also critical to enable remote working arrangements, which have been growing in importance. The size and complexity of our computer systems make us potentially vulnerable to IT system breakdowns, internal and external malicious intrusion, and computer viruses and ransomware, which may impact product production and key business processes. We also have outsourced significant elements of our information technology infrastructure and operations to third parties, which may allow them to access our confidential information and may also make our systems vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by such third parties or others.

In addition, our systems are potentially vulnerable to data security breaches - whether by employees or others - which may expose sensitive data to unauthorized persons. Data security breaches could lead to the loss of trade secrets or other intellectual property, result in demands for ransom or other forms of blackmail, or lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers, and others. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including industrial espionage or extortion) and expertise, including by organized criminal groups, “hacktivists,” nation states, and others. As a company with an increasingly global presence, our systems are subject to frequent attacks. There is the potential that our systems may be directly or indirectly affected as nation-states conduct global cyberwarfare, including in connection with the current Russia-Ukraine or Hamas-Israel armed conflict.

Due to the nature of some of these attacks, there is a risk that an attack may remain undetected for a period of time. While we continue to make investments to improve the protection of data and information technology, and to oversee and monitor the security measures of our suppliers and/or service providers, there can be no assurance that our efforts will prevent service interruptions or security breaches. In addition, we depend in part on third-party security measures over which we do not have full control to protect against data security breaches.

If we or our suppliers and/or service providers fail to maintain or protect our information technology systems and data security effectively and in compliance with U.S. and foreign laws, or fail to anticipate, plan for, or manage significant disruptions to these systems, we or our suppliers and/or service providers could have difficulty preventing, detecting, or controlling such disruptions or security breaches, which could result in legal proceedings, liability under U.S. and foreign laws that protect the privacy of personal information, disruptions to our operations, government investigations, breach of contract claims, and damage to our reputation (in each case in the U.S. or globally), which could have a material adverse effect on our business, prospects, operating results, and financial condition.

Our current operations are concentrated in one location, and we or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster, including earthquakes, outbreak of disease or other natural disasters.

Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Earthquakes or other natural disasters could further disrupt our operations, and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time.

The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Portions of our future clinical trials may be conducted outside of the United States and unfavorable economic conditions resulting in the weakening of the U.S. dollar would make those clinical trials more costly to operate. Furthermore, the most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or international trade disputes could also strain our suppliers, some of which are located outside of the United States, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development programs and the diseases our therapeutics are being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts following approval of our product candidates, if any. Social media practices in the biopharmaceutical industry continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off-label marketing or other prohibited activities. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. When such disclosures occur, there is a risk that trial enrollment may be adversely impacted, we fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

The estimates of market opportunity and forecasts of market growth included in this prospectus may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

Market opportunity estimates and growth forecasts included in this prospectus are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. The estimates and forecasts included in this prospectus relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meet the size estimates and growth forecasts included in this prospectus, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties.

Our employees, independent contractors, consultants, commercial partners, collaborators and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners, collaborators and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws will also increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. Although we have adopted a code of business conduct and ethics, it is not always possible to identify and deter misconduct by our employees, independent contractors, consultants, commercial partners and vendors, 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 these laws or regulations. If any actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, disgorgement, possible exclusion from participation in government healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and the curtailment of our operations.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business.

We and any potential collaborators may be subject to federal, state and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

International data protection laws, including, but not limited to, Regulation 2016/679, known as the General Data Protection Regulation ("GDPR") may also apply to health-related and other personal information obtained outside of the United States. The GDPR went into effect on May 25, 2018. The GDPR introduced new data protection requirements in the European Union, as well as potential fines for noncompliant companies. The regulation imposes numerous new requirements for the collection, use and disclosure of personal information, including more stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulators and affected individuals of personal data breaches, extensive new internal privacy governance obligations and obligations to honor expanded rights of individuals in relation to their personal information (e.g., the right to access, correct and delete their data). In addition, the GDPR includes restrictions on cross-border data transfer. The GDPR will increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules. In addition, as a result of the United Kingdom's vote in favor of exiting the EU, often referred to as Brexit, the United Kingdom's Data Protection Act of 2018, as amended, may apply to health-related and other personal information obtained outside of the United States.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil, criminal, and administrative penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.

Changes in U.S. tax law could adversely affect our financial condition and results of operations.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in U.S. tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisors regarding the implications of potential changes in U.S. tax laws on an investment in our common stock.

Risks Related to Our Common Stock

The price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this prospectus, these factors include:

- the commencement, enrollment or results of clinical trials and pre-clinical studies of our drug candidates or those of our competitors;
- any delay in identifying and advancing a clinical candidate for our other development programs;
- any delay in our regulatory filings for our drug candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including, without limitation, the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays in future clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of for our drug candidates;
- changes in laws or regulations applicable to our drug candidates, including, but not limited to, clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations, if needed;
- our failure to commercialize our product candidates, if approved;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our drug candidates;
- introduction of new products offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or product candidates in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- changes in the structure of the healthcare payment systems;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;

- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the market for biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources.

If we fail to comply with the continued listing requirements of The Nasdaq Capital Market, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

If we are unable to maintain our listing on Nasdaq and we are unable to obtain listing on another national securities exchange, a reduction in some or all of the following may occur, each of which could have a material adverse effect on our stockholders:

- the liquidity of our common stock;
- the market price of our common stock;
- our ability to obtain financing for the continuation of our operations;
- the number of investors that will consider investing in our common stock;
- the number of market makers in our common stock;
- the availability of information concerning the trading prices and volume of our common stock; and
- the number of broker-dealers willing to execute trades in shares of our common stock.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our 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. Furthermore, future debt or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock.

Our Certificate of Incorporation, as amended ("Certificate of Incorporation") provides that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between the Company and its stockholders, which could limit stockholders' ability to obtain a favorable judicial forum for disputes with the Company or its directors, officers or employees.

Our Certificate of Incorporation provides that unless we consent in writing to the selection of an alternative forum, the State of Delaware is the sole and exclusive forum for: (i) any derivative action or proceeding brought on behalf of us, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of our Company to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law (the "DGCL") or our Certificate of Incorporation or Bylaws, or (iv) any action governed by the internal affairs doctrine. This exclusive forum provision would not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. However, our Certificate of Incorporation contains a federal forum provision which provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act.

These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees and may result in increased costs to our stockholders, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find our choice of forum provisions contained in our Certificate of Incorporation 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, results of operations, and financial condition.

Our Certificate of Incorporation, Bylaws and Delaware law may have anti-takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline.

Our Certificate of Incorporation, our Bylaws and Delaware law could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our stockholders. We are authorized to issue up to 10 million shares of preferred stock. This preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our board of directors without further action by stockholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third party and thereby preserve control by the present management.

Provisions of our Certificate of Incorporation, our Bylaws and Delaware law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. Such provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, our Certificate of Incorporation, our Bylaws and Delaware law, as applicable, among other things:

- provide the board of directors with the ability to alter the Bylaws without stockholder approval;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings; and
- provide that vacancies on the board of directors may be filled by a majority of directors in office, although less than a quorum.

Unstable market and economic conditions and adverse developments with respect to financial institutions and associated liquidity risk may have serious adverse consequences on our business, financial condition and stock price.

The global credit and financial markets have recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, inflationary pressure and interest rate changes, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflict between Russia and Ukraine, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. More recently, the closures of Silicon Valley Bank and Signature Bank and their placement into receivership with the Federal Deposit Insurance Corporation ("FDIC") created bank-specific and broader financial institution liquidity risk and concerns. Although the Department of the Treasury, the Federal Reserve, and the FDIC jointly confirmed that depositors at SVB and Signature Bank would continue to have access to their funds, even those in excess of the standard FDIC insurance limits, under a systemic risk exception, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages, impair the ability of companies to access near-term working capital needs, and create additional market and economic uncertainty. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment or continued unpredictable and unstable market conditions. If the equity and credit markets deteriorate, or if adverse developments are experienced by financial institutions, it may cause short-term liquidity risk and also make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon our business plans. In addition, there is a risk that one or more of our current clients, financial institutions or other third parties with whom we do business may be adversely affected by the foregoing risks, which may have an adverse effect on our business.

General Risk Factors

Market and economic conditions may negatively impact our business, financial condition and share price.

Concerns over inflation, energy costs, geopolitical issues, the U.S. mortgage market and the real estate market, unstable global credit markets and financial conditions, and volatile oil prices have led to periods of significant economic instability, diminished liquidity and credit availability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth going forward, increased unemployment rates, and increased credit defaults in recent years. Our general business strategy may be adversely affected by any such economic downturns, volatile business environments and continued unstable or unpredictable economic and market conditions. If these conditions continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and share price and could require us to delay or abandon development or commercialization plans.

Future sales and issuances of our securities could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations, including research and development, increased marketing, hiring new personnel, commercializing our products, and continuing activities as an operating public company. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we completed our initial public offering, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700.0 million as of the prior June 30th and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We may choose to take advantage of some, but not all, of the available exemptions. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies, which may make our financial statements less comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates. We have chosen to take advantage of the extended transition periods available to emerging growth companies under the JOBS Act for complying with new or revised accounting standards until those standards would otherwise apply to private companies provided under the JOBS Act. As a result, our financial statements may not be comparable to those of companies that comply with public company effective dates for complying with new or revised accounting standards.

Financial reporting obligations of being a public company in the U.S. are expensive and time-consuming, and our management will be required to devote substantial time to compliance matters.

As a publicly traded company we incur significant additional legal, accounting and other expenses. The obligations of being a public company in the U.S. require significant expenditures and place significant demands on our management and other personnel, including costs resulting from public company reporting obligations under the Exchange Act and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, and The Nasdaq Capital Market. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. Moreover, despite recent reforms made possible by the JOBS Act, the reporting requirements, rules, and regulations will make some activities more time-consuming and costly, particularly after we are no longer an "emerging growth company" or a "smaller reporting company." Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation or being delisted, among other potential problems.

If securities or industry analysts do not publish research or reports, or publish unfavorable research or reports about our business, our stock price and trading volume may decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us, our business, our markets and our competitors. We do not control these analysts. If securities analysts do not cover our common stock, the lack of research coverage may adversely affect the market price of our common stock. Furthermore, if one or more of the analysts who do cover us downgrade our stock or if those analysts issue other unfavorable commentary about us or our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fails to regularly publish reports on us, we could lose visibility in the market and interest in our stock could decrease, which in turn could cause our stock price or trading volume to decline and may also impair our ability to expand our business with existing customers and attract new customers.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

We believe cybersecurity is critical to advancing our technological advancements. As a biopharmaceutical company, we face a multitude of cybersecurity threats that range from attacks common to most industries, such as ransomware and denial-of service. Our customers, suppliers, subcontractors, and business partners face similar cybersecurity threats, and a cybersecurity incident impacting us or any of these entities could materially adversely affect our operations, performance, and results of operations. These cybersecurity threats and related risks make it imperative that we expend resources on cybersecurity.

Our Board of Directors oversees management's processes for identifying and mitigating risks, including cybersecurity risks, to help align our risk exposure with our strategic objectives. Senior leadership, including our cybersecurity consultant, regularly briefs the Board of Directors on our cybersecurity and information security posture and the Board of Directors is apprised of cybersecurity incidents deemed to have a moderate or higher business impact, even if immaterial to us. The full Board retains oversight of cybersecurity because of its importance. In the event of an incident, we intend to follow our detailed incident response playbook, which outlines the steps to be followed from incident detection to mitigation, recovery, and notification, including notifying functional areas (e.g., legal), as well as senior leadership and the Board, as appropriate. Our Cybersecurity consultant has extensive information technology and program management experience. We have implemented a governance structure and processes to assess, identify, manage, and report cybersecurity risks.

As a biopharmaceutical company, we must comply with extensive regulations, including requirements imposed by the Federal Drug Administration related to adequately safeguarding patient information and reporting cybersecurity incidents to the SEC. We work with our cybersecurity consultant on assessing cybersecurity risk and on policies and practices aimed at mitigating these risks. We believe we are positioned to meet the requirements of the SEC. In addition to following SEC guidance and implementing pre-existing third party frameworks, we have developed our own practices and frameworks, which we believe enhance our ability to identify and manage cybersecurity risks. Third parties also play a role in our cybersecurity. We engage third-party services to conduct evaluations of our security controls, whether through penetration testing, independent audits, or consulting on best practices to address new challenges. Assessing, identifying, and managing cybersecurity related risks are factored into our overall business approach.

We rely heavily on our supply chain to deliver our products and services, and a cybersecurity incident at a supplier, subcontractor or business partner could materially adversely impact us. We require that our subcontractors report cybersecurity incidents to us so that we can assess the impact of the incident on us. Notwithstanding the extensive approach we take to cybersecurity, we may not be successful in preventing or mitigating a cybersecurity incident that could have a material adverse effect on us. While we maintain cybersecurity insurance, the costs related to cybersecurity threats or disruptions may not be fully insured. See "Risk Factors" for a discussion of cybersecurity risks.

ITEM 2. PROPERTIES

Our executive office, which we lease on a month-to-month basis, is located at 1200 Route 22 East, Suite 2000, Bridgewater, NJ 08807. We believe that our existing facilities are suitable and adequate to meet our current needs. We intend to add new facilities or expand existing facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. Litigation is subject to inherent uncertainties and an adverse result in these or other matters may arise from time to time that may harm our business. We are currently not aware of any such legal proceedings or claims that will have, individually or in the aggregate, a material adverse effect on our business, financial condition or operating results.

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

On January 12, 2022, our common stock began trading on The Nasdaq Capital Market under the symbol "HILS." Prior to that time, there was no public market for our common stock. Effective as of September 25, 2023, our common stock began trading under the ticker symbol "THAR."

Stockholders

As of March 20, 2025, there were 39 stockholders of record of our common stock. The actual number of holders of our common stock is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never paid or declared any cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

ITEM 6. [RESERVED]

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 plan of operations together with and our accompanying consolidated financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included elsewhere in this Annual Report on Form 10-K. All amounts in this report are in U.S. dollars, unless otherwise noted.

Overview

Tharimmune is a clinical-stage biotechnology company developing therapeutic candidates in immunology and inflammation with high unmet need. On November 3, 2023, we entered into a patent license agreement (the "Avior License Agreement") with Avior Inc. d/b/a Avior Bio, LLC ("Avior") pursuant to which we received an exclusive sublicensable right and license to Licensed Patent Rights and Licensed Technology to, among other things, Develop, have Developed, make, have made, use, sell, import, export and commercialize TH104 and TH103 and to practice the Licensed Technology in connection with the foregoing, throughout the world, each as defined in the Avior License Agreement. In February 2023, the U.S. Food and Drug Administration ("FDA") approved an investigational new drug ("IND") application for TH104. TH104 has a dual mechanism of action by affecting multiple receptors, known to suppress chronic, debilitating pruritus or "uncontrollable itching." With respect to TH104, we intend to first seek approval for the treatment of moderate-to-severe chronic pruritus in patients with primary biliary cholangitis ("PBC"), an orphan rare form of liver disease with no known cure in which more than 70% of patients suffer from debilitating chronic pruritic. We expect to obtain topline data from a Phase 2 trial in TH104 in Q4 2025 and with respect to TH103, we intend to develop the product candidate and potentially file an IND.

On September 11, 2024, we entered into a Patent License Agreement (the "Intract Agreement") with Intract Pharma Limited ("Intract"), pursuant to which, we exclusively licensed INT-023/TH023, an oral anti-Tumor Necrosis Factor-alpha (TNF-α) monoclonal antibody infliximab. Infliximab is a purified, recombinant DNA-derived chimeric IgG monoclonal antibody protein that contains both murine and human components that inhibit tumor TNF-α. Under the terms of the Intract Agreement, we licensed global development and commercialization rights (outside of South Korea) to Intract's Soteria® and Phloral® delivery platform along with an existing supply agreement for infliximab to be used in the oral product development program.

We are also developing an early-stage pipeline of novel therapeutic candidates targeting validated high value immuno-oncology ("IO") targets including human epidermal growth factor ("EGF") receptor 2 ("HER2"), human EGF receptor 3 ("HER3") and programmed cell death protein 1 ("PD-1"). We are developing antibodies including bispecific antibodies, antibody drug conjugates ("ADCs") and small molecular weight bovine-derived Picobodies™ or antibody "knob" domains which have the potential to target and bind more tightly to "undruggable" epitopes better than full sized antibodies. We are advancing HS3215, a bispecific against both HER2 and HER3 antibody which targets a novel "bridging epitope" encompassing multiple domains of the HER2 extracellular domain ("ECD") as well as ligand-dependent and independent blocking of the ECD of HER3 into IND-enabling studies in 2025. In addition, we anticipate that HS0059, a HER2/HER3 bispecific ADC ("bsADC"), and HS1940, a PD-1 Picobody, will progress to enter IND-enabling studies in 2025.

The critical components of our business strategy to achieve our goals include:

- Develop TH104 as a transmucosal buccal film product for the treatment of moderate-to-severe chronic pruritus in PBC and other inflammatory diseases;
- Develop TH023 by obtaining regulatory authorization to initiate a first-in-human bioavailability clinical trial and pursue an IND through the US FDA;
- Create a preclinical and clinical path forward for, HS1940, a unique PD-1 knob-domain antibody fragment with unique binding differentiation compared to full length antibodies for IO vulnerable tumors;
- Continue to advance pre-clinical candidate selection activities against HER2/HER3 receptors with various antibody formats, including HS3215 designed for multiple solid tumor types;
- Effectively create a strategy to develop HS0059 as a bispecific ADC specifically targeted to both HER2 and HER3 receptors in high unmet need standard-of-care resistant tumors with a high capacity to metastasize;
- Hasten the discovery of next generation multi-specific (bi- and tri) antibodies with binding capabilities to novel epitopes of combinations of HER2, HER3, PD-1, PD-L1, TROP2 with and without toxin delivery capacity to multiple high unmet need rare cancers and other validated immunology and metabolic targets, including glucose-dependent insulinotropic peptide (GIP);
- Pursue strategic collaboration opportunities including potential M & A transactions to maximize the value of our pipeline to bring novel therapies to patients suffering from high unmet need conditions

Applied Biomedical Research Institute Research and Development Collaboration and License Agreement

On July 5, 2023 (the "ABSI Effective Date"), we entered into a Research and Development Collaboration and License Agreement (the "ABSI Agreement") with Applied Biomedical Science Institute ("ABSI") pursuant to which ABSI granted us an exclusive royalty-bearing, sublicensable license to the ABSI Patents and a non-exclusive, royalty-bearing, sublicensable license to the ABSI Know-How to Exploit the ABSI Products for the treatment, diagnosis, prediction, detection or prevention of disease in humans and animals worldwide (the "Territory"). Pursuant to the ABSI Agreement, the parties shall form a committee to manage the preclinical, IND- enabling studies and such other activities as shall lead to the initiation of a Phase 1 clinical trial of the ABSI Product. The parties will collaborate on a Target-by-Target basis to identify and evaluate ABSI Products directed against such Target with a view to identifying or generating suitable Products for our Company to Exploit. "Target" means ErB2 (Her2) and ErbB3. Upon completion of the Discovery Timeline for a Target, subject to the terms and conditions of ABSI Agreement, we shall exclusively own any ABSI Products against such Target. In the event the committee determines that the discovery activities are unsuccessful with respect to a Target, we may propose an additional target, which, upon approval by ABSI, shall replace a failed Target, each capitalized term as defined in the ABSI Agreement.

As part of the ABSI Agreement, on July 26, 2023, we issued 1,674 shares of our common stock with a per share value of $149.34, representing total compensation expense of $250,000.

On March 11, 2024, we entered into an addendum to the ABSI Agreement to fund research services with quarterly payments of $50,000 beginning March 18, 2024 with subsequent payments due on the 18th of each calendar quarter.

Avior Patent License Agreement

On November 3, 2023 (the "Avior Effective Date"), we entered into the Avior Patent License Agreement with Avior pursuant to which we received an exclusive sublicensable right and license to Licensed Patent Rights and Licensed Technology to, among other things, develop, have developed, make, have made, use, sell, import, export and commercialize TH104 and TH103 and to practice the Licensed Technology in connection with the foregoing, throughout the world. Pursuant to the Avior Patent License Agreement, we paid Avior an up front license fee of $400,000 within ten days of the Avior Effective Date and an additional mid-six digit license fee which shall be paid in four equal installments within ten days of the end of each fiscal quarter following the Avior Effective Date. In addition, we shall pay Avior a high single digit percentage of any upfront payments received by us as a result of the grant of any sublicenses with respect to TH104. We shall also pay Avior milestone payments in the aggregate amount of $24.25 million upon the occurrence of various development milestones (the "Development Milestone Payments"). Furthermore, we shall pay Avior certain fees based upon sales milestones. The payments for such sales milestones range from the low seven digits to the low eight digits with higher sales being subject to higher fees. Finally, we shall pay Avior royalties based on net sales. Such royalties range from low single digit percentages to mid-single digit percentages with higher sales being subject to lower percentages. The Avior Patent License Agreement shall expire upon the expiration of the final payment obligation due to Avior as set forth in such agreement. Upon the expiration of the Avior Patent License Agreement, we shall have a fully paid-up, irrevocable, freely transferable and sublicensable worldwide license to the Licensed Patent Rights and Licensed Technology to Develop, have Developed, make, have made, use, have used sell, offer for sale, have sold, import, have imported, export, have exported, commercialize or have commercialized any and all Licensed Products and to practice the Licensed Technology worldwide. Pursuant to the Avior Patent License Agreement, we may terminate the agreement at any time without cause, upon 30 days' prior written notice to Avior along with payment of the next unpaid Development Milestone Payment, if any. Furthermore, either we or Avior may terminate the Avior Patent License Agreement (i) on written notice to the other party if the other party materially breaches any provision of the Avior Patent License Agreement and fails to cure such breach within 30 days after the breaching party receives written notice thereof or (ii) on written notice in the event that either party (A) becomes insolvent or admits its inability to pay its debts generally as they become due; (B) becomes subject, voluntarily or involuntarily, to any proceeding under any domestic or foreign bankruptcy or insolvency law, which is not fully dismissed or vacated within 60 days; (C) is dissolved or liquidated or takes any corporate action for such purpose; (D) makes a general assignment for the benefit of creditors; or (E) has a receiver, trustee, custodian or similar agent appointed by order of any court of competent jurisdiction to take charge of or sell any material portion of its property or business. Upon termination of the Avior Patent License Agreement, the license granted pursuant to such agreement shall terminate and all rights in the Licensed Patent Rights and Licensed Products shall revert back to Avior.

Enkefalos License Agreement

On June 17, 2024 (the "Enkefalos Effective Date"), we signed a letter of intent (the "Enkefelos LOI") to enter into the Enkefalos License Agreement with Enkefalos Biosciences Inc. pursuant to which we are licensing the global rights in all fields of use for the products related to the compounds knows as cyclotides to deliver HER2 antibodies across the blood-brain barrier and all associated know-how, technology, intellectual property and related information and constructs, and any associated authorized generic rights and all related assets (collectively, the "Products" referred to in this letter as ENBI-01) from Enkefalos Biosciences, Inc. Pursuant to the Enkefalos License Agreement, we paid Enkefalos an upfront license fee of $150,000 upon signing of the Enkefalos LOI and an additional $150,000 license fee to be paid 6 months after the Enkefalos Effective Date. In addition, we shall pay Enkefalos a $50,000 annual license fee and milestone payments in the aggregate amount of up to $8,500,000 upon the occurrence of various development milestones (the "Enkefalos Development Milestone Payments"). Furthermore, we shall pay Enkefalos royalties based on net sales. Such royalties range from low-single digit percentages to mid-single digit percentages with higher sales being subject to lower percentages. The Enkefalos License Agreement shall expire upon the expiration of the final payment obligation due to Enkefalos as set forth in such agreement. Upon the expiration of the Enkefalos Patent License Agreement, we shall have a fully paid, irrevocable, freely transferable and sublicensable worldwide license to the Licensed Patent Rights and Licensed Technology to Develop, have Developed, make, have made, use, have used sell, offer for sale, have sold, import, have imported, export, have exported, commercialize or have commercialized any and all Licensed Products and to practice the Licensed Technology worldwide. Pursuant to the Enkefalos License Agreement, either the Company or Enkefalos may terminate the Enkefalos License Agreement on written notice to the other party. Upon termination of the Enkefalos License Agreement, the license granted pursuant to such agreement shall terminate and all rights in the Licensed Patent Rights and Licensed Products shall revert back to Enkefalos.

Intract Patent License Agreement

On September 11, 2024 (the "Intract Effective Date"), we entered into a Patent License Agreement (the "Intract Agreement") with Intract Pharma Limited, ("Intract"), pursuant to which the Company exclusively licensed INT-023/TH023, an oral anti-Tumor Necrosis Factor-alpha (TNF-α) monoclonal antibody infliximab. Under the terms of the Intract Agreement, we licensed global development and commercialization rights (outside of South Korea) to Intract's Soteria® and Phloral® delivery platform along with an existing supply agreement for infliximab to be used in the oral product development program. Pursuant to the Intract Agreement, Intract recieved an upfront license fee of $400,000 and is eligible to receive additional payments upon an equity financing of the Company and for future development, regulatory and commercial milestones, as well as mid-single digit royalties based on net product sales. Under the terms of the Intract Agreement, we retain a right of first refusal to continue development and commercialization after a Phase 2 clinical trial and have the option to exercise the license to Intract's platform for up to four additional targets. The term of the Intract Agreement expires upon the final payment obligation of the Company under the Intract Agreement. In addition, the Intract Agreement may be terminated by us at any time upon 90 days written notice to Intract. Either party may terminate the Intract Agreement if the other party materially breaches any provision of the Intract Agreement and fails to cure such breach within thirty (30) days after the breaching party receives written notice thereof. In addition, either party may terminate the Intract Agreement on written notice in the event that either party declare: (a) becomes insolvent or admits inability to pay its debts generally as they become due; (b) becomes subject, voluntarily or involuntarily, to any proceeding under any domestic or foreign bankruptcy or insolvency law, which is not fully dismissed or vacated within sixty (60) days; (c) is dissolved or liquidated or takes any corporate action for such purpose; (d) makes a general assignment for the benefit of creditors; or (e) has a receiver, trustee, custodian or similar agent appointed by order of any court of competent jurisdiction to take charge of or sell any material portion of its property or business.

Recent Developments

On June 7, 2024, we entered into an at-the-market offering agreement (the "ATM Agreement") with Rodman & Renshaw LLC (the "ATM Sales Manager") under which we may sell, from time to time through the ATM Sales Manager, shares of common stock in one or more offerings up to a total dollar amount of $1.65 million. Sales of shares of our common stock through the ATM Sales Manager, if any, will be made by any method permitted by law deemed to be an "at-the-market offering" as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended (the "Securities Act"), including without limitation sales made directly on the Nasdaq Stock Market LLC or any other existing trading market for the common shares. Our common stock is being offered and sold pursuant to the effective shelf registration statement on Form S-3 and an accompanying prospectus declared effective by the U.S. Securities and Exchange Commission (the "SEC") on March 24, 2023, and pursuant to a prospectus supplement dated June 7, 2024.

On June 10, 2024, we reported positive results from our Phase 1 clinical trial with TH104. Results from healthy subjects demonstrated consistent pharmacokinetic (PK) profiles across buccal and intravenous routes of administration with a comparable safety and tolerability profile between routes of administration. This Phase 1 trial was a single-dose, single-center, open-label, randomized 2-way crossover study comparing 16 mg of TH104 with 1 mg intravenous nalmefene administered under fasting conditions, with a 7-day washout period between doses. Twenty healthy subjects were enrolled to complete both doses of the crossover design. All 20 subjects completed TH104 buccal dosing, while 19 of 20 subjects also completed the intravenous dosing. The primary objective was to evaluate the absolute bioavailability of TH104, as well as to assess safety and tolerability. Findings from the study indicated that the primary endpoint of the study which was absolute bioavailability (F) of TH104, or fraction (or percentage) of the administered dose absorbed into the systemic circulation compared to an equivalent intravenous dose of nalmefene, was 0.459 (45.9%). The median time to maximum concentration (C_{max}) of TH104 was 2.0 hours, and mean half-life ($T_{1/2}$) as measured in the blood of subjects was 14 hours after a single buccal administration of TH104, compared to 9 hours for the 1mg intravenous dose of nalmefene. These data were consistent and within range of previous findings of nalmefene in the literature and the Company believes PK results from this Phase 1 trial show proportional kinetics consistent with published findings of oral and intravenous formulations, suggesting TH104 could be developed for once-daily dosing in a target population of moderate-to-severe chronic pruritus in PBC patients. The Phase 1 trial also demonstrated that a 16mg dose of TH104 had a comparable safety and tolerability profile to the FDA-approved 1mg dose of nalmefene intravenous formulation. Treatment emergent adverse events (TEAEs) in this study were reported in 8 subjects (40.0%) in the TH104 group and 7 subjects (36.8%) in the intravenous group. All reported TEAEs were considered mild in severity. The most frequently reported TEAE for both TH104 and intravenous treatments was dizziness (4 subjects in the TH104 group; 7 subjects in the intravenous group). TEAEs reported in at least 2 subjects in any treatment group were nausea (3 subjects in each group) and somnolence (3 subjects in each group). There were no serious adverse events reported during this study. No subjects discontinued the study due to adverse events. No subjects exhibited abnormal results for the visual examinations of the buccal mucosa pre- or post-dosing with TH104 buccal film.

On June 17, 2024, we reported positive Type C meeting feedback from the U.S. Food and Drug Administration (FDA) for our Phase 2 clinical trial with TH104, confirming our plan to pursue a 505(b)(2) approval pathway, which permits inclusion of data from external studies when the active ingredient is already approved in the United States. The FDA also agreed that the nonclinical studies submitted to the FDA in advance of the meeting appear sufficient to support the proposed Phase 2 clinical trial. In addition, the FDA provided feedback on study design and certain recommendations regarding PBC patient inclusion, the primary endpoint to assess pruritus in these patients, and considerations for monitoring for adverse events in this patient population. Based on this interaction, in early 2025, we began start up activities in preparation for the Phase 2 trial with TH104 in moderate-to-severe chronic pruritus in PBC patients. We plan to plan to initiate a hepatic impairment study prior to launching the Phase 2 study.

On June 7, 2024, we entered into an at-the-market offering agreement (the "ATM Agreement") with Rodman & Renshaw LLC (the "Manager"), pursuant to which we may offer and sell, from time to time, shares of our common stock having an aggregate offering price of up to $1,650,000 through the Manager. Any shares sold under the ATM Agreement will be issued pursuant to our effective shelf registration statement on Form S-3 and the related prospectus supplement. We will pay the Manager a commission of 3.0% of the aggregate gross proceeds from the sales of shares of our common stock sold through the Manager pursuant to the ATM Agreement. During the year ended December 31, 2024, we raised gross proceeds of $83,568 pursuant to the ATM Agreement from the sale of 40,000 shares of our common stock at an average price of $2.0892 per share (the "ATM Sale"). The net proceeds from the ATM Sale during the year ended December 31, 2024 were $73,189, after deducting sales agent commissions of $2,507 and other fees of $7,992.

On June 21, 2024, we closed a private placement offering (the "June 2024 PIPE Offering") with certain accredited investors of $2.08 million of our securities consisting of shares of our common stock and/or pre-funded warrants to acquire shares of our common stock and warrants to acquire shares of our common stock. Net proceeds from the June 2024 PIPE Offering were approximately $1.8 million.

We signed a development agreement for TH1014 Phase 2A clinical trial manufacturing on July 25, 2024. In the study, our CMO will manufacture four increasing strengths of TH104 active material and their corresponding placebos. The manufacturing operation is a 5-month program, where each of the strengths will be released for clinical packaging by the end of the year. We are pleased to state that the developmental activities are on track and within budget. Updates to the developmental activities are provided biweekly, and we currently see no risks to the timely completion of the activities and procurement of the clinical trial materials in the proposed timeframe.

On December 9, 2024, we closed a private placement offering (the "December 2024 PIPE Offering") with certain accredited investors of $2.02 million of our securities consisting of shares of our common stock and/or pre-funded warrants to acquire shares of our common stock and warrants to acquire shares of our common stock. Net proceeds from the December 2024 PIPE Offering were approximately $1.8 million.

Components of Results of Operations

Revenue

We have not recognized revenue since inception or for the years ended December 31, 2024 and 2023.

Research and Development Expenses

Research and development expenses include personnel costs associated with research and development activities, including third-party contractors to perform research, conduct clinical trials, and manufacture drug supplies and materials as well as stock-based compensation for our research and development personnel. Research and development expenses are charged to operations as incurred.

We accrue costs incurred by external service providers, including contract research organizations and clinical investigators, based on estimates of service performed and costs incurred. These estimates include the level of services performed by third parties, patient enrollment in clinical trials, administrative costs incurred by third parties, and other indicators of the services completed. Based on the timing of amounts invoiced by service providers, we may also record payments made to those providers as prepaid expenses that will be recognized as expense in future periods as the related services are rendered.

We have incurred research and development expenses related to the development of HSB-1216, which has been deprioritized. We expect that our research and development expenses will increase as we plan for and commence our clinical trials of HS3215 and HS1940.

We cannot determine with certainty the duration and costs of future clinical trials of our product candidates, HS3215 and HS1940, or any other product candidates we may develop or if, when or to what extent we will generate revenue from the commercialization and sale of any of our product candidates for which we obtain marketing approval. We may never succeed in obtaining marketing approval for any of our product candidates. The duration, costs and timing of clinical trials and development of our current and future product candidates will depend on a variety of factors, including:

- the scope, rate of progress, expense and results of clinical trials of our current product candidates, as well as of any future clinical trials of our future product candidates and other research and development activities that we may conduct;
- uncertainties in clinical trial design and patient enrollment rates;
- the actual probability of success for our product candidates, including their safety and efficacy, early clinical data, competition, manufacturing capability and commercial viability;
- significant and changing government regulations and regulatory guidance; and
- the timing and receipt of any marketing approvals.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in our clinical trials due to slower than expected patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation and consulting related expenses, including stock-based compensation for our general and administrative personnel. General and administrative expenses also include professional fees and other corporate expenses, including legal fees relating to corporate matters; professional fees for accounting, auditing, tax, and consulting services; insurance costs; travel expenses and other operating costs that are not specifically attributable to research activities.

We expect that our general and administrative expenses will increase in the future as we increase our personnel headcount to support our continued research activities and development of our product candidates. We also incur expenses associated with being a public company, including expenses related to compliance with the rules and regulations of the SEC and Nasdaq, directors and officers insurance expenses, corporate governance expenses, investor relations activities and other administrative and professional services.

Interest Income

Interest income consists of interest income from funds held in our cash accounts.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

The following table sets forth key components of our results of operations for the years ended December 31, 2024 and 2023.

	Year Ended December 31,		
	2024	**2023**	**Change**
Consolidated Statements of Operations Data:			
Operating expenses:			
Research and development	$ 6,392,097	$ 3,559,635	$ 2,832,462
General and administrative	6,041,695	5,895,585	146,110
Total operating expenses	12,433,792	9,455,220	2,978,572
Other income (expense):			
Interest expense	(13,684)	(16,505)	2,821
Interest income	249,908	152,631	97,277
Total other income (expense)	236,224	136,126	100,098
Net loss	$ (12,197,568)	$ (9,319,094)	$ (2,878,474)

Research and Development Expenses

Research and development expenses increased by $2.8 million, or 80%, to $6.4 million for the year ended December 31, 2024 from $3.6 million for year ended December 31, 2023. The increase was primarily the result of an increase in clinical trial expenses of approximately $1.6 million due to completion of our Phase 1 clinical trial and start-up costs related to our Phase 2 clinical trial in TH104, an increase of $1.8 million in license fees, and an increase of $0.2 million in regulatory fees. These increases were offset by a decrease of $0.7 million in pre-clinical vendor expenses and a decrease of $0.1 million in stock-based compensation expense related to our research and development personnel.

General and Administrative Expenses

General and administrative expenses increased by $0.1 million, or 2%, to $6.0 million for the year ended December 31, 2024 from $5.9 million for the year ended December 31, 2023. The change in general and administrative expenses was primarily due to a decrease of $0.2 million in investor relations, a decrease of $0.4 million in insurance, and a decrease of $0.1 million in stock-based compensation expense related to our general and administrative personnel. These decreases were offset by an increase in wages of $0.4 million, an increase in $0.1 million in general corporate, and an increase of $0.1 million in director remuneration.

Interest Expense

Interest expense decreased by $2,821, or 17%, to $13,684 for the year ended December 31, 2024 from $16,505 for the year ended December 31, 2023. The decrease in interest expense was primarily related to the decrease in D&O insurance premium financing liability.

Interest Income

Interest income increased by $97,277, or 64%, to $249,908 for the year ended December 31, 2024 from $152,631 for year ended December 31, 2023. The increase in interest income was primarily due to the increase in cash from the June 2024 and December 2024 PIPE Offerings as well as a higher balance toward the end of 2023 which existed for most of 2024

Liquidity and Capital Resources

The accompanying consolidated financial statements have been prepared on the basis that we will continue as a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business. During the year ended December 31, 2024, we incurred operating losses in the amount of approximately $12.4 million, expended approximately $10.9 million in net cash used in operating activities, and had an accumulated deficit of approximately $36.9 million as of December 31, 2024. Through December 31, 2024, we have primarily financed our operations through public and private offerings of our equity securities. We received net proceeds from our initial public offering ("IPO") on January 14, 2022 of approximately $12.5 million. Additionally, we closed the May 2023 Offering and November 2023 Offering, public offerings with net proceeds of approximately $2.1 million and $8.7 million, respectively.

During the year ended December 31, 2024, we raised gross proceeds of $83,688 pursuant to the ATM Agreement from the sale of 40,000 shares of our common stock at an average price of $2.0892 per share. The net proceeds from the ATM Sale during the year ended December 31, 2024 were $73,189, after deducting sales agent commissions of $2,507 and other fees of $7,992.

Further, on June 17, 2024 and December 9, 2024, we closed private placement offerings (the "June 2024 PIPE Offering" and "December 2024 PIPE Offering") with certain accredited investors, consisting of offerings of shares of our common stock and/or pre-funded warrants to acquire shares of our common stock and warrants to acquire shares of our common stock, with combined net proceeds of approximately $3.6 million. The shares of our common stock began trading on The Nasdaq Capital Market on January 12, 2022 under the ticker symbol "HILS" and effective as of September 25, 2023, are traded under the ticker symbol "THAR."

Based on our limited operating history, recurring negative cash flows from operations, current plans and available resources, we will need substantial additional funding to support future operating activities. We have concluded that the prevailing conditions and ongoing liquidity risks faced by us raise substantial doubt about our ability to continue as a going concern for at least one year following the date these consolidated financial statements included elsewhere in this Annual Report on Form 10-K are issued. The accompanying consolidated financial statements do not include any adjustments that might be necessary should we be unable to continue as a going concern.

We may seek to raise additional funding through the sale of additional equity or debt securities, enter into strategic partnerships, grants or other arrangements or a combination of the foregoing to support our future operations; however, there can be no assurance that we will be able to obtain additional capital on terms acceptable to us, on a timely basis, or at all. The failure to obtain sufficient additional funding could adversely affect our ability to achieve our business objectives and product development timelines and may result in delaying or terminating clinical trial activities which could have a material adverse effect on our results of operations.

Cash Flow Activities for the Years Ended December 31, 2024 and 2023

The following table sets forth a summary of our cash flows for the periods presented.

	Year Ended December 31,	
	2024	2023
Net cash used in operating activities	$ (10,901,991)	$ (7,300,106)
Net cash provided by financing activities	3,526,000	11,724,924
Net (decrease) increase in cash	$ (7,375,991)	$ 4,424,818

Cash Flows from Operating Activities

Cash used in operating activities for the year ended December 31, 2024 was $10.9 million which consisted of net loss of $12.2 million, partially offset by non-cash stock-based compensation of approximately $0.7 million, non-cash stock issuance pursuant to a services agreement of less than $0.1 million, and net changes in operating assets and liabilities of approximately $0.6 million.

Cash used in operating activities for the year ended December 31, 2023 was $7.3 million which consisted of net loss of $9.3 million, partially offset by non-cash stock-based compensation of approximately $0.8 million, non-cash stock issuance pursuant to a services agreement of approximately $0.4 million, and net changes in operating assets and liabilities of approximately $0.8 million.

Cash Flows from Financing Activities

Cash provided by financing activities for the year ended December 31, 2024 was $3.5 million. The net increase in financing activities was due to proceeds from the PIPE Offerings of $4.1 million, proceeds from the ATM Sale of $0.1 million and insurance premium financing liability of $0.4 million, offset by payments of deferred offering costs of $0.7 million and repayments of insurance premium financing liability of $0.4 million.

Cash provided by financing activities for the year ended December 31, 2023 was $11.7 million. The net increase in financing activities was from net cash proceeds of $12.2 million from the issuance of our common stock in connection with public offerings and $0.7 million in proceeds received from insurance premium financing liability offset by deferred offering costs of $0.5 million and $0.7 million in repayments of insurance premium financing liability.

Reverse Stock Split

On May 24, 2024, the Company effectuated an additional reverse split of shares of its common stock at a ratio of 1-for-15 pursuant to an amendment to the Company's Certificate of Incorporation, as amended, filed with the Delaware Secretary of State and approved by the Company's board of directors and stockholders. The par value of the Company's common stock was not adjusted as a result of the reverse split. All issued and outstanding common stock share and per share amounts contained in the accompanying consolidated financial statements have been retroactively adjusted to reflect the reverse split for all periods presented.

Critical Accounting Policies and Use of Estimates

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Management bases its estimates on historical experience and on assumptions believed to be reasonable under the circumstances. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes, and management must select an amount that falls within that range of reasonable estimates. Estimates are used in the following areas, among others: research and development expense recognition, stock-based compensation, allowances of deferred tax assets, and cash flow assumptions regarding going concern considerations. Although management believes the estimates that have been used are reasonable, actual results could vary from the estimates that were used.

Critical Accounting Policies

Research and development

Research and development costs are expensed as incurred. Research and development expenses include personnel costs associated with research and development activities, including third-party contractors to perform research, conduct clinical trials and manufacture drug supplies and materials. We accrue for costs incurred by external service providers, including contract research organizations and clinical investigators, based on our estimates of service performed and costs incurred. These estimates include the level of services performed by third parties, patient enrollment in clinical trials, administrative costs incurred by third parties, and other indicators of the services completed.

Stock-based compensation

Stock-based compensation represents the cost related to stock-based awards granted to our employees, directors, consultants, and affiliates. We measure stock-based compensation costs at the grant date, based on the estimated fair value of the award and recognize the cost over the requisite service period.

We recognize compensation costs resulting from the issuance of stock-based awards to employees, non-employees and directors as an expense in the consolidated statements of operations over the requisite service period based on a measurement of fair value for each stock-based award. The fair value of each option grant to employees, non-employees and directors is estimated as of the date of grant using the Black-Scholes option-pricing model, net of actual forfeitures. The fair value is amortized as compensation cost on a straight-line basis over the requisite service period of the awards, which is generally the vesting period.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. Prior to January 12, 2022, we were a private company and our common stock has only been publicly traded since that date. As a result, we lack company-specific historical and implied volatility information. Therefore, we have estimated our expected stock price volatility based on the historical volatility of a publicly traded set of peer companies. The expected term of stock options granted was between five and seven years. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award.

Recently Issued and Adopted Accounting Standards

See Note 2 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act (the "JOBS Act") was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We have chosen to take advantage of the extended transition periods available to emerging growth companies under the JOBS Act for complying with new or revised accounting standards until those standards would otherwise apply to private companies provided under the JOBS Act. As a result, our financial statements may not be comparable to those of companies that comply with public company effective dates for complying with new or revised accounting standards.

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including, without limitation, (i) providing an auditor's attestation report on our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, as amended, and (ii) complying with the requirement adopted by the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on financial statements. We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our IPO; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

The Company is not required to provide the information required by this Item as it is a "smaller reporting company," as defined in Rule 12b-2 of the Exchange Act.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

THARIMMUNE, INC.
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Tharimmune, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Tharimmune, Inc. (the Company) as of December 31, 2024 and 2023, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2024, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for the years in the two-year period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

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

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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 audits 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 consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our 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.

We have served as the Company's auditor since 2023.

/s/ Rosenberg Rich Baker Berman P.A.

Somerset, New Jersey
March 25, 2025

THARIMMUNE, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2024	December 31, 2023
ASSETS		
Current assets		
Cash	$ 3,559,361	$ 10,935,352
Prepaid expenses and other current assets	45,263	11,041
Deferred offering costs	117,000	-
Total current assets	3,721,624	10,946,393
Total assets	$ 3,721,624	$ 10,946,393
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,089,666	$ 908,577
Accrued expenses	1,324,316	906,469
Total current liabilities	2,413,982	1,815,046
Total liabilities	2,413,982	1,815,046
Commitments and contingencies (see Note 6)		
Stockholders' equity		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued and outstanding as of December 31, 2024 and December 31, 2023	-	-
Common stock, $0.0001 par value, 250,000,000 shares authorized, 1,973,999 shares and 884,720 shares issued and 1,973,753 shares and 884,474 shares outstanding as of December 31, 2024 and December 31, 2023, respectively	198	89
Additional paid-in capital	38,278,503	33,904,749
Accumulated deficit	(36,901,094)	(24,703,526)
Treasury stock, at cost, 246 shares held in treasury as of December 31, 2024 and 2023	(69,965)	(69,965)
Total stockholders' equity	1,307,642	9,131,347
Total liabilities and stockholders' equity	$ 3,721,624	$ 10,946,393

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

THARIMMUNE, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Years Ended December 31,	
	2024	2023
Operating expenses		
Research and development	$ 6,392,097	$ 3,559,635
General and administrative	6,041,695	5,895,585
Total operating expenses	12,433,792	9,455,220
Loss from operations	(12,433,792)	(9,455,220)
Other income (expense)		
Interest expense	(13,684)	(16,505)
Interest income	249,908	152,631
Total other income (expense), net	236,224	136,126
Net loss	$ (12,197,568)	$ (9,319,094)
Net loss per share:		
Basic and diluted	$ (9.41)	$ (107.02)
Weighted average number of common shares outstanding:		
Basic and diluted	1,296,290	87,079

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

THARIMMUNE, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2024 AND 2023

	Common Stock		Additional	Accumulated	Treasury Stock		
	Shares	Amount	Paid-in Capital	Deficit	Shares	Amount	Total
Balance, December 31, 2022	31,001	$ 3	$ 20,998,049	$ (15,384,432)	246	$ (69,965)	$ 5,543,655
Stock issuance pursuant to services agreement	1,861	-	350,000	-	-	-	350,000
Public offering, net of issuance costs	135,801	14	11,715,735	-	-	-	11,715,749
Exercise of pre-funded warrants	614,280	62	9,113	-	-	-	9,175
Reverse stock-split adjustments	101,777	10	(10)	-	-	-	-
Net loss	-	-	-	(9,319,094)	-	-	(9,319,094)
Stock based compensation	-	-	831,862	-	-	-	831,862
Balance, December 31, 2023	884,720	89	33,904,749	(24,703,526)	246	(69,965)	9,131,347
Stock issuance pursuant to services agreement	3,334	1	20,549	-	-	-	20,550
Private investments in public equity offering, net of issuance costs	677,581	68	3,642,193	-	-	-	3,642,261
At-the-market offering, net of issuance costs	40,000	4	73,185	-	-	-	73,189
Issuance costs related to Form S-3 Registration Statement	-	-	(72,450)	-	-	-	(72,450)
Cashless exercise of pre-funded warrants, net of cancellation	368,364	36	(36)	-	-	-	-
Net loss	-	-	-	(12,197,568)	-	-	(12,197,568)
Stock based compensation	-	-	710,313	-	-	-	710,313
Balance, December 31, 2024	1,973,999	$ 198	$ 38,278,503	$ (36,901,094)	246	$ (69,965)	$ 1,307,642

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

THARIMMUNE, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (12,197,568)	$ (9,319,094)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation	710,313	831,862
Stock issuance pursuant to services agreement	20,550	350,000
Increase in operating assets:		
Prepaid expenses and other current assets	(34,222)	167,053
Increase (decrease) in operating liabilities:		
Accounts payable	181,089	(45,928)
Accrued expenses	417,847	716,001
Net cash used in operating activities	(10,901,991)	(7,300,106)
Net cash provided by (used in) investing activities	-	-
Cash flows from financing activities:		
Proceeds from issuance of common stock upon private investment in public equity offerings	4,104,161	-
Proceeds from issuance of common stock upon at-the-market offering	83,568	-
Proceeds from issuance of common stock upon public offering, net of underwriting discounts and issuance costs	-	12,234,929
Payment of deferred offering costs	(661,729)	(519,180)
Exercise of pre-funded warrants	-	9,175
Proceeds from insurance premium financing liability	393,960	716,775
Repayment of insurance premium financing liability	(393,960)	(716,775)
Net cash provided by financing activities	3,526,000	11,724,924
Net (decrease) increase in cash	(7,375,991)	4,424,818
Cash, beginning of period	10,935,352	6,510,534
Cash, end of period	$ 3,559,361	$ 10,935,352
Cash paid for interest expense	$ 13,684	$ 16,505
Supplemental disclosure of non-cash financing activities:		
Issuance of common stock for prepaid marketing and investor related consulting services	$ -	$ 100,000

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

Note 1 – Description of Business and Liquidity

Nature of Operations

Tharimmune, Inc. (formerly, Hillstream BioPharma, Inc.) ("Tharimmune" or the "Company") was incorporated on March 28, 2017, as a Delaware C-corporation. At December 31, 2024, Tharimmune had one wholly-owned subsidiary: Hillstream Oncology, Inc. ("Hillstream Oncology"), formerly, HB Pharma Corp.

Tharimmune is a clinical-stage biotechnology company developing therapeutic candidates in rare, inflammatory, and oncologic conditions with high unmet need. On November 3, 2023, the Company entered into a patent license agreement (the "Avior License Agreement") with Avior Inc. d/b/a Avior Bio, LLC ("Avior") pursuant to which it received an exclusive sublicensable right and license to Licensed Patent Rights and Licensed Technology to, among other things, Develop, have Developed, make, have made, use, sell, import, export and commercialize TH104 and TH103) and to practice the Licensed Technology in connection with the foregoing, throughout the world (each as defined in the Avior License Agreement. In February 2023, the U.S. Food and Drug Administration ("FDA") approved an investigational new drug ("IND") application for TH104. TH104 has a dual mechanism of action by affecting multiple receptors, known to suppress chronic, debilitating pruritis or "uncontrollable itching." With respect to TH104, the Company intends to first seek approval for the treatment of moderate to severe chronic pruritis in patients with primary biliary cholangitis ("PBC"), an orphan rare form of liver disease with no known cure in which more than 70% of patients suffer from debilitating chronic pruritis, and with respect to TH103, it intends to develop the product candidate and potentially file an IND.

On September 11, 2024, Tharimmune entered into a Patent License Agreement (the "Intract Agreement") with Intract Pharma Limited ("Intract"), pursuant to which, the Company exclusively licensed INT-023/TH023, an oral anti-Tumor Necrosis Factor-alpha (TNF-α) monoclonal antibody infliximab. Infliximab is a purified, recombinant DNA-derived chimeric IgG monoclonal antibody protein that contains both murine and human components that inhibit tumor TNF-α. Under the terms of the Agreement, the Company licensed global development and commercialization rights (outside of South Korea) to Intract's Soteria® and Phloral® delivery platform along with an existing supply agreement for infliximab to be used in the oral product development program.

The Company is also developing an early-stage pipeline of novel therapeutic candidates targeting validated high value immuno-oncology ("IO") targets including human epidermal growth factor ("EGF") receptor 2 ("HER2"), human EGF receptor 3 ("HER3") and programmed cell death protein 1 ("PD-1"). The Company is developing antibodies including bispecific antibodies, antibody drug conjugates ("ADCs") and small molecular weight bovine-derived Picobodies™ or antibody "knob" domains which have the potential to target and bind more tightly to "undruggable" epitopes better than full sized antibodies. The Company is advancing HS3215, a bispecific against both HER2 and HER3 antibody which targets a novel "bridging epitope" encompassing multiple domains of the HER2 extracellular domain ("ECD") as well as ligand-dependent and independent blocking of the ECD of HER3 into IND-enabling studies in 2024. In addition, the Company anticipates that HS0059, a HER2/HER3 bispecific ADC ("bsADC"), and TH1940, a PD-1 Picobody, will progress to enter IND-enabling studies in 2025.

Name Change

On September 21, 2023, Hillstream BioPharma, Inc. filed a Certificate of Amendment (the "Amendment") to its Certificate of Incorporation, as amended (the "Certificate of Incorporation"), with the Secretary of State of the State of Delaware pursuant to which it changed its name to Tharimmune, Inc. effective as of September 25, 2023. The name change became effective with The Nasdaq Capital Market on September 25, 2023 and the Company's common stock has since traded on The Nasdaq Capital Market under the new name and new ticker symbol, "THAR."

In addition, on May 23, 2024, HB Pharma Corp. filed a Certificate of Amendment to its Certificate of Incorporation, as amended, with the Secretary of State of the State of Delaware pursuant to which it changed its name to Hillstream Oncology, Inc. effective as of May 23, 2024.

Liquidity and Going Concern

The accompanying consolidated financial statements have been prepared on the basis that the Company will continue as a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business. During the year ended December 31, 2024, the Company incurred operating losses in the amount of approximately $12.4 million, expended approximately $10.9 million in net cash used in operating activities, and had an accumulated deficit of approximately $36.9 million as of December 31, 2024. Through December 31, 2024, the Company has primarily financed its operations through public and private offerings of its equity securities. The Company received net proceeds from its initial public offering ("IPO") on January 14, 2022 of approximately $12.5 million. Additionally, the Company received net proceeds of approximately $2.1 million from a public offering (the "May 2023 Offering") of its common stock on May 2, 2023. The Company closed an additional public offering (the "November 2023 Offering") of its common stock on November 30, 2023 with net proceeds of approximately $8.7 million.

In addition, on June 7, 2024, the Company filed a Registration Statement on Form S-3 with the SEC using a "shelf" registration process pursuant to which, under an at-the-market offering agreement (the "ATM Agreement"), the Company may sell, from time to time through the applicable sales manager, shares of common stock in one or more offerings up to a total dollar amount of $1.65 million. Under the ATM Agreement, the Company sold 40,000 shares of it's common stock for gross proceeds of $83,688 (the "ATM Sale"). Net proceeds from the ATM Sale after deducting commissions of $2,507 and other fees of $7,992 were $73,189.

Further, on June 17, 2024 and December 9, 2024, the Company closed private placement offerings (the "June 2024 PIPE Offering" and "December 2024 PIPE Offering") with certain accredited investors, of shares of the Company's common stock and/or pre-funded warrants to acquire shares of the Company's common stock and warrants to acquire shares of the Company's common stock, with combined net proceeds to the Company of approximately $3.6 million. See Note 3 to the consolidated financial statements for details regarding the various offerings. The shares of the Company's common stock began trading on The Nasdaq Capital Market on January 12, 2022 under the ticker symbol "HILS" and effective as of September 25, 2023, are traded under the ticker symbol "THAR."

Based on the Company's limited operating history, recurring negative cash flows from operations, current plans and available resources, the Company will need substantial additional funding to support future operating activities. The Company has concluded that the prevailing conditions and ongoing liquidity risks faced raise substantial doubt about the Company's ability to continue as a going concern for at least one year following the date these consolidated financial statements are issued. The accompanying consolidated financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern.

The Company may seek to raise additional funding through the sale of additional equity or debt securities, enter into strategic partnerships, grants, or other arrangements or a combination of the foregoing to support its future operations, however, there can be no assurance that the Company will be able to obtain additional capital on terms acceptable to the Company, on a timely basis or at all. The failure to obtain sufficient additional funding could adversely affect the Company's ability to achieve its business objectives and product development timelines and may result in the Company delaying or terminating clinical trial activities which could have a material adverse effect on the Company's results of operations.

Other Risks and Uncertainties

There can be no assurance that the Company's products, if approved, will be accepted in the marketplace, nor can there be any assurance that any future products can be developed or manufactured at an acceptable cost and with appropriate performance characteristics, or that such products will be successfully marketed, if at all. The Company is subject to risks common to biopharmaceutical companies including, but not limited to, the development of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, product liability, uncertainty of market acceptance of products and the need to obtain additional financing. The Company is dependent on third party suppliers. The Company's products require approval or clearance from the FDA prior to commencing commercial sales in the United States. Approvals or clearances are also required in foreign jurisdictions in which the Company may license or sell its products. There can be no assurance that the Company's products will receive all of the required approvals or clearances.

Note 2 – Summary of Significant Accounting Policies

Basis of Presentation

These accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The Company operates in one segment.

Reverse Stock Splits

On November 17, 2023, the Company effectuated a reverse split of shares of its common stock at a ratio of 1-for-25 pursuant to an amendment to the Company's Certificate of Incorporation, as amended, filed with the Delaware Secretary of State and approved by the Company's board of directors and stockholders. On May 24, 2024, the Company effectuated an additional reverse split of shares of its common stock at a ratio of 1-for-15 pursuant to an amendment to the Company's Certificate of Incorporation, as amended, filed with the Delaware Secretary of State and approved by the Company's board of directors and stockholders. The par value of the Company's common stock was not adjusted as a result of either reverse split. All issued and outstanding common stock share and per share amounts contained in the consolidated financial statements have been retroactively adjusted to reflect these reverse splits for all periods presented.

Principles of Consolidation

The consolidated financial statements include the accounts of Tharimmune and its wholly-owned subsidiaries, HB and Farrington Therapeutics LLC. All significant intercompany balances and transactions have been eliminated in consolidation. On February 27, 2023, the Company filed a Certificate of Cancellation with the Delaware Secretary of State with respect to Farrington Therapeutics LLC.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Management bases its estimates on historical experience and on assumptions believed to be reasonable under the circumstances. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes, and management must select an amount that falls within that range of reasonable estimates. Areas of the consolidated financial statements where estimates may have the most significant effect include research and development expense recognition, valuation of common shares and share-based compensation, allowances of deferred tax assets, valuation of debt related instruments, and cash flow assumptions regarding going concern considerations. Although management believes the estimates that have been used are reasonable, actual results could vary from the estimates that were used.

Concentration of Credit Risk

The Company maintains cash balances with various financial institutions. Account balances at these institutions are insured by the Federal Deposit Insurance Corporation up to $250,000 per depositor. At various times during the year, bank account balances may have been in excess of federally insured limits. The Company has not experienced losses in such accounts. The Company believes that it is not subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. Cash equivalents, if any, are stated at cost and consist primarily of money market accounts.

Research and Development

Research and development costs are expensed as incurred. Research and development expenses include personnel costs associated with research and development activities, including third-party contractors to perform research, conduct clinical trials, and manufacture drug supplies and materials. The Company accrues for costs incurred by external service providers, including contract research organizations and clinical investigators, based on its estimates of service performed and costs incurred. These estimates include the level of services performed by third parties, patient enrollment in clinical trials, administrative costs incurred by third parties, and other indicators of the services completed.

Stock-Based Compensation

The Company recognizes compensation costs resulting from the issuance of stock-based awards to employees, non-employees, and directors as an expense in the consolidated statements of operations over the requisite service period based on a measurement of fair value for each stock-based award. The fair value of each option grant to employees, non-employees, and directors is estimated as of the date of grant using the Black-Scholes option-pricing model, net of actual forfeitures. The fair value is amortized as compensation cost on the straight-line basis over the requisite service period of the awards, which is generally the vesting period.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. Prior to January 12, 2022, the Company was a private company and the Company's common stock has only been publicly traded since that date. As a result, the Company has lacked company-specific historical and implied volatility information. Therefore, it has estimated its expected stock volatility based on the historical data regarding the volatility of a publicly traded set of peer companies. The expected term of stock options granted was between five and seven years. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award.

Fair Value Measurements

The Company applies Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 820, *Fair Value Measurement* ("ASC 820"), which establishes a framework for measuring fair value and clarifies the definition of fair value within that framework. ASC 820 defines fair value as an exit price, which is the price that would be received for an asset or paid to transfer a liability in the Company's principal or most advantageous market in an orderly transaction between market participants on the measurement date. The fair value hierarchy established in ASC 820 generally requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Observable inputs reflect the assumptions that market participants would use in pricing the asset or liability and are developed based on market data obtained from sources independent of the reporting entity. Unobservable inputs reflect the entity's own assumptions based on market data and the entity's judgments about the assumptions that market participants would use in pricing the asset or liability and are to be developed based on the best information available in the circumstances.

The carrying value of the Company's cash, prepaid expenses, accounts payable, and accrued expenses approximate fair value because of the short-term maturity of these financial instruments.

The valuation hierarchy is composed of three levels. The classification within the valuation hierarchy is based on the lowest level of input that is significant to the fair value measurement. The levels within the valuation hierarchy are described below:

Level 1 Inputs: Observable inputs such as quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2 Inputs: Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for assets or liabilities recently traded in active markets, with similar underlying terms, as well as direct or indirect observable inputs, such as interest rates and yield curves that are observable at commonly quoted intervals, as well as quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3 Inputs: Unobservable inputs, such as estimates, assumptions, and valuation techniques when little or no market data exists for the assets or liabilities, that reflect the reporting entity's own assumptions.

Deferred Offering Costs

Deferred offering costs consists primarily of legal, accounting, underwriters' fees, printing, and filing fees that are incurred prior to an offering of the Company's common stock and are initially capitalized and then subsequently reclassified to additional paid-in capital upon completion of the offering. If an offering is not completed, any associated offering costs will be expensed immediately upon termination of the offering. At December 31, 2024, there are $117,000 in deferred offering costs associated with the ATM Agreement.

Insurance Premium Financing Liability

In January 2023, the Company entered into an insurance premium financing agreement for $955,700, with a term of nine months and an annual interest rate of 5.25%. The Company made a down payment of $238,925 and was required to make monthly principal and interest payments of $81,394 over the term of the agreement, which was repaid in full in October 2023.

In January 2024, the Company entered into an insurance premium financing agreement for $492,450, with a term of 10 months and an annual interest rate of 7.5%. The Company made a down payment of $98,490 and is required to make monthly principal and interest payments of $40,763 over the term of the agreement, which was repaid in full in November 2024.

Retirement Plan

The Company has a 401(k) defined contribution plan which covers all employees that meet the plan's eligibility requirements. Eligible employees may contribute a percentage of their salary subject to certain limitations. The Company makes a discretionary match which is currently equal to 3% of employee contributions. Total company contributions to the plan were $6,793 and $19,336 for the years ended December 31, 2024 and 2023, respectively.

Income Taxes

The Company accounts for income taxes using the asset-and-liability method in accordance with FASB ASC Topic 740, *Income Taxes* ("ASC 740"). Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards.

Deferred income taxes are recognized for the tax effect of temporary differences between the financial statement carrying amount of assets and liabilities and the amounts used for income tax purposes and for certain changes in valuation allowances. Valuation allowances are recorded to reduce certain deferred tax assets when, in management's estimation, it is more-likely-than-not that a tax benefit will not be realized. A full valuation allowance has been recognized for all periods since it is more-likely-than-not that some portion or all of the deferred tax assets will not be realized in future periods.

The Company follows the guidance in FASB ASC Subtopic 740-10 in assessing uncertain tax positions. The standard applies to all tax positions and clarifies the recognition of tax benefits in the financial statements by providing for a two-step approach of recognition and measurement. The first step involves assessing whether the tax position is more-likely-than-not to be sustained upon examination based upon its technical merits. The second step involves measurement of the amount to be recognized. Tax positions that meet the more-likely-than-not threshold are measured at the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate finalization with the taxing authority. The Company recognizes the impact of an uncertain income tax position in the financial statements if it believes that the position is more-likely-than-not to be sustained by the relevant taxing authority. The Company will recognize interest and penalties related to tax positions in income tax expense. At December 31, 2024 and 2023, the Company had no unrecognized uncertain income tax positions, and therefore no amounts have been recognized in the consolidated financial statements.

Net Loss per Share

The Company reports loss per share in accordance with FASB ASC Subtopic 260-10, *Earnings Per Share*, which provides for calculation of basic and diluted earnings per share. Basic earnings per share includes no dilution and is computed by dividing net income or loss available to common stockholders by the weighted average common shares outstanding for the period. Diluted earnings per share reflect the potential dilution of securities that could share in the earnings of an entity. The calculation of diluted net earnings (loss) per share gives effect to common stock equivalents; however, potential common shares are excluded if their effect is anti-dilutive.

Potentially dilutive securities not included in the computation of loss per share for the years ended December 31, 2024 and 2023 included options to purchase 108,955 and 6,102 shares of common stock, respectively. Other potentially dilutive securities not included in the computation of loss per share for the years ended December 31, 2024 and 2023 included warrants to purchase 500 shares of the Company's common stock related to the IPO and warrants to purchase an additional 424 and 20,000 shares of the Company's common stock issued in the May 2023 and November 2023 Offerings, respectively, warrants to purchase an additional 480,721 shares and 329,771 shares of the Company's common stock issued in the December 2024 and June 2024 PIPE Offerings, respectively, and warrants to purchase 19,786 shares of the Company's common stock issued to the placement agents in the June 2024 PIPE Offering. All common share amounts as of December 31, 2024 and 2023 and per share amounts for the years ended December 31, 2024 and 2023 have been retroactively adjusted to reflect a 1-for-25 reverse stock split of the Company's common stock effectuated on November 17, 2023 and a 1-for-15 reverse stock split of the Company's common stock effectuated on May 24, 2024.

Recently Adopted Accounting Pronouncements

The Company has evaluated all recent accounting pronouncements that were required to be adopted and believes that other than the following, none of them will have a material effect on the Company's financial position, results of operations, or cash flows.

The FASB issued Accounting Standards Update ("ASU") 2020-06, *Debt - Debt with Conversion and Other Options* (Subtopic 470-20) and *Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"), to reduce complexity in applying U.S. GAAP to certain financial instruments with characteristics of liabilities and equity. The guidance in ASU 2020-06 simplifies the accounting for convertible debt instruments and convertible preferred stock by removing the existing guidance that requires entities to account for beneficial conversion features and cash conversion features in equity, separately from the host convertible debt or preferred stock. The guidance in ASC Subtopic 470-20 applies to convertible instruments for which the embedded conversion features are not required to be bifurcated from the host contract and accounted for as derivatives. In addition, the amendments revise the scope exception from derivative accounting in ASC Subtopic 815-40 for freestanding financial instruments and embedded features that are both indexed to the issuer's own stock and classified in stockholders' equity, by removing certain criteria required for equity classification. These amendments are expected to result in more freestanding financial instruments qualifying for equity classification (and, therefore, not accounted for as derivatives), as well as fewer embedded features requiring separate accounting from the host contract. The amendments in ASU 2020-06 further revise the guidance in FASB ASC Topic 260, *Earnings Per Share*, to require entities to calculate diluted earnings per share ("EPS") for convertible instruments by using the if-converted method. In addition, entities must presume share settlement for purposes of calculating diluted EPS when an instrument may be settled in cash or shares. The amendments in ASU 2020-06 are effective for public entities that meet the definition of an SEC filer, excluding smaller reporting companies as defined by the SEC for fiscal years beginning after December 15, 2021. For all other entities, including the Company, the amendments are effective for fiscal years beginning after December 15, 2023. The Company adopted this guidance effective January 1, 2024 and the adoption of ASU 2020-06 did not have a material impact on its consolidated financial statements.

Note 3 – Common Stock

Pursuant to an amendment to the Company's Certificate of Incorporation filed in April 2019, the Company increased the number of authorized shares of common stock to 250,000,000 shares. On November 17, 2023, the Company effectuated a reverse split of shares of its common stock at a ratio of 1-for-25 pursuant to an amendment to the Company's Certificate of Incorporation filed with the Delaware Secretary of State and approved by the Company's board of directors and stockholders. Further, on May 24, 2024, the Company effectuated an additional reverse split of shares of its common stock at a ratio of 1-for-15 pursuant to an amendment to the Company's Certificate of Incorporation filed with the Delaware Secretary of State and approved by the Company's board of directors and stockholders. The par value of the Company's common stock was not adjusted as a result of either reverse stock split.

On February 16, 2022, the Company entered into an agreement for marketing and investor related consulting services. Pursuant to the agreement, compensation includes a monthly fee and an upfront issuance of shares of the Company's common stock. On the effective date of February 16, 2022, the Company issued 85 shares of its common stock with a per share value of $1,176.47 and a total value of $100,000 as compensation expense. The agreement automatically renews annually and upon renewal, a payment of $100,000 of shares of the Company's common stock is issued. On February 16, 2023, the agreement was renewed and on the effective date of August 22, 2023, an additional 187 shares of the Company's common stock were issued with a per share value of $534.76 (as calculated based on the trailing 10-day average closing value of the Company's common stock prior to the renewal date) representing compensation expense of $100,000.

On March 17, 2023, the Company filed a Registration Statement on Form S-3 with the SEC using a "shelf" registration process pursuant to which, the Company may sell, from time to time in one or more offerings, shares of common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or as units comprised of a combination of one or more of the other securities in one or more offerings up to a total dollar amount of $75 million.

On May 2, 2023, the Company closed a public offering pursuant to which it issued 14,134 shares of its common stock at a public offering price of $188.00 per share. The gross proceeds to the Company from the May Offering were approximately $2.7 million, prior to deducting underwriting discounts and commissions of approximately $186,000 and other offering expenses of approximately $417,000. The net proceeds to the Company from the May Offering were approximately $2.1 million. The Company granted the underwriters a 45-day option to purchase up to an additional 53,000 shares of common stock at the public offering price less discounts and commissions, to cover over-allotments; however, this option expired unexercised.

On July 26, 2023, pursuant to the research and development collaboration and license agreement with Applied Biomedical Science Institute ("ABSI"), further described in Note 5 to the consolidated financial statements, the Company issued 1,674 shares of its common stock with a per share value of $149.34, representing total compensation expense of $250,000 (as calculated based on the trailing 10-day average closing value of the Company's common stock prior to the agreement date).

On November 30, 2023, the Company closed a public offering pursuant to which it issued 121,667 shares of its common stock at a public offering price of $15.00 per share and pre-funded warrants to purchase up to 545,000 shares of the Company's common stock, exercisable at an exercise price of $0.015 per share, to those purchasers whose purchase of common stock in the offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of the Company's outstanding common stock immediately following the consummation of the offering. The gross proceeds to the Company from the November Offering were approximately $10.0 million, prior to deducting underwriting discounts, commissions, and other expenses of approximately $1.3 million. The net proceeds to the Company from the November Offering were approximately $8.7 million. The Company granted the underwriters a 45-day option to purchase up to an additional 100,000 shares of common stock and/or pre-funded warrants, to cover over-allotments. The underwriter exercised the option to purchase 66,667 pre-funded warrants to purchase shares of the Company's common stock for gross proceeds of $1.0 million, prior to deducting underwriting discounts and commissions of approximately $70,000.

On January 24, 2024, pursuant to a corporate advisory consulting agreement, the Company issued 3,334 shares of its common stock with a per share value of $6.16, representing total compensation expense of $20,550 (as calculated based on the closing value of the Company's common stock at the effective transfer date).

On June 7, 2024, the Company entered into the ATM Agreement with Rodman & Renshaw LLC (the "ATM Sales Manager") under which the Company may sell, from time to time through the ATM Sales Manager, shares of common stock in one or more offerings up to a total dollar amount of $1.65 million. Sales of shares of the Company's common stock through the ATM Sales Manager, if any, will be made by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended (the "Securities Act"), including without limitation sales made directly on the Nasdaq Stock Market LLC or any other existing trading market for the common shares. The Company's common stock is being offered and sold pursuant to the Company's effective shelf registration statement on Form S-3 and an accompanying prospectus declared effective by the U.S. Securities and Exchange Commission (the "SEC") on March 24, 2023, and pursuant to a prospectus supplement dated June 7, 2024.

On June 21, 2024, the Company closed a private placement offering with certain accredited investors of $2.08 million of the Company's securities consisting of shares of the Company's common stock and/or pre-funded warrants to acquire shares of the Company's common stock and warrants to acquire shares of the Company's common stock. Pursuant to the June 2024 PIPE Offering, the Company issued 207,292 shares of its common stock at an offering price of $3.16 per share, pre-funded warrants to purchase up to 452,253 shares of the Company's common stock (the "June 2024 Pre-Funded Warrants"), exercisable at $0.001 per share, and warrants to purchase up to 329,771 shares of the Company's common stock, exercisable at $3.09 (the "June 2024 PIPE Warrants"). Net proceeds to the Company from the PIPE Offering were approximately $1.8 million, after a deduction of approximately $268,000 in offering costs. In addition, the Company issued placement agent warrants to purchase up to 19,786 shares of the Company's common stock, exercisable at $3.09 per share (the "June 2024 Placement Agent Warrants").

On December 9, 2024, the Company closed an additional private placement offering with certain accredited investors of $2.02 million of the Company's securities consisting of shares of the Company's common stock and/or pre-funded warrants to acquire shares of the Company's common stock and warrants to acquire shares of the Company's common stock. Pursuant to the December 2024 PIPE Offering, the Company issued 470,289 shares of its common stock at an offering price of $2.101 per share, pre-funded warrants to purchase up to 491,157 shares of the Company's common stock (the "December 2024 Pre-Funded Warrants"), exercisable at $0.001 per share, and warrants to purchase up to 480,721 shares of the Company's common stock, exercisable at $2.031 (the "December 2024 PIPE Warrants"). Net proceeds to the Company from the PIPE Offering were approximately $1.8 million, after a deduction of approximately $0.2 million in offering costs.

On December 20, 2024, the Company sold 40,000 shares of its common stock under the ATM Agreement at an offering price of $2.0892 per share (the "ATM Sale"). Net proceeds from the ATM Sale were $73,189, after deducting fees and other offering costs.

Note 4 – Stock Based Compensation

Incentive Plans and Options

Under the Company's 2017 Stock Incentive Plan (the "2017 Plan") the Company may grant incentive stock options, non-statutory stock options, rights to purchase common stock, stock appreciation rights, restricted stock, performance shares, and performance units to employees, directors, and consultants of the Company and its affiliates. Up to 261 shares of the Company's common stock may be issued pursuant to the 2017 Plan.

The Company has granted options to acquire 255 shares of common stock at $4,950 per share under the 2017 Plan, and 6 options to acquire shares of common stock remain available for issuance. As of December 31, 2024 and 2023, there were options outstanding to acquire 255 shares of common stock. As of December 31, 2024 and 2023, all such options were fully vested, and the weighted average remaining contractual life for such options was approximately 3.2 and 4.2 years, respectively.

In July 2019, the Company authorized an additional plan, the 2019 Stock Incentive Plan (the "2019 Plan"). Under the 2019 Plan, the Company may grant incentive stock options, non-statutory stock options, rights to purchase common stock, stock appreciation rights, restricted stock, performance shares, and performance units to employees, directors, and consultants of the Company and its affiliates. At both December 31, 2024 and December 31, 2023, a total of 10,452 shares were authorized for issuance under the 2019 Plan.

As of December 31, 2024 and 2023, the Company has granted options to acquire 10,452 shares of common stock under the 2019 Plan and 0 shares of common stock remain available for issuance under the 2019 Plan. There are stock options outstanding to acquire 5,512 shares of common stock with a weighted-average exercise price of $1,105.50 and weighted average contractual terms of 6.8 years and 7.8 years at December 31, 2024 and 2023, respectively.

On August 17, 2023, the Company authorized a new plan, the Tharimmune, Inc. 2023 Omnibus Incentive Plan (the "2023 Plan"). Under the 2023 Plan, the Company may grant incentive stock options, non-statutory stock options, rights to purchase common stock, stock appreciation rights, restricted stock, performance shares, and performance units to employees, directors, and consultants of the Company and its affiliates. Initially, options to purchase up to 6,934 shares of the Company's common stock were available to be issued pursuant to the 2023 Plan. Under an amendment to the 2023 Plan by vote of the Company's stockholders on May 14, 2024, an amended total of up to 173,600 options to purchase shares of the Company's common stock may be issued pursuant to the 2023 Plan. In addition, under the amendment, an "evergreen" provision was added to automatically increase the number of shares available under the 2023 Plan on January 1 annually, beginning January 1, 2025 and ending January 1, 2033, equal to the lesser of five percent of the shares of Common Stock outstanding (on an as-converted basis) on the final day of the immediately preceding calendar year or such lesser number of shares of the Company's Common Stock as determined by the Board of Directors. Effective January 1, 2025, an additional 98,688 options to purchase shares of the Company's common stock were added to the 2023 Plan.

During the year ended December 31, 2024, the Company granted 102,853 options to acquire shares of common stock under the 2023 Plan. At December 31, 2024 and 2023, 70,412 and 6,934 shares of common stock remain available for issuance under the 2023 Plan, respectively. There are stock options outstanding to acquire 103,188 and 335 shares of common stock with a weighted-average exercise price of $3.11 and $59.14 and weighted-average contractual terms of 9.6 years and 9.9 years at December 31, 2024 and 2023, respectively.

The following table summarizes stock-based activities under the 2017, 2019, and 2023 Stock Incentive Plans:

	Shares Underlying Options		Weighted Average Exercise Price	Weighted Average Contractual Terms
Outstanding at December 31, 2022	4,393	$	1,628.69	7.2 years
Granted	1,709	$	129.17	9.2 years
Outstanding at December 31, 2023	6,102	$	1,208.72	7.8 years
Granted	102,853	$	2.925	9.6 years
Outstanding at December 31, 2024	108,955	$	70.46	9.5 years
Exercisable options at December 31, 2024	48,435	$	138.56	9.2 years
Vested and expected to vest at December 31, 2024	108,955	$	70.46	9.5 years

The fair value of stock option awards is estimated at the date of grant using the Black-Scholes option-pricing model. The estimated fair value of each stock option is then expensed over the requisite service period, which is generally the vesting period (ranging between immediate vesting and four years). The determination of fair value using the Black-Scholes model is affected by the Company's share price as well as assumptions regarding a number of complex and subjective variables, including expected price volatility, expected life, risk-free interest rate and forfeitures. Forfeitures are accounted for as they occur.

Stock options granted during the years ended December 31, 2024 and 2023 were valued using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	For the years ended December 31,	
	2024	2023
Expected volatility	100.8%	95.10% - 103.3%
Risk-free interest rate	3.80%	3.99% - 4.53%
Expected dividend yield	0%	0%
Expected life of options in years	5.0	5.0
Estimated fair value of options granted	$ 2.23	$46.05 - $108.22

The weighted-average grant date fair value of stock options granted during years ended December 31, 2024 and 2023 was approximately $2.23 and $96.04, respectively. The weighted-average fair value of stock options vested during the years ended December 31, 2024 and 2023 was approximately $16.38 and $95.97, respectively.

Total stock-based compensation expense included in the accompanying consolidated statements of operations was as follows:

	For the years ended December 31,	
	2024	2023
Research and development	$ 338,022	$ 404,895
General and administrative	372,291	426,967
Total stock-based compensation	$ 710,313	$ 831,862

As of December 31, 2024, the total unrecognized compensation expense related to non-vested options was approximately $0.8 million and is expected to be recognized over the remaining weighted-average service period of approximately 0.59 years.

Warrants

In connection with the IPO, the Company issued warrants to purchase such number of shares of the Company's common stock equal to 5% of the total shares of common stock issued in the IPO, or 500 warrants. The warrants are exercisable at $1,875.00 per share, were not exercisable within the first six months after issuance, and may, under certain circumstances, be exercised on a cashless basis. The exercise price of the warrants is subject to standard antidilutive provision adjustments for stock splits, stock combinations, or similar events affecting the Company's common stock. The Company has determined that these warrants should be classified as equity instruments since they do not require the Company to repurchase the underlying common stock and do not require the Company to issue a variable amount of common stock. In addition, these warrants are indexed to common stock and do not have any unusual antidilution rights.

In connection with the May 2023 Offering as described in Note 3 to the consolidated financial statements, the Company issued warrants to designees of the underwriter (the "Representative's Warrants") to purchase 424 shares of the Company's common stock (which is equal to 3% of the number of shares sold in the public offering) at an initial exercise price of $234.375 per share, subject to adjustment. The Representative's Warrants are exercisable at any time and from time to time, in whole or in part, during the four- and one-half year period commencing 180 days from the commencement of sales of the shares of common stock in the public offering.

In connection with the November 2023 Offering as described in Note 3 to the consolidated financial statements, the Company issued pre-funded warrants to purchase 545,000 shares of the Company's common stock at an exercise price of $0.015 (the "November 2023 Pre-Funded Warrants"). The November 2023 Pre-Funded Warrants were issued to those purchasers whose purchase of common stock in the November 2023 Offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of outstanding common stock immediately following the consummation of the offering. The November 2023 Pre-Funded Warrants were immediately exercisable and could be exercised at any time until exercised in full. The Company also granted the underwriters a 45-day option to purchase up to an additional 100,000 shares of common stock and/or prefunded warrants. The underwriters exercised the option to purchase 66,667 pre-funded warrants at an initial exercise price of $0.015 per share, subject to adjustment (the "November 2023 Underwriters Pre-Funded Warrants"). These pre-funded warrants were immediately exercisable and could be exercised at any time until exercised in full. The underwriters received warrants to purchase 20,000 shares of common stock with an initial exercise price of $18.75, exercisable beginning May 27, 2024, and expiring May 2, 2028 (the "November 2023 Underwriters Warrants"). As of December 31, 2024 and 2023, all of the November 2023 Pre-Funded Warrants and the November 2023 Underwriters Pre-Funded Warrants have been exercised and the additional warrants to purchase 20,000 shares of common stock have not yet been exercised.

In connection with the June 2024 PIPE Offering as described in Note 3 to the consolidated financial statements, the Company issued the June 2024 Pre-Funded Warrants to purchase 452,253 shares of the Company's common stock at an exercise price of $0.001, the June 2024 PIPE Warrants to purchase 329,771 shares of the Company's common stock at an exercise price of $3.09, and the June 2024 Placement Agent Warrants to purchase up to 19,786 shares of the Company's common stock, exercisable at $3.09 per share. The June 2024 Pre-Funded Warrants were immediately exercisable and are able to be exercised at any time until exercised in full. The June 2024 PIPE Warrants and June 2024 Placement Agent Warrants were immediately exercisable and are able to be exercised until five and a half years from the effective date, or December 21, 2029. As of December 31, 2024, 368,533 of the June 2024 Pre-Funded Warrants have been exercised and none of the June 2024 PIPE Warrants or June 2024 Placement Agent Warrants have been exercised.

In connection with the December 2024 PIPE Offering as described in Note 3 to the consolidated financial statements, the Company issued the December 2024 Pre-Funded Warrants to purchase 491,157 shares of the Company's common stock at an exercise price of $0.001 and the December 2024 PIPE Warrants to purchase 480,721 shares of the Company's common stock at an exercise price of $2.031. The December 2024 Pre-Funded Warrants were immediately exercisable and are able to be exercised at any time until exercised in full. The December 2024 PIPE Warrants are exercisable six months from the date of issuance and are able to be exercised until five and a half years from the effective date, or December 9, 2030. As of December 31, 2024, none of the December 2024 Pre-Funded Warrants and December 2024 PIPE Warrants have been exercised.

Terms of the warrants outstanding at December 31, 2024 are as follows:

Issuance Date	Initial Exercise Date	Expiration Date	Exercise Price	Warrants Issued	Warrants Exercised	Warrants Outstanding
January 14, 2022	July 10, 2022	January 11, 2027	$ 1,875.00	500	-	500
May 2, 2023	November 2, 2023	May 2, 2028	$ 234.375	424	-	424
November 30, 2023	November 30, 2023	N/A	$ 0.015	545,000	545,000	-
November 30, 2023	November 30, 2023	N/A	$ 0.015	66,667	66,667	-
November 30, 2023	May 27, 2024	May 2, 2028	$ 18.75	20,000	-	20,000
June 21, 2024	June 21, 2024	N/A	$ 0.001	452,253	368,533	83,720
June 21, 2024	June 21, 2024	December 21, 2029	$ 3.09	329,771	-	329,771
December 9, 2024	June 9, 2025	December 9, 2030	$ 2.031	480,721	-	480,721
December 9, 2024	December 9, 2024	N/A	$ 0.001	491,157	-	491,157

Note 5 – Income Taxes

The Company does not have any significant current income taxes due because of the losses generated in each year.

Deferred income taxes represent the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and income tax purposes. The Company's deferred tax assets relate primarily to its net operating loss carryforwards and other balance sheet basis differences. In accordance with FASB ASC 740, the Company recorded a valuation allowance to fully offset the gross deferred tax asset because it is not more likely than not that the Company will realize future benefits associated with these deferred tax assets at December 31, 2024 and 2023. The valuation allowance increased by approximately $3.5 million and $2.8 million for the years ended December 31, 2024 and 2023, respectively.

The significant components of the Company's deferred tax assets and liabilities as of December 31, 2023 and 2022 were as follows:

	December 31,	
Deferred tax asset (liabilities) related to:	2024	2023
Federal net operating loss carryforward	$ 4,264,000	$ 3,017,000
State net operating loss carryforward	1,444,000	1,021,000
Capitalized costs	1,957,000	1,261,000
Acquired in-process research and development	1,027,000	319,000
Research and development credit	382,000	243,000
Stock compensation	904,000	733,000
Accrued expenses and other	211,000	84,000
Total deferred tax assets	10,189,000	6,678,000
Valuation allowance	(10,189,000)	(6,678,000)
Deferred tax asset, net of valuation allowance	$ -	$ -

The income tax benefit for the years ended December 31, 2024 and 2023 differ from the amounts computed by applying the U.S. federal income tax rate of 21% to loss before income tax benefit as a result of non-deductible expenses, tax credits generated, and increases in the Company's valuation allowance.

	For the years ended December 31,	
	2024	2023
Income tax benefit at the federal statutory rate	$ (2,550,000)	$ (1,957,000)
Permanent differences and other	30,000	34,000
State income taxes	(853,000)	(661,000)
Research and development credit	(216,000)	(238,000)
Other	78,000	45,000
Change in valuation allowance	3,511,000	2,777,000
Effective income tax expense	$ -	$ -

A valuation allowance is required to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of the available evidence, both positive and negative, the Company determined that valuation allowances of approximately $10.2 million and $6.7 million at December 31, 2024 and 2023, respectively, were necessary to reduce the deferred tax assets to the amount that will more likely than not be realized.

At December 31, 2024 and 2023, the Company had available net operating loss carryforwards of approximately $20.3 million and $14.4 million, respectively, for federal income tax purposes, all of which were generated after 2017 and can be carried forward indefinitely under the Tax Cuts and Jobs Act. At December 31, 2024 and 2023, the Company had approximately $382,000 and $243,000 of federal research and development ("R&D") tax credit carryforwards. If not utilized, the federal R&D credits will begin to expire in 2038. The Company also had $20.3 million and $14.9 million of state net operating losses that will begin to expire in 2037.

Sections 382 and 383 of the Internal Revenue Code, and similar state regulations, contain provisions that may limit the NOL carryforwards available to be used to offset income in any given year upon the occurrence of certain events, including changes in the ownership interests of significant stockholders. In the event of a cumulative change in ownership in excess of 50% over a three-year period, the amount of the NOL carryforwards that the Company may utilize in any one year may be limited. Although the Company has not undertaken a formal analysis, it is likely that such an ownership change occurred during 2021.

The Tax Cuts and Jobs Act of 2017 ("TCJA") has modified the IRC 174 expenses related to research and development for the tax years beginning after December 31, 2021. Under the TCJA, the Company must now capitalize the expenditures related to research and development activities and amortize over five years for U.S. activities and 15 years for non-U.S. activities using a mid-year convention. Therefore, the capitalization of research and development costs in accordance with IRC 174 results in a gross deferred tax asset of $6,961,000.

Note 6 – Commitments and Contingencies

Small Molecule Analogues

On December 30, 2019, the Company acquired a series of small molecule analogues pursuant to an Asset Purchase Agreement ("APA"). Pursuant to the APA, the Company is required to make a payment of $50,000 upon raising of at least $2.0 million in funding, and up to approximately $1.75 million based upon successfully meeting clinical and sales milestones. The Company included, in accounts payable at both December 31, 2024 and 2023, the $50,000 required initial payment. Milestone based payments, if any, will be expensed as incurred.

Research Collaboration and Product License Agreement with Minotaur Therapeutics, Inc. ("Minotaur") and Commercial License Agreement with Taurus Biosciences, LLC ("Taurus")

The Company has entered into a research collaboration and product license agreement with Minotaur (as amended, the "Minotaur Agreement") and a commercial license agreement with Taurus (the "Taurus Agreement") for use of certain technology, including OmniAb antibodies, to advance Picobodies against novel, unreachable, and undruggable epitopes in high-value validated targets starting with PD-1. The Minotaur Agreement and Taurus Agreement are for the development of proprietary targeted biologics, including TH 1940, against PD-1. It is anticipated that the Company will collaborate with Minotaur under the license from Taurus to discover, develop, and advance biotherapeutics against high-value validated IO targets starting with PD-1.

The Minotaur Agreement included an up-front payment of $150,000, which was paid in January 2023. In addition, the Company shall fund the discovery and characterization study performed by Minotaur as set forth in the Minotaur Agreement. Pursuant to the Minotaur Agreement, the Company shall pay Minotaur a milestone payment of $1,000,000 for each first Product (as defined in the Minotaur Agreement) directed against a target and first regulatory approval in the U.S. In addition, the Company shall pay a low single digit royalty on net sales until the later of (i) ten years after the First Commercial Sale (as defined in the Minotaur Agreement) of such Product in such country and (ii) the expiration of the last-to-expire Valid Claim (as defined in the Minotaur Agreement) of a Collaboration Patent (as defined in the Minotaur Agreement) or MINT Patent (as defined in the Minotaur Agreement) covering the manufacture, use, or sale of such Product. The Taurus Agreement contains single digit payments on net product sales and certain development milestone payments tied to the advancement through clinical trials and final regulatory approval.

Research and Development Collaboration and License Agreement with Applied Biomedical Science Institute

On July 5, 2023 (the "ABSI Effective Date"), the Company entered into a Research and Development Collaboration and License Agreement (the "ABSI Agreement") with ABSI pursuant to which ABSI granted the Company an exclusive royalty-bearing, sublicensable license to the ABSI Patents (as defined in the ABSI Agreement) and a non-exclusive, royalty-bearing, sublicensable license to the ABSI Know-How (as defined in the ABSI Agreement) to Exploit (as defined in the ABSI Agreement) the ABSI Products (as defined in the ABSI Agreement) for the treatment, diagnosis, prediction, detection or prevention of disease in humans and animals worldwide (the "Territory").

Pursuant to the ABSI Agreement, the parties shall form a committee to manage the preclinical, investigational new drug enabling studies and such other activities as shall lead to the initiation of a Phase 1 clinical trial of the ABSI Product. The parties will collaborate on a Target-by-Target basis to identify and evaluate ABSI Products directed against such Target (as defined below) with a view to identifying or generating suitable Products (as defined in the ABSI Agreement) for the Company to Exploit. "Target" means ErB2 (Her2) and ErbB3. Upon completion of the Discovery Timeline (as defined in the ABSI Agreement) for a Target, subject to the terms and conditions of ABSI Agreement, the Company shall exclusively own any ABSI Products against such Target. In the event the committee determines that the discovery activities are unsuccessful with respect to a Target, the Company may propose an additional target, which, upon approval by ABSI, shall replace a failed Target.

Pursuant to the ABSI Agreement: (i) the Company issued ABSI 25,107 shares of its common stock which is equal to $250,000 based on the ten day trailing volume weighted-average price of the Company's common stock prior to the date of issuance (see Note 3 to the consolidated financial statements for details of the July 27, 2023 issuance of the Company's common stock to ABSI); (ii) in the event the Company closes a financing pursuant to which it receives more than $10 million in Net Proceeds (as defined in the ABSI Agreement), the Company paid ABSI an up front license fee of $250,000; (iii) upon the achievement of certain milestones as set forth in the ABSI Agreement, the Company shall pay ABSI up to an aggregate of $8,250,000; (iv) after the second anniversary of the ABSI Effective Date, the Company shall pay ABSI a low five digit amount for the first year and a mid-five digit amount thereafter during the Royalty Term (as defined in the ABSI Agreement); and (v) during the Royalty Term for each Product, the Company shall pay ABSI a quarterly royalty on the Net Sales (as defined in the ABSI Agreement) with royalties at percentages which range from the low to mid-single digits, with high Net Sales being subject to lower royalty rates, subject to adjustment as set forth in the ABSI Agreement. In addition, in the event the Company transfers all or substantially all of its rights to a Product to a third party, the Company shall pay to ABSI the percentage of Net Proceeds attributable to the transfer of the Product. Specifically, the Company shall pay ABSI amounts at percentages which range from the mid-single digit to low double digits depending on the Company Expenses (as defined in the ABSI Agreement), with higher Company Expenses being subject to lower rates.

On a Product-by-Product basis, upon the expiration of the last Royalty Term of such Product in the Territory, licenses granted to the Company with respect to such Product shall be deemed non-exclusive, fully paid, royalty-free, perpetual and irrevocable. The ABSI Agreement shall expire upon the expiration of the last Royalty Term of the last Product, unless such agreement is terminated earlier pursuant to its terms. The ABSI Agreement may also be terminated (i) by either the Company or ABSI for (A) a material breach of the ABSI Agreement or (B) bankruptcy, (ii) ABSI may terminate the ABSI Agreement upon the commencement of a Challenge Proceeding (as defined in the ABSI Agreement) or (iii) the Company may terminate the ABSI Agreement at any time upon 90 days prior written notice to ABSI. Upon termination or expiration of the ABSI Agreement other than as a result of a bankruptcy or Challenge Proceeding, all licenses granted to the Company pursuant to such agreement will terminate and all rights under such licenses shall revert to ABSI.

On March 11, 2024, the Company entered into an addendum to the ABSI Agreement to fund research services with quarterly payments of $50,000 beginning March 18, 2024 with subsequent payments due on the 18th of each calendar quarter. During the year ended December 31, 2024, the Company made payments of $200,000 to ABSI.

During the year ended December 31, 2023, the Company paid milestone fees of $500,000 to ABSI in accordance with the terms of the agreement, which included a non-cash common stock equity grant of $250,000.

Avior Patent License Agreement

On November 3, 2023 (the "Avior Effective Date"), the Company entered into the Avior Patent License Agreement with Avior pursuant to which the Company received an exclusive sublicensable right and license to Licensed Patent Rights and Licensed Technology to, among other things, Develop, have Developed, make, have made, use, sell, import, export and commercialize TH104 and TH103 and to practice the Licensed Technology in connection with the foregoing, throughout the world. Pursuant to the Avior Patent License Agreement, the Company shall paid Avior an up front license fee of $400,000 within ten days of the Avior Effective Date and an additional mid six-digit license fee which shall be paid in four equal installments within ten days of the end of each fiscal quarter following the Avior Effective Date. In addition, the Company shall pay Avior a high single digit percentage of any upfront payments received by it as a result of the grant of any sublicenses with respect to TH104. The Company shall also pay Avior milestone payments in the aggregate amount of $24,250,000 upon the occurrence of various development milestones (the "Development Milestone Payments"). Furthermore, the Company shall pay Avior certain fees based upon sales milestones. The payments for such sales milestones range from the low seven digits to the low eight digits with higher sales being subject to higher fees. Finally, the Company shall pay Avior royalties based on net sales. Such royalties range from low single digit percentages to mid-single digit percentages with higher sales being subject to lower percentages. The Avior Patent License Agreement shall expire upon the expiration of the final payment obligation due to Avior as set forth in such agreement. Upon the expiration of the Avior Patent License Agreement, the Company shall have a fully paid, irrevocable, freely transferable and sublicensable worldwide license to the Licensed Patent Rights and Licensed Technology to Develop, have Developed, make, have made, use, have used sell, offer for sale, have sold, import, have imported, export, have exported, commercialize or have commercialized any and all Licensed Products and to practice the Licensed Technology worldwide. Pursuant to the Avior Patent License Agreement, the Company may terminate the agreement at any time without cause, upon 30 days' prior written notice to Avior along with payment of the next unpaid Development Milestone Payment, if any. Furthermore, either the Company or Avior may terminate the Avior Patent License Agreement (i) on written notice to the other party if the other party materially breaches any provision of the Avior Patent License Agreement and fails to cure such breach within 30 days after the breaching party receives written notice thereof or (ii) on written notice in the event that either party (A) becomes insolvent or admits its inability to pay its debts generally as they become due; (B) becomes subject, voluntarily or involuntarily, to any proceeding under any domestic or foreign bankruptcy or insolvency law, which is not fully dismissed or vacated within 60 days; (C) is dissolved or liquidated or takes any corporate action for such purpose; (D) makes a general assignment for the benefit of creditors; or (E) has a receiver, trustee, custodian or similar agent appointed by order of any court of competent jurisdiction to take charge of or sell any material portion of its property or business. Upon termination of the Avior Patent License Agreement, the license granted pursuant to such agreement shall terminate and all rights in the Licensed Patent Rights and Licensed Products shall revert back to Avior.

During the year ended December 31, 2024, the Company paid license fees of $600,000 to Avior in accordance with the terms of the agreement. In addition, during the years ended December 31, 2024 and 2023, the Company incurred milestone fees of $750,000 and $380,000, respectively.

Enkefalos License Agreement

On June 17, 2024 (the "Enkefalos Effective Date"), the Company signed a letter of intent to enter into the Enkefalos License Agreement with Enkefalos Biosciences Inc. pursuant to which the Company is licensing the global rights in all fields of use for the products related to the compounds knows as cyclotides to deliver HER2 antibodies across the blood-brain barrier and all associated know-how, technology, intellectual property and related information and constructs, and any associated authorized generic rights and all related assets (collectively, the "Products" referred to in this letter as ENBI-01) from Enkefalos Biosciences, Inc. Pursuant to the Enkefalos License Agreement, the Company shall pay Enkefalos an up-front license fee of $150,000 within ten days of the Enkefalos Effective Date and an additional license fee of $150,000 to be paid 6 months after the Enkefalos Effective Date and an annual license fee of $50,000. The Company shall also pay Enkefalos milestone payments in the aggregate amount of up to $8,500,000 upon the occurrence of various development milestones (the "Enkefalos Development Milestone Payments"). Furthermore, the Company shall pay Enkefalos royalties based on net sales ranging from low single-digit percentages to mid-single digit percentages with higher sales being subject to lower percentages. The Enkefalos License Agreement shall expire upon the expiration of the final payment obligation due to Enkefalos as set forth in such agreement and upon expiration, the Company shall have a fully paid, irrevocable, freely transferable and sublicensable worldwide license to the Licensed Patent Rights and Licensed Technology to Develop, have Developed, make, have made, use, have used sell, offer for sale, have sold, import, have imported, export, have exported, commercialize or have commercialized any and all Licensed Products and to practice the Licensed Technology worldwide. Pursuant to the Enkefalos License Agreement, either the Company or Enkefalos may terminate the Enkefalos License Agreement on written notice to the other party. Upon termination of the Enkefalos License Agreement, the license granted pursuant to such agreement shall terminate and all rights in the Licensed Patent Rights and Licensed Products shall revert back to Enkefalos.

During the year ended December 31, 2024, the Company incurred license fees of $150,000 to Enkefalos in accordance with the terms of the agreement.

Intract Patent License Agreement

On September 11, 2024, the Company entered into a patent license agreement (the "Intract Agreement") with Intract. Pursuant to the Intract Agreement, the Company exclusively licensed INT-023/TH023, an oral anti-Tumor Necrosis Factor-alpha (TNF-α) monoclonal antibody infliximab. Under the terms of the Intract Agreement, the Company licensed global development and commercialization rights (outside of South Korea) to Intract's Soteria® and Phloral® delivery platform along with an existing supply agreement for infliximab to be used in the oral product development program. Pursuant to the Intract Agreement, the Company paid Intract an up-front license fee of $400,000 and Intract is eligible to receive additional payments upon an equity financing of the Company and additional payments for future development, regulatory and commercial milestones, as well as mid-single digit royalties based on net product sales. The Agreement retains a right of first refusal to continue development and commercialization after a Phase 2 clinical trial. In addition, the Company has the option to exercise the license to Intract's platform for up to four additional targets. The term of the Intract Agreement expires upon the final payment obligation of Tharimmune and may be terminated by Tharimmune at any time upon 90 days written notice to Intract. Either party may terminate the Intract Agreement if the other party materially breaches any provision of the Intract Agreement and fails to cure such breach within thirty (30) days after the breaching party receives written notice thereof. In addition, either party may terminate the Intract Agreement on written notice in the event that either party declare: (a) becomes insolvent or admits inability to pay its debts generally as they become due; (b) becomes subject, voluntarily or involuntarily, to any proceeding under any domestic or foreign bankruptcy or insolvency law, which is not fully dismissed or vacated within sixty (60) days; (c) is dissolved or liquidated or takes any corporate action for such purpose; (d) makes a general assignment for the benefit of creditors; or (e) has a receiver, trustee, custodian or similar agent appointed by order of any court of competent jurisdiction to take charge of or sell any material portion of its property or business.

During the year ended December 31, 2024, the Company incurred fees of $400,000 to Intract in accordance with the terms of the agreement.

Employment Agreements

On June 1, 2021, the Company entered into an Amended and Restated Employment Agreement with the Company's CEO, as amended periodically (the "Amended and Restated Employment Agreement"). The term of the Amended and Restated Employment Agreement commenced upon the closing of the Company's IPO in January 2022 and continues for a period of five years and automatically renews for successive one-year periods at the end of each term unless either party provides written notice of their intent not to renew at least 60 days prior to the expiration of the then effective term. Pursuant to the Amended and Restated Employment Agreement, the CEO will receive an annual base salary of $485,000, which may be increased from time to time, and shall be eligible to receive an annual cash bonus equal to 55% of his then base salary based upon the achievement of Company and individual performance targets established by the Company's board of directors. In addition, in the first year in which the Company's market capitalization (as defined in the Amended and Restated Employment Agreement) equals or exceeds (i) $250 million, the CEO shall receive a cash payment of $150,000; (ii) $500 million, the CEO shall receive a cash payment of $350,000; and (iii) $1.0 billion, the CEO shall receive a cash payment of $750,000. Furthermore, following the date of the Company's IPO, the CEO was issued an option to purchase 2,021 shares of the Company's common stock at an exercise price of $1,500.00 per share, which options shall vest over a 48-month period commencing 12 months after the date of grant. This shall be in addition to any additional equity-based compensation awards the Company may grant the CEO from time to time.

On January 1, 2023, in lieu of half of his 2023 salary, the CEO was issued options to purchase up to 1,374 shares of the Company's common stock at an exercise price of $146.25 per share, which options vested immediately on the date of grant.

On July 6, 2023, the Company entered into an amended and restated employment agreement (the "CEO Employment Agreement") with the CEO. The Employment Agreement has the same terms as the COO Employment Agreement (as defined below) except, the CEO shall (i) receive a base salary of $500,000 per year, which may be increased by the Board; and (ii) be eligible to receive an annual bonus equal to 60% of his then base salary based upon the achievement of Company and individual targets to be established by the Board, in its sole discretion. In addition, in the event the CEO's employment is terminated by the Company other than as a result of his death or Disability and other than for Cause, or if the CEO terminates his employment for Good Reason, then, in addition to the Accrued Compensation, the Company shall continue to pay the CEO's base salary and provide health benefits for a period of 18 months following the termination date (each as defined in the CEO Employment Agreement). In addition, all Restricted Shares and Stock Options that have not vested as of the date of termination shall be forfeited and outstanding unvested time-based equity awards shall be accelerated in accordance with the applicable vesting schedule as if the CEO had been in service for an additional 12 months as of the termination date.

In connection with the appointment of the Company's Chief Operating Officer, on July 11, 2023 (the "Effective Date"), the Company entered into an employment agreement (the "COO Employment Agreement") with the COO. The COO Employment Agreement shall continue for a period of five years and, thereafter, shall automatically renew for successive one-year terms unless either party provides the other party with written notice of non-renewal at least 60 days prior to the last day of the then-current term. Pursuant to the COO Employment Agreement, the COO shall: (i) receive a base salary of $400,000 per year, which may be increased by the Board; (ii) be eligible to receive an annual bonus equal to 50% of his then base salary based upon the achievement of Company and individual targets to be established by the Board, in its sole discretion; (iii) shall be eligible to receive equity-based compensation awards as determined by the Company; (iv) receive reimbursement of reasonable business expenses; and (v) receive such other benefits that the Company may make available to its senior executives from time to time along with vacation, sick and holiday pay in accordance with the Company's policies established and in effect from time to time.

In accordance with the employment agreements, the compensation committee approved a bonus of 50% in equity compensation and 50% in cash on January 13, 2025, based on corporate performance objectives earned during the year ended December 31, 2024. The total bonus earned for the CEO for the year ended December 31, 2024 was made up of cash of $156,250 and options to purchase up to 80,958 shares of the Company's common stock. The total bonus earned for the COO for the year ended December 31, 2024 was made up of cash of $102,050 and options to purchase up to 52,875 shares of the Company's common stock. The total cash bonus of $258,300 and total equity compensation bonus of $202,122 are recorded within accrued expenses on the accompanying consolidated balance sheet at December 31, 2024. The equity compensation is valued at the grant and effective date of the options, which is January 13, 2025.

Note 7 – Subsequent Events

Except as noted below, there were no material subsequent events that required recognition or additional disclosure in these consolidated financial statements.

Insurance Financing Agreement

In January 2025, the Company entered into an insurance premium financing agreement for $386,280, with a term of 10 months and an annual interest rate of 7.15%. The Company made a down payment of $77,356 and is required to make monthly principal and interest payments of $31,914 over the term of the agreement, which matures in November 2025.

Settlement Agreement

In March 2025, the Company entered into an agreement with its previous attorney to reduce the outstanding balance of legal fees to $240,000 (the "Settlement Agreement") for amounts owed related to services performed prior to the year ended December 31, 2024. The Company will adjusts its accounts payable by $54,240 in the first quarter of 2025.

In accordance with the terms of the Settlement Agreement, payments of $24,000 are due each month beginning in March 2025 through December 2025, at which time the full balance of $240,000 will be satisfied. If payments are not made timely or the Company becomes insolvent (defined as event of default in the Settlement Agreement), interest will begin to accrue at a rate of 3.7% per annum until all past due amounts have been paid in full. No interest will accrue if no event of default occurs.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls

Our principal executive officer and principal financial officer evaluated the effectiveness of our "disclosure controls and procedures" as of December 31, 2024, the end of the period covered by this Annual Report on Form 10-K. The term "disclosure controls and procedures" as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files under the Exchange Act is accumulated and communicated to a company's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. Based on the evaluation of our disclosure controls and procedures as of December 31, 2024, our Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with U.S. GAAP. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

As of December 31, 2024, our principal executive officer and principal financial officer, conducted an evaluation of the effectiveness of our internal control over financial reporting based on the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework - 2013. Based on this assessment and implementation of our remediation plans, management concluded that, as of December 31, 2024, our internal controls over financial reporting were effective.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to the exemption provided to issuers that are not "large accelerated filers" nor "accelerated filers" under the Dodd-Frank Wall Street Reform and Consumer Protection Act as well as issuers that are "emerging growth companies" under the JOBS Act.

Changes in Internal Control Over Financial Reporting

Except as set forth above, there were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

During the quarter ended December 31, 2024, none of our directors or executive officers adopted, modified, or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement" as such terms are defined under Rule 408 of Regulation S-K.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated herein by reference from our Proxy Statement, which will be filed with the SEC within 120 days after the end of our 2024 fiscal year pursuant to Regulation 14A for our 2024 Annual Meeting of Stockholders (the "Proxy Statement"), under the captions "Executive Officer of the Company."

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of the code is filed as an exhibit to this Annual Report on Form 10-K and is posted on our website, *www.tharimmune.com*. We intend to post on our website all disclosures that are required by law or Nasdaq rules concerning any amendments to, or waivers from, any provision of the code.

Changes in Nominating Procedures

None.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated herein by reference from the Proxy Statement under the caption "Executive Compensation."

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated herein by reference from the Proxy Statement, under the captions "Security Ownership of Beneficial Owners and Management" and "Equity Compensation Plan Information."

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated herein by reference from the Proxy Statement, under the captions "Corporate Governance" and "Certain Relationships and Related Party Transactions."

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item will be set forth in our Proxy Statement under the caption "Principal Accountant Fees and Service."

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report:

(1) Financial Statements:

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Index to Consolidated Financial Statements:	F-1
Consolidated Financial Statements:	
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2024 and 2023	F-3
Consolidated Statements of Operations for the Years Ended December 31, 2024 and 2023	F-4
Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the Years ended December 31, 2024 and 2023	F-5
Consolidated Statements of Cash Flows for the Years Ended December 31, 2024 and 2023	F-6
Notes to the Consolidated Financial Statements	F-7

The consolidated financial statements required by this Item are included beginning at page F-1.

(1) Financial Statement Schedules:

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the consolidated financial statements or the notes thereto.

(b) Exhibits

The following documents are included as exhibits to this report.

Exhibit No.	Title of Document
3.1	Certificate of Incorporation (Incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1 filed with the SEC on September 27, 2021)
3.2	Amendment to Certificate of Incorporation dated August 7, 2019 (Incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-1 filed with the SEC on September 27, 2021)
3.3	Amendment to Certificate of Incorporation dated September 16, 2021 (Incorporated by reference to Exhibit 3.3 to the Company's Registration Statement on Form S-1 filed with the SEC on September 27, 2021)
3.4	Amendment to Certificate of Incorporation dated October 11, 2021 (Incorporated by reference to Exhibit 3.5 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 15, 2021)
3.5	Bylaws (Incorporated by reference to Exhibit 3.4 to the Company's Registration Statement on Form S-1 filed with the SEC on September 27, 2021)
3.6	Certificate of Amendment to Certificate of Incorporation dated September 21, 2023 (Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on September 25, 2023)
3.7	Certificate of Amendment to Certificate of Incorporation, as amended, dated November 17, 2023 (Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on November 17, 2023)
3.8	Amendment to the Bylaws of Tharimmune, Inc. (Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on March 11, 2024)
3.9	Certificate of Amendment to Certificate of Incorporation, as amended, dated May 22, 2024 (Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on May 22, 2024)
4.1	Specimen Stock Certificate Evidencing the Shares of Common Stock (Incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 filed with the SEC on September 27, 2021)
4.2	Form of Underwriter Warrant (Incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1/A filed with the SEC on December 10, 2021)
4.3	Description of the Registrant's Securities (Incorporated by reference to Exhibit 4.3 to the Company's Annual Report on Form 10-K filed with the SEC on March 16, 2023)
4.4	Form of Pre-Funded Warrant (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on June 20, 2024)
4.5	Form of Common Warrant (Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on June 20, 2024)
4.6	Form of Pre-Funded Warrant (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on December 6, 2024)
4.7	Form of Common Warrant (Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on December 6, 2024)
10.1+	Amended and Restated Employment Agreement by and between the Company and Randy Milby dated June 1, 2021 (Incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 filed with the SEC on September 27, 2021)
10.2+	First Amendment to Amended and Restated Employment Agreement by and between the Company and Randy Milby dated June 1, 2021 (Incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1 filed with the SEC on September 27, 2021)
10.3+	Hillstream BioPharma, Inc. 2017 Stock Incentive Plan (Incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1 filed with the SEC on September 27, 2021)
10.4+	Hillstream BioPharma, Inc. 2019 Stock Incentive Plan (Incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-8 filed with the SEC on February 22, 2022)
10.5+	Amended and Restated Employment Agreement by and between the Company and Randy Milby dated July 6, 2023 (Incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the SEC on July 11, 2023)
10.6+	Tharimmune, Inc. 2023 Omnibus Equity Incentive Plan (Incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-8 filed with the SEC on November 2, 2023)
10.7#	Patent License Agreement by and between the Company and Avior Inc. dba Avior Bio dated November 3, 2023 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on November 7, 2023)
10.8#	Research and Development Collaboration and License Agreement by and between the Company and Applied Biomedical Science Institute dated July 5, 2023 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 11, 2023)
10.9+	Employment Agreement by and between the Company and Sireesh Appajosyula dated July 11, 2023 (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on July 11, 2023)
10.10	ATM Agreement between the Company and Rodman & Renshaw dated June 7, 2024 (Incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on June 7, 2024)
10.11	Tharimmune Inc. Amended and Restated 2023 Omnibus Equity Incentive Plan (Incorporated by reference to Appendix B to the Company's definitive proxy statement on Schedule 14A for the Company's 2024 annual meeting of stockholders filed with the SEC on March 21, 2024)
10.12	Form of Securities Purchase Agreement (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on June 20, 2024)
10.13	Patent License Agreement by and between the Company and Intract Pharma Limited dated September 11, 2024 (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 7, 2024)
10.14	Form of Securities Purchase Agreement (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on December 6, 2024)
14.1	Code of Business Conduct and Ethics (Incorporated by reference to Exhibit 14.1 to the Company's Annual Report on Form 10-K filed with the SEC on April 1, 2022)
16.1	Letter of Mayer Hoffman McCann P.C. dated June 20, 2023 (Incorporated by reference to Exhibit 16.1 to the Company's Current Report on Form 8-K filed with the SEC on June 20, 2023)
21.1	Subsidiaries (Incorporated by reference to Exhibit 21.1 to the Company's Annual Report on Form 10-K filed with the SEC on March 16, 2023)
23.1*	Consent of Rosenberg Rich Baker Berman P.A.
24.1*	Power of Attorney (included on signature page hereto)
31.1*	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of the Chief Executive Officer and Chief Financial Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002
97.1	Tharimmune, Inc. Clawback Policy (Incorporated by reference to the Company's Annual Report on Form 10-K filed with the SEC on February 23, 2024)
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
104*	Cover Page Interactive Data File - the cover page of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2024 is formatted in Inline XBRL

* Filed herewith.
** Furnished herewith.
+ Management contract or compensatory plan or arrangement.
# Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit were omitted by means of marking such portions with an asterisk because such information is both not material and is the type that the Company treats as private or confidential.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 and 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized on this 25th day of March, 2025.

THARIMMUNE, INC.

/s/ Randy Milby
Randy Milby
Chief Executive Officer (Principal Executive Officer) and Chairman of the Board of Directors

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Randy Milby as his or her attorney-in-fact, with full power of substitution and resubstitution, for him or her in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Randy Milby Randy Milby	Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	March 25, 2025
/s/ Thomas Hess Thomas Hess	Chief Financial Officer (Principal Financial and Accounting Officer)	March 25, 2025
/s/ Lynne Bui Lynne Bui	Director	March 25, 2025
/s/ Leonard Mazur Leonard Mazur	Director	March 25, 2025
/s/ Sireesh Appajosyula Sireesh Appajosyula	Director	March 25, 2025
/s/ Kelly Anderson Kelly Anderson	Director	March 25, 2025
/s/ Sanam Parikh Sanam Parikh	Director	March 25, 2025

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-280141 on Form S-8 and Registration Statement No. 333-290814 and 333-283936 on Form S-3 of our report dated March 25, 2025 (which report includes an explanatory paragraph relating to the existence of substantial doubt about the Company's ability to continue as a going concern), with respect to the consolidated financial statements of Tharimmune, Inc. as of December 31, 2024 and for the year then ended, included in this Annual Report on Form 10-K for the year ended December 31, 2024.

/s/ Rosenberg Rich Baker Berman P.A.
Somerset, NJ
March 25, 2025

Exhibit 31.1

Certification of Chief Executive Officer of Tharimmune, Inc.
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Randy Milby, certify that:

1. I have reviewed this Annual Report on Form 10-K of Tharimmune, 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 consolidated 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 15(d)-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 consolidated 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 (or persons performing the equivalent functions):

   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 25, 2025

/s/ Randy Milby
Randy Milby
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Chief Financial Officer of Tharimmune, Inc.
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Thomas Hess, certify that:

1. I have reviewed this Annual Report on Form 10-K of Tharimmune, 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 consolidated 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 15(d)-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 consolidated 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 (or persons performing the equivalent functions):

   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 25, 2025

/s/ Thomas Hess
Thomas Hess
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

Statement of Chief Executive Officer and Chief Financial Officer
Pursuant to Section 1350 of Title 18 of the United States Code

Pursuant to Section 1350 of Title 18 of the United States Code as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned, Randy Milby and Thomas Hess, the Chief Executive Officer and Chief Financial Officer, respectively, of Tharimmune, Inc. (the "Company"), hereby certify that based on the undersigned's knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2024 (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.

Date: March 25, 2025

/s/ Randy Milby
Randy Milby
Chief Executive Officer
(Principal Executive Officer)

Date: March 25, 2025

/s/ Thomas Hess
Thomas Hess
Chief Financial Officer
(Principal Financial and Accounting Officer)