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 001-13467

Inhibitor Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**30-0793665** **(I.R.S. Employer Identification No.)**
3014 W. Palmira Avenue **Suite 302** **Tampa, FL** **(Address of principal executive offices)**	**33629-7264** **(Zip Code)**

Issuer's telephone number: 813-864-2562

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of exchange on which registered
None	n/a

Securities registered pursuant to Section 12(g) of the Act: Common stock, par value $.0001

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 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. Yes ☐ No ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or 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 require a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of June 30, 2024 was approximately $6.6 million based on the closing sale price of the company's common stock on such date of $0.08 per share, as reported by the OTC Markets Group, Inc.

As of March 28, 2025, there were 172,323,545 shares of company common stock issued and outstanding.

Inhibitor Therapeutics, Inc.
Annual Report on Form 10-K
For the fiscal year ended December 31, 2024
TABLE OF CONTENTS

Unless we have indicated otherwise, or the context otherwise requires, references in this Report to "INTI," the "Company," "we," "us" and "our" or similar terms refer to Inhibitor Therapeutics, Inc., a Delaware corporation.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Report and the documents we have filed with the Securities and Exchange Commission (the "SEC") that are incorporated by reference herein contain forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that involve significant risks and uncertainties. Any statements contained, or incorporated by reference, in this Report that are not statements of historical fact may be forward-looking statements. When we use the words "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "predict," "project," "will" and other similar terms and phrases, including references to assumptions, we are identifying forward-looking statements. Forward-looking statements involve risks and uncertainties which may cause our actual results, performance or achievements to be materially different from those expressed or implied by those forward-looking statements.

A variety of factors, some of which are outside our control, may cause our operating results to fluctuate significantly. They include:

- acceptance of our business model by investors and potential commercial collaborators;
- our future capital requirements and our ability to satisfy our capital needs;
- our ability to commence and complete required clinical trials of our product candidates and obtain approval from the U.S. Food and Drug Administration (FDA) or other regulatory agencies in different jurisdictions;
- our ability to secure and maintain key development and commercialization partners for our product candidates;
- our ability to obtain, maintain or protect the validity of our owned or licensed patents and other intellectual property;
- our ability to internally develop, acquire or license new inventions and intellectual property;
- our ability to retain key executive members; and
- interpretations of current laws and the passages of future laws, rules and regulations applicable to our business.

The foregoing does not represent an exhaustive list of risks that may impact upon the forward-looking statements used herein or in the documents incorporated by reference herein. Please see "Risk Factors" for additional risks which could adversely impact our business and financial performance and related forward-looking statements.

Moreover, new risks regularly emerge, and it is not possible for our management to predict all risks, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. All forward-looking statements included in this Report are based on information available to us on the date hereof. Except to the extent required by applicable laws or rules, we undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements contained throughout this Report and the documents we have filed with the SEC.

SUMMARY OF MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

The following is a summary of risks, uncertainties and other factors related to our company. You should carefully consider all of the risk factors presented in "Item 1A. Risk Factors" and all other information contained in this Report, including the financial statements.

- From 2018 through 2022 we conducted only minimal operations due to litigation that was settled in late 2022 and was impeding our ability to finance and progress our business. Since closing the litigation on December 13, 2022, our efforts are centered on progressing a revised business plan, including a website overhaul to reflect our ongoing direction to continue development of our intellectual property and acquire additional assets to enhance shareholder value.

- We are a pre-revenue pharmaceutical development company and are thus subject to the risks associated with early-stage businesses in that industry.

- Raising additional capital or issuing new securities in connection with strategic transactions may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

- We are early in our development efforts. Assuming we are able to raise new funding, if we are unable to clinically develop and ultimately commercialize Itraconazole or other product candidates, or experience significant delays in doing so, our business will be materially harmed.

- Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidate.

- Even if any of our product candidates receive marketing approval for any indication, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

- If we are unable to obtain and maintain patent protection for our technology and products (particularly itraconazole as an anti-cancer therapy), or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to commercialize our technology and products may be impaired.

- Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

- If we fail to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidate, and our ability to generate revenue and the viability of our company will be materially impaired.

- Special FDA regulatory designations, such as fast track, breakthrough therapy and orphan designation may not be available for our product candidates.

- An active trading market for our common stock does not exist and may not develop or be sustained.

- Even if a market for our common stock develops, the market price of our common stock may be significantly volatile, which could result in substantial losses for purchasers.

PART I

Item 1. Description of Business.

Overview

We are a pharmaceutical development company that is focused on developing and ultimately commercializing innovative therapeutics based on already approved active pharmaceuticals that have patent-protected methods of use and/or methods of delivery for patients with certain cancers and certain non-cancerous proliferation disorders. We also have explored and expect to continue to explore acquiring or licensing other innovative pre-clinical and clinical stage therapeutics addressing unmet needs for the treatment of cancer and other diseases based on repurposing active ingredients of already approved drugs.

Our current primary focus is on the development of therapies initially for basal cell carcinoma nevus syndrome ("BCCNS"), prostate and lung cancers in the United States utilizing itraconazole, a drug currently approved by the FDA to treat fungal infections, and which has an extensive history of safe and effective use in humans. We have developed intellectual property and know-how related to the treatment of cancer patients using itraconazole. On December 12, 2023, we entered into an Exclusive License Agreement (the "Agreement") with Johns Hopkins University ("JHU"). Pursuant to the Agreement, JHU granted to our Company the exclusive worldwide patent rights to a Granted US Patent, No. 8,980,930 entitled "New Angiogenesis Inhibitors" (the "Patent"). The Patent relates to the treatment of prostate cancer, basal cell carcinoma ("BCC") including BCCNS, and lung cancer.

Pursuant to the Agreement: (i) we received an exclusive worldwide license to the Patent; (ii) we paid JHU an upfront license fee, (iii) we are required to make certain Minimum Annual Royalty ("MAR") payments to JHU, (iv) we are required to pay to JHU a royalty on cumulative net sales, with an additional supplement due where a licensed product is given exclusivity in the U.S. by patent rights, (v) if we enter into any sublicense we will pay to JHU a certain percentage of all consideration received from sublicensee, (vi) should we receive compensation in the form of a voucher, we will pay a certain percentage of the sale to JHU and (vii) we are required to pay to JHU certain development-related milestone payments upon the achieving each of a series of agreed upon milestones. The Agreement contains other customary terms and conditions.

JHU has the right to terminate the Agreement upon the occurrence of certain events, including delinquency in payments, failure to timely reach milestones, noncompliance with audit or insurance obligations, or the Company entering into voluntary bankruptcy or insolvency. We may terminate the Agreement without cause upon 90 days advance written notice.

In May 2024, we formally requested a Type-B, pre-investigational new drug application ("pre-IND") meeting with the FDA to obtain feedback on the overall drug development and regulatory plan to use itraconazole for the treatment of BCC tumors in BCCNS patients, for which we have engaged the services of external experts in the field to assist with the process. Our Phase 2b clinical study (HP2001) uses a novel formulation of itraconazole, which we reference in our pre-IND submission.

The Company was granted a meeting in June 2024 with the Dermatology Division of the FDA, which we subsequently cancelled (with acknowledgement from the FDA), as we believed it required input from the FDA's Division of Oncology. Additionally, the FDA required further understanding of the right of use to the HP2001 study to further discuss some of the Pre-IND questions. The FDA has agreed to consult the Division of Oncology as necessary and we believe we have provided sufficient information around the right of use to proceed with our Pre-IND.

We have engaged Avior Bio, Inc. ("Avior"), which is currently creating a novel formulation of itraconazole from which results are expected in the first half of 2025. Avior is a privately held drug development company whose President and Chairman of the Board, Niraj Vasisht, is a member of the Company's Board of Directors. Upon finalization of the formulation, Avior will conduct a pharmacokinetic (PK) crossover study to the generic formulation and the formulation that was used within the HP2001 study in preparation for a new IND and NDA. Given all formulations consist of the same active pharmaceutical ingredients (API), it is expected that the Company's new, novel formulation will have extremely similar properties to the formulation used in the HP2001 clinical study.

The development of itraconazole capsules is progressing through preclinical and formulation stages, with a strong focus on intellectual property positioning and bioavailability optimization. Key milestones include micronized particle formulation, analytical testing, and upcoming dissolution studies to compare with reference drugs. A recommended nonclinical PK, safety, and tolerability study will extend the timeline by 1.5–2 months and add $225,000–$275,000 in costs but will strengthen regulatory filings for an investigational medicinal product dossier ("IMPD")/IND submission. The project remains on track, with a clear path toward human pharmacokinetic studies and further clinical development.

We have entered into a new agreement with BCS Stats to develop a comprehensive statistical analysis plan (SAP). This collaboration aims to enhance the robustness of clinical data interpretation, ensuring regulatory compliance and optimizing study outcomes. BCS Stats will provide advanced biostatistical expertise to support key analyses, including efficacy and safety assessments for our HP2001 study. The partnership reflects a strategic commitment to strengthening our clinical development efforts and highlighting key points when assessing the study on a per lesion basis, consistent with our Avior contract. We believe this strategy will simplify and accelerate the processes with the FDA.

Intellectual Property

We strive to protect the intellectual property that we believe will be important to our business, including seeking our own patent protection (or seeking licenses to patents) intended to cover the composition of matter of our product candidates, their methods of use, related technology and other inventions that are important to our business.

We have developed, licensed, optioned to license, and are seeking to acquire and/or license, intellectual property and know-how related to the treatment of cancer patients using itraconazole-based compounds.

The following is a summary of intellectual property in the form of issued U.S. patents we own, or for which we have exclusive licenses, regarding the use of itraconazole as an anti-cancer therapy.

Name	Number	Application Date	Issuance Date	Expiration Date
Treatment and Prognostic Monitoring of Proliferation Disorders Using Hedgehog Pathway Inhibitors	9,129,609	February 5, 2014	November 24, 2015	February 5, 2034
Treatment and Prognostic Monitoring of Cancerous Proliferation Disorders Using Hedgehog Pathway Inhibitors	9,962,381	January 31, 2017	May 8, 2018	February 5, 2034
Treatment and Prognostic Monitoring of Non-Cancerous Proliferation Disorders Using Hedgehog Pathway Inhibitors	9,968,600	January 31, 2017	May 15, 2018	February 5, 2034
Treatment of Lung Cancer Using Hedgehog Pathway Inhibitors	10,328,072	April 30, 2018	June 25, 2019	February 5, 2034
Treatment of Prostate Cancer Using Hedgehog Pathway Inhibitors	10,363,252	April 30, 2018	July 30, 2019	February 5, 2034
Administering Itraconazole to Inhibit Angiogenesis in Undesired Tissue	8,980,930	June 27, 2005	March 17, 2015	February 4, 2029

We also plan to continue to expand our intellectual property estate and are filing additional patent applications directed to dosage forms, methods of treatment, therapies for other cancers and additional Hedgehog inhibitor compounds and their derivatives. We will also rely on trade secrets and careful monitoring of our proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

The Hedgehog Pathway

Based on the results of physician-sponsored studies conducted by others (including *in vitro*, animal, and human studies), we believe that itraconazole affects the Hedgehog signaling pathway in cells and that it is a potent antiangiogenic, which in turn impacts the development and growth of certain cancers. The studies, conducted at prominent medical institutions, primarily in the United States, were published in the *Journal of Thoracic Oncology, The Oncologist and the Journal of Clinical Oncology* between May 2013 and February 2014. Based on these studies, it appears that itraconazole has notable anti-cancer effects by one or more independent or synergistic mechanisms, some of which are not clearly understood and will continue to be the subject of ongoing research. These studies, and our own work in the clinic, formed the basis of our continued interest in the clinical development of itraconazole for treatment of human cancers.

The Hedgehog signaling pathway is a major regulator of many fundamental cellular processes in vertebrates, including primarily at the embryonic stage of development but also as it relates to stem cell maintenance, cell differentiation, tissue polarity and cell proliferation. Based on published research and our experience in human testing, we believe that inhibiting the Hedgehog pathway can delay or possibly prevent the development of certain cancers in patients. Research has shown that activation of the Hedgehog pathway can lead to the formation of cancerous tumors (a process known as tumorigenesis) such as the most common form of skin cancer known as BCC. It is apparent, however, that other mutations seem to be required for the development of a basal cell carcinoma even in BCCNS. The antiangiogenic effects of itraconazole, therefore, play a key role in its ability to treat cancers. A variety of other human cancers, including brain, gastrointestinal, lung, breast and prostate cancers, also demonstrate inappropriate activation of this pathway. Hedgehog signaling from the tumor to the surrounding cell structures has been shown to sometimes promote further tumorigenesis as well. This pathway has also been shown to regulate proliferation of cancer stem cells and to increase tumor invasiveness.

We believe that the targeted inhibition of Hedgehog signaling is or may be effective in the treatment and prevention of many types of human cancers. We also believe that the discovery and synthesis of specific Hedgehog pathway inhibitors may have significant clinical implications regarding the development of novel cancer therapies. Several synthetic Hedgehog antagonists are now being studied, some of which are undergoing clinical evaluation. The orally available compound, Erivedge®, vismodegib, developed by Curis and sold to Genentech, Inc. (a subsidiary of Roche), was the first Hedgehog inhibitor-based therapy and Odomzo®, sonidegib (developed by Novartis and sold to Sun Pharma in 2015 by Novartis) is the second orally available compound, that has been approved for treatment of advanced stages of BCC by the FDA. Most recently, in 2018, Daurismo®, glasdegib oral capsules developed by Pfizer, was approved by FDA for use in combination with low dose cytarabine for patients with newly diagnosed acute myeloid leukemia (AML), aged 75 or older who are too frail to be treated with intensive chemotherapy.

Repurposing Itraconazole for Treating Cancer

We are implementing clinical and regulatory plans to enable the repurposing of itraconazole. This strategy is intended to significantly reduce the risk and time to potential FDA approvals for marketing in the United States.

Itraconazole appears to have notable anti-cancer effects by one or more independent or synergistic mechanisms, some of which are not clearly understood and continue to be the subject of ongoing research. These anti-cancer effects have been demonstrated in various animal models and, subsequently, in human studies over the last several years.

In animal models, itraconazole has also demonstrated an anti-angiogenic effect (i.e., inhibiting the formation of new blood vessels), which may be important in controlling the proliferation of cancerous cells and tumors in humans based upon its interaction with certain cell-based growth factors. Itraconazole also appears to induce changes related to the mTOR pathway, an important regulator of cell growth, proliferation and survival which, when unregulated, can also lead to cancer. These effects have been demonstrated in a physician-based study conducted to test the effects of itraconazole on late-stage lung cancer.

Prostate Cancer

Itraconazole has already been tested as a treatment for men with metastatic castrate resistant prostate cancer ("mCRPC") in a multi-institutional Phase 2 trial completed in 2011 and led by Johns Hopkins University which was published in 2013. This study showed that, at a specified dose, there was a significant correlation to slowing the progression of cancer and extending survival.

Lung Cancer

Physicians treating patients with advanced non-squamous non-small cell lung cancer ("NSCLC"), most often caused by cigarette smoking have a variety of options when considering therapies to extend survival, particularly based upon recent approvals of immunotherapies, known as checkpoint inhibitors for PD-L1 (programmed death ligand 1) such as Keytruda®, pembrolizumab marketed by Merck and approved by FDA in 2017 and potentially useful in about 25% of patients. However, if patients are not candidates for immunotherapy based on genetic marker testing (PD-L1 positive) or do not have mutations for EGFR (epidermal growth factor receptor, 15% of patients), ALK (anaplastic lymphoma kinase, 3-5% of patients), ROS1 (c-ros oncogene 1, 1-2% of patients) or BRAF (proto-oncogene B-Raf, 1-3% of patients) in order to be treated with tyrosine kinase inhibitors, they will be given chemotherapy, in particular platinum based doublet therapy with pemetrexed (Alimta®).With a median survival of only 8-10 months while on these approved chemotherapy regimens, we believe that new therapies for these patients are needed. We believe that the pre-clinical data and reported human data between 2011 and 2018 on the use of itraconazole in conjunction with chemotherapy reflects positively on the use of itraconazole as an anti-cancer therapy for this form of lung cancer in patients who do not present with markers that enable their treatment with the agents mentioned above. If these data prove to be applicable to human treatment by improving survival, while dosing Itraconazole in combination with chemotherapy therapy (the combination of platinum-based chemotherapy drugs in conjunction with pemetrexed), the treatment may qualify for one or more FDA accelerated programs, such as a breakthrough therapy or fast track status.

Basal Cell Carcinoma

Utilizing SUBA-Itraconazole (a branded formulation of itraconazole) to treat BCC in patients with Gorlin Syndrome was the first indication that we studied in a Phase 2b trial which was launched in August of 2015. We began recruiting and dosing subjects during the fourth quarter of 2015, and we completed enrollment in the fourth quarter of 2017. Individuals who were enrolled in this trial must have been diagnosed with Gorlin Syndrome and had numerous BCC tumors as well as met well-defined inclusion criteria in order to qualify for enrollment and treatment with SUBA-Itraconazole (the patented formulation of itraconazole owned by Mayne).

BCCs in individuals with Gorlin Syndrome also known as BCCNS are primarily driven by genetic mutations that lead to the abnormal activation of the Hedgehog signaling pathway. Most commonly, mutations occur in the PTCH1 gene, a key regulator that normally inhibits the pathway by controlling the activity of the Smoothened (SMO) protein. When PTCH1 is mutated, this inhibition is lifted, resulting in unchecked SMO activity and subsequent overactivation of the Hedgehog pathway. This deregulation promotes continuous cell growth and proliferation, leading to the development of multiple BCCs over time.

Additionally, because BCCNS is an inherited autosomal dominant disorder, affected individuals already have one mutated copy of the PTCH1 gene from birth, predisposing them to further genetic hits in skin cells. Environmental factors such as ultraviolet radiation can act as secondary triggers, exacerbating the risk by inducing additional mutations. The combination of an inherent genetic defect with potential environmental influences results in the frequent and often early onset of BCCs seen in patients with BCCNS, along with other associated abnormalities like jaw cysts and skeletal anomalies

The key objective of our Phase 2b trial was to demonstrate patient benefit by reducing tumor burden that requires on-going intervention for tumor growth via surgery and/or use of more toxic Hedgehog inhibitor therapies. After the Company completed the phase 2b study on 477 distinct basal cell carcinomas demonstrating an ORR in over 50% of these basal cell carcinomas, Mayne Pharma assumed control of the SUBA-Itraconazole BCCNS program in December 2018 in exchange for (among other consideration) a 9% quarterly cash royalty on future net sales, if any, of SUBA-Itraconazole BCCNS in the United States. To the best of the Company's knowledge, Mayne Pharma has discontinued its development efforts of SUBA itraconazole for BCCNS and the Company is unaware of any plans for its future development by Mayne. The aforementioned settlement agreement provides INTI with the right to pursue development or licensure of an itraconazole formulation for any indication and the right to pursue a license to the JHU patents.

Our Potential Market

The following table depicts our current estimate of the total available market opportunity for our proposed anti-cancer therapies based upon independent market research, scientific and industry publications, and management's knowledge of the U.S. oncology market. Our estimates (including estimated product pricing) are based on assumptions and are subject to change.

Inhibitor Therapeutics, Inc. – Summary Estimated U.S. Market Opportunity

Cancer Type	Therapy Indication	Potential for Itraconazole	Target Patient Population	U.S. Total Estimated Available Market (*)
Prostate [(1)]	Patients with metastatic castrate resistant prostate cancer (mCRPC) and rising PSA levels no longer responding to androgen deprivation therapy (ADT) or have discontinued use of newer anti-androgen therapies due to lack of efficacy or toxicity	Delay the progression of metastatic disease	23,000 high-risk men with metastatic prostate cancer who are no longer responding to currently approved therapies due to biochemical resistance or toxicity	$215M at year 5 ($843M cumulative from launch) based on estimates of $4,000 - $5,000 monthly cost of 2nd line therapy
Lung [(2)]	Patients with advanced non-squamous cell, non-small cell lung cancer (NSCLC) who will be placed on Platinum Doublet/Pemetrexed IV Therapy	Improve the current median 8 - 10 month survival achieved with best supportive care for patients who are not eligible for treatment with tyrosine kinase or checkpoint inhibitors	45,000 men and women with late-stage disease who may be treated with chemotherapy if not eligible for other therapies	$270M at year 5 ($945M cumulative from launch based on estimates of $4,000 - $5,000 monthly cost of 2nd or 3rd line therapy
Skin [(3)]	Patients with BCC lesions First indication: BCC tumors in Gorlin Syndrome Patients requiring surgery. Potential for follow-on Indication: Patients with BCC facial lesions pending MOHs or other surgical procedures.	Less toxic therapy than vismodegib or sonidegib for Gorlin Patients to delay surgeries; low toxicity therapy to delay or minimize surgical intervention for head and neck BCC tumors	10,000 Gorlin patients needing chronic BCC therapy; 65,000 BCC patients pending surgical treatment for facial tumors that require excision and potential plastic surgery	$300M for Gorlin patients and $600M for patients with BCC facial lesions requiring surgery based upon estimates of $4,000 - $5,000 monthly cost of therapy for target populations

(*) estimated pricing subject to adjustment at the time of launch taking into consideration comparable products and required gross-to-net adjustments.

References:

(1) J. Urology, 2003; Oncology, 2004; American J. Hematologic Oncology, 2014; NIH NCI SEER 2014; Medscape, 2015; Future Oncology 2015; Global Data2015; Pennside Partners 2017

(2) STATS MGU, 2009; Global Industry Analysts, 2010; World Health Organization, 2015; Cost of Treating Lung Cancer, 2012; LUNGevity Foundation 2017; NEJM 2015; Pennside Partners 2017

(3) J Am Academy Dermatology, 2006; Skin Cancer Foundation, 2009; International Medicine News, 2011; Seeking Alpha, 2017; BCCNS Life Support Network 2017, Genetics Home Reference 2015; Pennside Partners 2016

Our Strategy

Our goal is to be a leader in the development and commercialization of itraconazole-based therapeutics for the treatment of cancer patients and patients with non-cancerous proliferation disorders, assuming in all cases that we obtain sufficient funding to recommence and thereafter continue our operations. We believe that we can accomplish this goal by implementing the following key elements of our business strategy:

- *Seek FDA Programs to Expedite Drug Approvals.* The FDA has various programs intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening conditions. These expedited programs help ensure that therapies for serious conditions are available as soon as it can be concluded that the therapies' benefits justify their risks, taking into account the seriousness of the condition and the availability of alternative treatments. These programs include breakthrough therapy designation, fast track designation, accelerated approval, and priority review. We believe that Itraconazole for the treatment of cancer may qualify for one or more of these designations, which could help expedite the regulatory review process.

- *Commercialize and Market with Exclusivity.* We are developing specific clinical trial designs to address different forms of cancer and non-cancerous proliferation disorders in order to pursue FDA approvals for multiple indications. Further, we believe Itraconazole can be commercialized in a way that maximizes benefits for patients, based on our specific therapy regimens, while eliminating generic substitution and providing us with market exclusivity protections through our intellectual property rights.

- *Formation of Scientific Advisory Board.* We have a premier Scientific Advisory Board consisting of five experienced Mohs surgeons to critically review the outcomes of our Phase 2b clinical trial in BCCNS, and to provide continuing guidance to us as we navigate the FDA approval process and corporate strategy.

- *Pursuing Strategic Partnerships.* We have partnered with Avior Bio, Inc. for the creation of a new, patentable formulation of Itraconazole. Avior will assist us with FDA proceedings to ensure the best possible opportunity for approval. Additionally, we have partnered with an industry experienced AI consultant to expedite further research in current data and opinions from recently published studies.

- *Exploring potential acquisitions.* We continue to review the market for potential acquisitions. We have explored and will continue to explore acquiring or licensing other innovative pre-clinical and clinical stage therapeutics addressing unmet needs and orphan indications for the treatment of cancer and other diseases.

We have and expect to continue to finance our research and development, commercialization and distribution efforts and our working capital needs primarily through:

- proceeds from public and private financings and, potentially, from other strategic transactions, including potential royalty-related financing transactions;

- potential partnerships with other pharmaceutical companies to assist in the supply, manufacturing and distribution of our products for which we would expect to receive milestone and royalty payments;

- potential licensing and joint venture arrangements with third parties, including other pharmaceutical companies where we would receive funding based on out-licensing our product; and/or

- government or private foundation grants or loans which would be awarded to us to further develop our current and future anti-cancer therapies.

Notwithstanding the foregoing, our only source of financial liquidity as of the date of this Report is the cash on hand realized from the net proceeds of the payment required pursuant to the settlement with the former majority shareholder of the Company.

Background on Cancer

Cancer is a heterogeneous group of diseases characterized by uncontrolled cell division and growth. Cancerous cells that arise in the lymphatic system and bone marrow are referred to as hematological tumors. Cancer cells that arise in other tissues or organs are referred to as solid tumors. Researchers believe that exposure to some chemicals, viruses and various forms of radiation can cause genetic alterations that cause cancer. Genetic predispositions also can increase the risk of cancer in some people.

Cancer is the second leading cause of death in the United States, exceeded only by heart disease. The American Cancer Society reported that an estimated total of approximately 2 million new cancer cases diagnosed and approximately 612,000 deaths occurred in the United States in 2024.

The most common methods of treating patients with cancer are surgery, radiation and drug therapy. A cancer patient often receives treatment with a combination of these methods. Surgery and radiation therapy are particularly effective in patients in whom the disease is localized (not spread beyond the initial site of disease). Physicians generally use systemic drug therapies in situations in which cancer has spread beyond the primary site or cannot otherwise be treated through surgery. The goal of drug therapy is to damage and kill cancer cells or to interfere with the molecular and cellular processes that control the development, growth and survival of cancer cells or tumors. In many cases, drug therapy entails the administration of several different drugs in combination. Over the past several decades, drug therapy has evolved from non-specific drugs that damage both healthy and cancerous cells, to drugs that target specific molecular pathways involved in cancer and more recently to therapeutics that target the specific oncogenic “drivers” of cancer.

Cytotoxic Chemotherapies. The earliest approach to pharmacological cancer treatment was to develop drugs, referred to as cytotoxic drugs, which kill rapidly proliferating cancer cells through non-specific mechanisms, such as disrupting cell metabolism or causing damage to cellular components required for survival and rapid growth. While these kinds of drugs have been effective in the treatment of some cancers, many unmet medical needs for the treatment of cancer remain. Also, cytotoxic drug therapies act in an indiscriminate manner, acting upon the metabolism of healthy as well as cancerous cells. Due to their mechanism of action, many cytotoxic drugs have a narrow dose range above which the toxicity causes unacceptable or even fatal levels of damage and below which the drugs are not effective in eradicating cancer cells.

Targeted Therapies. The next approach to pharmacological cancer treatment was to develop drugs, referred to as targeted therapeutics, that target specific biological molecules in the human body that play a role in rapid cell growth and the spread of cancer. Targeted therapeutics include vascular disruptors, also referred to as angiogenesis inhibitors, which prevent the formation of new blood vessels and restrict a tumor’s blood supply. Other targeted therapies affect cellular signaling pathways that are critical for the growth of cancer. While these drugs have been effective in the treatment of some cancers, most do not address the underlying cause of the disease. These drugs focus on inhibiting processes that help the cancer cell survive, but not the oncogenes that are the drivers or cause of the cancer itself.

Oncogenic Therapies. A more recent approach to pharmacological cancer treatment is to develop drugs that affect the drivers that cause uncontrolled growth of cancer cells because of a specific genetic alteration. In some cases, these agents were identified as therapeutics without knowledge of the underlying genetic change causing the disease. To date, the shortcoming of this research approach has been that it often follows a conventional trial and error approach to drug discovery. In this approach, clinical development involves the treatment of large populations from which a defined subpopulation that responds to treatment is identified. As a result, this approach can be time-consuming and costly, with success often uncertain. Another major concern of these newly discovered drugs, some of which have been recently approved, is that resistance to them occurs as the cancer finds new ways to circumvent the genetic pathway.

Immunotherapies. Immunotherapy is the use of medicines to stimulate a person's own immune system to recognize and destroy cancer cells more effectively. Immunotherapy can be used to treat many different types of cancer, including lung cancer, melanoma, renal, liver, cervical and gastric cancers. An important part of the immune system is its ability to keep itself from attacking normal cells in the body. To do this, it uses "checkpoints" – molecules on immune cells that need to be turned on (or off) to start an immune response. Cancer cells sometimes use these checkpoints to avoid being attacked by the immune system. But newer drugs that target these checkpoints are demonstrating a lot of promise as cancer treatments. These drugs target PD-1, a protein on immune system T cells that normally helps keep these cells from attacking other cells in the body. By blocking PD-1, these drugs boost the immune response against cancer cells. This can shrink many types of tumors or slow their growth. The new drugs can also target PD-L1, a protein related to PD-1 that is found on some tumor cells and immune cells. Blocking this protein can also help boost the immune response to cancer cells. These drugs can be used in people with certain types of cancer which starts growing again after chemotherapy or other drug treatments. They are also used as a first treatment (instead of chemo) in some people and are given as an intravenous (IV) infusion every 2 or 3 weeks.

The Itraconazole Approach to Treating Cancer

We are focusing our developments on Hedgehog pathway inhibitor therapeutics for patients with certain cancers.

Background of Itraconazole. Itraconazole is FDA approved for and used to treat serious fungal or yeast infections. This medicine works by killing the fungus or yeast and preventing its growth. Itraconazole is a prescription-based medication, available as an IV solution, oral liquid, capsule or tablet.

Cancer and Hedgehog Inhibitors. The Hedgehog (also known as Hh) proteins comprise a group of secreted proteins that regulate cell growth, differentiation and survival. They are involved in organogenesis (the formation of organs) and have been shown to promote adult stem cell proliferation. Inappropriate activation of the Hh signaling pathway has been implicated in the development of several types of cancers including prostate, lung, pancreas, breast, brain and skin. Hedgehog pathway inhibitors are a relatively new class of therapeutic agents that act by targeting the proteins involved in the regulation of the Hh pathway. Many of these newly discovered inhibitors are currently undergoing preclinical testing and some have entered clinical studies as anti-cancer agents for a variety of cancers. Vismodegib was approved for treatment of locally advanced and metastatic basal cell carcinoma in early 2012, sonidegib was approved for locally advanced BCC in mid-2015 and glasdegib was approved in late 2018 for treatment of acute myeloid leukemia.

Similarly, itraconazole has also been shown to suppress growth of brain tumors in animal models. It has also been shown to have anti-cancer effects in basal cell carcinoma, lung cancer and prostate cancer in human clinical trials. Itraconazole acts as a SMO (a protein receptor of the Hh pathway) antagonist (blocker), in a manner distinct from its anti-fungal activity which targets a compound found in fungi and yeast known as ergosterol (a steroid found in the cell walls of fungi and yeast that functions in a fashion similar to cholesterol in humans) as well as having anti-angiogenic properties.

Sales and Marketing

We are currently a pharmaceutical development company with no FDA approved products, and thus have not yet established a sales, marketing or product distribution infrastructure because our product candidates are still in development. We may either license commercialization rights to our product candidate to larger third-party partners, who will be responsible for sales, distribution and marketing efforts, or we may (assuming adequate resources are available) retain commercial rights for our product candidates, in which case we would seek to access the oncology market through a focused, specialized sales force of our own or in conjunction with a marketing partner under a co-promotion agreement.

Competition

The pharmaceutical industry is highly competitive and subject to rapid and substantial regulatory and technological changes, particularly in the oncology field. Developments by others may render our itraconazole therapies, or any proposed product candidates and formulations under development, non-competitive or obsolete, or we may be unable to keep pace with anti-cancer therapy developments or other market factors. Anti-cancer therapy competition from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase.

Genentech (Roche) was the first to achieve FDA approval for a Hedgehog pathway inhibitor with the development of vismodegib (Erivedge). Approved in 2012, Erivedge is indicated for the treatment of advanced BCCs, including cases in BCCNS patients where surgery is not a viable option.

Similarly, Novartis introduced sonidegib (Odomzo), another Hedgehog pathway inhibitor approved for treating locally advanced BCCs in adult patients who are not candidates for surgery or radiation. Odomzo provides an alternative targeted therapy for patients with BCCNS who require systemic treatment to manage tumor burden.

PellePharm, a company focused on rare dermatological conditions, has developed topical patidegib, a Hedgehog pathway inhibitor designed to reduce BCC formation in BCCNS patients. Patidegib has received FDA Breakthrough Therapy and Orphan Drug Designations.

Kintara Therapeutics has also made strides in BCCNS treatment with its REM-001 Therapy, which has received FDA Orphan Drug Designation. This therapy aims to provide an innovative photodynamic treatment option for patients suffering from multiple BCCs.

Itraconazole offers several advantages as a treatment option for BCCNS. Acting as a Hedgehog pathway inhibitor, it targets the underlying mechanism of basal cell carcinoma growth, and its well-established safety profile from years of use as an FDA-approved antifungal supports its repurposing for cancer therapy. Its oral administration allows for systemic treatment, which is particularly beneficial for patients with multiple or recurrent tumors. Additionally, itraconazole may present a more tolerable side effect profile compared to other Hedgehog inhibitors, making it a promising alternative for patients who experience significant adverse effects with current treatments.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export of pharmaceutical products such as those we are developing. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

United States Government Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing 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 United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

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

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP regulations;
- submission to the FDA of an IND application which must become effective before human clinical trials may begin;
- approval by an independent institutional review board (or IRB) at each clinical site before each trial may be initiated;
- performance of human clinical trials, including adequate and well-controlled clinical trials, in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practices (of cGMP) and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, as well as satisfactory completion of an FDA inspection of selected clinical sites to determine GCP compliance; and
- FDA review and approval of the NDA.

Preclinical Studies. Preclinical studies include laboratory evaluation of product chemistry, toxicity, and formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

We successfully avoided pre-clinical studies or any Phase 1 studies to demonstrate safety based on the fact that itraconazole has an established history of safe and effective use in humans for anti-fungal indications and the fact that human data are already available and published regarding use of itraconazole in humans for anti-cancer indications, such as basal cell carcinoma, lung cancer and prostate cancer.

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

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined. In Phase 1, the drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an initial indication of its effectiveness. In Phase 2, the drug typically is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. In Phase 3, the drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

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

Marketing Approval. Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act ("PDUFA") guidelines that are currently in effect, the FDA has agreed to certain performance goals regarding the timing of its review of an application.

The FDA also may require submission of a risk evaluation and mitigation strategy ("REMS") plan to mitigate any identified or suspected serious risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. We believe that a REMS program, which includes intellectual property related to SUBA-Itraconazole and itraconazole, and the specific use of SUBA-Itraconazole for anti-cancer indications, may likely provide additional protection of our proposed therapies from generic substitution.

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

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

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

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, including a boxed warning, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms under a REMS (Risk Evaluation Mitigation Strategy) which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Special FDA Expedited Review and Approval Programs. The FDA has various programs, including fast track designation, accelerated approval, priority review and breakthrough designation, that are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures. To be eligible for a fast-track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it provides a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors.

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

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

Moreover, under the provisions of the new Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We believe that we may qualify for one or more of these expedited approvals since our itraconazole anti-cancer therapies offer significant improvements in therapy for all of our targeted anti-cancer indications should they be approved by FDA.

Post-Approval Requirements. Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-NDA analyses, such as overall survival (OS) or post-marketing testing, including Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before implementation. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Once approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labelling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

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

The FDA strictly regulates marketing, labelling, advertising, and promotion of products that are placed on the market. Although physicians, in the practice of medicine, may prescribe approved drugs for unapproved indications, pharmaceutical companies generally are required to promote their drug products only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act (or PDMA), which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Federal and State Fraud and Abuse and Data Privacy and Security Laws and Regulations. In addition to FDA restrictions on marketing of pharmaceutical products, federal and state fraud and abuse laws restrict business practices in the biopharmaceutical industry. These laws include anti-kickback and false claims laws and regulations as well as data privacy and security laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any item or service reimbursable under Medicare, Medicaid, or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting some common activities from prosecution, the exemptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated.

The reach of the Anti-Kickback Statute was also broadened by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (which we refer to collectively as the PPACA), which, among other things, amended the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act or the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. PPACA also created new federal requirements for reporting, by applicable manufacturers of covered drugs, payments, and other transfers of value to physicians and teaching hospitals.

The federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-reimbursable, uses. The federal Health Insurance Portability and Accountability Act of 1996 (or HIPAA) created new federal criminal statutes that prohibit knowingly and wilfully executing a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and wilfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act (or HITECH) and its implementing regulations, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Coverage and Reimbursement. The commercial success of our product candidate and our ability to commercialize any approved product candidate will depend in part on the extent to which governmental authorities, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for our therapeutic product candidates and related companion diagnostics. Government health administration authorities, private health insurers and other organizations generally decide which drugs they will pay for and establish reimbursement levels for healthcare. In particular, in the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. In the United States, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which often has resulted in average selling prices lower than they would otherwise be. Further, the increased emphasis on managed healthcare in the United States will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

Third-party payors are increasingly imposing additional requirements and restrictions on coverage and limiting reimbursement levels for medical products. For example, federal and state governments reimburse covered prescription drugs at varying rates generally below average wholesale price. These restrictions and limitations influence the purchase of healthcare services and products. Legislative proposals to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our products and product candidates or exclusion of our products and product candidates from coverage. The cost containment measures that healthcare payors and providers are instituting and any healthcare reform could significantly reduce our revenues from the sale of any approved product candidates. We cannot provide any assurances that we will be able to obtain and maintain third-party coverage or adequate reimbursement for our product candidate in whole or in part.

Impact of Healthcare Reform on Coverage, Reimbursement, and Pricing. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (or MMA) imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Part D plans include both standalone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for any products for which we receive marketing approval. However, any negotiated prices for our future products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from Medicare Part D may result in a similar reduction in payments from non-governmental payors.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of any product, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates. If third-party payors do not consider our product candidates to be cost-effective compared to other available therapies, they may not cover our product candidates, once approved, as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The United States is considering enacting or has enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives, including, most recently, PPACA, which became law in March 2010 and substantially changes the way healthcare is financed by both governmental and private insurers. Among other cost containment measures, the PPACA establishes an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; a new Medicare Part D coverage gap discount program; and a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program. In the future, there may continue to be additional proposals relating to the reform of the U.S. healthcare system, some of which could further limit the prices we are able to charge for our product candidates, once approved, or the amounts of reimbursement available for our product candidates once they are approved.

Exclusivity and Approval of Competing Products

Hatch-Waxman Patent Exclusivity. In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's product or a method of using the product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application (or ANDA), or a 505(b)(2) NDA.

Generally, an ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths, dosage form and route of administration as the listed drug and has been shown to be bioequivalent through *in vitro* or *in vivo* testing or otherwise to the listed drug. ANDA applicants are not required to conduct or submit results of preclinical or clinical tests to prove the safety or effectiveness of their drug product, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and these drugs can often be substituted by pharmacists under prescriptions written for the original listed drug. 505(b)(2) NDAs generally are submitted for changes to a previously approved drug product, such as a new dosage form or indication. The 505(b)(2) regulatory pathway appears to be available for our proposed application of itraconazole as an anti-cancer therapy based upon our communications with FDA to date.

The ANDA or 505(b)(2) NDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable, or will not be infringed by the new product.

Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except when the ANDA or 505(b)(2) NDA applicants challenge a listed drug. A certification that the proposed product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicate that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA or 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of notice of the Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

Hatch-Waxman Non-Patent Exclusivity. Market and data exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications for competing products. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the activity of the drug substance. During the exclusivity period, the FDA may not accept an ANDA for review or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The FDC also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA, or supplement to an existing NDA or 505(b)(2) NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant, are deemed by the FDA to be essential to the approval of the application or supplement. Three-year exclusivity may be awarded for changes to a previously approved drug product, such as new indications, dosages, strengths or dosage forms of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and, as a general matter, does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Orphan Drug Exclusivity. The Orphan Drug Act provides incentives for the development of drugs intended to treat rare diseases or conditions, which generally are diseases or conditions affecting less than 200,000 individuals annually in the United States. If a sponsor demonstrates that a drug is intended to treat a rare disease or condition, the FDA grants orphan drug designation to the product for that use. The benefits of orphan drug designation include research and development tax credits and exemption from user fees. A drug that is approved for the orphan drug designated indication is granted seven years of orphan drug exclusivity. During that period, the FDA generally may not approve any other application for the same product for the same indication, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with exclusivity. We obtained orphan drug designation for SUBA-Itraconazole BCCNS in May 2016.

Foreign Regulation. Although it is not presently our intention to seek approval of our product candidates outside of the United States, in the future we may do so, either directly or in conjunction with a marketing partner. In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. We do however intend to include sites outside the United States for our clinical trials in order to be able to recruit more patients for testing at a greater number of locations and in less time than if we were to focus only on US-based sites. For example, in the European Union, we would need to obtain authorization of a clinical trial application in each member state in which we intend to conduct a clinical trial. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Human Capital Resources

As of the date of this Report, we have three full-time employees and six part-time employees. The full-time employees include our Executive Chairman who is involved in our clinical development program history and status, as well as vetting additional opportunities and operations, as well as our Vice President of Operations. The part-time employees include our Interim CFO, as well as administrative, legal and accounting functions. None of our employees are covered by collective bargaining agreements. From time to time, we also employ independent contractors to support our clinical development and administrative functions. We consider the number of our employees, their compensation, and their functions to be appropriate for the current status of our business, and we also consider relations with each of our employees to be good. Each of our employees has entered into confidentiality, intellectual property assignment and non-competition agreements with us.

Corporate History

We were founded under the name "Commonwealth Biotechnologies, Inc." in Virginia in 1992, and completed an initial public offering in October 1997 (we refer to our company prior to our emergence from bankruptcy as CBI). CBI previously provided, on a contract basis, specialized life sciences services to the pharmaceutical and biotechnology sector. On January 20, 2011, CBI filed a voluntary petition for bankruptcy. We recommenced our business operations in August 2013 as a Delaware corporation following the emergence of CBI from its voluntary bankruptcy.

After approximately five years of extended litigation between a minority shareholder and the former majority shareholder of the Company was finalized through mediation in 2022, the former majority shareholder surrendered all equity securities of the Company for cancellation. Certain defendants in the litigation were directors and officers of the Company at the time, and as a result of the legal settlement, resigned from these positions. New officers and directors were then elected and the Company continued under new management.

Available Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Exchange Act are filed with the SEC. Such reports and other information that we file with the SEC are available free of charge on our website at http://www.inhibitortx.com when such reports are available on the SEC website. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers like us that file electronically with the SEC at http://www.sec.gov. The contents of these websites are not incorporated into this filing. Further, the foregoing references to the URLs for these websites are intended to be inactive textual references only.

Item 1A. RISK FACTORS

Investing in our common stock is highly speculative and involves a high degree of risk. Before purchasing our common stock, you should carefully consider the following risk factors as well as all other information contained in this Report, including our financial statements and the related notes. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties that we are unaware of, or that we currently deem immaterial, also may become important factors that affect us. If any of the following risks occur, our business, financial condition or results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose some or all of your investment.

Risks Relating to Our Business

We presently conduct only minimal operations. We are also subject to the risks associated with early-stage businesses in the pharmaceutical industry.

We are a pharmaceutical development company with no history of revenue-generating operations. Therefore, we are, and expect for the foreseeable future to be, subject to all the risks and uncertainties inherent in an early-stage pharmaceutical development company.

Accordingly, you should consider our prospects in light of the ongoing costs, uncertainties, delays and difficulties frequently encountered by companies in their pre-revenue generating stages, particularly those in the pharmaceutical field. Potential investors should carefully consider the risks and uncertainties that a company with no operating history will face. In particular, potential investors should consider that there is a significant risk that we will not be able to:

- implement or execute our current business plan, or that our business plan is sound;
- maintain our management team or board of directors;
- raise sufficient funds in capital markets or otherwise to effectuate our business plan but may require additional information to expand it;
- determine that the processes and technologies that we have developed are commercially viable; and/or
- attract, enter into or maintain contracts with potential commercial partners such as licensors of technology and suppliers.

If we cannot execute any one of the foregoing, our business may fail, in which case you may lose the entire amount of your investment in our company.

In addition, we have in the past and expect that we may in the future encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be able to reach such point of transition or make such a transition, which would have a material adverse effect on our company.

Our limited operating history makes it difficult for you to evaluate our business to date and to assess our future viability.

Currently, our primary focus is the development of therapies initially for BCCNS, prostate and lung cancers in the United States utilizing itraconazole, although we are limited in the extent of our operations until there are further developments in the FDA approval process.

Our operations presently consist of planning and conducting of pre-clinical testing and potential additional clinical trials, should they be required, evaluating opportunities for the raising of capital, developing our technology or seeking technology licenses or acquisitions, and at some point, identifying potential commercial partners. We have not yet demonstrated our ability to obtain regulatory 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 product commercialization. Consequently, any predictions you make about our future viability or ability to accomplish our business goals may not be as accurate as they could be if we had a longer operating history.

We are dependent upon our officers and directors and their loss could adversely affect our ability to operate.

Our operations are dependent upon a very small group of individuals and, in particular, our current officers and directors, including most notably Dr. Francis E. O'Donnell. We believe that our ability to implement our business plans depends on the continued service of these individuals and/or other officers and directors. The unexpected loss of the services of one or more of our directors or officers could have a detrimental effect on us.

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

Our internal computer systems and those of our current and any future partners, contractors, and consultants are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. This is particularly true in the case of collecting and analyzing clinical data, which is a key component of our business. System failures, accidents, or security breaches could cause interruptions in our operations, and could result in a material disruption of our commercialization activities, development programs and our business operations, in addition to possibly requiring substantial expenditures of resources to remedy. 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, and the commercialization of any potential product candidate could be delayed.

Risks Related to Our Financial Position and Need For Additional Capital

We have no cash generating operations and may consume resources faster than expected.

We currently do not generate any revenue from product sales, royalties, or otherwise, and we therefore have a limited source of cash to meet our future capital requirements. We do not expect to generate revenues or receive royalty revenue for the foreseeable future, and we may not be able to raise funds in the future due to the nature of our company or other factors (some of which are beyond our control), and our inability to raise funds would leave us without resources to continue operations and force us to resort to stockholder investments or loans, which may not be available to us on reasonable terms or at all.

Additionally, we may have difficulty raising needed capital in the near or longer term as a result of, among other factors, the clinical stage nature of our business, as well as the inherent business risks associated with our company and present and future market conditions. Also, we may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated. Our inability to raise funds could lead to decreases in the price of our common stock and the failure of our business.

Raising additional capital or issuing new securities in connection with strategic transactions may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Since we will be unable to generate any revenue from actual sales of products and expect to be in the development stage for the foreseeable future, we will need to seek equity or debt financing to provide the capital required to execute our business plan. We will need significant funding for developing, acquiring, or licensing our intellectual property, conducting clinical trials and entering into collaborations with third-party partners as well as for working capital requirements and other operating and general corporate purposes.

There can be no assurance that we will be able to raise sufficient capital on acceptable terms, or at all. If such financing is not available on satisfactory terms, or is not available at all, we may be required to delay, scale back or eliminate the development of business opportunities and our operations and financial condition may be adversely affected to a significant extent.

If we raise additional capital by issuing equity securities, the percentage and/or economic ownership of our existing stockholders may be reduced, and accordingly these stockholders may experience substantial dilution. We may also issue equity securities that provide for rights, preferences and privileges senior to those of our common stock.

Debt financing, if obtained, may involve agreements that include liens on our assets, covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, increases in our expenses and requirements that our assets be provided as security for such debt. Debt financing would also be required to be repaid regardless of our operating results.

If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our technologies or product candidate, or to grant licenses on terms that are not favorable to us.

Funding from any source may be unavailable to us on acceptable terms, or at all. If we do not have sufficient capital to fund our operations and expenses, our business could fail or become subject to bankruptcy.

Moreover, we may issue equity securities in connection with potential strategic transactions such as acquisitions or licenses of other companies or technologies. Such issuances could be in significant amounts and would also cause dilution to our stockholders and grant the recipients of such securities varying amounts of control over our company and our business.

Risks Related to the Clinical Development of Our Product Candidate

We are early in our development efforts. Although we were able to settle our recent extended litigation and have adequate cash for near-term planned operations, if we are unable to clinically develop and ultimately commercialize Itraconazole or other product candidates, or experience significant delays in doing so, our business will be materially harmed.

We are early in our development efforts as of the date of this Report. Therefore, our ability to generate product or royalty revenues, which we do not expect will occur for several years, if ever, will depend heavily on our ability to raise new funding and develop and eventually commercialize our product candidate. The positive development of our product candidate will depend on several factors, including the following:

- our ability to raise funds to progress our business, of which no assurances can be given;
- FDA agrees that our proposed regulatory strategy of using a per-tumor analysis of the 477 surgically eligible distinct non-metastatic tumors from baseline is acceptable;
- positive commencement and completion of clinical trials;
- successful preparation of regulatory filings and receipt of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and potential regulatory exclusivity for our product candidate and protecting our rights in our intellectual property portfolio;
- launching commercial sales of our product, if and when approved for one or more indications, whether alone or in collaboration with others;
- acceptance of the product for one or more indications, if and when approved, by patients, the medical community and third-party payors;
- protection from generic substitution based upon our own or licensed intellectual property rights;
- effectively competing with other therapies;
- obtaining and maintaining adequate reimbursement from healthcare payors; and
- maintaining a continued acceptable safety profile of our product following approval, if any.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to clinically develop and commercialize therapies for cancer and non-cancerous proliferation disorders, which would materially harm our business.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidate.

The risk of failure for product candidates in clinical development is high. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. Moreover, the outcome of early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products.

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

- regulators or institutional review boards 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 of our product candidate may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs, which would be time consuming and costly;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials may be greater than we anticipate;
- the supply or quality of materials necessary to conduct clinical trials of our product candidate may be insufficient or inadequate;
- our product candidate may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, or institutional review boards to suspend or terminate the trials; and
- interactions with other drugs.

If we are required to conduct additional clinical trials or other testing of our product candidate, if we are unable to complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidate for one or more indications;
- not obtain marketing approval at all for one or more indications;

- obtain approval for indications or patient populations that are not as broad as intended or desired (particularly, in our case, for different types of cancer);
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know which, if any, of our clinical trials will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the right to commercialize our product candidate or allow our competitors to bring products to market before we do and impair our ability to commercialize our product candidate and may harm our business and results of operations.

If we experience delays or difficulties in enrollment of patients in any future clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue future clinical trials for our present or future product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidate, and patients who would otherwise be eligible for our future clinical trials may enroll in clinical trials of our competitors' product candidates.

Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for any future clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidate, which would cause the value of our company to decline and otherwise materially and adversely affect our company.

If serious adverse or unacceptable side effects are identified during the development of our product candidate, we may need to abandon or limit such development, which would adversely affect our company.

If clinical testing of our product candidates results in undesirable side effects or demonstrates characteristics that are unexpected, we may need to abandon such development or limit such 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. Many compounds that initially showed promise in early-stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound.

We expect to rely on collaborations with third parties for key aspects of our business. If we are unable to secure or maintain any of these collaborations, or if these collaborations do not achieve their goals, our business could be adversely affected.

We presently have very limited capabilities for drug development and do not yet have any capability for manufacturing, sales, marketing or distribution. Accordingly, we expect to enter into collaborations with other companies that we believe can provide such capabilities. These collaborations may also provide us with important funding for our development programs.

There is a risk that we may not be able to maintain our current collaboration or to enter into additional collaborations on acceptable terms or at all, which would leave us unable to progress our business plan. We will face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to maintain or reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of our product candidate, reduce or delay its development program, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

Risks Related to the Commercialization of Our Product Candidates

Even if any of our product candidates receive marketing approval for any indication, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if product candidates we may acquire or license receive marketing approval for any indication, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current cancer treatments such as chemotherapy, immunotherapy and radiation therapy are well established in the medical community, and doctors may continue to rely on these treatments. If our product candidate does not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of product candidates for the treatment of cancer and non-cancerous proliferation disorders, if approved for commercial sale, will depend on a number of factors, including:

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

If we are unable to establish sales, marketing and distribution capabilities, we may not be able to commercialize our product candidate if and when it is approved.

We currently do not have a sales or marketing infrastructure. To achieve any level of commercial success for any product for which we have obtained marketing approval, we will need to establish a sales and marketing organization or outsource sales and marketing functions to third parties.

There are risks involved with establishing our own sales, marketing and distribution 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 product 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. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

If approved, factors that may inhibit our efforts to commercialize our product on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe our product;
- the lack of complementary products offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to or choose not to establish our own sales, marketing and distribution capabilities and instead enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, are likely to be lower than if we were to market, sell and distribute any products that we develop ourselves. In addition, we may be unable to enter into arrangements with third parties to sell, market and distribute our product candidate or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product effectively. If we do not establish sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we will not be able to commercialize our product candidate, which would have a material adverse effect on our company.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidate and will face competition with respect to any product candidate that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of cancer. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, 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, which could result in our competitors establishing a strong market position before we are able to enter the market.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs, and we may be unable to effectively compete with these companies for these or other reasons.

Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals.

Our ability to commercialize any product candidate also will depend in part on the extent to which coverage and adequate reimbursement for our product candidate will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to commercialize any product candidate for which we obtain marketing approval.

In addition, there may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA. Moreover, eligibility for reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

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

We face an inherent risk of product liability exposure related to the testing of our product candidate in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot defend ourselves against claims that our product candidate or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- damage to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

We currently do not have product liability insurance coverage, which leaves us exposed to any product-related liabilities that we may incur. We may be unable to obtain insurance on reasonable terms or at all. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to commercialize our technology and products may be impaired.

Our business plan depends in large part on our ability to obtain and maintain patent protection in the United States with respect to our proprietary technology and products. We will also need to obtain and maintain patent protection for any technologies we may acquire or license in the future.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control (in whole or in part) the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

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

Specifically, United States Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances. From time to time, the United States Supreme Court, other federal courts, the United States Congress, or interpretation by the United States Patent and Trademark Office or USPTO, may change the standards of patentability and any such changes could have a negative impact on our business. Some cases decided by the United States Supreme Court have involved questions of when claims reciting abstract ideas, laws of nature, natural phenomena and/or natural products are eligible for a patent, regardless of whether the claimed subject matter is otherwise novel and inventive. These cases include *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013), also known as the Myriad decision; *Alice Corp. v. CLS Bank International*, 573 U.S. 208 (2014), also known as the Alice decision; and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, also known as the Prometheus decision, 566 U.S. 66 (2012). The full impact of these decisions is not yet known. In view of these and subsequent court decisions, the USPTO has issued materials to patent examiners providing guidance for determining the patent eligibility of claims reciting laws of nature, natural phenomena, or natural products.

In addition, patent reform legislation could further increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent Office has developed regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, became effective on March 16, 2013. Accordingly, since we have patent applications pending and plan to file for additional patents in the future, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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

Even if our owned and licensed patent applications are issued as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of our product candidate, patents protecting such candidate might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

Competitors may infringe on our owned or licensed patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly.

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

We have and/or expect to enter into licenses with third parties that hold intellectual property, including patent rights, that are important or necessary to the development of itraconazole as an anti-cancer therapy, and it may be necessary for us to use the patented or proprietary technology of third parties to commercialize itraconazole as an anti-cancer therapy, in which case we have or would be required to obtain a license from these third parties on commercially reasonable terms, or else our business could be harmed, possibly materially. Even though we have had patents issued for our own inventions in the United States in November 2015, May 2018, June 2019 and July 2019, if we were not able to maintain our current license or obtain additional licenses or were not able to maintain or obtain such licenses on commercially reasonable terms, our business could be harmed, possibly substantially.

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

Our business will depend upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our primary product candidate or other products and technology, including interference or derivation proceedings before the U.S. Patent and Trademark Office. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. 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 access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have wilfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially damage our business. Claims that we have misappropriated confidential information or trade secrets of third parties could have a similar negative impact on our business.

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

We are and expect to be party to one or more licenses or similar agreements that may impose due diligence, development and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under current or future licenses, our counterparties may have the right to terminate these agreements, in which case we might not be able to develop, manufacture or market any product that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could materially adversely affect the value of the product 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.

Intellectual property litigation 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Risks Related to Regulatory Approval of Our Product Candidates and Other Legal and Compliance Matters

If we fail to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidate, and our ability to generate revenue and the viability of our company will be materially impaired.

Our product candidates and the activities associated with their clinical development and commercialization, including matters relating to design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA (including under the Federal Food, Drug and Cosmetic Act) and other regulatory agencies in the United States and by the European Medicines Agency (known as the EMA) and similar regulatory authorities outside the United States. Failure to obtain marketing approval for our product candidates will prevent us from commercializing the product candidate.

Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidate 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 us from obtaining marketing approval or prevent or limit commercial use of our product. In particular, new cancer drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed.

The process of obtaining marketing approvals in the United States is very 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 product candidate 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 product 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 preclinical, clinical or other studies.

In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of our product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidate, the commercial prospects for our product candidate will be harmed and our ability to generate revenues, and the viability of our company generally, will be materially impaired.

Risks Related to Our Securities

An active trading market for our common stock does not exist and may not develop or be sustained.

An investment in our company will likely require a long-term commitment, with no certainty of return. Although our common stock is listed for quotation on the OTCQB marketplace operated by OTC Markets Group, Inc., trading has been very limited, and we cannot predict whether an active market for our common stock will ever develop in the future. In the absence of an active trading market:

- investors may have difficulty buying and selling or obtaining market quotations;
- market visibility for shares of our common stock may be limited; and
- a lack of visibility for shares of our common stock may have a depressive effect on the market price for shares of our common stock.

The OTCQB market is a relatively unorganized, inter-dealer, over-the-counter market that provides significantly less liquidity than NASDAQ or the NYSE American (formerly known as the American Stock Exchange). This illiquid trading market for our common stock may make it difficult for you to dispose of your common stock at desirable prices or at all.

The lack of an active market impairs your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire additional intellectual property assets by using our shares as consideration.

Moreover, while we may seek to have our common stock listed on the NASDAQ Stock Market, there is a risk that we will be unable to do so, which would leave our common stock listed on the OTCQB and subject to the foregoing risks of illiquidity.

We may not maintain qualification for OTCQB inclusion, and therefore you may be unable to sell your shares.

Our common stock is eligible for quotation on the OTCQB. However, trading of our common stock could be suspended, including due to our inability to pay the required fees to the OTC Markets for listing our common stock on the OTCQB. If for any reason our common stock does not become eligible or maintain eligibility for quotation on the OTCQB or a public trading market does not develop, purchasers of shares of our common stock may have difficulty selling their shares should they desire to do so. If we are unable to satisfy the requirements for quotation on the OTCQB, any quotation in our common stock could be conducted on the OTC Pink Market, which is an unorganized and often illiquid market. As a result, a purchaser of our common stock may find it more difficult to dispose of, or to obtain accurate quotations as to the price of their shares. This would materially and adversely affect the liquidity of our securities.

Even if a market for our common stock develops, the market price of our common stock may be significantly volatile, which could result in substantial losses for purchasers.

The market price for our common stock may be significantly volatile and subject to wide fluctuations in response to factors including the following:

- actual or anticipated fluctuations in our quarterly or annual operating results;
- changes in financial or operational estimates or projections;
- conditions in markets generally;
- changes in the economic performance or market valuations of companies similar to ours;
- general economic or political conditions in the United States or elsewhere; and
- litigation.

In particular, the market prices for securities of biotechnology companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- any delay in or the results of our clinical trials;
- the announcements of clinical trial data, and the investment community's perception of and reaction to those data;
- the results of clinical trials conducted by others on products that would compete with our product candidate;
- any litigation in which the Company is a party, including the Action;
- any delay or failure to receive NDA acceptance and approval by FDA and other regulatory agencies or bodies;
- our inability to commercially launch our product or market and generate sales of our product;
- failure of our product, even if approved for marketing, to achieve any level of commercial success;
- our failure to obtain or maintain patent protection for any of our technologies and products or the issuance of third-party patents that cover our technologies or product;
- developments or disputes concerning our product's intellectual property rights;
- our competitors' technological innovations;
- general and industry-specific economic conditions that may affect our expenditures;
- changes in market valuations of similar companies;
- announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies, or patents;

- failure to adequately manufacture our product through third parties for purposes of clinical trials or actual sales;
- future sales of our common stock or other securities;
- period-to-period fluctuations in our financial results;
- low trading volume of our common stock; and
- failure to obtain or maintain license agreements.

In addition, if we fail to reach an important research, development or commercialization milestone or result by a publicly expected deadline, even if by only a small margin, there could be significant impact on the market price of our common stock. Additionally, as we approach the announcement of anticipated significant information and as we announce such information, we expect the price of our common stock to be particularly volatile, and negative results would have a substantial negative impact on the price of our common stock.

In some cases, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our business operations and reputation.

Our management and three significant stockholders collectively own a substantial majority of our common stock and voting power.

Collectively, our officers, our directors and three significant stockholders own or exercise voting and investment control of approximately 56% of our common stock as of the date of this Report. As a result, investors may be prevented from affecting matters involving our company, including:

- the composition of our Board of Directors and, through it, any determination with respect to our business direction and policies, including the appointment and removal of officers;
- any determinations with respect to mergers or other business combinations;
- our acquisition or disposition of assets; and
- our corporate financing activities.

Furthermore, this concentration of voting power could have the effect of delaying, deterring or preventing a change of control or other business combination that might otherwise be beneficial to our stockholders. This significant concentration of share ownership may also adversely affect the trading price for our common stock because investors may perceive disadvantages in owning stock in a company that is controlled by a small number of stockholders.

Future sales of our common stock in the public market could lower the price of our common stock and impair our ability to raise funds in future securities offerings.

Significant blocks of our stock and options to purchase our common stock are held by our management and significant shareholders. Future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the then prevailing market price of our common stock and could make it more difficult for us to raise funds in the future through a public offering of our securities.

Our common stock is considered a "penny stock," and thereby is subject to additional sale and trading regulations that may make it more difficult to sell.

Our common stock is considered a "penny stock" as it does not qualify for one of the exemptions from the definition of "penny stock" under Section 3a51-1 of the Securities Exchange Act of 1934. Our common stock will be a "penny stock" for so long as it meets one or more of the following conditions: (i) the stock trades at a price less than $5 per share; (ii) it is not traded on a "recognized" national exchange; or (iii) is issued by a company (such as ours) that has been in business less than three years with net tangible assets less than $5 million.

The principal result or effect of being designated a "penny stock" is that securities broker-dealers participating in sales of our common stock will be subject to the "penny stock" regulations set forth in Rules 15g-2 through 15g-9 promulgated under the Exchange Act. For example, Rule 15g-2 requires broker-dealers dealing in penny stocks to provide potential investors with a document disclosing the risks of penny stocks and to obtain a manually signed and dated written receipt of the document at least two business days before effecting any transaction in a penny stock for the investor's account. Moreover, Rule 15g-9 requires broker-dealers in penny stocks to approve the account of any investor for transactions in such stocks before selling any penny stock to that investor. This procedure requires the broker-dealer to: (i) obtain from the investor information concerning his or her financial situation, investment experience and investment objectives; (ii) reasonably determine, based on that information, that transactions in penny stocks are suitable for the investor and that the investor has sufficient knowledge and experience as to be reasonably capable of evaluating the risks of penny stock transactions; (iii) provide the investor with a written statement setting forth the basis on which the broker-dealer made the determination in (ii) above; and (iv) receive a signed and dated copy of such statement from the investor, confirming that it accurately reflects the investor's financial situation, investment experience and investment objectives. Compliance with these requirements may make it more difficult and time-consuming for holders of our common stock to resell their shares to third parties or to otherwise dispose of them in the market or otherwise.

FINRA sales practice requirements may also limit your ability to buy and sell our common stock, which could depress the price of our shares.

FINRA rules require broker-dealers to have reasonable grounds for believing that an investment is suitable for a customer before recommending that investment to the customer. Prior to recommending speculative low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status and investment objectives, among other things. Under interpretations of these rules, FINRA believes that there is a high probability such speculative low-priced securities will not be suitable for at least some customers. Thus, FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our shares, have an adverse effect on the market for our shares, and thereby depress our share price.

There may be limitations on the effectiveness of our internal controls, and failure of our control systems to prevent error or fraud may materially harm our company.

Proper systems of internal controls over financial accounting and disclosure are critical to the operation of a public company. Given the size of our company and the limited number of full-time employees that we have employed, there may be certain limitations on the effectiveness of our internal controls. Moreover, we do not expect that disclosure controls or internal control over financial reporting will prevent all errors and all fraud, if any. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Failure of our control systems to prevent error or fraud could materially and adversely impact us.

If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts who cover us downgrade our stock, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Anti-takeover provisions in our charter documents and Delaware law could discourage, delay or prevent a change in control of our company and may affect the trading price of our common stock.

We are a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change in control would be beneficial to our existing stockholders.

In addition, our certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a change in our management or control over us that stockholders may consider favorable. In particular, our certificate of incorporation and amended and restated bylaws, among other matters:

- permit our Board of Directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that all vacancies on our Board of Directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice; and
- do not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election;

We do not intend to pay dividends on our common stock.

We have never declared or paid any cash dividend on our common stock. We currently intend to retain any future earnings and do not expect to pay any dividends for the foreseeable future. Therefore, you should not invest in our common stock in the expectation that you will receive dividends.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity

We recognize the importance of assessing, identifying, and managing material risks associated with cybersecurity threats, as such term is defined in Item 106(a) of Regulation S-K. These risks include, among other things: operational risks, intellectual property theft, fraud, extortion, harm to employees or customers and violation of data privacy or security laws. Our Chief Financial Officer manages our risk management program to assess third party risk exposure to identify and mitigate risks from vendors, suppliers, and other business partners. We have not had any cybersecurity issues in the past. We maintain cybersecurity insurance coverage (first and third-party) with an insurance carrier that is a leader in the cybersecurity insurance industry.

Identifying and assessing cybersecurity risk is integrated into our overall risk management systems and processes. We are cognizant of cybersecurity risks related to our business, technical operations, privacy and compliance issues, IT security, governance, risk and compliance reviews. To defend, detect and respond to cybersecurity incidents, we are proactive in privacy and cybersecurity issues with vendors and conduct employee training as needed, monitor emerging laws and regulations related to data protection and information security and implement appropriate changes.

Cybersecurity risks are evaluated when determining the selection and oversight of applicable third-party service providers and potential fourth-party risks when handling and/or processing our employee, business or vendor data. In addition to new vendor onboarding, we would perform risk management during potential third-party cybersecurity compromise incidents, should they occur, to identify and mitigate risks to us from third-party incidents.

Item 2. Description of Property.

Effective March 1, 2025, we entered into a new three-year lease at 3014 West Palmira Ave in Tampa, Florida.

Item 3. Legal Proceedings.

We are not currently subject to any material legal proceedings. However, we may from time to time become a party to various legal proceedings arising in the ordinary course of our business.

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.

Our common stock is listed for quotation on the OTCQB market under the symbol "INTI". The range of reported high and reported low sales prices per share for our common stock for each fiscal quarter during 2024 and 2023, as reported by the OTC Markets Group, is set forth below.

Quarterly common stock Price Ranges

Fiscal Year 2024, Quarter Ended:	**High**	**Low**
March 31, 2024	$ 0.12	$ 0.03
June 30, 2024	$ 0.13	$ 0.06
September 30, 2024	$ 0.10	$ 0.05
December 31, 2024	$ 0.10	$ 0.04

Fiscal Year 2023, Quarter Ended:	**High**	**Low**
March 31, 2023	$ 0.09	$ 0.06
June 30, 2023	$ 0.10	$ 0.02
September 30, 2023	$ 0.05	$ 0.02
December 31, 2023	$ 0.30	$ 0.04

Since our common stock is not listed on a national exchange, any over-the-counter market quotations shown above reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

As of the date of this Report, we had approximately 84 holders of record of our common stock. No cash dividends have been paid on the common stock to date. We currently intend to retain earnings for further business development and do not expect to pay cash dividends in the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information as of December 31, 2024 with respect to the shares of our common stock that may be issued under our existing equity compensation plan.

	Number of securities to be issued upon exercise of outstanding options, warrants and rights	**Weighted-average exercise price of outstanding options, warrants and rights**	**Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in the first column)**
Awards under equity compensation plans approved by security holders (1)	2,865,646	$ 0.09	8,134,354
Awards under equity compensation plans not approved by security holders	-	-	-
Total	2,865,646	$ 0.09	8,134,354

(1) The 2014 Equity Incentive Plan (the "EIP") was adopted by the Board of Directors and approved by a majority of our stockholders on September 30, 2014. The Board of Directors approved an increase to the number of shares available for issuance under the EIP of 11,000,000 shares which was subsequently approved by our majority shareholder in December 2018. As of December 31, 2024, there are 8,134,354 shares available for issuance under the EIP.

Item 6. Reserved.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes appearing elsewhere in this Report. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. The actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including, but not limited to, those which are not within our control.

Background of Our Company

We are a pharmaceutical development company that is focused on developing and ultimately commercializing innovative therapeutics based on already approved active pharmaceuticals that have patent-protected methods of use and/or methods of delivery for patients with certain cancers and certain non-cancerous proliferation disorders. We also have explored and expect to continue to explore acquiring or licensing other innovative pre-clinical and clinical stage therapeutics addressing unmet needs for the treatment of cancer and other diseases based on repurposing active ingredients of already approved drugs.

Our current primary focus is on the development of therapies initially for BCCNS, prostate and lung cancers in the United States utilizing itraconazole, a drug currently approved by the FDA to treat fungal infections, and which has an extensive history of safe and effective use in humans. We have developed intellectual property and know-how related to the treatment of cancer patients using itraconazole.

On December 12, 2023, we entered into an Exclusive License Agreement (the "Agreement") with Johns Hopkins University ("JHU"). Pursuant to the Agreement, JHU granted to our Company the exclusive worldwide patent rights to a Granted US Patent, No. 8,980,930 entitled "New Angiogenesis Inhibitors" (the "Patent"). The Patent relates to the treatment of prostate cancer, BCC including BCCNS, and lung cancer.

In May 2024, we formally requested a Type-B, pre-investigational new drug application ("pre-IND") meeting with the FDA to obtain feedback on the overall drug development and regulatory plan to use itraconazole for the treatment of BCC tumors in BCCNS patients, for which we have engaged the services of external experts in the field to assist with the process. Our Phase 2b clinical study (HP2001) uses a novel formulation of itraconazole, which we reference in our pre-IND submission.

The Company was granted a meeting in June 2024 with the Dermatology Division of the FDA, which we subsequently cancelled (with acknowledgement from the FDA), as we believed it required input from the FDA's Division of Oncology. Additionally, the FDA required further understanding of the right of use to the HP2001 study to further discuss some of the Pre-IND questions. The FDA has agreed to consult the Division of Oncology as necessary and we believe we have provided sufficient information around the right of use to proceed with our Pre-IND.

We have engaged Avior Bio, Inc. ("Avior"), which is currently creating a novel formulation of itraconazole from which results are expected in the next several months. Avior is a privately held drug development company whose President and Chairman of the Board, Niraj Vasisht, is a member of the Company's Board of Directors. Upon finalization of the formulation, Avior will conduct a pharmacokinetic (PK) crossover study of the generic formulation and the formulation that was used within the HP2001 study in preparation for a new IND and NDA. Given all formulations consist of the same active pharmaceutical ingredients (API), it is expected that the Company's new, novel formulation will have extremely similar properties to the formulation used in the HP2001 clinical study.

Critical Accounting Policies and Estimates

Estimates

The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Actual results could differ from those estimates.

Stock-Based Compensation

We account for stock-based awards to employees and non-employees using a fair value-based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. Fair values of restricted stock units issued are determined by the Company based predominantly on the trading price of the common stock on the date of grant. The fair value of each common stock option is estimated on the date of grant using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. Expected volatility is based on historical volatility of a peer group's common stock and other factors estimated over the expected term of the options. The expected term of the options granted is derived using the "simplified method" which computes the expected term as the average of the weighted-average vesting term and the contract term. The risk-free rate is based on the U.S. Treasury yield.

Results of Operations

For the Year Ended December 31, 2024 Compared to the Year Ended December 31, 2023

Research and Development Expenses. We incurred $1.7 million and $1.4 million in research and development expenses during the years ended December 31, 2024 and 2023, respectively. These expenses are primarily internal personnel costs, consisting of salaries, benefits and other related costs, as well as amounts paid to third parties to support the Company's research and development activities. The $0.3 million increase is primarily the result of an increase in internal personnel costs associated with the Company's R&D activities as a result of the relative significance of R&D activity and developments during the year ended December 31, 2024 compared to the year ended December 31, 2023.

General and Administrative Expenses. We incurred approximately $2.0 million in general and administrative expenses during each of the years ended December 31, 2024, and 2023. During the year ended December 31, 2024, general and administrative expenses were composed primarily of compensation costs of $1.1 million, professional services fees of $0.5 million and insurance costs of $0.4 million, which represented an increase of $0.2 million in compensation costs and a decrease of $0.2 million in insurance costs, year-over-year.

Interest income. We earned approximately $0.3 million and $0.4 million of interest income during the years ended December 31, 2024 and December 31, 2023, respectively. The interest income is generated from deposits held in our depository accounts and will continue to fluctuate consistent with the level of deposits held in our accounts.

Liquidity and Capital Resources

We are presently focused on our business plan for developing and ultimately commercializing innovative therapeutics based on already approved active pharmaceuticals that have patent-protected methods of use and/or methods of delivery. We expect to progress with the FDA to reach a conclusion on whether any additional clinical trials are required before submitting our New Drug Application (NDA). Our current cash on hand, approximately $5.6 million on December 31, 2024, is sufficient to continue to execute our business plan as currently anticipated, without another required clinical trial. Based on our current operational plan and budget, we expect that we will have sufficient cash to manage our business and continue to pursue the FDA process for the BCCNS product (without further clinical trials) and explore other drug development opportunities. Once we determine our requirements for the BCCNS NDA, we will assess capital requirements for additional opportunities, at which time we will consider raising additional capital in the public market.

Contractual Obligations and Commercial Commitments

In accordance with the Exclusive License Agreement (the "Agreement") with Johns Hopkins University ("JHU"), we are contractually obligated to make Minimum Annual Royalty ("MAR") payments to JHU, as defined within the Agreement. As of December 31, 2024, the remaining MAR payments owed are as follows: By January 1, 2025: $10,000; By January 1, 2026: $15,000; By January 1, 2027 and every year thereafter until the first commercial sale of an associated licensed product: $50,000.

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

We are a "smaller reporting company" as defined by Regulation S-K and as such, are not required to provide the information contained in this item pursuant to Regulation S-K.

Item 8. Financial Statements and Supplementary Data.

Our Financial Statements and Notes thereto and the report of Cherry Bekaert LLP, our independent registered public accounting firm (PCAOB ID 677), are set forth beginning on page F-1 of this Report.

Item 9. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Interim Chief Financial Officer, we carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, our Chief Executive Officer and our Interim Chief Financial Officer have concluded that, at December 31, 2024, such disclosure controls and procedures were effective.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted 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 in our reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Interim Chief Financial Officer, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

Limitations on the Effectiveness of Controls

Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Our Chief Executive Officer and Interim Chief Financial Officer have concluded that, based on their evaluation as of the end of the period covered by this Report, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

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.

Management's Report on Internal Control Over Financial Reporting

As required by the SEC rules and regulations for the implementation of Section 404 of the Sarbanes-Oxley Act, our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with U.S. GAAP. Our internal control over financial reporting includes those policies and procedures that:

(1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of our company,
(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors, and
(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

In the course of completing its assessment of internal control over financial reporting as of December 31, 2024, management did not identify any material weaknesses but does acknowledge a significant deficiency in the number of personnel available to serve the Company's accounting function, specifically management believes that we may not be able to adequately segregate responsibility over financial transaction processing and reporting. A significant deficiency is a deficiency, or a combination of deficiencies, in internal control over financial reporting, that is less severe than a material weakness yet important enough to merit attention by those responsible for oversight of the Company's financial reporting. Although we are unable to remediate the significant deficiency with current personnel, we are mitigating its potential impact, primarily through greater involvement of senior management in the review and monitoring of financial transaction processing and financial reporting.

Management assessed the effectiveness of our internal control over financial reporting at December 31, 2024. In making these assessments, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control — Integrated Framework*. Based on our assessments and those criteria, management determined that we maintained effective internal control over financial reporting at December 31, 2024.

Item 9B. Other Information.

None

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Our directors and executive officers and their ages as of the date of this Report are as follows:

Name	Age	Position
Francis E. O'Donnell	75	Executive Chairman of the Board and Chief Executive Officer
James A. McNulty	74	Interim Chief Financial Officer, Treasurer and Secretary
Samuel J. Sears	81	Director
Niraj Vasisht	61	Director
Michelle Yanez	53	Director
Michael Jerman	41	Director and Audit Committee Financial Expert
Ronald E. Osman	78	Director

There are no family relationships between any of our directors or executive officers.

To the best of our knowledge, during the past ten years, none of the following occurred with respect to a present director or executive officer of the Company: (1) any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time; (2) any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offenses); (3) being subject to any order, judgment or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his or her involvement in any type of business, securities or banking activities; (4) being found by a court of competent jurisdiction (in a civil action), the SEC or the Commodities Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended or vacated; (5) being subject of, or a party to, any Federal or State judicial or administrative order, judgment, decree or finding relating to an alleged violation of the federal or state securities, commodities, banking or insurance laws or regulations or any settlement thereof or involvement in mail or wire fraud in connection with any business entity not subsequently reversed, suspended or vacated and (6) being subject of, or a party to, any disciplinary sanctions or orders imposed by a stock, commodities or derivatives exchange or other self-regulatory organization.

Francis E. O'Donnell, Jr. M.D. is the founder of several specialty pharmaceutical companies. He is the founder of BioDelivery Sciences Int. Inc (BDSI: NASDAQ) and served in various leadership positions including President, CEO, Executive Chairman, and Chairman at the Company. BDSI was acquired by Collegium Pharmaceuticals in April 2022. He is also the founder of Repurposed Therapeutics, Inc (RPTI dba Defender Pharma). RPTI is a privately-held pharma company which has partnered with the Dept. of Defense and the National Aeronautical and Space Administration (NASA) to develop pharmaceuticals (such as intranasal scopolamine for the prevention of motion sickness) and chemical countermeasures to address unmet medical needs in operational personnel. Since September 2014, he has served as Executive Chairman. Dr. O'Donnell is also the founder of Inhibitor Therapeutics, Inc. (then called Hedgepath Pharmaceuticals, Inc. with OTCQB stock symbol HPPI) where he served as Executive Chairman until 2016. Dr. O'Donnell is a graduate of the Johns Hopkins university (BS) and the JHU School of Medicine (MD). He received his specialty training at the Wilmer Ophthalmologic Institute. He is the former Professor and Chairman of the Dept. of Ophthalmology, St. Louis University School of Medicine. He served on the Board of Trustees of St. Louis University for over 17 years. He is an inventor or co-inventor on over twenty patents, including patents assigned to the Company.

James A. McNulty, CPA, was CFO of Mira Pharmaceuticals, Inc. and Telomir Pharmaceuticals, Inc. prior to the respective initial public offerings of the companies in 2023 and 2024. Mr. McNulty was the CEO of MYMD Pharmaceuticals, Inc. until it became a public company in 2020. He serves on the Board of Directors of Renovaro Inc. (NASDAQ: RENB). After leaving public accounting in 1998 after a 26-year career in Tampa as founder of three CPA firms, he served as CFO in the biopharmaceutical industry including 15 years with BioDelivery Sciences International, Inc. (NASDAQ: BDSI). He served five years on the board as Lead Director/Audit Committee Chair of CV Sciences, Inc (OTC: CVSI). He has extensive experience in privately held companies, including five years as a Director of Quantum Technology Sciences, Inc. until its acquisition by a public company, and since 2000 as CFO of Hopkins Capital Group, an affiliation of limited liability companies which engage in venture activities primarily in the development of pharmaceuticals, including as CFO of Defender Pharmaceuticals, Inc. He is a partner in Perfect Golf Event, LLC, an online organizer of approximately 5,000 charity golf events annually. Mr. McNulty's career in accounting and consulting services includes expert testimony as a Certified Public Accountant, primarily in construction litigation and personal injury cases. He is a 1972 graduate of the University of South Florida.

Samuel J. Sears, Jr. has been a corporate attorney for over 40 years and is currently Of Counsel to the Boston law firm Cetrulo LLP, a position he has held since 2019; he was Managing Partner of that firm from 2006 through 2018. He was also Managing Partner of the Boston law firm Burns & Levinson from 1981 to 1993. Mr. Sears has extensive experience as a member of the Board of Directors of publicly owned corporations. He was a Director of Hedgepath Pharmaceuticals, Inc. (predecessor of the Company) and its predecessor, Commonwealth Biotechnologies, Inc. from 1998 to 2017, serving as Chairman of its Compensation Committee from 2012 to 2017. He has been a Director of six other publicly owned corporations, including, most recently, BioDelivery Sciences International, Inc. (Chairman of the Compensation Committee) from 2011 to 2017. Mr. Sears is a 1965 graduate of Harvard College and a 1968 graduate of Boston College Law School.

Niraj Vasisht, PhD, has been the Chairman of the Board, President and CEO of Avior Bio Inc. since March 2018. He has over thirty years of experience in the pharmaceutical industry. Under his leadership, he built Avior into a clinical-stage, a manufacturing-integrated pharmaceutical company that is developing a treatment for pruritus and skin inflammation for patients suffering from chronic liver and kidney diseases. Before Avior, Dr. Vasisht was the Chief Technology Officer at BioDelivery Sciences (BDSI). He spent 13 years in multiple roles and oversaw the development, approval, and manufacturing of Belbuca®, Bunavail®, and Onsolis® for the US and ROW market addition. Before BDSI, he was the Director at Southwest Research Institute', where he ran the pharmaceutical and nanomaterials business unit. At Southwest Research, he developed several drug delivery technologies and assisted the development of third-party commercial products, i.e., Citracal®, Meg-3®, and Probuphine®. Dr. Vasisht received a bachelor's degree in chemical engineering from the Indian Institute of Technology, India, and a Doctorate in Chemical Engineering from Rensselaer Polytechnic Institute. He has over 25 US patents and numerous publications and authored a book on Microencapsulation and Controlled Release.

Michelle Yanez, MBA, is a senior financial executive with over 25 years of experience in public and privately held biotech, pharmaceuticals, and life science companies. She currently serves as CFO of MIRA Pharmaceuticals, Inc. and Telomir Pharmaceuticals, Inc. (NASDAQ: MIRA/TELO). Ms. Yanez' experience includes a broad range of responsibilities in a highly complex and regulated market. She also brings deep corporate governance experience through her work with corporate boards, including audit and finance committees and is qualified to serve on audit committees as a financial expert. Ms. Yanez held various positions, including the Director of Financial Reporting, of BioDelivery Sciences International, Inc., (Nasdaq: BDSI). In her role, she led financial offerings, managed due diligence for product acquisitions and financings and managed finance documents and filings for the tender offer, leading to the acquisition of BDSI in April 2022 for over $600M. Ms. Yanez is also Co-Founder and Chief Financial Officer of Santander Pharma Consulting, a privately held life sciences consulting firm that provides business development and commercial strategy services to pharmaceutical, medical device, and life science companies offering guidance throughout all stages of commercial development, from inception to product launch, since February 2024. Ms. Yanez is a member of the Institute of Management Accountants and a member of the SEC Professionals Group. Ms. Yanez received her MBA from Rutgers School of Business, *Cum Laude*.

Michael Jerman, CPA, has previously been a chief financial officer of multiple private equity-backed companies in the energy, Software as a Service (SaaS), and manufacturing industries, was a Captain with the United States Air Force and was a Director with PricewaterhouseCoopers (PwC) in the US and UK. He was a member of the PwC national office within the SEC PCAOB quality group supporting Europe and the EMEA regions with complex accounting and audit consultations. He has significant experience in a wide variety of technical accounting and finance matters as well as stakeholder management. He specialized in rapid project mobilization and deployment of skilled resources for emergency issues, design, and implementation of small to large scale assurance requirements and advisory projects. The Company believes Mr. Jerman is qualified to serve on the Board and as a qualified financial expert on the Company's Audit Committee due to his substantial experience with the SEC PCAOB quality group at PwC and his experience assisting public reporting companies with their annual and quarterly requirements.

Ronald E. Osman is the founder of Ronald E. Osman & Associates, Ltd. He has been a licensed attorney for over 40 years, representing clients in a variety of issues before both state and federal courts. His practice has concentrated on complex civil litigation, including actions brought under the Federal False Claims Act which resulted in recovery of over $500 million for Medicare, Medicaid, and other federal health insurance programs. He has provided expert testimony to the United States Senate and numerous federal courts regarding the Federal False Claims Act and has been actively involved in drafting and modifying both federal and state legislation, including the Federal False Claims Act, Liability Standards for Medicare Contractors, and the Illinois Hydraulic Fracturing Regulatory Act. In addition to his law practice, Mr. Osman is Chairman of the Board of Cell Culture, Inc. (C3), one of the founders of Rural Health, Inc., a not-for-profit Illinois corporation that provides medical services to patients in southern Illinois counties, and he supports the efforts of several charitable not-for-profits in Missouri and Illinois. He has been involved in efforts with the United States Department of Health and Human Services and Federal Drug Administration related to standards for use in testing and approving cancer treatment methods. Prior to becoming an attorney, Mr. Osman served in the United States Marine Corp, where he was a Commanding Officer of Artillery Battery and Headquarters Company and received an Officer of the Deck qualification from the U.S. Navy.

Board Committees and Director Independence

Director Independence

Of our current directors, we have determined that Samuel J. Sears, Jr., Niraj Vasisht, Michelle Yanez and Michael Jerman are "independent" as defined by NASDAQ Stock Market rules. Accordingly, a majority of our Board of Directors is "independent."

Board Committees

Our Board of Directors has established four standing committees – Audit, Nominating and Corporate Governance, Compensation and a Scientific Advisory Board. All standing committees operate under a charter that has been approved by our Board of Directors.

Audit Committee

Our Board of Directors has an Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act, composed of Samuel J. Sears, Jr., Niraj Vasisht, Michelle Yanez and Michael Jerman. All members are independent directors as defined in accordance with Rule 10A-3 of the Exchange Act and the rules of the NASDAQ Stock Market. Mr. Jerman serves as chairman of the committee. The Board of Directors has determined that Mr. Jerman is an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K.

Our Audit Committee oversees our corporate accounting, financial reporting practices and the audits of financial statements. For this purpose, the Audit Committee has a charter (which is reviewed annually) and performs several functions. The Audit Committee:

- evaluates the independence and performance of, and assesses the qualifications of, our independent auditor and engages such independent registered public accounting firm;
- approves the plan and fees for the annual audit, quarterly reviews, tax and other audit-related services and approves in advance any non-audit service and fees to be provided by the independent registered public accounting firm;
- monitors the independence of the independent registered public accounting firm and the rotation of partners of the independent auditor on our engagement team as required by applicable regulations;
- reviews the financial statements to be included in our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q and reviews with management and the independent registered public accounting firm the results of the annual audit and reviews of our quarterly financial statements; and
- provides oversight assistance in connection with legal, ethical and risk management compliance programs established by management and the board, including compliance with requirements of Sarbanes-Oxley and makes recommendations to the Board of Directors regarding corporate governance issues and policy decisions.

Nominating and Corporate Governance Committee

Our Board of Directors has a Nominating and Corporate Governance Committee composed of Samuel J. Sears, Jr., Niraj Vasisht, Ph.D., and Michelle Yanez. Dr. Vasisht serves as the chairman of the committee. The Nominating and Corporate Governance Committee is charged with the responsibility of reviewing our corporate governance policies and with proposing potential director nominees to the Board of Directors for consideration. The Nominating and Corporate Governance Committee has a charter which is reviewed annually. All members are independent directors in accordance with the rules of the NASDAQ Stock Market. The Nominating and Corporate Governance Committee will consider director nominees recommended by security holders.

Compensation Committee

Our Board of Directors also has a Compensation Committee, which reviews or recommends the compensation arrangements for our management and employees and assists the Board of Directors in reviewing and approving matters such as company benefit and insurance plans, including monitoring the performance thereof. The Compensation Committee has a charter (which is reviewed annually) and is composed of three members: Samuel J. Sears, Jr., Niraj Vasisht, Ph.D., and Michelle Yanez. Mr. Sears serves as chairman of this committee. All members are independent in accordance with rules of the NASDAQ Stock Market.

Scientific Advisory Board

On October 13, 2023, the Board of Directors created a Scientific Advisory Board ("SAB") to provide input and advice to the Company's management and to the Board on various aspects of the Company's clinical development activities and strategies. The duties of the SAB will include but are not limited to advising the Board regarding endorsement to current and planned research and development programs, validating timelines, budget and key milestones; advising the Board about the progress on the approved research and development activities; advising the Board regarding the scientific merit of compounds for licensing and acquisition opportunities; providing strategic advice regarding emerging science, therapeutic trends and foreseeable opportunities; and providing advice to the Company's scientific team on aspects of the programs as requested.

The Board has entered into a form of consulting agreement with Dr. Elizabeth Billingsley for provision of consulting services related to the Company's clinical development activities. The Board has appointed Dr. Billingsley as the initial member and Chairperson of the SAB, to be compensated for her time and efforts on behalf of the Company's SAB pursuant to the terms of the consulting agreement.

Dr. Elizabeth M. Billingsley, MD, is a Professor of Dermatology with Penn State Health Hershey Medical Center, and Penn State College of Medicine. She received her undergraduate degree from Cornell University and her medical degree from Penn State University College of Medicine. She is a Mohs micrographic surgeon with more than 30 years' experience in Mohs Surgery and skin cancer management. She also has performed numerous clinical trials related to skin cancer. Dr Billingsley is a past president of the American College of Mohs Surgery. She is affiliated with the Gorlin Syndrome Alliance and is a member of their Medical and Scientific Advisory Committee.

Dr. Marc D. Brown, MD, completed a dermatology residency at the University of Michigan in 1987. Following this came a two-year fellowship training for Mohs Surgery and Cutaneous Oncology. He joined the faculty at the University of Rochester Medical Center in 1989 and is a tenured professor of Dermatology and Oncology and is a member of the Wilmot Cancer Center. He served as the director of the Dermatology Residency Program and the Mohs Surgery Fellowship Program at the Rochester Medical Center. He has been included in the Best Doctors in America directory and has published a lengthy list of literature. Dr. Brown performs Mohs surgery on over 2,000 patients per year and has performed a total of more than 50,000 Mohs procedures.

Dr. Allison Vidimos, RPH, MD, was appointed Chairman of the Department of Dermatology at Cleveland Clinic 2005 and Vice Chairman of the Dermatology and Plastic Surgery Institute in 2006. She was appointed Professor of Dermatology, Cleveland Clinic Lerner College of Medicine, Case Western Reserve University in 2011. She became the program director of the Micrographic Surgery and Dermatologic Oncology fellowship in 2013. She was a member of the Scientific Assembly Committee and Membership Committee for the American Academy of Dermatology (AAD) 2012-17. She was elected to the Board of Directors of the AAD in 2022. She served as President of the American College of Mohs Surgery (ACMS) in 2017-2018. Dr. Vidimos received the Frederic Mohs Lifetime Achievement Award in 2021. She was appointed to the Board of Directors for the American Board of Dermatology for 2019-2027 and is a member and Chairman of the board question writing committee for dermatologic surgery. She was elected to the Board of Directors of the Ohio Dermatological Association (ODA) in 2019-21 and is President of ODA 2022-23. Her clinical practice and research encompass skin cancer prevention, diagnosis and treatment, and patient safety.

Dr. Sean R. Christensen, MD, PhD, is an Associate Professor of Dermatology; Director of Resident Education in Dermatologic Surgery; Director of Dermatologic Surgery at Yale Dermatology-Branford. Dr. Christensen has been practicing dermatologic surgery since completing training in 2013. His surgical specialization includes Mohs surgery, treatment of early-stage melanoma, and surgical reconstruction. Additionally, Dr. Christensen focuses on complex skin cancer issues such as field characterization, preventative strategies in high-risk patients and management of advanced or aggressive skin cancer. Dr. Christensen has published extensively on skin cancer pathogenesis and treatment and has experience in clinical trials for basal cell carcinoma. He is a frequent lecturer at national meetings for organizations such as the American Academy of Dermatology and the American College of Mohs surgery and currently serves as the Treasurer for the International Transplant Skin Cancer Collaborative.

Dr. Iam Maher, MD, is a Professor of Dermatology and Director of Dermatologic Surgery at University of Minnesota. He is board certified in Mohs surgery, specializing in the treatment of a broad range of common and rare skin cancers as well as post-skin cancer reconstruction. Dr. Maher has served on the Boards of multiple national Dermatologic organizations. He has published over 100 peer-reviewed articles.

Board Meetings and Attendance

The Board of Directors held five meetings in 2024. The Audit and Compensation Committees met four times in 2024. The Nominating and Corporate Governance Committee had no meetings in 2024. The Scientific Advisory Board convened once for a formal meeting in 2024. All directors attended the meetings of the Board for the periods in which they were directors.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires that our directors and executive officers and persons who beneficially own more than 10% of our common stock (referred to herein as the "reporting persons") file with the SEC various reports as to their ownership of and activities relating to our common stock. Such reporting persons are required by the SEC regulations to furnish us with copies of all Section 16(a) reports they file.

Based solely upon a review of copies of Section 16(a) reports and representations received by us from reporting persons, and without conducting any independent investigation of our own, in fiscal year 2024, all Forms 3, 4 and 5 were timely filed with the SEC by such reporting persons.

Code of Ethics

We have adopted a formal code of ethics that applies to our directors and principal executives and financial officers or persons performing similar functions. A copy of our Code of Ethical Conduct can be found on our website under "Investors" at http://www.inhibitortx.com/.

Item 11. Executive Compensation.

The following table sets forth all compensation paid to our named executive officers at the end of the fiscal years ended December 31, 2024 and 2023. Individuals we refer to as our "named executive officers" include our Executive Chairman and Chief Executive Officer and our Interim Chief Financial Officer, Secretary and Treasurer.

Name and principal position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non- Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($) [1]	Total ($)
Francis E. O'Donnell Executive Chairman and Chief Executive Officer	2024	598,000	506,598	3,500	-	-	-	29,788 [2]	1,137,886
	2023	598,000	461,042	-	-	-	-	30,295 [2]	1,089,337
James A. McNulty Interim Chief Financial Officer, Secretary and Treasurer	2024	200,000	138,487	-	6,700	-	-	14,569	359,756
	2023	200,000	128,500	-	-	-	-	9,458	337,958

(1) Amounts include medical reimbursements and health insurance premiums paid.
(2) Amounts also include compensation received for serving as Chairman of the Board

Narrative Disclosure to Summary Compensation Table

Employment Agreements

Except as set forth below, we currently have no written employment agreements with any of our officers, directors, or key employees.

Francis E. O'Donnell, Executive Chairman and Chief Executive Officer

On December 13, 2022, pursuant to Dr. O'Donnell's appointment as Executive Chairman of the Board and Chief Executive Officer, the Company entered into an employment agreement with Dr. O'Donnell (the "FEO Employment Agreement"). In addition to his duties as a director and officer of the Company, Dr. O'Donnell's duties include clinical development, corporate development, intellectual property, and licensing. The FEO Employment Agreement is not for a definite time period, but rather, will continue until terminated in accordance with its terms. Pursuant to the FEO Employment Agreement, Dr. O'Donnell will earn $598,000 per year. Dr. O'Donnell is entitled to a sign-on bonus for his services related to the change of control of the Company. In addition, Dr. O'Donnell is eligible to receive a discretionary annual bonus based on his achievement of performance objectives as mutually agreed between Dr. O'Donnell and the Board. The FEO Employment Agreement further provides that Dr. O'Donnell is entitled to participate in any employee benefit plans that the Company has adopted or may adopt. Dr. O'Donnell did not receive any equity compensation in connection with his appointment as Executive Chairman and CEO of the Company.

The FEO Employment Agreement is terminable for "Cause" (as defined in the FEO Employment Agreement) or without "Cause" by the Company, and for "Good Reason" (as defined in the FEO Employment Agreement) or voluntarily by Dr. O'Donnell. In the event of Dr. O'Donnell death or disability, or termination for "Cause" by the Company or without "Good Reason" by Dr. O'Donnell, Dr. O'Donnell (or his estate) is entitled to receive any unpaid base salary through the termination date, reimbursement for unreimbursed business expenses, accrued but unused vacation time in accordance with the Company's policy and any other payments or benefits that Dr. O'Donnell as entitled to in accordance with any Company benefit plans (collectively, the "Accrued Benefits"). Upon termination without "Cause" (other than by reason of death or disability) or resignation for "Good Reason," Dr. O'Donnell will be entitled to receive an amount equal to two times the sum of his annual base salary and target annual bonus, in addition to all Accrued Benefits. Any outstanding unvested securities owned by Dr. O'Donnell on the termination date will vest (or terminate) in accordance with the terms of such grant.

James A. McNulty, Interim Chief Financial Officer, Treasurer and Secretary

On December 13, 2022, pursuant to Mr. McNulty's appointment as Interim Chief Financial Officer and Treasurer, the Company entered into an employment agreement with Mr. McNulty (the "JAM Employment Agreement"). The JAM Employment Agreement is not for a definite time period, but rather, will continue until it is terminated in accordance with its terms. Pursuant to the JAM Employment Agreement, Mr. McNulty will earn $200,000 per year. Mr. McNulty is entitled to a sign-on bonus for his services related to the change of control of the Company. In addition, Mr. McNulty is eligible to receive a discretionary annual bonus based on his achievement of performance objectives as mutually agreed between Mr. McNulty and the Board. The JAM Employment Agreement further provides that Mr. McNulty is entitled to receive a long-term incentive bonus and participate in any employee benefit plans that the Company has adopted or may adopt. Mr. McNulty received a grant of stock options in 2024, exercisable for 100,000 shares of common stock.

The JAM Employment Agreement is terminable for any or no particular reason or cause, In the event of termination of the JAM Employment Agreement by either party, Mr. McNulty (or his estate) is entitled to receive any unpaid base salary through the termination date, reimbursement for unreimbursed business expenses, accrued but unused vacation time in accordance with the Company's policy and any other payments or benefits that Mr. McNulty as entitled to in accordance with any Company benefit plans. Any outstanding unvested securities owned by Mr. McNulty on the termination date will vest (or terminate) in accordance with the terms of such grant.

Outstanding equity awards

The following table summarizes outstanding unexercised options held by each of our named executive officers and directors, as of December 31, 2024. There were no outstanding unvested stock or equity incentive plan awards held by our named executive officers, as of December 31, 2024.

	OPTION AWARDS					STOCK AWARDS			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Options Exercise Prices ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Been Issued (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Been Issued ($)
Samuel J. Sears Jr.	150,000	—	—	$ 0.24	July 1, 2026	—	—	—	—
James A. McNulty	150,000	—	—	$ 0.24	July 1, 2026	—	—	—	—
	100,000	—	—	$ 0.08	March 15, 2034	—	—	—	—

2014 Equity Incentive Plan

In July 2014, our Board of Directors adopted our EIP. On September 30, 2014, the EIP was approved by the majority of stockholders pending delivery of required notice to all Company stockholders. On December 31, 2018, the EIP was comprised of 32,583,475 shares. In December 2018, the Board of Directors approved an increase to the number of shares available for issuance under the EIP of 11,000,000 shares which was subsequently approved by our majority shareholder in December 2018, resulting in a total of 43,583,475 shares available for issuance under the EIP (ranking pari passu with our issued and outstanding common stock) to be available in the form of incentive stock options, non-qualified stock options, restricted stock, restricted stock units, performance awards and other customary equity incentives.

The purpose of our EIP is to attract and retain directors, officers, consultants, advisors, and employees whose services are considered valuable, to encourage a sense of proprietorship and to stimulate an active interest of such persons in our development and financial achievements. The EIP is administered by the Compensation Committee of our Board of Directors or by the full Board of Directors, which may determine, among other things, (a) the persons who are to receive awards, (b) the type or types of awards to be granted to such persons, (c) the number of shares of common stock to be covered by, or with respect to which payments, rights, or other matters are to be calculated in connection with the awards, (d) the terms and conditions of any awards, (e) whether, to what extent, and under what circumstances awards may be settled or exercised in cash, shares of common stock, other securities, other awards or other property, or cancelled, forfeited, or suspended and the method or methods by which awards may be settled, exercised, cancelled, forfeited, or suspended, (f) whether, to what extent, and under what circumstances the delivery of cash, shares of common stock, other securities, other awards or other property and other amounts payable with respect to an award, (g) interpret, administer, reconcile any inconsistency in, settle any controversy regarding, correct any defect in and/or complete any omission in the EIP and any instrument or agreement relating to, or award granted under, the EIP, (h) establish, amend, suspend, or waive any rules and regulations and appoint such agents as the Compensation Committee deems appropriate for the proper administration of the EIP, (i) accelerate the vesting or exercisability of, payment for or lapse of restrictions on, awards and (j) make any other determination and take any other action that the compensation committee deems necessary or desirable for the administration of the EIP.

The EIP provides that in the event of a change of control event, (i) all of the then outstanding options and stock appreciation rights granted pursuant to the EIP will immediately vest and become immediately exercisable as of a time prior to the change in control, (ii) any performance goal restrictions related to an award will expire as of a time prior to the change in control and (iii) any performance periods that relating to an award which have not yet expired on the date the change in control occurs will end on such date, and the compensation committee will (a) determine the extent to which performance goals with respect to each such performance period have been met based upon such audited or unaudited financial information or other information then available as it deems relevant and (b) cause the relevant participant to receive partial or full payment of awards for each such performance period based upon the compensation committee's determination of the degree of attainment of the performance goals, or assuming that the applicable "target" levels of performance have been attained or on such other basis determined by the compensation committee.

In addition, subject to our Equity Holders Agreement, our Board of Directors may amend our EIP at any time. However, without stockholder approval, our EIP may not be amended in a manner that would:

- increase the number of shares that may be issued under our EIP;
- materially modify the requirements for eligibility for participation in our EIP;
- materially increase the benefits to participants provided by our EIP; or
- otherwise disqualify our EIP for coverage under Rule 16b-3 promulgated under the Exchange Act.

Awards previously granted under our EIP may not be impaired or affected by any amendment of our EIP, without the consent of the affected grantees.

Option Exercises and Stock Vested

There were no options exercised by the executive officers during the years ended December 31, 2024 or 2023.

Pension Benefits

None of our employees participate in or have account balances in qualified or non-qualified defined benefit plans sponsored by us. Our Compensation Committee may elect to adopt qualified or non-qualified benefit plans in the future if it determines that doing so is in our company's best interest.

Non-qualified Deferred Compensation

None of our employees participate in or have account balances in non-qualified defined contribution plans or other non-qualified deferred compensation plans maintained by us. Our Compensation Committee may elect to provide our officers and other employees with non-qualified defined contribution or other non-qualified compensation benefits in the future if it determines that doing so is in our company's best interest.

Compensation of Directors

The following table sets forth all compensation paid to our Board members during the year ended December 31, 2024:

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Change in Pension Value and Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Samuel J. Sears Jr. [1]	$ 20,000	$ 3,500	—	—	—	—	$ 23,500
Niraj Vasisht [1]	$ 20,000	$ 3,500	—	—	—	—	$ 23,500
Michelle Yanez [2]	$ 20,000	$ 3,500	—	—	—	—	$ 23,500
Michael Jerman [3]	$ 20,000	$ 3,500	—	—	—	—	$ 23,500
Ronald E. Osman [4]	$ 20,000	$ 3,500	—	—	—	—	$ 23,500

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

The following table sets forth, as of the date of this Report, the ownership of our securities by: (i) each of our directors, (ii) all persons who, to our knowledge, are the beneficial owners of more than 5% of the outstanding shares of common stock, (iii) each of the executive officers, and (iv) all of our directors and executive officers, as a group. Each person named in this table has sole investment power and sole voting power with respect to the shares of common stock set forth opposite such person's name, except as otherwise indicated.

Name and address of beneficial owners[1]	Amount and nature of beneficial ownership of Common Stock	Approximate percentage of outstanding common stock[2]
Named Executive Officers and Directors		
Francis O'Donnell	100,000	*
James McNulty [3]	25,297,192	14%
Samuel J. Sears, Jr. [4]	1,279,543	*
Michelle Yanez	1,121,271	*
Niraj Vasisht	100,000	*
Michael Jerman	80,411	*
Ronald E. Osman [5]	23,564,985	14%
All directors and executive officers as a group (7 persons)	51,543,402	29%
5% Stockholders		
TPB 2012 LLC [6]	27,917,250	16%
MOAB Investments LP [6]	10,555,000	6%
Nicholas Virca [7]	8,727,519	5%

* Less than 1%

(1) The address of each holder listed below, except as otherwise indicated, is 3014 West Palmira Ave., Suite 302, Tampa, FL 33629.

(2) Applicable percentages are based on 172,323,545 common shares outstanding, and 2,865,646 shares to be issued upon the exercise of vested outstanding options, as of the date of this filing. This table is based upon information supplied by officers, directors, and principal stockholders and Schedule 13D(s) and Schedule 13G(s) filed with the SEC. Unless indicated in the footnotes to this table and subject to community property laws where applicable, we believe that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned.

(3) Includes 20,101,057 shares of common stock held by Black Robe Capital LLC, 3,000,000 shares of common stock held by Hopkins Capital Group II, LLC, 1,946,135 shares owned personally, as well as 250,000 shares to be issued upon the exercise of vested stock options. Our Interim Chief Financial Officer, Treasurer and Secretary, James A. McNulty, has sole voting and dispositive power over the securities held by Black Robe Capital LLC and Hopkins Capital Group II, LLC. Mr. McNulty disclaims beneficial ownership of the shares held by Black Robe Capital LLC and Hopkins Capital Group II, LLC, in which he does not have a pecuniary interest.

(4) Includes 150,000 shares to be issued upon the exercise of vested stock options.

(5) Includes 23,489,985 shares of common stock held by Ronald E. Osman Irrevocable Trust III.

(6) Jim Donovan is the Manager of TPB 2012 LLC and MOAB Investments LP, with sole voting and dispositive powers over the subject securities. Mr. Donovan disclaims beneficial ownership of the shares held by TPB 2012 LLC and MOAB Investments LP. The address of TPB 2012 LLC and MOAB Investments LP is 12412 Powerscourt Drive, Suite 35, Saint Louis, MO, 63131.

(7) Nicholas Virca is the former Chief Executive Officer and President of the Company. Mr. Virca's address is 449 South 12th Street, Unit 1705 Tampa, FL 33602.

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

Pursuant to the Settlement Agreement, which was effective December 13, 2022, Mayne Pharma surrendered all equity securities in the Company for cancellation, forgave certain debts owed by the Company and cancelled, converted or terminated all previous agreements between the Company and Mayne Pharma. Accordingly, as of December 31, 2024 and the date of this report, Mayne Pharma is no longer deemed a related party of the Company and none of the previously disclosed agreements with Mayne Pharma, which were required to be included in this Item 13, are in effect as of the date of this report.

The Company has engaged Avior Bio, Inc. ("Avior"), which is currently creating a novel formulation of itraconazole. Avior is a privately held drug development company whose President and Chairman of the Board, Niraj Vasisht, is a member of the Company's Board of Directors. Upon finalization of the formulation, Avior will conduct a pharmacokinetic (PK) crossover study to the generic formulation and the formulation that was used within the HP2001 study in preparation for a new IND and NDA. Given all formulations consist of the same active pharmaceutical ingredients (API), it is expected that the Company's new, novel formulation will have extremely similar properties to the formulation used in the HP2001 clinical study. The Company's independent directors of the Board, excluding Niraj Vasisht, approved the engagement of Avior.

See "Item 10. *Directors, Executive Officers and Corporate Governance*" regarding the FEO Employment Agreement and JAM Employment Agreement.

All transactions between us and our officers, directors or five percent stockholders, and respective affiliates will be on terms no less favorable than could be obtained from unaffiliated third parties and will be approved by a majority of our independent directors who do not have an interest in the transactions and who had access, at our expense, to our independent legal counsel. The Board has determined that Samuel J. Sears, Jr. Niraj Vasisht, Michelle Yanez and Michael Jerman are independent directors as defined under Regulation S-K.

Item 14. Principal Accountant Fees and Services.

Audit Fees. The aggregate fees billed by Cherry Bekaert LLP for professional services rendered for the audit of our annual financial statements, review of the financial information included in our Forms 10-Q for the respective periods and other required filings with the SEC for the years ended December 31, 2024 and 2023 totalled $84,200 and $68,250, respectively.

Audit-Related Fees. There were no aggregate fees billed by Cherry Bekaert LLP for professional services for the years ended December 31, 2024 and December 31, 2023.

Tax Fees. The aggregate fees billed by Cherry Bekaert LLP for professional services rendered for tax compliance, for the years ended December 31, 2024 and 2023 totalled $2,095 and $13,902, respectively.

All Other Fees. None.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

The following exhibits are filed with this Report.

Exhibit No.	Description
3.1	Certificate of Incorporation of the Company, dated July 30, 2013 as filed on 8-K on August 16, 2013
3.2	Certificate of Amendment to the Company's Certificate of Incorporation, dated May 19, 2016, as filed with Form 8-K, dated May 26, 2016
3.3	Certificate of Amendment to the Company's Certificate of Incorporation, dated July 13, 2015, as filed with Form S-1/A on July 22, 2015
3.4	Second Amended and Restated Bylaws of the Company, adopted July 12, 2023, as filed with Form 8-K, dated August 29, 2023
3.5	Amended and Restated Certificate of Designation of Series B Preferred Stock of the Company, dated February 1, 2019, filed with Definitive Information Statement, filed on January 8, 2019
3.6	Certificate of Amendment to the Company's Certificate of Incorporation, dated August 20, 2019, as filed with Form 8-K dated August 20, 2019
3.7	Charter of the Scientific Advisory Board, dated October 13, 2023, filed with Form 8-K dated October 13, 2023
4.1	Warrant, dated June 24, 2014 issued to Hedgepath, LLC, as filed with Form 8-K, dated June 30, 2014
10.1+	Master Clinical Services Agreement, dated June 15, 2015, by and between the Company and SciQuus, Inc., as filed with Form 10-Q on August 14, 2015
10.2	Stipulation and Agreement of Compromise, Settlement, and Release, dated September 9, 2022, as filed with Form 8-K, dated December 19, 2022
10.3	License Agreement by and between the Company and Mayne Pharma, dated December 13, 2022, as filed with Form 8-K, dated December 19, 2022
10.4	Employment Agreement by and between the Company and Francis E. O'Donnell, dated December 13, 2022, as filed with Form 8-K, dated December 19, 2022
10.5	Employment Agreement by and between the Company and James A. McNulty, dated December 13, 2022, as filed with Form 8-K, dated December 19, 2022
10.6	License Agreement by and between the Company and Johns Hopkins University, Dated December 12, 2023 (Portions of this exhibit have been redacted pursuant to a request for confidential treatment.), as filed with Form 10-K, dated March 29, 2024
14	Code of Ethical Conduct, as filed with Form 10-K on February 13, 2015
23.1*	Consent of Cherry Bekaert LLP
31.1*	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

Exhibit No.	Description
31.2*	Certification of the Interim Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*#	Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*#	Certification of the Interim Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.ins	Inline XBRL Instance Document
101.sch	Inline XBRL Taxonomy Extension Schema Document
101.cal	Inline XBRL Taxonomy Calculation Linkbase Document
101.def	Inline XBRL Taxonomy Definition Linkbase Document
101.lab	Inline XBRL Taxonomy Label Linkbase Document
101.pre	Inline XRL Taxonomy Presentation Linkbase Document

* Filed herewith

\+ Confidential treatment has been granted for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2.

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

Item 16. Form 10-K Summary.

We have elected not to include a summary pursuant to this Item 16.

INHIBITOR THERAPEUTICS, INC.
INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Inhibitor Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Inhibitor Therapeutics, Inc. (the "Company") as of December 31, 2024, and 2023, and the related statements of operations, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the 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 then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there were no critical audit matters.

/s/ Cherry Bekaert LLP

We have served as the Company's auditors since 2013.

Tampa, Florida
March 28, 2025

INHIBITOR THERAPEUTICS, INC.
BALANCE SHEETS
DECEMBER 31, 2024 AND 2023

	December 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,606,863	$ 8,839,912
Prepaid expenses and other assets	87,795	109,243
Total current assets	5,694,658	8,949,155
Total assets	$ 5,694,658	8,949,155
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 15,896	33,731
Accrued expenses and other liabilities	693,722	631,433
Total current liabilities	709,618	665,164
Deferred revenue	3,000,000	3,000,000
Total liabilities	3,709,618	3,665,164
Commitments and contingencies (Note 7)	-	-
Stockholders' equity:		
Series A Preferred Stock, $0.0001 par value; 500,000 shares authorized; no shares issued and outstanding at December 31, 2024 and December 31, 2023	-	-
Series B Convertible Preferred Stock, $ 0.0001 par value; 7,246,377 shares authorized; no shares issued and outstanding at December 31, 2024 and December 31, 2023	-	-
Undesignated Preferred Stock, $0.0001 par value; 2,253,623 shares authorized; no shares issued or outstanding at December 31, 2024 and December 31, 2023	-	-
Common stock, $0.0001 par value; 500,000,000 shares authorized; 172,323,545 and 172,023,545 shares issued and outstanding at December 31, 2024 and December 31, 2023	17,232	17,202
Additional paid-in capital	54,087,065	54,046,845
Accumulated deficit	(52,119,257)	(48,780,056)
Total stockholders' equity	1,985,040	5,283,991
Total liabilities and stockholders' equity	$ 5,694,658	$ 8,949,155

See notes to financial statements

INHIBITOR THERAPEUTICS, INC.
STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31, 2024 AND 2023

	Year Ended December 31,	
	2024	**2023**
Revenues:	$ -	$ -
Expenses:		
Research and development	1,682,550	1,381,066
General and administrative	1,974,859	2,023,913
Total expenses	3,657,409	3,404,979
Loss from operations	(3,657,409)	(3,404,979)
Other income:		
Interest income	318,208	378,844
Net loss	$ (3,339,201)	(3,026,135)
Basic and diluted net loss per share	$ (0.02)	$ (0.02)
Weighted average common shares outstanding – basic and diluted	172,262,889	171,950,108

See notes to financial statements

INHIBITOR THERAPEUTICS, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED DECEMBER 31, 2024 AND 2023

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances, January 1, 2023	**171,793,134**	**$ 17,179**	**$ 54,033,084**	**$ (45,753,921)**	**$ 8,296,342**
Issuance of common stock under equity incentive plan	230,411	23	13,761	—	13,784
Net loss				(3,026,135)	(3,026,135)
Balances, December 31, 2023	**172,023,545**	**$ 17,202**	**$ 54,046,845**	**$ (48,780,056)**	**$ 5,283,991**
Issuance of common stock under equity incentive plan	300,000	30	20,970	—	21,000
Stock-based compensation	—	—	19,250	—	19,250
Net loss	—	—	—	(3,339,201)	(3,339,201)
Balances, December 31, 2024	172,323,545	$ 17,232	$ 54,087,065	$ (52,119,257)	$ 1,985,040

See notes to financial statements

INHIBITOR THERAPEUTICS, INC.
STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2024 AND 2023

	Year Ended December 31,	
	2024	**2023**
OPERATING ACTIVITIES		
Net loss	$ (3,339,201)	$ (3,026,135)
Adjustments to reconcile net loss to net cash flows used in operating activities		
Stock based compensation	40,250	13,784
Changes in assets and liabilities:		
Prepaid expense and other assets	21,448	(85,343)
Accounts payable and other current liabilities	44,454	397,382
Net cash used in operating activities	(3,233,049)	(2,700,312)
FINANCING ACTIVITIES		
Payments made on notes payable	—	(411,000)
Net cash used in financing activities	—	(411,000)
Net decrease in cash and cash equivalents	(3,233,049)	(3,111,312)
Cash and cash equivalents at beginning of year	8,839,912	11,951,224
Cash and cash equivalents at end of year	$ 5,606,863	$ 8,839,912
Supplemental disclosures of cash flow information:		
Cash paid for taxes	$ —	$ 53,088

See notes to financial statements

1. Corporate Overview

Overview

The accompanying audited financial statements of Inhibitor Therapeutics, Inc., a Delaware corporation (the "Company", "INTI", "we", "us" or similar terminology) have been prepared by the Company as a going concern, and in accordance with accounting principles generally accepted in the United States of America ("GAAP"). As used herein, the term "common stock" means the Company's common stock, $0.0001 par value per share.

Nature of the Business

The Company is a pharmaceutical development company focused on developing and ultimately commercializing innovative therapeutics based on already approved active pharmaceuticals that have patent-protected methods of use and/or methods of delivery for patients with certain cancers and certain non-cancerous proliferation disorders. The Company has also explored and expect to continue to explore acquiring or licensing other innovative pre-clinical and clinical stage therapeutics addressing unmet needs for the treatment of cancer and other diseases based on repurposing active ingredients of already approved drugs.

The Company's primary focus is on the development of therapies initially for basal cell carcinoma ("BCC"), prostate and lung cancers in the United States utilizing itraconazole, a drug currently approved by the FDA to treat fungal infections, and which has an extensive history of safe and effective use in humans. The Company has developed intellectual property and know-how related to the treatment of cancer patients using itraconazole. In particular, on December 12, 2023, the Company entered into an Exclusive License Agreement (the "Agreement") with Johns Hopkins University ("JHU"). Pursuant to the Agreement, JHU granted to the Company the exclusive worldwide patent rights to a Granted US Patent, No. 8,980,930 entitled "New Angiogenesis Inhibitors" (the "Patent"). The Patent relates to the treatment of prostate cancer, BCC including basal cell carcinoma nevus syndrome ("BCCNS"), and lung cancer.

2. Liquidity and Management's Plans

The Company is presently focused on its business plan for developing and ultimately commercializing innovative therapeutics based on already approved active pharmaceuticals that have patent-protected methods of use and/or methods of delivery. The Company expects to progress with the FDA in 2025 with a new formulation of itraconazole (the API: Active Pharmaceutical Ingredient) developed with Avior Bio, Inc. ("Avior"), coupled with a crossover PK trial to show that our formulation of itraconazole delivers comparable levels of itraconazole as the SUBA Cap formulation used in prior clinical trials. As such, we expect to justify the conclusion that we can submit a NDA without any required additional clinical trials. The current cash on hand, approximately $5.6 million on December 31, 2024, is sufficient to continue to execute the Company's business plan as currently anticipated, without another required clinical trial. Based on the current operational plan and budget, the Company expects to have sufficient cash to manage its business and continue to pursue the FDA process for the BCCNS product (without further clinical trials) and explore other drug development opportunities. Once the requirements for the BCCNS NDA are determined, the Company will assess capital requirements for additional opportunities, at which time raising additional capital in the public market will be considered.

3. Summary of Significant Accounting Policies

Estimates

The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Actual results could differ from those estimates.

Revenue Recognition

The Company currently has no ongoing source of revenue. Miscellaneous income, including interest, is recognized when earned by the Company. Deferred revenue represents cash received for royalties in advance of being earned. Such payments are reflected as deferred revenue until recognized under the Company's revenue recognition policy. Deferred revenue would be classified as current if management believes the Company will be able to recognize the deferred amount as revenue within twelve months of the balance sheet date. Deferred revenue will be recognized when the product is sold and the royalty is earned. Since all deferred revenue is related to the BCCNS product, which is yet to be approved by FDA, the Company has determined that 100% of the advances of the royalty received from Mayne Pharma should be classified as non-current. As of December 31, 2024 and 2023, deferred revenue consisted of $3 million of royalties advanced by Mayne Pharma under the Third Amended Supply and License Agreement ("SLA").

Cash and Cash Equivalents

The Company considers all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents. The Company maintains cash balances in bank accounts in excess of Federal Deposit Insurance Corporation insured amounts. The Company continues to monitor the third-party depository institutions that hold the Company's cash and limits its cash deposits to financial institutions with high credit standing.

Research and Development Expenses

Research and development ("R&D") costs are expensed in the period in which they are incurred and include salaries, benefits and other related costs to support the Company's R&D operations, amounts paid to third parties who conduct research and development activities on behalf of the Company, as well as the costs of discovery research, preclinical and clinical development, drug formulation and licensing payments. Upfront and advanced licensing payments for future use in R&D activities are recorded as prepaid expenses and are expensed as the related services are performed.

General and Administrative Expenses

General and administrative ("G&A") expenses are expensed in the period in which they are incurred and include operating expenses not classified as R&D expenses, such as salaries, benefits, insurance, board of directors' fees, travel costs, as well as fees for professional services related to accounting, tax and legal matters. Penalties and interest assessed as a result of unresolved tax liabilities are also classified as G&A expenses.

3. Summary of Significant Accounting Policies (continued)

Stock-Based Compensation

The Company accounts for stock-based awards to employees and non-employees using a fair value-based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. Fair values of restricted stock units issued are determined by the Company based predominantly on the trading price of the common stock on the date of grant. The fair value of each common stock option is estimated on the date of grant using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. Expected volatility is based on historical volatility of a peer group's common stock and other factors estimated over the expected term of the options. The expected term of the options granted is derived using the "simplified method" which computes the expected term as the average of the weighted-average vesting term and the contract term. The risk-free rate is based on the U.S. Treasury yield.

Income Taxes

Deferred tax assets and liabilities are recognized for future tax consequences, attributed to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and are measured using enacted tax rates that are expected to apply to the differences in the periods that they are expected to reverse. Management has evaluated the guidance relating to accounting for uncertainty in income taxes and has determined that the Company had no uncertain income tax positions that could have a significant effect on the financial statements for the years ended December 31, 2024 or 2023.

Recent Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2023-07, *"Improvements to Reportable Segment Disclosures (Topic 280)"* which is intended to improve reportable segment disclosure requirements, primarily through incremental disclosures of segment information on an annual and interim basis for all public entities. The ASU expands public entities' segment disclosures by requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items and interim disclosures of a reportable segment's profit or loss and assets. The ASU is to be applied retrospectively to all prior periods presented in the financial statements and is effective for our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, and interim periods thereafter. The Company adopted this guidance with no material impact on its financial statements. Refer to Note 8 for further details.

Management has considered all other recent accounting pronouncements that are issued, but not effective, and it does not believe that they will have a significant impact on the Company's results of operations or financial position.

4. Income Taxes

The difference between expected income tax benefit and income tax benefit recorded in the financial statements is explained below:

	Years Ended December 31,	
	2024	2023
Income tax benefit computed at statutory rate	$ (700,508)	$ (635,488)
State income tax benefit	(144,939)	(131,486)
Other	5,584	45,096
Change in valuation allowance	839,863	721,878
Total	$ —	$ —

The significant components of deferred income tax assets consist of the following:

	December 31,	
Deferred tax assets	2024	2023
In-process research and development	$ 742,574	$ 742,574
Net operating loss carry forward	4,042,984	3,516,913
Capitalized research expense	628,820	315,028
Deferred income	760,350	760,350
R&D credit	78,336	78,336
Share-based compensation	34,231	34,231
Other	6,061	6,061
	6,293,356	5,453,493
Less: valuation allowance	(6,293,356)	(5,453,493)
Total	$ —	$ —

In accordance with GAAP, it is required that a deferred tax asset be reduced by a valuation allowance if, based on the weight of available evidence it is more likely than not (a likelihood of more than 50%) that some portion or all of the deferred tax assets will not be realized. At December 31, 2024 and 2023, the Company recorded a 100% valuation allowance against its deferred tax assets as it has determined such amounts will not be currently realizable.

The Company has historically generated federal and state net operating losses ("NOLs"). Under Section 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a "loss corporation", as defined, there are annual limitations on the amount of the NOLs and other deductions which are available to the Company. NOLs incurred prior to December 13, 2022 are subject to this limitation. As such, the use of these NOLs to offset taxable income is limited to approximately $0.7 million per year in 2023 and future periods. As of December 31, 2024 and 2023, the Company's federal and state NOLs are approximately $16 million and $14 million, respectively.

The Company follows the provisions of ASC 740-10 *"Uncertainty in Income Taxes"* wherein certain recognition thresholds must be met before a tax position is recognized in the financial statements. An entity may only recognize or continue to recognize tax positions that meet a "more-likely-than-not" threshold. As of December 31, 2024 and 2023, the Company does not believe it has any uncertain tax positions that would require either recognition or disclosure in the accompanying financial statements.

5. Stockholders' Equity

Employee Stock Plans

During 2014, the Equity Incentive Plan ("EIP") was adopted by the Company's Board of Directors and approved by a majority of stockholders. The total number of shares available for issuance under the EIP is 11,000,000. Incentive awards may be in the form of stock options, restricted stock, restricted stock units and performance and other awards. In the case of incentive stock options, the exercise price will not be less than 100% of the fair market value of shares covered at the time of the grant, or 110% for incentive stock options granted to persons who own more than 10% of the Company's voting stock. Options granted will generally be exercisable for ten years, except that the term may not exceed five years for incentive stock options granted to persons who own more than 10% of the Company's outstanding common stock.

Stock option activity for the years ended December 31, 2024 and 2023 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at December 31, 2022	**2,575,646**	**$ 0.09**	**$ 111,774**
Granted	-		
Exercised	-		
Forfeited	-		
Outstanding at December 31, 2023	**2,575,646**	**$ 0.09**	**$ 93,633**
Granted	290,000	0.08	
Exercised	-		
Forfeited	-		
Outstanding at December 31, 2024	**2,865,646**	**$ 0.09**	**$ 33,164**

Options outstanding (all are exercisable) at December 31, 2024 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$0.03 - $0.10	2,305,646	5.9	$ 0.05	$ 33,164
$0.11 - $0.30	560,000	2.3	$ 0.25	$ -
	2,865,646			$ 33,164

5. Stockholders' Equity (continued)

During the year ended December 31, 2024, the Company issued 290,000 common stock options with an exercise price of $0.08 per share and a weighted-average grant date fair value of $0.07 per share. The aggregate fair value of the options issued was approximately $0.02 million, as determined by using the Black-Scholes valuation model. The weighted-average assumptions used to estimate the fair value of the options issued during the period were as follows: risk-free interest rate: 4.33%; expected term: 5 years; expected volatility: 129.18%; and no dividend yield. The options are fully vested upon issuance and the contractual terms expire in 2034. There were no stock options issued during the year ended December 31, 2023.

During the year ended December 31, 2024, the Company granted 300,000 restricted shares of common stock with an aggregate grant date fair value of approximately $0.02 million to the members of the Board of Directors under the equity incentive plan. During the year ended December 31, 2023, the Company granted 230,411 restricted shares of common stock with an aggregate grant date fair value of approximately $0.01 million to the members of the Board of Directors under the equity incentive plan. The shares of common stock were fully vested upon issuance but are restricted from trading for a period of one year from the date of grant.

6. Related Party Transactions

The Company has engaged Avior, which is currently creating a novel formulation of itraconazole from which results are expected in the second quarter of 2025. Avior is a privately held drug development company whose President and Chairman of the Board, Niraj Vasisht, is a member of the Company's Board of Directors. Upon finalization of the formulation, Avior will conduct a pharmacokinetic (PK) crossover study to the generic formulation and the formulation that was used within the HP2001 study in preparation for a new IND and NDA. Given all formulations consist of the same active pharmaceutical ingredients (API), it is expected that the Company's new, novel formulation will have extremely similar properties to the formulation used in the HP2001 clinical study. During the year ended December 31, 2024, the Company incurred $0.3 million of costs associated with its engagement of Avior, which are included in Research and development expenses in the Statements of Operations.

7. Commitments and Contingencies

Exclusive License Agreement with Johns Hopkins University

On December 12, 2023, the Company entered into an Exclusive License Agreement (the "Agreement") with Johns Hopkins University ("JHU"). Pursuant to the Agreement, JHU granted to the Company the exclusive worldwide patent rights to a Granted US Patent, No 8,980,930 entitled "New Angiogenesis Inhibitors" (the "Patent"). The Patent relates to the treatment of prostate cancer, basal cell carcinoma including basal cell carcinoma nevus syndrome, and lung cancer.

Pursuant to the Agreement: (i) the Company has received an exclusive worldwide license to the Patent; (ii) the Company paid JHU an upfront license fee in December 2023, (iii) the Company shall be required to make certain Minimum Annual Royalty ("MAR") payments to JHU no later than January 1st of each calendar year in accordance with an agreed upon schedule, (iv) the Company shall be required to pay to JHU a royalty on cumulative net sales, with an additional supplement due where a licensed product is given exclusivity in the U.S. by patent rights, (v) if the Company enters into any sublicense they will pay to JHU a certain percentage of all consideration received from sublicensee but excluding (i) any consideration received by Licensee for Royalties on Sublicensee Sales (Royalties on Sales by Sublicensees will be treated as if Licensee made the Sale), and (ii) any payment of Past Patent Costs or Patent Costs made by Sublicensee to License), (vi) should the Company receive compensation in the form of a voucher, the Company will pay a certain percentage of the sale to JHU and (vii) the Company shall be required to pay to JHU certain development-related milestone payments upon the Company meeting each of a series of agreed upon milestones. The Agreement contains other customary terms and conditions.

7. Commitments and Contingencies (continued)

JHU has the right to terminate the Agreement upon the occurrence of certain events, including delinquency in payments, failure to timely reach milestones, noncompliance with audit or insurance obligations, or the Company entering into voluntary bankruptcy or insolvency. The Company may terminate the Agreement without cause upon 90 days advance written notice.

In compliance with the agreement, the Company paid in December 2023 the upfront license fee of $40,000, which has been recorded as a prepaid expense and will be expensed over the term of the Agreement. Additionally, the first two MAR payments of $10,000 each have also been paid in accordance with the agreed upon schedule. The remaining MAR payments required to be paid by the Company no later than January 1st of each calendar year are as follows:

- By January 1, 2026: $15,000
- By January 1, 2027 and every year thereafter until the first commercial sale of an associated licensed product: $50,000

Legal Proceedings

The Company may from time to time become a party to various legal proceedings arising in the ordinary course of business. The Company is not currently the subject of any pending legal proceedings.

8. Segment Information

The Company operates in one reportable segment related to the development and commercialization of therapeutics. The chief operating decision maker for the Company is the Chief Executive Officer (the "CEO"). The Company's CEO reviews operating results on an aggregate basis and manages the Company's operations as a whole for the purpose of evaluating financial performance and allocating resources. Accordingly, the Company has determined that it has a single reportable and operating segment structure. The CEO uses aggregate net loss to allocate resources in the annual budgeting and forecasting process and also uses that measure as a basis for evaluating financial performance regularly by comparing actual results with established budgets and forecasts.

The accounting policies of the Company's single segment are the same as those described in the summary of significant accounting policies within Note 3. The CEO assesses performance for the Company and decides how to allocate resources based on the aggregate net loss that is also reported on the income statement as net loss. The measure of segment assets is reported on the balance sheets as total assets.

The table below provides information about the Company's revenue, significant segment expenses and other segment expenses.

	Years Ended December 31,	
	2024	**2023**
Revenues	$ —	$ —
Less:		
Research and development	1,682,550	1,381,066
General and administrative	1,974,859	2,023,913
Loss from operations	(3,657,409)	(3,404,979)
Plus:		
Interest income	318,208	378,844
Net loss	$ (3,339,201)	$ (3,026,135)

9. Subsequent Events

In January 2025, the Company executed a lease agreement for office space. The lease term is three years with a commencement date of March 1, 2025 with no renewal options available. Base rent and other pass-through charges will initially be approximately $22,000 on an annual basis, subject to customary base rent annual escalations of 3%. The Company expects the lease agreement to be classified as an operating lease and currently assessing the measurement of the associated lease obligation and corresponding right-of-use asset.

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INHIBITOR THERAPEUTICS, INC.

Date: March 28, 2025

By: */S/ Francis E. O'Donnell*
Name: **Francis E. O'Donnell**
Title: **Chief Executive Officer**
(Principal Executive Officer)

By: */s/ James A. McNulty*
Name: **James A. McNulty**
Title: **Interim Chief Financial Officer, Treasurer and Secretary**
(Principal Accounting Officer)

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Person	Capacity	Date
/S/ Francis E. O'Donnell **Francis E. O'Donnell**	Chairman and Director	March 28, 2025
/S/ Samuel J. Sears **Samuel J. Sears**	Director	March 28, 2025
/S/ Niraj Vasisht **Niraj Vasisht**	Director	March 28, 2025
/S/ Michelle Yanez **Michelle Yanez**	Director	March 28, 2025
/S/ Michael Jerman **Michael Jerman**	Director	March 28, 2025
/S/ Ronald E. Osman **Ronald E. Osman**	Director	March 28, 2025

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-214207) of our report dated March 28, 2025 included in this Annual Report on Form 10-K of Inhibitor Therapeutics, Inc. (the "Company"), relating to the balance sheets of the Company as of December 31, 2024 and 2023, and the related statements of operations, stockholders' equity, and cash flows for the years then ended.

/s/ Cherry Bekaert LLP

Tampa, Florida
March 28, 2025

Exhibit 31.1

Certification Pursuant to Rule 13a-14(a)

I, Francis E. O'Donnell, hereby certify that:

1. I have reviewed this Annual Report on Form 10-K of Inhibitor Therapeutics, Inc.

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

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

   a. 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-15I and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant 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 that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

   e. 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. 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

   f. 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 28, 2025

/s/ Francis E. O'Donnell
Francis E. O'Donnell
Chief Executive Officer

Exhibit 31.2

Certification Pursuant to Rule 13a-14(a)

I, James A. McNulty, hereby certify that:

1. I have reviewed this Annual Report on Form 10-K of Inhibitor Therapeutics, Inc.

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

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

   a. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

   e. 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. 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

   f. 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 28, 2025

/s/ James A. McNulty
James A. McNulty
Interim Chief Financial Officer, Treasurer and Secretary

Exhibit 32.1

CERTIFICATION

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(18 U.S.C. 1350)

Pursuant to Section 906 of the Sarbanes-Oxley Act of (18 U.S.C. 1350), the undersigned officer of Inhibitor Therapeutics, Inc., a Delaware corporation (the "Company"), does hereby certify, to the best of such officer's knowledge and belief, that:

(1) The Annual Report on Form 10-K for the year ended December 31, 2024 (the "Form 10-K") of the Company 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 Form 10-K fairly presents, in all materials respects, the financial condition and results of operations of the Company.

Date: March 28, 2025

/s/ Francis E. O'Donnell
Francis E. O'Donnell, Chief Executive Officer

This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Securities Exchange Act.

Exhibit 32.2

CERTIFICATION

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(18 U.S.C. 1350)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350), the undersigned officer of Inhibitor Therapeutics, Inc., a Delaware corporation (the "Company"), does hereby certify, to the best of such officer's knowledge and belief, that:

(1) The Annual Report on Form 10-K for the year ended December 31, 2024 (the "Form 10-K") of the Company 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 Form 10-K fairly presents, in all materials respects, the financial condition and results of operations of the Company.

Date: March 28, 2025

/s/ James A. McNulty
James A. McNulty, Interim Chief Financial Officer, Treasurer and Secretary

This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Securities Exchange Act.