**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 September 30, 2021

OR

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

For the transition period from _____ to _____

Commission file number **333-191083**

## RASNA THERAPEUTICS, INC.

**(Exact name of registrant as specified in its charter)**

| **Nevada** | **39-2080103** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification Number)** |

**420 Lexington Ave, Suite 2525, New York, NY 10170**
**(Address of principal executive offices) (Zip Code)**

**Telephone: (646) 396-4087**
**(Registrant's telephone number)**

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

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

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

Indicate by check 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 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definition of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

| | | | |
|---|---|---|---|
| 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. ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was $2,632,000 as of March 31, 2021 , based upon the closing price on the OTCQB market reported for such date.

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 68,908,003 shares of common stock were issued and outstanding as of February 28, 2022.

**DOCUMENTS INCORPORATED BY REFERENCE: None**

**TABLE OF CONTENTS**

## PART I

**Forward Looking Statements.**

This annual report contains 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. These statements relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as “may”, “should”, “expects”, “plans”, “anticipates”, “believes”, “estimates”, “predicts”, “potential” or “continue” or the negative of these terms or other comparable terminology. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks in the section entitled “Risk Factors”, any of which may cause our or our industry’s actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. These risks include, by way of example and not in limitation:.

This list is not an exhaustive list of the factors that may affect any of our forward-looking statements. These and other factors should be considered carefully and readers should not place undue reliance on our forward-looking statements.

Forward looking statements are made based on management’s beliefs, estimates and opinions on the date the statements are made and we undertake no obligation to update forward-looking statements if these beliefs, estimates and opinions or other circumstances should change. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to actual results.

Our financial statements are stated in United States dollars (US$) and are prepared in accordance with United States Generally Accepted Accounting Principles.

In this annual report, unless otherwise specified, all dollar amounts are expressed in United States dollars and all references to “common stock” refer to the common shares in our capital stock.

As used in this annual report, the terms “we”, “us”, “our”, “Rasna” and the “Company” mean Rasna Therapeutics, Inc. unless the context clearly requires otherwise.

### ITEM 1. BUSINESS

**General.**

We are a leukemia-focused biotechnology company that has been developing therapeutics to address the unmet need that exists for acute myeloid leukemia, or AML, and other forms of leukemia and lymphoma. AML is generally a disease of older adults, with onset typically after the age of 45 (average patient age approximately 68 years old). Our strategy is to develop small molecule drug candidates targeting two genes: NPM1 and LSD1, which are considered to control major pathways underlying etiology of majority of AML sub-types.

RASP-201 is a novel, orally dosed, selective reversible inhibitor of lysine specific demethylase, or LSD1, a pathway that blocks differentiation and confers a poor prognosis to AML. We expect RASP-201 to display a safer metabolic profile than competitor irreversible inhibitors such as GSK2879552 (GlaxoSmithKline) and ORY-1001 (Oryzon/Roche). RASP-201 when dosed orally shows *in vivo* therapeutic utility in murine (mouse) models of AML.

RASP-301 is our innovative, first- in-class, oral, small molecule inhibitor that in preclinical studies has been shown to disrupt NPM1 oligomerization (aggregation of individual subunits) and has the potential to treat refractory AML with reduced toxicity at low dose levels. RASP-301 exhibits cytotoxic effects at nanomolar concentrations against AML cells in culture and was not cytotoxic to normal cells at the same concentrations. In vivo usefulness of these compounds in AML murine models has been evaluated confirming the druggability of the target and its potential to treat refractory AML.

Our primary indication is AML which may be fatal within weeks to months, has a 5-year survival rate of only about 25% and very poor prospects for long-term survival of patients. Treatment options for AML comprise a variety of chemotherapy regimens, biologic agents, and stem cell transplantation. Current standard chemotherapy regimens cure only a minority of patients with AML. As a result, all patients should be evaluated for entry into well-designed clinical trials. If a clinical trial is not available, the patient can be treated with standard therapy. For consolidation chemotherapy or for the management of toxic effects of chemotherapy, readmission is required. Our strategy is to target master regulators of cancer through deep knowledge of highly conserved pathways that are common to leukemia sub-types. Employing a multi-pronged approach, our programs are focused on three druggable intervention points with a potential to improve safety and efficacy of current AML mono and/or combination therapies.

**Leukemia Overview and Market Opportunity**

Leukemia is a cancer of the blood or bone marrow involving abnormal proliferation of white blood cells, called WBCs or leukocytes. Leukemia is caused by a mutation of the DNA in bone marrow stem cells resulting in the abnormal multiplication of leukocytes. If untreated, surplus leukocytes will overwhelm the bone marrow, enter the bloodstream and eventually invade other parts of the body, such as the lymph nodes, spleen, liver, and central nervous system. In this way, the behavior of leukemia is different from that of other cancers, which usually begin in major organs and ultimately spread to the bone marrow. Leukemia is an umbrella term covering a large group of blood cancers.

All leukemia arises from mutations or damage to the DNA within the blood cells. These mutations may occur spontaneously or as a result of exposure to radiation or carcinogenic substances. Ionizing radiation, as well as exposure to chemicals such as benzene, increases the risk of AML, while agricultural chemicals have been linked to an increased incidence of chronic lymphocytic leukemia, or CLL. A weak immune system, some virus forms such as human T-cell Leukemia virus I, or HTLV-1, genetic predisposition, cigarette smoking, and reactions to some therapeutic drugs are also implicated in the etiology of leukemia.

*Diagnosis, Treatment, and Management*

The first symptoms of leukemia are often vague and are correlated with other disorders. Common symptoms include fatigue and malaise, excessive bruising, and abnormal bleeding due to low platelet count. Further symptoms can include weight loss, bone and joint pain, infection and fever, and an enlarged spleen, lymph nodes and liver. After a blood test, several blood abnormalities such as anemia, or leucopenia may be observed, and in most cases a bone marrow test is required to confirm the diagnosis.

The preliminary diagnostic test for leukemia is a blood cell count, which is followed by immune-phenotyping to assess whether the abnormal lymphocyte levels are caused by inflammation or cancer. The physician may also require additional confirmatory tests such as cytogenetic analysis or bone marrow sampling.

The specific variety and combination of anticancer drugs prescribed depends on the form and stage of the disease. For example, treatment for AML, the most common form of leukemia, usually involves chemotherapy with cytotoxic cytarabine in conjunction with an anthracycline such as daunorubicin or idarubicin. Because of the severity of the cytotoxic treatment, bone marrow transplants, or BMTs are sometimes necessary. By transplanting healthy bone marrow into the body, BMTs help rebuild tissue damaged by the treatment. Interferon, or INF, therapy, particularly with INF-alpha, is an alternative or additional treatment offered to almost all newly diagnosed patients in these markets. However, it is very difficult to cure, even though early treatment indicates it will help people to live longer.

The standard first-line treatment strategy for CLL for patients who might not be able to tolerate the side effects of strong chemotherapy is to be treated with chlorambucil alone or with a monoclonal antibody like rituximab (Rituxan) or obinutuzumab (Gazyva). Other options include ibrutinib (Imbruvica), rituximab alone, or a corticosteroid like prednisone.

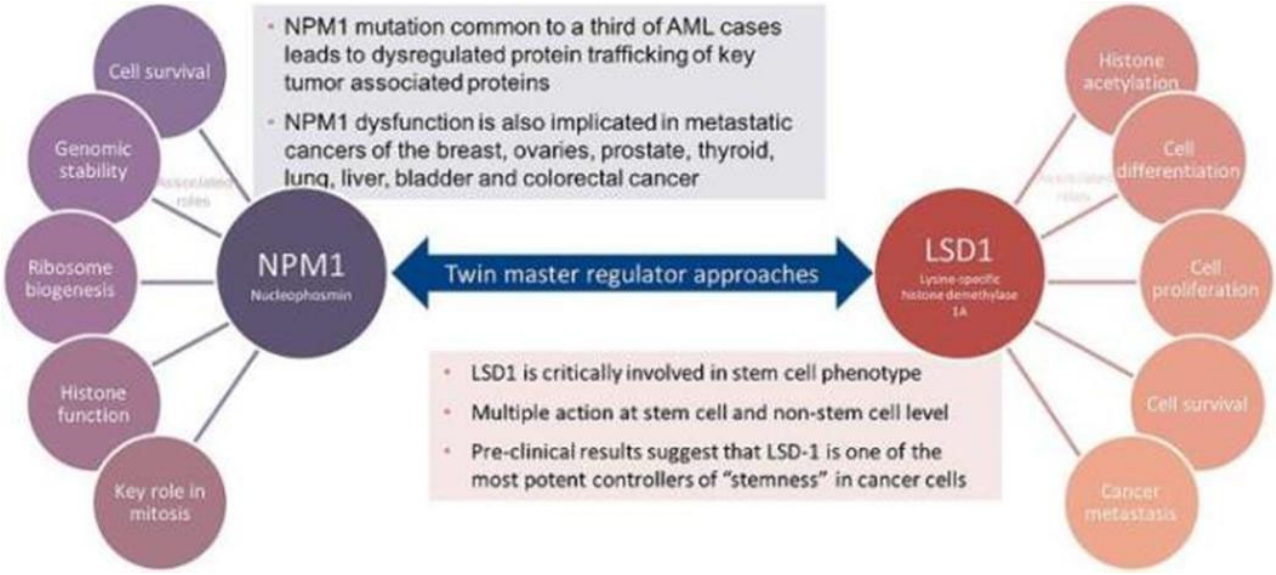
Other drugs or combinations of drugs may also be also used. If the only problem is an enlarged spleen or swollen lymph nodes in one region of the body, localized treatment with low-dose radiation therapy may be used. Splenectomy (surgery to remove the spleen) is another option if the enlarged spleen is causing symptoms.

In addition, very high numbers of leukemia cells in the blood causes problems with normal circulation. This is called leukostasis. Leukapheresis is also sometimes used before chemotherapy if there are very high numbers of leukemia cells (even when they aren’t causing problems) to prevent tumor lysis syndrome.

Upon the failure of first line therapy, the standard therapy is usually to administer many of the drugs and combinations listed above as potential second-line treatments. For many people who have already had fludarabine, alemtuzumab seems to be helpful as second-line treatment, but it carries an increased risk of infections. Other purine analog drugs, such as pentostatin or cladribine (2-CdA), may also be tried. Newer drugs such as ofatumumab, ibrutinib, idelalisib (Zydelig), and venetoclax (Venclexta) may be other options. If these types of chemotherapy fail, the next option is usually a bone marrow transplant. A stem cell transplant is a third treatment option depending on leukemia response.

Our business strategy focuses on differentiated targeted therapies for genetic pathways which are known to be involved in etiologies of number of leukemia and other cancers. Our clinical program is based around three druggable intervention points with potential to improve safety and efficacy of current AML therapies, namely "stemness" (activation of stem cell-like growth patterns), cell signaling (between nucleus and cytoplasm) and stress-induced apoptosis (programmed cell death). Our focus is to target two specific genetic pathways NPM1 and LSD1, which are known to be associated with etiologies of a number of cancers, including AML (Figure 1).

**Figure 1 Key Regulators for Developing Targeted AML Therapies**




**Roles of NPM1 and LSD1 in Tumorigenesis**

Leukemia arises due to DNA damage or mutations. Chromosomal aberrations involving NPM1 and LSD1 have been found in patients with non-Hodgkin lymphoma, acute promyelocytic leukemia, myelodysplastic syndrome, and AML. Thus, targeting NPM1 and LSD1 is an appropriate approach for treatment of AML. In addition, combination of therapies targeting these two genes could also be effective in treatment of relapse AML.

The NPM1 gene is up-regulated, mutated and chromosomally translocated in many tumor types. NPM1 is transferred from nucleolus to nucleoplasm and cytoplasm by anticancer drugs. When expressed at high level, NPM1 could promote tumor growth by inactivation of tumor suppressor p53/ARF pathway; when expressed at low level, NPM1 could suppress tumor growth by inhibition of centrosome duplication. NPM1 is haplo insufficient in hemizygous mice that are vulnerable to tumor development. NPM1c+ (cytoplasm form) translocation into cytoplasm could serve as an AML remission signal. NPM1 forms a pentamer that could serve as a potential anticancer target. Our technology (the process of targeting the mutation of the NPM1 gene), is believed to inhibit the NPM1 gene, reducing levels of NPM1 and consequently reducing a tumor cell's ability to duplicate. High affinity, NPM1 binding molecules exhibiting cytotoxic activity on AML cells and safe on normal cells have been identified.

The histone H3K4/K9 demethylase LSD1 can regulate gene activation and repression in epigenetic regulation and is a key effector of the differentiation block in *MLL*-rearranged leukemia. High LSD1 expression blocks differentiation and is associated with a poor prognosis in AML. LSD1 can be targeted by tranylcypromine analogs or downregulated by RNA interference which induces differentiation of *MLL*-rearranged leukemic cells. A number of different small molecular inhibitors of LSD1 have been in clinical evaluation. While this class of inhibitors has shown clinical activity in AML patients, toxicities associated with irreversible inhibitors prohibited their further development. Reversible inhibitors of LSD1 have shown good potential for further development.

**Other Leukemias**

Differences between the different leukemias are dependent on the types of cells involved. Myeloid leukemias originate in the bone marrow and involve granulocytes, white and red blood cells. Lymphoid leukemias, including lymphomas, originate in the lymph nodes and lymphoid tissue but involve immune cells including lymphocytes, T cells and B cells. MDS are group of bone marrow failure disorders that have various subtypes with variable onsets, prognoses and risks of developing leukemia.

**RASP-201 (LSD1)**

LSD1 is an enzyme that demethylates (remove methyl groups) lysine side chain of histones. The levels of LSD1 are elevated (overexpressed) in several human cancers as compared to healthy normal adults. In AML, elevated levels of LSD1 are observed in less differentiated blood cells (immature cells). Inhibition of the enzyme activity was found to promote differentiation. Hence, inhibitors of LSD1 are promising therapeutic candidates that can make drug-insensitive forms of AML, due to reduced levels of methylated histones, responsive to treatment with all-trans-retinoic acid, or ATRA an agent that induces differentiation (maturation)and used to treat a subtype of AML called acute promyelocytic leukemia, or APL.

Working from this premise, we executed a research agreement with TES Pharma for screening of compounds and to conduct animal studies to identify lead compounds with suitable druggability properties. TES Pharma has screened ~34000 compounds across 4 chemical series for their ability to inhibit LSD1 *in vitro*. The hit rate was ~1%. The hits from this assay were expanded and IC50 (half maximal inhibitory concentration) values were determined for 115 compounds. One chemical class namely, Thienopyrrole series was prioritized for further expansion and *in vitro* characterization.

We have filed patent applications covering this novel potent inhibitor class. The current lead compound DDP_43242 inhibitory effect on the LSD1 in *in-vitro* assay and *in-vivo* efficacy in two AML animal models.

These studies have facilitated the selection of DDP_43242 as the current lead compound. Additional absorption, distribution, metabolism and excretion, or ADME, and selectivity characterization is underway for drug candidate selection for clinical trials. We anticipate filing an investigation new drug application, or IND, in the near future. We believe that this breakthrough program may have significant benefits across all forms of leukemia. We are focusing on reversible small molecular inhibitors of LSD1 because these compounds are expected to exhibit less toxicity while retaining desirable efficacy.

**RASP-301 (NPM1)**

The NPM1 gene provides instructions for making a protein called nucleophosmin (NPM) which is found in a small region inside the nucleus of the cell called the nucleolus. Nucleophosmin shuttles back and forth between the nucleus and the fluid surrounding it (the cytoplasm). Nucleophosmin helps to transport other proteins from ribosomes (sites of protein synthesis) through the membrane surrounding the nucleus. The NPM-1 gene is mutated in approximately 35% of new cases of AML. However, mutations in the NPM1 gene, result in dislocation of NPM1 protein in the cytoplasm. NPM1 mutation may be an early event in development of leukemia. Given that NPM1 is thought to have a tumor-suppressor function, alterations in its localization in the cell (from the nucleus to the cytoplasm) may be crucial for the cell to change from normal to cancerous state. Our approach is to identify small molecule drugs that physically interfere with the aggregation of NPM1 which is important for normal function. RASP-301 is our innovative, first- in-class, oral, small molecule, potent inhibitor that disrupts NPM1-1 oligomerization (aggregation of individual subunits) and has the potential to treat refractory (resistant to treatment) AML with reduced toxicity at low dose levels The current lead candidate, TES-2169, exhibits cytotoxic (toxic to cancer cells) effects at nanomolar concentrations against AML cells in culture and was not cytotoxic to normal cells at the same concentrations. In vivo usefulness of these compounds in AML murine (mouse) models has been evaluated confirming the druggability of the target and its potential to treat refractory AML.

**Strategy**

Our strategy is to target master regulators of cancer through deep knowledge of highly conserved pathways that are common to leukemia sub-types. Employing a multi-pronged approach, our programs are focused on two druggable intervention points with a potential to improve safety and efficacy of current AML mono and/or combination therapies. For the RASP-201 program, the lead reversible LSD-1 candidate has been identified and manufacturing will be scaled for production of cGMP supplies for animal safety/toxicology studies, Phase 1, Phase 2 and Phase 3 clinical studies to support submission via the traditional 505(b)(1) regulatory pathway used for new chemical entities, or NCEs. We expect to use a similar pathway for the RASP-301 program, following identification of the lead drug candidate.

- Complete development of orally-available, small molecule, highly-selective, reversible inhibitor of LSD1 (RASP-201) and file IND in the near future. Manufacture of the lead RASP -201 candidate will be scaled to supply animal safety/toxicology studies and Phase 1, 2 and 3 clinical studies following the traditional 505(b)(1) pathway used for marketing approval of NCEs.

- Selection of a lead candidate for first in class NPM1 inhibitor (RASP-301).

- Evaluate strategic opportunities to accelerate development timelines and maximize the commercial potential of the drug candidates. Such opportunities may include partnering to achieve business objectives and achieve maximum return on investment.

**Research Agreement**

On December 17, 2013 TES Pharma S.R.L. (“TES”) and our predecessor, Arna Therapeutics Limited, entered into a research agreement pursuant to which TES agreed to perform research related to the development of products and services associated with NPM1 and AML. The initial term of the agreement was for two years and was extended by amendment on May 3, 2016 for an additional year. On September 8, 2016, the agreement was assigned to our subsidiary, Rasna Research, Inc. The agreement was further extended on March 24, 2017 until August 30, 2017. We are currently in discussions with TES Pharma S.R.L, profiling the next stage of research activity to be included in a new research agreement.

**Manufacturing**

We do not have any manufacturing facilities or personnel. We currently rely, and expect to continue to rely, on third parties for the manufacturing of our product candidates for preclinical as well as for commercial manufacturing if our product candidates receive marketing approval.

**Commercialization**

We plan to retain our worldwide commercialization rights for some of our key product candidates while for other product candidates we might consider partnership opportunities to maximize returns.

While we currently have no sales, marketing or commercial product distribution capabilities and have no experience as a company in commercializing products, we intend to build our own commercialization organization and capabilities over time. When appropriate, we will decide whether to build a specialty sales force to manage commercialization for these product candidates on our own or in combination with a larger pharmaceutical partner, to maximize patient coverage in the United States and to support global expansion especially as our programs have substantial opportunity for additional follow-up indications alone or in combinations.

As product candidates advance through our pipeline, our commercial plans may change. Clinical data, the size of the development programs, the size of the target market, the size of a commercial infrastructure and manufacturing needs may all influence our United States, European Union and rest-of-world strategies

**Government Regulation**

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

**U.S. Government Regulation of Drug Products**

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

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

- submission to the FDA of an IND application which must become effective before human clinical trials may begin and must be updated annually;
- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA's GLP regulations. Preclinical testing generally includes evaluation of our products in the laboratory or in animals to characterize the product and determine safety and efficacy;
- approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice, or GCP, requirements to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of a NDA after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA to accept the filing for review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the active pharmaceutical ingredient, or API, and finished drug product are produced and tested to assess compliance with cGMP regulations and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including the potential requirement to implement a REMS and the potential requirement to conduct post-approval 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 is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. The IND also includes results of preclinical studies or other human studies, as appropriate, as well as manufacturing information, analytical data and any available clinical data or literature to support the use of the investigational new drug. An IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical trials. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before clinical trials can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to commence. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical trials involve the administration of the new investigational drug to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety, and the efficacy 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.

Additionally, approval must also be obtained from each clinical trial site's Institutional Review Board, or IRB, before the trials may be initiated, and the IRB must monitor the study until completed. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

The clinical investigation of a drug is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined. The three phases of an investigation are as follows:

1. **Phase 1.** Phase 1 includes the initial introduction of an investigational new drug into humans. Phase 1 clinical trials are typically closely monitored and may be conducted in patients with the target disease or condition or in healthy volunteers. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness. During Phase 1 clinical trials, sufficient information about the investigational drug's pharmacokinetics and pharmacological effects may be obtained to permit the design of well-controlled and scientifically valid Phase 2 clinical trials.

2. **Phase 2.** Phase 2 includes controlled clinical trials conducted to preliminarily or further evaluate the effectiveness of the investigational drug for a particular indication(s) in patients with the disease or condition under study, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the drug. Phase 2 clinical trials are typically well-controlled, closely monitored, and conducted in a limited patient population.

3. **Phase 3.** Phase 3 clinical trials are generally controlled clinical trials conducted in an expanded patient population generally at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug product, and to provide an adequate basis for product approval.

A pivotal study is any clinical study, which adequately meets regulatory agency requirements for the evaluation of a drug candidate's efficacy and safety such that it can be used to justify the approval of the product. Generally, pivotal studies are Phase 3 studies but may also be Phase 2 studies if the trial design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations where there is an unmet medical need.

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. The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the study. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational drug product information is submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications.

The application includes all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA.

In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision.

In addition, under the Pediatric Research Equity Act of 2003, or PREA, as amended and reauthorized, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

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

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the NDA submission has been accepted for filing, the FDA's goal is to review applications within ten months of submission or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months from submission. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee but it typically follows such recommendations.

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 assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements. 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 assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements.

After the FDA evaluates the NDA and conducts inspections of manufacturing facilities where the drug product and/or its active pharmaceutical ingredient, or API, will be produced, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA could also approve the NDA with a Risk Evaluation and Mitigation Strategies, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. Regulatory approval of oncology products often requires that patients in clinical trials be followed for long periods to determine the overall survival benefit of the drug. 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.

After regulatory approval of a drug product is obtained, a company is required to comply with a number of post-approval requirements. As a holder of an approved NDA, we would be required to report, among other things, certain adverse reactions and production problems to the FDA, to provide updated safety and efficacy information, and to comply with requirements concerning advertising and promotional labeling for any of our products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval to ensure and preserve the long-term stability of the drug product. 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. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in, among other things,

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

Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs or devices may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Also, from time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

*Marketing Exclusivity*

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain 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 action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an approved NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active pharmaceutical ingredient. 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.

*The Hatch-Waxman Amendments: 505(b)(2) approval process*

Section 505(b)(2) of the FDCA provides an alternate regulatory pathway to FDA approval for new or improved formulations or new uses of previously approved drug products. Specifically, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon the FDA's findings of safety and effectiveness for an approved product that acts as the Reference Listed Drug, or RLD. If the 505(b)(2) applicant can establish that reliance on FDA's previous findings of safety and effectiveness is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require 505(b)(2) applicants to perform additional studies or measurements to support the change from the RLD. The FDA may then approve the new product candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant may also elect to submit a ''section viii'' statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the reference NDA holder and patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired.

Our current and anticipated product candidates will be based on already approved active pharmaceutical ingredients, or APIs, rather than new chemical entities, and a formulation that has been through Phase 1 studies. Accordingly, we expect to be able to rely on information from previously conducted formulation studies involving our clinical development plans and our NDA submissions. For product candidates that involve novel fixed-dose combinations of existing drugs or for studies of an existing product or product candidate in a new indication, we believe we generally will be able to initiate Phase 2/3 studies without conducting any new non-clinical or Phase 1 studies, though the FDA may not agree with our conclusions and may require us to conduct additional clinical or preclinical studies prior to initiating Phase 3 or other pivotal clinical trials. In those instances where our product candidate is a pharmacokinetically enhanced version of an approved API, we will need to conduct certain non-clinical and Phase 1 studies to confirm the pharmacokinetic profile of the product candidate prior to conducting Phase 2/3 studies.

*U.S. Foreign Corrupt Practices Act*

The U.S. Foreign Corrupt Practices Act, to which we are subject, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party or political candidate to obtain or retain business or to otherwise influence a person working in an official capacity.

*Federal and State Fraud and Abuse Laws*

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of drug and biologic product candidates which obtain marketing approval. In addition to FDA restrictions on marketing of pharmaceutical products, pharmaceutical manufacturers are exposed, directly, or indirectly, through customers, to broadly applicable fraud and abuse and other healthcare laws and regulations that may affect the business or financial arrangements and relationships through which a pharmaceutical manufacturer can market, sell and distribute drug and biologic products. These laws include, but are not limited to:

The federal Anti-Kickback Statute which prohibits, any person or entity from, among other things, knowingly and willfully offering, paying, soliciting, or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in-kind, to induce or reward either the referring of an individual for, or the purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any healthcare item or service reimbursable, in whole or in part, under Medicare, Medicaid, or any other federally financed healthcare program. The term "remuneration" has been broadly interpreted to include anything of value. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other hand. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

The federal false claims and civil monetary penalty laws, including the Federal False Claims Act, which imposes significant penalties and can be enforced by private citizens through civil qui tam actions, prohibits any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to the federal government, or knowingly making, using or causing to be made, a false statement or record material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, 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 False Claims Act. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. Criminal prosecution is also possible for making or presenting a false, fictitious or fraudulent claim to the federal government. Recently, 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 company's marketing of the product for unapproved, and thus non-reimbursable, uses.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statements or representations, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of, or payment for, benefits, items or services.

HIPAA, as amended by the Health Information Technology and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which impose certain requirements relating to the privacy, security, transmission and breach reporting of individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses and healthcare providers and their respective business associates that perform services for them that involve individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

The federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act," and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

State and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by non-governmental third-party payors, including private insurers.

State and foreign laws that require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to track and report gifts, compensation and other remuneration provided to physicians and other healthcare providers, and other federal, state and foreign laws that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure, and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus requiring additional compliance efforts.

Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some business activities can be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Ensuring that business arrangements with third parties comply with applicable healthcare laws and regulations is costly and time consuming. If business operations are found to be in violation of any of the laws described above or any other applicable governmental regulations a pharmaceutical manufacturer may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from governmental funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and curtailment or restructuring of operations, any of which could adversely affect a pharmaceutical manufacturer's ability to operate its business and the results of its operations.

*Healthcare Reform in the United States*

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

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- implementation of the federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act";
- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price, or AMP;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted or injected;

- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and

- expansion of the entities eligible for discounts under the Public Health program.

Some of the provisions of the PPACA have yet to be implemented, and there have been legal and political challenges to certain aspects of the PPACA. Since January 2017, former President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Congress may consider other legislation to repeal or replace elements of the PPACA.

Many of the details regarding the implementation of the PPACA are yet to be determined, and at this time, the full effect that the PPACA would have on a pharmaceutical manufacturer remains unclear. In particular, there is uncertainty surrounding the applicability of the biosimilars provisions under the PPACA. The FDA has issued several guidance documents, but no implementing regulations, on biosimilars. A number of biosimilar applications have been approved over the past few years. The regulations that are ultimately promulgated and their implementation are likely to have considerable impact on the way pharmaceutical manufacturers conduct their business and may require changes to current strategies. A biosimilar is a biological product that is highly similar to an approved drug notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biological product and the approved drug in terms of the safety, purity, and potency of the product.

Individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm a pharmaceutical manufacturer's business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce ultimate demand for certain products or put pressure product pricing, which could negatively affect a pharmaceutical manufacturer's business, results of operations, financial condition and prospects.

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

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. No one can be sure whether future changes to the regulatory environment will be favorable or unfavorable to business prospects. For example, average review times at the FDA for marketing approval applications can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

*International Regulations*

In addition to regulations in the United States, we are and will be subject to a variety of foreign regulations regarding development, approval, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must 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 review periods, and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing, among other things, the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. 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. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

To obtain regulatory approval of an investigational drug under European Union regulatory systems, we must submit a marketing authorization application. The application used to file the NDA in the United States is similar to that required in Europe, with the exception of, among other things, country-specific document requirements. For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

*Centralized Procedure*

The European Medicines Agency, or EMA, implemented the centralized procedure for the approval of human medicines to facilitate marketing authorizations that are valid throughout the EU. This procedure results in a single marketing authorization issued by the European Commission following a favorable opinion by the EMA that is valid across the European Union, as well as Iceland, Liechtenstein, and Norway. The centralized procedure is compulsory for human medicines that are: derived from biotechnology processes, such as genetic engineering, contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and officially designated orphan medicines. For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

There are also two other possible routes to authorize medicinal products in several European Union countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure: the decentralized procedure and the mutual recognition procedure. Under the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country for medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure. Under the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following a national authorization, the applicant may seek further marketing authorizations from other EU countries under a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

In the EU, medicinal products designated as orphan drug products benefit from financial incentives such as reductions in marketing authorization application fees or fee waivers and 10 years of marketing exclusivity following medicinal product approval. For a medicinal product to qualify as orphan drugs: (i) it must be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating; (ii) the prevalence of the condition in the EU must not be more than five in 10,000 or it must be unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development; and (iii) no satisfactory method of diagnosis, prevention or treatment of the condition concerned can be authorized, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

*Other Regulations*

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances and biological materials. We may incur significant costs to comply with such laws and regulations now or in the future.

**Reimbursement**

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process that can require the provision of supporting scientific, clinical and cost effectiveness data for the use of drug or biologic products to the payor. There may be significant delays in obtaining such coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers operating costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of product from countries where they may be sold at lower prices than in the United States.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. It is difficult to predict what third party payors will decide with respect to coverage and reimbursement for new drug and biologic product candidates. An inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products could have a material adverse effect on a pharmaceutical manufacturer's operating results, ability to raise capital needed to commercialize products and overall financial condition.

Reimbursement may impact the demand for, and/or the price of, any product which obtains marketing approval. Even if coverage is obtained for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with those medications. Patients are unlikely to use products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of the products. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

The U.S. government, state legislatures and foreign governmental entities have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and coverage and requirements for substitution of generic products for branded prescription drugs. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could exclude or limit our products from coverage and limit payments for pharmaceuticals.

In addition, it is expected that the increased emphasis on managed care and cost containment measures in the United States by third-party payors and government authorities will continue and place further pressure on pharmaceutical pricing and coverage. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more drug products that gain regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

**Intellectual Property**

Our success depends, in part, on our ability to obtain, maintain, and enforce patents and other proprietary protections of our commercially important technologies and product candidates, to operate without infringing the proprietary rights of others, and to maintain trade secrets or other proprietary know-how, both in the United States and other countries. Our ability to stop third parties from making, using, selling, offering to sell or importing our products will depend on the extent to which we have rights under valid and enforceable patents or trade secrets that protect these activities. We seek to protect proprietary technology, inventions, and improvements that are commercially important to our business by seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties.

We have two active patent families relating to our dactinomycin program. Currently, we have one granted US patent and ten pending patent applications in these families in the US, Australia, Canada, Europe, and Japan.

We also have an exclusive license to patents and patent applications across seven different patent families relating to our LSD1 program. We currently have four granted patents and two pending application in the U.S. We also have granted patents and/or pending applications in these families in Europe, Australia, Brazil, Canada, China, Eurasia, India, Israel, Japan, Mexico, and South Africa.

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, we do not know whether the product candidates we are developing will gain patent protection or, if patents are issued, whether they will provide significant proprietary protection or will be challenged, circumvented, invalidated, or found to be unenforceable. Because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions or filing dates covered by pending patent applications. Moreover, we may have to participate in post-grant proceedings, interference proceedings, or third-party *ex parte* or *inter partes* reexamination proceedings before the U.S. Patent and Trademark Office, or in opposition proceedings in a foreign patent office, any of which could result in substantial cost to us, even if the eventual outcome is favorable to us. There can be no assurance that the patents, if issued, would be held valid and enforceable by a court of competent jurisdiction. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using specific compounds or technology. To the extent prudent, we intend to bring litigation against third parties that we believe are infringing one or more of our patents or other intellectual property rights.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in granting a patent, or may be shortened if a patent is terminally disclaimed over another patent. Certain of our patents currently benefit from patent term adjustment and some of our patents issuing in the future may benefit from patent term adjustment.

The patent term of a patent that covers an FDA-approved product may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the product is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved product may be extended. Similar provisions are available in Europe and other non-U.S. jurisdictions to extend the term of a patent that covers an approved product. In the future, if and when our product candidates receive FDA approval, we expect to apply for patent-term extensions on patents covering those products.

To protect our rights to any of our issued patents and proprietary information, we may need to litigate against infringing third parties, or avail ourselves of the courts or participate in hearings to determine the scope and validity of those patents or other proprietary rights. These types of proceedings are often costly and could be very time-consuming to us, and there can be no assurance that the deciding authorities will rule in our favor. An unfavorable decision could allow third parties to use our technology without being required to pay us licensing fees or may compel us to license needed technologies to avoid infringing third-party patent and proprietary rights. Such a decision could even result in the invalidation or a limitation in the scope of our patents or forfeiture of the rights associated with our patents or pending patent applications.

We intend to seek orphan drug status whenever it is available. If a product which has an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, meaning that the applicable regulatory authority may not approve any other applications to market the same drug for the same indication, except in certain very limited circumstances, for a period of seven years in the United States and 10 years in the European Union. Orphan drug designation does not prevent competitors from developing or marketing different drugs for an indication.

We also rely on trade secret protection for our confidential and proprietary information. No assurance can be given that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technology, or that we can meaningfully protect our trade secrets. However, we believe that the substantial costs and resources required to develop technological innovations will help us to protect the competitive advantage of our products.

It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting or collaborative relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual shall be and are our exclusive property. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

**Competition**

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, development experience and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Several types of existing treatments may be used for people with AML. The main treatments include chemotherapy, bone marrow transplants, stem cell transplants and/or interferon therapy. In most cases AML can progress rapidly, so it is important to start treatment as soon as possible after the diagnosis is made. In addition to currently marketed therapies, there are also a number of products in late stage clinical development to treat AML. These products in development may provide efficacy, safety, convenience and other benefits that are not provided by currently marketed therapies. As a result, they may provide significant competition for any of our product candidates for which we obtain market approval.

There are other companies and research institutions working to develop therapies that target AML. Many of our competitors may have significantly greater financial resources and expertise in research and development, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

A listing of approved products currently used for treatment of AML include the following: topoisomerase II inhibitors, e.g., Cerubidine® (daunorubicin HCL, Bedford Labs), Novantrone® (mitoxantrone HCL, Pfizer) and Idamycin® (idarubicin HCl, Pfizer); alkylating agents, e.g., Cytoxan® (cyclophosphamide, Baxter); DNA polymerase inhibitors, e.g,. Cytarabine® (cytarabine, Pfizer); DNA binding agents, e.g., Doxil® (doxorubicin HCl liposome, Alza); purine analogs, e.g., Tabloid® (thioguanine, GlaxoSmithKline); mitotic spindle inhibitors, e.g., Vincasar PFS® (vincristine sulfate, Teva); DNA fragmentation agents, e.g,. Trisenox® (arsenic trioxide, Cephalon); FLT3 inhibitors, e.g., Rydapt® (midostaurin, Novartis); IDH2 inhibitors, e.g., IDHIFA® (enasidenib mesylate, Celgene).

A listing of AML drugs in advanced clinical development by our competitors include the following: (irreversible) LSD-1 inhibitors, e.g. ORY-1001 (Oryzon); FLT3 inhibitors, e.g., quizartinib (Daiichi Sankyo), crenolanib (Arog Pharma) and gilteritinib (Astellas); topoisomerase inhibitors, e.g., Vosaroxin® (qinprezo, Sunesis Pharma), CPX-351 (vyxeos, Celator Pharma); DNA hypomethylating agents, e.g., guadecditabine (ASTX Pharma); PLK1 inhibitors, e.g., volasertib (Boehringer Ingelheim); IDH2 inhibitors, e.g., enasidenib (Agios Pharma); IDH1 inhibitors, e.g., ivosidenib (Agios Pharma); DOT1L ihibitors, e.g., pinometostat (Epizyme); BCL2 inhibitors, e.g., venetoclax (Roche); BET inhibitors, e.g., OTX-015 (OncoEthix) and HDAC inhibitors, e.g., pracinostat (MEI Pharma).

A large number of irreversible inhibitors of LSD1 have been developed by major pharmaceutical companies and research institutes. Among them, ORY-1001 and GSK2879552, two TCP derivatives, developed by Oryzon Genomics and GSK, respectively, have been in Phase 1 clinical trials for treatment of AML We have focused on development of reversible inhibitors instead of irreversible inhibitors with the expectation of better therapeutic effect, safety profiles and lower toxicity compared to the irreversible inhibitors

The key competitive factors affecting the success of all our targets, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

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. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. There are many generic products currently on the market for the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If our therapeutic product candidates are approved, we expect that they will be priced at a significant premium over competitive generic products.

**Shared Services Agreement**

On January 1, 2017, Tiziana Life Sciences plc, a company incorporated in England and Wales (“Tiziana”), entered into a Shared Services Agreement with us pursuant to which Tiziana agreed to provide certain services to us including various administrative, financial, legal, tax, insurance, facility and information technology services. The term of the agreement is until April 1, 2018 and is renewed automatically thereafter for successive three month terms with respect to any services still in effect unless either party elects not to renew the agreement or any specific service by notice in writing to the other party no later than 45 days prior to the end of any term. We may terminate any of the services provided under the agreement at any time upon 30 days prior written notice. Tiziana may terminate any of the services provided under the agreement if we shall have failed to perform any of our material obligations under the agreement and failed to cure any such failure within 30 days after receiving notice thereof.

**Employees**

As of September 30, 2021, and September 30, 2020 we had no employees.

**ITEM 1A. RISK FACTORS**

**Risks Relating to Our Business**

***We are a leukemia-focused biotechnology company with limited operations to date.***

We are a leukemia-focused biotechnology company with limited operations to date and no revenue. We have not yet commenced clinical trials, have no product candidates ready for commercialization, have not generated any revenue from operations and expect to incur substantial net losses for the foreseeable future to further develop and commercialize our product candidates. We are unable to predict the extent of these future net losses, or when we may attain profitability, if at all. We may never be able to generate any revenues or royalties from the sales of our therapeutics or become profitable even if we do generate revenues or royalties.

***We expect to continue to incur increasing net losses for the foreseeable future, and we may never achieve or maintain profitability.***

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. For the year ended September 30, 2021 and 2020, we reported a net loss of $785,082 and $5,346,672, respectively. As of September 30, 2021, we had an accumulated deficit of $23,443,563.

To become and remain profitable, we or our partners must succeed in developing our product candidates, obtaining regulatory approval for them, and manufacturing, marketing and selling those products for which we or our partners may obtain regulatory approval. We or they may not succeed in these activities, and we may never generate revenue from product sales that is significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with biopharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of future expenses or when, or if, we will be able to achieve or maintain profitability. Currently, we have no products approved for commercial sale, and to date we have not generated any product revenue. We have financed our operations primarily through the sale of equity securities. The size of our future net losses will depend, in part, on the rate of growth or contraction of our expenses and the level and rate of growth, if any, of our revenues. Our ability to achieve profitability is dependent on our ability, alone or with others, to complete the development of our products successfully, obtain the required regulatory approvals, manufacture and market our proposed products successfully or have such products manufactured and marketed by others, and gain market acceptance for such products. There can be no assurance as to whether or when we will achieve profitability.

***We will require substantial additional funding which may not be available to us on acceptable terms, or at all. If we fail to raise the necessary additional capital, we may be unable to complete the development and commercialization of our product candidates, or continue our development programs.***

We expect to escalate moderately our spending to advance the pre-clinical and clinical development of our product candidates.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidate. We may also seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available. Any of these events could significantly harm our business, financial condition and prospects.

Our future capital requirements will depend on many factors, including:

- the progress of the development of our product candidates;
- the number of product candidates we pursue;

- the time and costs involved in obtaining regulatory approvals;
- the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims;
- our plans to establish sales, marketing and/or manufacturing capabilities;
- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- general market conditions for offerings from biopharmaceutical companies;
- our ability to establish, enforce and maintain selected strategic alliances and activities required for product commercialization; and
- our revenues, if any, from successful development and commercialization of our product candidates.

In order to carry out our business plan and implement our strategy, we anticipate that we will need to obtain additional financing from time to time and may choose to raise additional funds through strategic collaborations, licensing arrangements, public or private equity or debt financing, bank lines of credit, asset sales, government grants, or other arrangements. We cannot be sure that any additional funding, if needed, will be available on terms favorable to us or at all. Furthermore, any additional equity or equity-related financing may be dilutive to our stockholders, and debt or equity financing, if available, may subject us to restrictive covenants and significant interest costs. If we obtain funding through a strategic collaboration or licensing arrangement, we may be required to relinquish our rights to certain of our product candidate or marketing territories. Our inability to raise capital when needed would harm our business, financial condition and results of operations, and could cause our stock price to decline or require that we wind down our operations altogether.

***Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing.***

Our consolidated financial statements as of September 30, 2021 were prepared under the assumption that we will continue as a going concern for the next twelve months. Due to our recurring losses from operations, we concluded that there is substantial doubt in our ability to continue as a going concern within one year after the financial statements are issued without additional capital becoming available. Our independent registered public accounting firm has issued an audit opinion that included an explanatory paragraph referring to our projected future losses along with recurring losses from operations and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

***If we fail to select product candidates, fail to successfully complete clinical trials and commercialize product candidates or fail to obtain regulatory approval, our business would be harmed and the value of our securities would decline.***

We must be evaluated in light of the uncertainties and complexities affecting a pre-commercial biopharmaceutical company. We have not completed preclinical or clinical research and have not completed the development of our product candidates. Our failure to develop and commercialize such product candidates successfully may cause us to cease operations. We are performing preclinical research on NPM1 and LSD1. This research will require significant additional development efforts by us and significant additional development efforts by us and regulatory approvals prior to commercialization. We cannot be certain that our efforts in this regard will lead to commercially viable therapeutics. We do not know what the final cost to select and commercialize product candidates will be.

We do not know whether any of our molecular targets under development ultimately will be selected as product candidates or whether our product candidates will be shown to be effective. Moreover, governmental authorities may enact new legislation or regulations that could limit or restrict our development efforts. We may receive unfavorable results from pre-clinical studies or clinical studies on the molecular targets, which may cause us to abandon the product selection process and further development efforts.

Regulatory agencies must approve our product candidates, if any, before they can be marketed or sold. The approval process is lengthy, requires significant capital expenditures, and uncertain as to outcome. Our ability to obtain regulatory approval of any product candidate depends on, among other things, completion of additional clinical trials, whether our clinical trials demonstrate statistically significant efficacy with safety issues that do not potentially outweigh the therapeutic benefit of the product candidates, and whether the regulatory agencies agree that the data from our future clinical trials are sufficient to support approval for any of our product candidates. The final results of our current and future preclinical or clinical trials may not meet FDA or other regulatory agencies' requirements to approve a product candidate for marketing, and the regulatory agencies may otherwise determine that our manufacturing processes or facilities are insufficient to support approval. We or our collaborators may need to conduct more preclinical or clinical trials than we currently anticipate. Even if we do receive FDA or other regulatory agency approval, we or our collaborators may not be successful in commercializing approved product candidates. If any of these events occur, our business could be materially harmed and the value of our securities would decline.

***All of our current data for our lead product candidate are the result of Phase 2 clinical trials conducted by third parties and do not necessarily provide sufficient evidence that our product candidates will be viable as potential pharmaceutical products.***

To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for our product candidates. Favorable results in early studies or trials may not be repeated in later studies or trials. Even if our clinical trials are initiated and completed as planned, we cannot be certain that the results will support our product candidate claims. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. We cannot be sure that the results of later clinical trials would replicate the results of prior clinical trials and preclinical testing, nor that they would satisfy the requirements of the FDA or other regulatory agencies. Clinical trials may fail to demonstrate that our product candidate is safe for humans and effective for indicated uses. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Any delay in, or termination of, our clinical trials would delay our obtaining FDA or EMA approval for the affected product candidate and, ultimately, our ability to commercialize that product candidate.

***If we cannot demonstrate an acceptable toxicity profile for our product candidates, if any, in non-clinical studies, we will not be able to initiate or continue clinical trials or obtain approval for our product candidates.***

To move a product candidate into human clinical trials, we must first demonstrate an acceptable toxicity profile in preclinical testing. Furthermore, to obtain approval, we must also demonstrate safety in various non-clinical tests. We may not have conducted or may not conduct the types of non-clinical testing required by regulatory authorities, or future non-clinical tests may indicate that our product candidates are not safe for use. Preclinical and non-clinical testing is expensive, time-consuming and has an uncertain outcome. In addition, success in initial non-clinical testing does not ensure that later non-clinical testing will be successful. We may experience numerous unforeseen events during the non-clinical testing process, which could delay or prevent our ability to develop or commercialize our product candidates, including:

- our preclinical and non-clinical testing may produce inconclusive or negative safety results, which may require us to conduct additional non-clinical testing or to abandon product candidates;
- our product candidates may have unfavorable pharmacology or toxicity characteristics;
- our product candidates may cause undesirable side effects such as negative immune responses that lead to complications;
- our enrolled patients may have allergies that lead to complications after treatment; and
- the FDA or other regulatory authorities may determine that additional safety testing is required.

Any such events would increase our costs and could delay or prevent our ability to commercialize our product candidates, which could adversely impact our business, financial condition and results of operations.

***We, or our collaborators, may face delays in completing our pre-clinical or clinical trials, and may not be able to complete them at all.***

We have not completed the pre-clinical and clinical trials necessary to support an application for approval to market of our product candidates, if any. Our or our collaborators' current and future clinical trials may be delayed, unsuccessful, or terminated as a result of many factors, including:

- delays in designing an appropriate clinical trial protocol and reaching agreement on trial design with investigators and regulatory authorities;
- governmental or regulatory delays, failure to obtain regulatory approval or changes in regulatory requirements, policy or guidelines;
- adding new clinical trial sites
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- the actual performance of CROs and clinical trial sites in ensuring the proper and timely conduct of our clinical trials;
- adverse effects experienced by subjects in clinical trials;
- manufacturing sufficient quantities of product candidates for use in clinical trials; and
- delays in achieving study endpoints and completing data analysis for a trial.

In addition to these factors, our trials may be delayed, unsuccessful or terminated because:

- regulators or institutional review boards, or IRBs, may not authorize us to commence a clinical trial;
- regulators or IRBs may suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or concerns about patient safety;
- we may suspend or terminate our clinical trials if we believe that they expose the participating patients to unacceptable health risks;
- patients may not complete clinical trials due to safety issues, side effects, such as injection site discomfort, a belief that they are receiving placebo instead of our product candidates, or other reasons;
- patients with serious diseases included in our clinical trials may die or suffer other adverse medical events for reasons that may not be related to our product candidates;
- in those trials where our product candidate is being tested in combination with one or more other therapies, deaths may occur that may be attributable to the other therapies;
- we may have difficulty in maintaining contact with patients after treatment, preventing us from collecting the data required by our study protocol;
- product candidates may demonstrate a lack of efficacy during clinical trials;
- personnel conducting clinical trials may fail to properly administer our product candidates; and
- our collaborators may decide not to pursue further clinical trials.

We could encounter delays if our clinical trials are suspended or terminated by us, by IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Boards for such trials or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including potential for unacceptable safety risks to patients, inspection of the clinical trial operation or trial site, changes in government regulations or administrative actions.

In addition, we rely on academic institutions, physician practices and CROs to conduct, supervise or monitor some or all aspects of clinical trials involving our product candidates. We have less control over the timing and other aspects of these clinical trials than if we conducted the monitoring and supervision entirely on our own. Third parties may not perform their responsibilities for our clinical trials on our anticipated schedule or consistent with a clinical trial protocol or applicable regulations. We also may rely on CROs to perform our data management and analysis. They may not provide these services as required or in a timely or compliant manner, and we may be held legally responsible for any or all of their performance failures or inadequacies.

Moreover, our development costs will increase because we will be required to complete additional or larger clinical trials for our product candidates prior to FDA or other regulatory approval. If we or our collaborators experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed or eliminated. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also lead to the denial of regulatory approval of our product candidates.

***We have limited experience in the development of therapeutic product candidates and therefore may encounter difficulties developing our product candidate or managing our operations in the future.***

We have limited experience in the discovery, development and manufacturing of therapeutic compounds. In order to successfully develop our product candidate, we must continuously supplement our research, clinical development, regulatory, medicinal chemistry, and manufacturing capabilities through the addition of key employees, consultants or third-party contractors to provide certain capabilities and skill sets that we do not possess.

Furthermore, we have adopted an operating model that largely relies on the outsourcing of a number of responsibilities and key activities to third-party consultants, and contract research and manufacturing organizations in order to advance the development of our product candidates. Therefore, our success depends in part on our ability to retain highly qualified key management, personnel, and directors to develop, implement and execute our business strategy, operate the company and oversee the activities of our consultants and contractors, as well as academic and corporate advisors or consultants to assist us in this regard. We are currently highly dependent upon the efforts of our management team. In order to develop our product candidates, we need to retain or attract certain personnel, consultants or advisors with experience in drug development activities that include a number of disciplines, including research and development, clinical trials, medical matters, government regulation of pharmaceuticals, manufacturing, formulation and chemistry, business development, accounting, finance, regulatory affairs, human resources and information systems..

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. The competition for qualified personnel in the biotechnology and pharmaceuticals field is intense. We will need to hire additional personnel as we expand our clinical development and commercial activities. While we have not had difficulties recruiting qualified individuals, to date, we may not be able to attract and retain quality personnel on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical and other companies. Although we have not experienced material difficulties in retaining key personnel in the past, we may not be able to continue to do so in the future on acceptable terms, if at all.

***We have limited capacity for recruiting and managing clinical trials, which could impair our timing to initiate or complete clinical trials of our product candidates and materially harm our business.***

We have limited capacity to recruit and manage the clinical trials necessary to obtain FDA approval or approval by other regulatory authorities. By contrast, larger pharmaceutical and bio-pharmaceutical companies often have substantial staff with extensive experience in conducting clinical trials with multiple product candidates across multiple indications. In addition, they may have greater financial resources to compete for the same clinical investigators and patients that we are attempting to recruit for our clinical trials. If potential competitors are successful in completing drug development for their product candidates and obtain approval from the FDA, they could limit the demand for our product candidates.

As a result, we may be at a competitive disadvantage that could delay the initiation, recruitment, timing, completion of our clinical trials and obtaining regulatory approvals, if at all, for our product candidate.

***If we encounter difficulties enrolling patients in our clinical trials, our clinical trials could be delayed or otherwise adversely affected.***

Clinical trials for our product candidates, if any, will require us to identify and enroll a large number of patients with the disease under investigation. We may not be able to enroll a sufficient number of patients, or those with required or desired characteristics, in a timely manner. Patient enrollment is affected by factors including:

- severity of the disease under investigation;
- design of the trial protocol;
- the size and nature of the patient population;
- eligibility criteria for the study in question;
- lack of a sufficient number of patients who meet the enrollment criteria for our clinical trials;
- delays required to characterize the infection to allow us to select a product candidate, which may lead patients to seek to enroll in other clinical trials or seek alternative treatments;
- perceived risks and benefits of the product candidate under study;
- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- scheduling conflicts with participating clinicians;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

If we have difficulty enrolling a sufficient number or diversity of patients to conduct our clinical trials as planned, we may need to delay or terminate ongoing or planned clinical trials, either of which would have an adverse effect on our business.

***Results of earlier studies and clinical trials may not be predictive of future trial results.***

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates, if any, may not be predictive of the design or results of later-stage clinical trials. Any positive results generated to date do not ensure that later trials will demonstrate similar results. While we have observed statistically significant improvements in the outcomes of some of our clinical trials, many of the improvements we have seen have not reached statistical significance. Statistical significance is a statistical term that means that an effect is unlikely to have occurred by chance. In order to be approved, product candidates must demonstrate that their effect on patients' diseases in the trial is statistically significant. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Early clinical trials frequently enroll patient populations that are different from the patient populations in later trials, resulting in different outcomes in later clinical trials from those in earlier stage clinical trials. In addition, adverse events may not occur in early clinical trials and only emerge in larger, late-stage clinical trials or after commercialization. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier clinical trials. If later stage clinical trials do not demonstrate efficacy and safety of our product candidates we will not be able to market them and our business will be materially harmed.

***Regulatory authorities may not approve our product candidates, if any, even if they meet safety and efficacy endpoints in clinical trials.***

Under certain circumstances, regulatory authorities may revise or retract previous guidance during the course of our clinical activities or after the completion of our clinical trials. A regulatory authority may also disqualify a clinical trial in whole or in part from consideration in support of approval of a potential product for commercial sale or otherwise deny approval of that product. Prior to regulatory approval, a regulatory authority may elect to obtain advice from outside experts regarding scientific issues and/or marketing applications under a regulatory authority review. In the United States, these outside experts are convened through the FDA's Advisory Committee process, which would report to the FDA and make recommendations that may differ from the views of the FDA. Should an Advisory Committee be convened, it would be expected to lengthen the time for obtaining regulatory approval, if such approval is obtained at all.

The FDA and foreign regulatory agencies may delay, limit or deny marketing approval for many reasons, including:

- a product candidate may not be considered safe or effective;
- our manufacturing processes or facilities may not meet the applicable requirements;
- changes in the agencies' approval policies or adoption of new regulations may require additional work on our part, for example, the FDA may require us to change or expand the endpoints in our clinical trials;
- different divisions of the FDA are reviewing different product candidates and those divisions may have different requirements for approval; and
- changes in regulatory law, FDA or foreign regulatory agency organization, or personnel may result in different requirements for approval than anticipated.

Our product candidates may not be approved even if they achieve their endpoints in clinical trials. Regulatory agencies, including the FDA, or their advisors may disagree with our trial design and our interpretations of data from preclinical studies and clinical trials. Regulatory agencies also may approve a product candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

Any delay in or failure to receive or maintain approval for any of our product candidates could prevent us from ever generating revenues or achieving profitability.

***We may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive, or the trials are not well designed.***

Clinical trials must be conducted in accordance with FDA regulations governing clinical studies, or other applicable foreign government guidelines, and are subject to oversight by the FDA, other foreign governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced under current Good Manufacturing Practices, or cGMP, and may require large numbers of test subjects. Clinical trials may be suspended by the FDA, other foreign governmental agencies or us for various reasons, including:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- deficiencies in the clinical trial operations or trial sites;
- the product candidate may have unforeseen adverse side effects;
- the time required to determine whether the product candidate is effective may be longer than expected;
- deaths or other adverse events arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;
- the product candidate may not appear to be more effective than current therapies;
- the quality or stability of the product candidate may fall below acceptable standards; and
- insufficient quantities of the product candidate might be available to complete the trials.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Due to these and other factors, our product candidates could take longer to gain regulatory approval than we expect or we may never gain approval for any product candidates, which could reduce or eliminate our revenue by delaying or terminating the commercialization of our product candidates.

***Any product candidate for which we, or our collaborators, obtain marketing approval could be subject to restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.***

Any product candidate that we or our collaborators obtain marketing approval for, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information, reports, registration and listing requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use. If we market our products outside of their approved indications, we will be subject to enforcement action for off-label marketing.

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

- restrictions on such products, manufacturers or manufacturing processes;

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

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

***If we, or our collaborators, are unable to comply with foreign regulatory requirements or obtain foreign regulatory approvals, our ability to develop foreign markets for our products could be impaired.***

Sales of our product candidates, if any, outside the United States will be subject to foreign regulatory requirements governing clinical trials, marketing approval, manufacturing, product licensing, pricing and reimbursement. These regulatory requirements vary greatly from country to country. As a result, the time required to obtain approvals outside the United States may differ from that required to obtain FDA approval and we may not be able to obtain foreign regulatory approvals on a timely basis or at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA and foreign regulatory authorities could require additional testing. Failure to comply with these regulatory requirements or obtain required approvals could impair our ability to develop foreign markets for our products.

***Competitive products for treatment of AML may reduce or eliminate the commercial opportunity for our product candidates, if any.***

The clinical and commercial landscape for AML is rapidly changing. New data from commercial and clinical-stage products continue to emerge. It is possible that these data may alter current standards of care, completely precluding us from further developing our product candidates, if any, or getting them approved by regulatory agencies. Further, it is possible that we may initiate a clinical trial or trials for these product candidates, only to find that data from competing products make it impossible for us to complete enrollment in these trials, resulting in our inability to file for marketing approval with regulatory agencies. Even if these products are approved for marketing in a particular indication or indications, they may have limited sales due to particularly intense competition in these markets.

***We will need to develop or acquire additional manufacturing and distribution capabilities in order to commercialize our product candidates, if any, that obtain marketing approval, and we may encounter unexpected costs or difficulties in doing so.***

If we independently develop and commercialize one or more of our product candidates, if any, we will need to invest in acquiring or building additional capabilities and effectively manage our operations and facilities to successfully pursue and complete future research, development and commercialization efforts. We will require additional investment and validation process development in order to qualify our commercial-scale manufacturing process to manufacture clinical trial materials and commercial material if any of our products are approved for marketing. This investment and validation process development may be expensive and time-consuming. We will require additional personnel with experience in commercial-scale manufacturing, managing of large-scale information technology systems and managing a large-scale distribution system. We will need to add personnel and expand our capabilities, which may strain our existing managerial, operational, regulatory compliance, financial and other resources. To do this effectively, we must:

- recruit, hire, train, manage and motivate a growing employee base;
- accurately forecast demand for our products;
- assemble and manage the supply chain to ensure our ability to meet demand; and
- expand existing operational, manufacturing, financial and management information systems.

We may seek FDA approval for our production process and facilities simultaneously with seeking approval for sale of our product candidates. Should we not complete the development of adequate capabilities, including manufacturing capacity, or fail to receive timely approval of our manufacturing process and facilities, our ability to supply clinical trial materials for planned clinical trials or supply products following regulatory approval for sale could be delayed, which would further delay our clinical trials or the period of time when we would be able to generate revenues from the sale of such products, if we are even able to obtain approval or generate revenues at all.

Additionally, we may decide to outsource some or all of our manufacturing activities to a third party commercial manufacturing organization, or CMO. Under any agreement with a CMO, we would have less control over the timing and quality of manufacturing than if we were to perform such manufacturing ourselves. A CMO would be manufacturing other pharmaceutical products in the same facilities as our product candidates, increasing the risk of cross product contamination. Further, there is no guarantee that any CMO will continue ongoing operations, causing potential delays in product supply, reduced revenues and other liabilities for us.

Any such events would increase our costs and could delay or prevent our ability to commercialize our product candidates, which could adversely impact our business, financial condition and results of operations.

***Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.***

Undesirable side effects caused by our product candidates, if any, could cause us, our collaborators, or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. As a result of any side effects, our clinical trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development, or deny approval, of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;

- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

***If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we may not be successful in commercializing our product candidates if and when they are approved.***

We do not have a sales and marketing infrastructure or any experience in the sales, marketing or distribution of pharmaceutical products. We may seek additional third-party collaborators for the commercialization of our other product candidates. In the future, we may choose to build a focused sales and marketing infrastructure to market or co-promote some of our product candidates if and when they are approved, which would be expensive and time-consuming. Alternatively, we may elect to outsource these functions to third parties. Either approach carries significant risks. For example, recruiting and training a sales force is expensive and time-consuming and, if done improperly, could delay a product launch and result in limited sales. 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.

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

- our inability to recruit, manage and retain adequate numbers of effective sales and marketing personnel;
- the inability of marketing personnel to develop effective marketing materials;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be 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.

***The availability and amount of reimbursement, if approved, for our product candidates, if any, and the manner in which government and private payors may reimburse for any potential products, are uncertain.***

In both U.S. and foreign markets, sales of any products will depend in part on the availability of reimbursement from third-party payors such as government health administration authorities, private health insurers and other organizations. The future magnitude of our revenues and profitability may be affected by the continuing efforts of governmental and third-party payors to contain or reduce the costs of health care. We cannot predict the effect that private sector or governmental health care reforms may have on our business, and there can be no assurance that any such reforms will not have a material adverse effect on our business, financial condition and results of operations.In addition, in both the United States and elsewhere, sales of prescription drugs are dependent in part on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. The ability to obtain reimbursement of our products from these parties is a critical factor in the commercial success for any of our products. Failure to obtain appropriate reimbursement could result in reduced or no sales of our products.

Third-party payors are increasingly challenging the price and cost-effectiveness of medical products and services. Significant uncertainty exists as to the reimbursement status of newly-approved health care products. There can be no assurance that our products will be considered cost-effective or that adequate third-party reimbursement will be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Legislation and regulations affecting the pricing of pharmaceuticals may change before any of our products are approved for marketing. Adoption of such legislation could further limit reimbursement for medical products and services. We, or our collaborators, may elect not to market future products in certain markets.

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

Because we have limited financial and managerial resources, we focus on research programs and eventually product candidates for the indications that we believe are the most scientifically and commercially promising. Our resource allocation decisions may cause us to fail to capitalize on viable scientific or commercial products or profitable market opportunities. In addition, we may spend valuable time and managerial and financial resources on research programs and product candidates for specific indications that ultimately do not yield any scientifically or commercially viable products. If we do not accurately evaluate the scientific and commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in situations where it would have been more advantageous for us to retain sole rights to development and commercialization.

***Failure to attract and retain key personnel could impede our ability to develop our products and to obtain new collaborations or other sources of funding.***

Because of the specialized scientific nature of our business, our success is highly dependent upon our ability to attract and retain qualified scientific and technical personnel, consultants and advisors. We will also need to recruit a considerable number of additional personnel to achieve our operating goals and financial reporting obligations. To pursue our product development and marketing and sales plans, we will need to hire additional qualified scientific personnel to perform research and development, as well as personnel with expertise in clinical testing, government regulation, manufacturing, marketing and sales, which may strain our existing managerial, operational, regulatory compliance, financial and other resources. We also rely on consultants and advisors to assist in formulating our research and development strategy and adhering to complex regulatory requirements. We face competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities and other research institutions. There can be no assurance that we will be able to attract and retain such individuals on acceptable terms, if at all. The failure to attract and retain qualified personnel, consultants and advisors could have a material adverse effect on our business, financial condition and results of operations.

***The ongoing COVID-19 pandemic may, directly or indirectly, adversely affect our business, results of operations and financial condition.***

Our business could be materially adversely affected, directly or indirectly, by the widespread outbreak of contagious disease, including the ongoing COVID-19 pandemic, which has spread to many of the countries in which we, our suppliers and our collaboration partners do business. National, state and local governments in affected regions have implemented and may continue to implement safety precautions, including quarantines, border closures, increased border controls, travel restrictions, shelter in place orders and shutdowns, business closures, cancellations of public gatherings and other measures. Organizations and individuals are taking additional steps to avoid or reduce infection, including limiting travel and staying home from work. These measures are disrupting normal business operations both in and outside of affected areas and have had significant negative impacts on businesses and financial markets worldwide.

We continue to monitor our operations and applicable government recommendations, and we have made some modifications to our normal operations because of the COVID-19 pandemic, including requiring most office-based support staff to work remotely. Notwithstanding these measures, the COVID-19 pandemic could affect the health and availability of our support staff as well as those of the third parties we rely on taking similar measures. We also recognize that the global economic climate may impact our ability to raise funds.

**Risks Relating to Our Industry**

***The biopharmaceutical industry is subject to significant regulation and oversight in the United States, in addition to approval of products for sale and marketing. We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, transparency, health information privacy and security laws and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.***

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any future product candidates we may develop and any product candidates for which we obtain marketing approval. In addition to FDA restrictions on marketing of biopharmaceutical products, we are exposed, directly, or indirectly, through our customers, to broadly applicable fraud and abuse and other healthcare laws and regulations that may affect the business or financial arrangements and relationships through which we would market, sell and distribute our products. The laws that may affect our ability to operate include, but are not limited to:

The federal Anti-Kickback Statute which prohibits any person or entity from, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in-kind, to induce or reward either the referring of an individual for, or the purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable, in whole or in part, under Medicare, Medicaid or any other federally financed healthcare program. The term "remuneration" has been broadly interpreted to include anything of value. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers and formulary managers on the other hand. Although there are many statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

The federal false claims and civil monetary penalty laws, including the Federal False Claims Act, which imposes significant penalties and can be enforced by private citizens through civil qui tam actions, prohibits any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to the federal government, or knowingly making, using or causing to be made, a false statement or record material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, 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 False Claims Act. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. Further, manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. Criminal prosecution is also possible for making or presenting a false, fictitious or fraudulent claim to the federal government. Several pharmaceutical and other health care 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 marketing of the product for unapproved, and thus non-reimbursable, uses.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statements or representations, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of, or payment for, benefits, items or services.

HIPAA, as amended by the Health Information Technology and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which impose certain requirements relating to the privacy, security, transmission and breach reporting of individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses and healthcare providers and their respective business associates that perform services for them that involve individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

The federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act," and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

State and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by non-governmental third-party payors, including private insurers.

State and foreign laws that require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to track and report gifts, compensation and other remuneration provided to physicians and other healthcare providers, and other federal, state and foreign laws that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure, and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus requiring additional compliance efforts.

Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially considering the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to several investigations, prosecutions, convictions and settlements in the healthcare industry.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly and time consuming. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from governmental funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

***Health care reform measures could adversely affect our business.***

In the United States and foreign jurisdictions, there have been, and continue to be, many legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. There have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs. In 2010, the PPACA was enacted, which includes measures to significantly change the way health care is financed by both governmental and private insurers. Among the provisions of the PPACA of greatest importance to the pharmaceutical and biotechnology industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- implementation of the federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act";
- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;

- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price, or AMP;

- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted or injected;

- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and

- expansion of the entities eligible for discounts under the Public Health program.

Some of the provisions of the PPACA have yet to be implemented, and there have been legal and political challenges to certain aspects of the PPACA. Since January 2017, former President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Congress may consider other legislation to repeal or replace elements of the PPACA.

Many of the details regarding the implementation of the PPACA are yet to be determined, and at this time, the full effect that the PPACA would have on our business remains unclear. There is uncertainty surrounding the applicability of the biosimilars provisions under the PPACA to our product candidates. The FDA has issued several guidance documents, but no implementing regulations, on biosimilars. Many biosimilar applications have been approved over the past few years. It is not certain that we will receive 12 years of biologics marketing exclusivity for any of our products. The regulations that are ultimately promulgated and their implementation are likely to have considerable impact on the way we conduct our business and may require us to change current strategies. A biosimilar is a biological product that is highly similar to an approved drug notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biological product and the approved drug in terms of the safety, purity, and potency of the product.

Individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce ultimate demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

In addition, given recent federal and state government initiatives directed at lowering the total cost of healthcare, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and biologics and the reform of the Medicare and Medicaid programs. While we cannot predict the full outcome of any such legislation, it may result in decreased reimbursement for drugs and biologics, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm our ability to generate revenues. Increases in importation or re-importation of pharmaceutical products from foreign countries into the United States could put competitive pressure on our ability to profitably price our products, which, in turn, could adversely affect our business, results of operations, financial condition and prospects. We might elect not to seek approval for or market our products in foreign jurisdictions to minimize the risk of re-importation, which could also reduce the revenue we generate from our product sales. It is also possible that other legislative proposals having similar effects will be adopted.

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

***We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.***

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

***An NDA submitted under Section 505(b)(2) subjects us to the risk that we may be subject to a patent infringement lawsuit that would delay or prevent the review or approval of our product candidate.***

Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies that were not conducted by, or for, the applicant and on which the applicant has not obtained a right of reference. The 505(b)(2) application would enable us to reference published literature and/or the FDA's previous findings of safety and effectiveness for the branded reference drug. For NDAs submitted under Section 505(b)(2) of the FDCA, the patent certification and related provisions of the Hatch-Waxman Act apply. In accordance with the Hatch-Waxman Act, such NDAs may be required to include certifications, known as paragraph IV certifications, that certify that any patents listed in the Patent and Exclusivity Information Addendum of the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, with respect to any product referenced in the 505(b)(2) application, are invalid, unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505(b)(2) NDA.

Under the Hatch-Waxman Act, the holder of patents that the 505(b)(2) application references may file a patent infringement lawsuit after receiving notice of the paragraph IV certification. Filing of a patent infringement lawsuit against the filer of the 505(b)(2) applicant within 45 days of the patent owner's receipt of notice triggers a one-time, automatic, 30-month stay of the FDA's ability to approve the 505(b)(2) NDA, unless patent litigation is resolved in the favor of the paragraph IV filer or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all. In addition, a 505(b)(2) application will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, or NCE, listed in the Orange Book for the referenced product has expired. The FDA may also require us to perform one or more additional clinical studies or measurements to support the change from the branded reference drug, which could be time consuming and could substantially delay our achievement of regulatory approvals for such product candidates. The FDA may also reject our future 505(b)(2) submissions and require us to file such submissions under Section 505(b)(1) of the FDCA, which would require us to provide extensive data to establish safety and effectiveness of the drug for the proposed use and could cause delay and be considerably more expensive and time consuming. These factors, among others, may limit our ability to successfully commercialize our product candidates.

***We may seek Fast Track designation for one or more of our product candidates, but we might not receive such designation, and even if we do, such designation may not actually lead to a faster development or regulatory review or approval process.***

If a product is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a product sponsor may apply for FDA Fast Track designation. If we seek Fast Track designation for a product candidate, we may not receive it from the FDA. However, even if we receive Fast Track designation, Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

***If the FDA does not conclude that our product candidates satisfy the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of any of our product candidates under Section 505(b)(2) are not as we expect, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.***

We intend to seek FDA approval through the 505(b)(2) regulatory pathway for certain of our product candidates. The Hatch-Waxman Act, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant. If the FDA does not allow us to pursue the 505(b)(2) regulatory pathway for our product candidates as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates would likely substantially increase. Moreover, the inability to pursue the 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than our product candidates, which could materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the 505(b)(2) regulatory pathway for a product candidate, we cannot assure you that we will receive the requisite or timely approvals for commercialization of such product candidate. In addition, we expect that our competitors will file citizens' petitions with the FDA in an attempt to persuade the FDA that our product candidates, or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

***We expect to rely heavily on orphan drug status to commercialize some of our product candidates, if approved, but we might not receive such designation and any orphan drug designations we receive may not confer marketing exclusivity or other expected commercial benefits.***

We expect to rely heavily on orphan drug exclusivity for our product candidates. Designation of orphan drug status is within the discretion of the FDA and the FDA may determine that we do not meet the criteria for orphan drug status. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity in the United States provides that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances the applicable exclusivity period is ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Even if we, or any future collaborators, obtain orphan drug designation for a product candidate, we, or they, may not be able to obtain or maintain orphan drug exclusivity for that product candidate. We may not be the first to obtain marketing approval of any product candidate for which we have obtained orphan drug designation for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products, and it is possible that another company also holding orphan drug designation for the same product candidate will receive marketing approval for the same indication before we do. If that were to happen, our applications for that indication may not be approved until the competing company's period of exclusivity expires. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we, or any future collaborators, obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process, nor does it prevent competitors from obtaining approval of the same product candidate as ours for indications other than those in which we have been granted orphan drug designation.

***We may seek a breakthrough therapy designation for one or more of our other product candidates, we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process.***

We may seek a breakthrough therapy designation for one or more of our other product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for priority review if supported by clinical data at the time the NDA is submitted to the FDA. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. Even if we receive breakthrough therapy designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

***We may seek priority review designation for one or more of our other product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process.***

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily mean a faster development or regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

**Risks Related to Third Parties**

***We may rely on third parties to conduct our non-clinical studies and our clinical studies. If these third parties do not perform as contractually required or expected, we may not be able to select product candidates or obtain market acceptance for our product candidates, if any, or we may be delayed in doing so.***

We often rely on third parties, such as CROs, medical institutions, academic institutions, clinical investigators and contract laboratories, to conduct our clinical studies. We are responsible for confirming that our clinical studies are conducted in accordance with applicable regulations and in accordance with its general investigational plan and protocol. Our reliance on third parties does not relieve us of these responsibilities. If the third parties conducting our clinical studies do not perform their contractual duties or obligations, do not meet expected deadlines, fail to comply with Good clinical practice (GCP), do not adhere to our clinical study protocols or otherwise fail to generate reliable clinical data, we may need to enter into new arrangements with alternative third parties and our clinical study may be more costly than expected or budgeted, extended, delayed or terminated or may need to be repeated, and we may not be able to obtain regulatory approval for or commercialize the target molecules or product candidates, if any, tested in such studies.

***We may explore strategic collaborations that may never materialize or may fail.***

We may, in the future, periodically explore a variety of possible strategic collaborations including international distributors and partners, in an effort to gain access to new product candidates or resources. At the current time, we cannot predict what form such a strategic collaboration might take. We are likely to face significant competition in seeking appropriate strategic collaborators, and these strategic collaborations can be complicated and time-consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic collaborations because of the numerous risks and uncertainties associated with establishing strategic collaborations.

**Risks Related to Our Intellectual Property**

***If we are unable to protect our proprietary rights or to defend against infringement claims, we may not be able to compete effectively or operate profitably.***

Our success will depend, in part, on our ability to obtain patents, operate without infringing the proprietary rights of others and maintain trade secrets, both in the United States and other countries. Patent matters in the biotechnology and pharmaceutical industries can be highly uncertain and involve complex legal and factual questions. Accordingly, the validity, breadth and enforceability of our patents and the existence of potentially blocking patent rights of others cannot be predicted, either in the United States or in other countries.

There can be no assurance that we will discover or develop patentable products or processes or that patents will issue from any of the currently pending patent applications or that claims granted on issued patents will be sufficient to protect our technology or adequately cover the actual products we may actually sell. Potential competitors or other researchers in the field may have filed patent applications, been issued patents, published articles or otherwise created prior art that could restrict or block our efforts to obtain additional patents. There also can be no assurance that our issued patents or pending patent applications, if issued, will not be challenged, invalidated, rendered unenforceable or circumvented or that the rights granted hereunder will provide us with proprietary protection or competitive advantages. Our patent rights also depend on our compliance with technology and patent licenses upon which our patent rights are based and upon the validity of assignments of patent rights from consultants and other inventors that were, or are, not employed by us.

In addition, competitors may manufacture and sell our potential products in those foreign countries where we have not filed for patent protection or where patent protection may be unavailable, not obtainable or ultimately not enforceable. In addition, even where patent protection is obtained, third-party competitors may challenge our patent claims in the various patent offices, for example via opposition in the European Patent Office or reexamination or interference proceedings in the United States Patent and Trademark Office, or USPTO. The ability of such competitors to sell such products in the United States or in foreign countries where we have obtained patents is usually governed by the patent laws of the countries in which the product is sold.

We will incur significant ongoing expenses in maintaining our patent portfolio. Should we lack the funds to maintain our patent portfolio or to enforce our rights against infringers, we could be adversely impacted. Even if claims of infringement are without merit, any such action could divert the time and attention of management and impair our ability to access additional capital and/or cost us significant funds to defend.

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

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or our licensors or strategic collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.
- We or our licensors or strategic collaborators might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- It is possible that our pending patent applications will not lead to issued patents.
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.

- Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.

- We may not develop additional proprietary technologies that are patentable.

- The patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

***Patent reform legislation could 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 U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO is currently developing 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 will not become effective until one year or 18 months after its enactment. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business, our current and pending patent portfolio and future intellectual property strategy. 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.

***We may be subject to litigation with respect to the ownership and use of intellectual property that will be costly to defend or pursue and uncertain in its outcome.***

Our success also will depend, in part, on our refraining from infringing patents or otherwise violating intellectual property owned or controlled by others. Pharmaceutical companies, biotechnology companies, universities, research institutions and others may have filed patent applications or have received, or may obtain, issued patents in the United States or elsewhere relating to aspects of our technology. It is uncertain whether the issuance of any third-party patents will require us to alter our products or processes, obtain licenses, or cease certain activities. Some third-party applications or patents may conflict with our issued patents or pending applications. Any such conflict could result in a significant reduction of the scope or value of our issued or licensed patents.

In addition, if patents issued to other companies contain blocking, dominating or conflicting claims and such claims are ultimately determined to be valid, we may be required to obtain licenses to these patents or to develop or obtain alternative non-infringing technology and cease practicing those activities, including potentially manufacturing or selling any products deemed to infringe those patents. If any licenses are required, there can be no assurance that we will be able to obtain any such licenses on commercially favorable terms, if at all, and if these licenses are not obtained, we might be prevented from pursuing the development and commercialization of certain of our potential products. Our failure to obtain a license to any technology that we may require to commercialize our products on favorable terms may have a material adverse impact on our business, financial condition and results of operations.

Litigation, which could result in substantial costs to us (even if determined in our favor), may also be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of the proprietary rights of others. The FDA has only recently published draft guidance documents for implementation of the Biologics Price Competition and Innovation Act (BPCIA) under the PPACA, related to the development of follow-on biologics (biosimilars), and detailed guidance for patent litigation procedures under this act has not yet been provided. If another company files for approval to market a competing follow-on biologic, and/or if such approval is given to such a company, we may be required to promptly initiate patent litigation to prevent the marketing of such biosimilar version of our product prior to the normal expiration of the patent. There can be no assurance that our issued or licensed patents would be held valid by a court of competent jurisdiction or that any follow-on biologic would be found to infringe our patents.

In addition, if our competitors file or have filed patent applications in the United States that claim technology also claimed by us, we may have to participate in interference proceedings to determine priority of invention. These proceedings, if initiated by the USPTO, could result in substantial costs to us, even if the eventual outcome is favorable to us. Such proceedings can be lengthy, are costly to defend and involve complex questions of law and fact, the outcomes of which are difficult to predict. Moreover, we may have to participate in post-grant proceedings or third-party ex parte or inter partes reexamination proceedings under the USPTO. An adverse outcome with respect to a third-party claim or in an interference proceeding could subject us to significant liabilities, require us to license disputed rights from third parties, or require us to cease using such technology, any of which could have a material adverse effect on our business, financial condition and results of operations.

***The patent protection and patent prosecution for some of our target molecules and product candidates, if any, is dependent or may be dependent in the future on third parties.***

While we normally seek and gain the right to fully prosecute the patents relating to our target molecules and product candidates, if any, there may be times when platform technology patents or product-specific patents that relate to the target molecules or product candidates are controlled by our licensors. In addition, our licensors and/or licensees may have back-up rights to prosecute patent applications in the event that we do not do so or choose not to do so, and our licensees may have the right to assume patent prosecution rights after certain milestones are reached. If any of our licensing collaborators fails to appropriately prosecute and maintain patent protection for patents covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

***We have licensed, or will license, from third parties certain technology necessary to develop and commercialize its therapeutics. If these licenses terminate, or if these third parties do not comply with the terms of the license, or if the underlying licensed patents are found to be invalid, our business could be negatively impacted.***

We have licensed, or will license, from third parties, technology necessary to research, develop and commercialize our product candidiates. In return for the use of their technology, we have paid or agreed, or will agree, to pay the licensor certain fees. We may need to license additional technology to in the future. If these licenses terminate, if the licensors fail to abide by the terms of the license or fail to prevent infringement by third parties, if the licensed patents or other rights are found to be invalid or if we are unable to enter into necessary licenses on acceptable terms, our business could be negatively impacted.

***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 our patents, trademarks, copyrights 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 and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

***We may rely on trade secret and proprietary know-how which can be difficult to trace and enforce and, if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

We also rely on trade secrets to protect technology, especially where patent protection is not believed to be appropriate or obtainable or where patents have not issued. For example, our manufacturing process involves many trade secret steps, processes, and conditions. Trade secrets and know-how can be difficult to protect. We attempt to protect our proprietary technology and processes, in part, with confidentiality agreements and assignment of invention agreements with our employees and confidentiality agreements with our consultants and certain contractors. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third party consultants and vendors that we engage to perform research, clinical studies or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed.

There can be no assurance that these agreements are valid and enforceable, will not be breached, that we would have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by competitors. We may fail in certain circumstances to obtain the necessary confidentiality agreements or assignment of invention agreements, or their scope or term may not be sufficiently broad to protect our interests or transfer adequate rights to us.

If our trade secrets or other intellectual property become known to our competitors, it could result in a material adverse effect on our business, financial condition and results of operations. To the extent that we or our consultants or research collaborators use intellectual property owned by others in work for us, disputes may also arise as to the rights to related or resulting know-how and inventions.

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

Patents are of national or regional effect, and filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. As such, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals or biologics, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. In addition, certain developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

***Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.***

Patent rights are of limited duration. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. A patent term extension based on regulatory delay may be available in the United States. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

***We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property.***

Some of our employees and our licensors' employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees may have executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

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

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

**Risks Relating to Litigation**

***We are exposed to potential product liability or similar claims, and insurance against these claims may not be available to us at a reasonable rate in the future.***

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing and marketing of human therapeutic products. Clinical trials involve the testing of product candidates on human subjects or volunteers under a research plan, and carry a risk of liability for personal injury or death to patients due to unforeseen adverse side effects, improper administration of the product candidate, or other factors. Many of these patients are already seriously ill and are therefore particularly vulnerable to further illness or death.

We currently do not carry clinical trial liability insurance but we will need to once we begin clinical trials. There can be no assurance that we will be able to obtain such insurance or that the amount of such insurance will be adequate to cover claims. We could be materially and adversely affected if we were required to pay damages or incur defense costs in connection with a claim outside the scope of indemnity or insurance coverage, if the indemnity is not performed or enforced in accordance with its terms, or if our liability exceeds the amount of applicable insurance. In addition, there can be no assurance that insurance will continue to be available on terms acceptable to us, if at all, or that if obtained, the insurance coverage will be sufficient to cover any potential claims or liabilities. Similar risks would exist upon the commercialization or marketing of any products by us or our collaborators.

Regardless of their merit or eventual outcome, product liability claims may result in:

- decreased demand for our product;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial volunteers;
- costs of litigation;
- distraction of management; and
- substantial monetary awards to plaintiffs.

Should any of these events occur, it could have a material adverse effect on our business and financial condition.

***Information technology security breaches and other disruptions could compromise our information and expose us to legal responsibility which would cause our business and reputation to suffer.***

We are increasingly dependent on information technology systems and infrastructure, much of which is outsourced to third parties including on "cloud" based platforms. We collect, store, and use sensitive or confidential data, including intellectual property, our proprietary business information and that of our suppliers, and business partners. The secure maintenance of this information is critical to our operations and business strategy. We are subject to laws and regulations in the United States and abroad, such as the Health Insurance Portability and Accountability Act of 1996 and European Union regulations related to data privacy, which require us to protect the privacy and security of certain types of information. Our information technology and infrastructure may be vulnerable to attacks by hackers, breached due to employee error, malfeasance, or other disruptions, or subject to system failures. Because the techniques used to obtain unauthorized access, disable, or degrade service, or sabotage systems change frequently and may be difficult to detect for long periods of time, we may be unable to anticipate these techniques or implement adequate preventive measures. Any breaches or failures could compromise sensitive and confidential information stored on our networks or those of third parties and expose such information to public disclosure, loss, or theft. Any actual or alleged unauthorized access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disruption of our operations, and damage to our reputation, any of which could adversely affect our business, financial condition, or results of operations. Costs we may incur as a result of any of the foregoing, could adversely affect our business, financial condition, or results of operations. Given the increasing use of conferencing technologies to conduct business virtually in light of the COVID-19 pandemic, these cybersecurity risks are becoming more prevalent.

**Risks Relating to Our Stock**

***Our common stock is deemed a "penny stock," which would make it more difficult for our investors to sell their shares.***

Our common stock is subject to the "penny stock" rules adopted under Section 15(g) of the Exchange Act. The penny stock rules generally apply to companies whose common stock is not listed on the NASDAQ Stock Market or other national securities exchange and trades at less than $4.00 per share, other than companies that have had average revenue of at least $6,000,000 for the last three years or that have tangible net worth of at least $5,000,000 ($2,000,000 if the company has been operating for three or more years). These rules require, among other things, that brokers who trade penny stock to persons other than "established customers" complete certain documentation, make suitability inquiries of investors and provide investors with certain information concerning trading in the security, including a risk disclosure document and quote information under certain circumstances. Many brokers have decided not to trade penny stocks because of the requirements of the penny stock rules and, as a result, the number of broker-dealers willing to act as market makers in such securities is limited. If we remain subject to the penny stock rules for any significant period, it could have an adverse effect on the market, if any, for our securities. If our securities are subject to the penny stock rules, investors will find it more difficult to dispose of our securities.

***We have not paid cash dividends in the past and do not expect to pay dividends in the future. Any return on investment may be limited to the value of our common stock.***

We have never paid cash dividends on our common stock and do not anticipate doing so in the foreseeable future. The payment of dividends on our common stock will depend on earnings, financial condition and other business and economic factors affecting us at such time as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if our stock price appreciates.

***The price of our common stock may fluctuate substantially.***

You should consider an investment in our common stock to be risky, and you should invest in our common stock only if you can withstand a significant loss and wide fluctuations in the market value of your investment. Some factors that may cause the market price of our common stock to fluctuate, in addition to the other risks mentioned in this "Risk Factors" section and elsewhere in this prospectus, are:

- sale of our common stock by our stockholders, executives, and directors;
- volatility and limitations in trading volumes of our shares of common stock;
- our ability to obtain financings to conduct and complete research and development activities including, but not limited to, our human clinical trials, and other business activities;
- our announcements or our competitors' announcements regarding new products or services, enhancements, significant contracts, acquisitions or strategic investments;
- failures to meet external expectations or management guidance;
- changes in our capital structure or dividend policy;
- our cash position;
- announcements and events surrounding financing efforts, including debt and equity securities;
- our inability to enter into new markets or develop new products;
- reputational issues;
- announcements of acquisitions, partnerships, collaborations, joint ventures, new products, capital commitments, or other events by us or our competitors;
- changes in general economic, political and market conditions in any of the regions in which we conduct our business;
- changes in industry conditions or perceptions;
- changes in valuations of similar companies or groups of companies;
- analyst research reports, recommendation and changes in recommendations, price targets, and withdrawals of coverage;
- departures and additions of key personnel;
- disputes and litigations related to contractual obligations;

- changes in applicable laws, rules, regulations, or accounting practices and other dynamics; or
- other events or factors, many of which may be out of our control.

In addition, if the market for stocks in our industry or industries related to our industry, or the stock market in general, experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, financial condition and results of operations. If any of the foregoing occurs, it could cause our stock price to fall and may expose us to lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management.

***Our ability to use our net operating loss carry-forwards and certain other tax attributes is limited by Sections 382 and 383 of the Internal Revenue Code.***

Net operating loss carryforwards allow companies to use past year net operating losses to offset against future years' profits, if any, to reduce future tax liabilities. Sections 382 and 383 of the Internal Revenue Code of 1986 limit a corporation's ability to utilize its net operating loss carryforwards and certain other tax attributes (including research credits) to offset any future taxable income or tax if the corporation experiences a cumulative ownership change of more than 50% over any rolling three-year period. State net operating loss carryforwards (and certain other tax attributes) may be similarly limited. An ownership change can therefore result in significantly greater tax liabilities than a corporation would incur in the absence of such a change and any increased liabilities could adversely affect the corporation's business, results of operations, financial condition and cash flow.

Even if another ownership change has not occurred and does not occur as a result of this offering, additional ownership changes may occur in the future as a result of additional equity offerings or events over which we will have little or no control, including purchases and sales of our equity by our five percent security holders, the emergence of new five percent security holders, redemptions of our securities or certain changes in the ownership of any of our five percent security holders.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.***

As of September 30, 2021, our executive officers, directors and principal security holders, together with their respective affiliates, owned approximately 51.1% of our outstanding securities. Accordingly, this group of security holders will be able to exert a significant degree of influence over our management and affairs and over matters requiring security holder approval, including the election of our Board of Directors, future issuances of our securities, declaration of dividends and approval of other significant corporate transactions. This concentration of ownership could have the effect of delaying or preventing a change-of-control of our company or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our securities. In addition, this significant concentration of share ownership may adversely affect the trading price for our common stock if investors perceive disadvantages in owning stock in a company with such concentrated ownership.

***U.S. federal income tax reform could adversely affect us.***

On December 22, 2017, former President Trump signed into law the "Tax Cuts and Jobs Act" (TCJA) that significantly reforms the Internal Revenue Code of 1986, as amended. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest, allows for the expensing of capital expenditures, and puts into effect the migration from a "worldwide" system of taxation to a territorial system. The tax reform did not have a material impact to our projection of minimal cash taxes or to our net operating losses. Our net deferred tax assets and liabilities are revalued at the newly enacted U.S. corporate rate, and the impact has been recognized in our tax expense in the year of enactment. Further, any eligibility we may have or may someday have for tax credits associated with the qualified clinical testing expenses arising out of the development of orphan drugs was reduced to 25% as a result of the TCJA; thus, our net taxable income is affected. We continue to examine the impact this tax reform legislation may have on our business. The impact of this tax reform on holders of our common stock is uncertain and could be adverse. This prospectus does not discuss any such tax legislation or the way it might affect purchasers of our common stock. We urge our stockholders, including purchasers of common stock in this offering, to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

***In preparing our consolidated financial statements, our management determined that our disclosure controls and procedures and internal controls were ineffective as of September 30, 2021 and if they continue to be ineffective could continue to result in material misstatements in our financial statements.***

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15 (f) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. As of September 30, 2021, our management has determined that our disclosure controls and procedures and internal controls were ineffective due to weaknesses in our financial closing process, inadequate segregation of duties over authorization, review and recording of transactions, lack of accounting resources, as well as the financial reporting of such transactions.

We intend to implement remedial measures designed to address the ineffectiveness of our disclosure controls and procedures and internal controls. If these remedial measures are insufficient to address the ineffectiveness of our disclosure controls and procedures and internal controls, or if material weaknesses or significant deficiencies in our internal control are discovered or occur in the future and the ineffectiveness of our disclosure controls and procedures and internal controls continues, we may fail to meet our future reporting obligations on a timely basis, our consolidated financial statements may contain material misstatements, we could be required to restate our prior period financial results, our operating results may be harmed, we may be subject to class action litigation, and our common stock could be delisted. Any failure to address the ineffectiveness of our disclosure controls and procedures could also adversely affect the results of the periodic management evaluations regarding the effectiveness of our internal control over financial reporting and our disclosure controls and procedures that are required to be included in our annual report on Form 10-K. Internal control deficiencies and ineffective disclosure controls and procedures could also cause investors to lose confidence in our reported financial information. We can give no assurance that the measures we plan to take in the future will remediate the ineffectiveness of our disclosure controls and procedures or that any material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or adequate disclosure controls and procedures or circumvention of these controls. In addition, even if we are successful in strengthening our controls and procedures, in the future those controls, and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our consolidated financial statements.

***Future sales and issuances of our common stock or rights to purchase common stock pursuant to our equity incentive plan could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.***

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

***We may be at risk of securities class action litigation.***

We may be at risk of securities class action litigation. This risk is especially relevant for us due to our dependence on positive clinical trial outcomes and regulatory approvals of each of our product candidates. In the past, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business and results in a decline in the market price of our common stock.

***Our articles of incorporation and bylaws and Nevada law may have anti-takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline.***

Our amended and restated articles of incorporation, our amended and restated bylaws and Nevada law could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our stockholders. Although we currently do not have shares of preferred stock outstanding, our board of directors could authorize the issuance of a series of preferred stock that would grant holders preferred rights to our assets upon liquidation, special voting rights, the right to receive dividends before dividends would be declared to common stockholders, and the right to the redemption of such shares, possibly together with a premium, prior to the redemption of the common stock. To the extent that we do issue preferred stock, the rights of holders of common stock could be impaired thereby, including without limitation, with respect to liquidation.

Provisions of our bylaws may also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, our bylaws, among other things:

- provide the board of directors with the ability to alter the bylaws without stockholder approval; and
- provide that vacancies on the board of directors may be filled by a majority of directors in office, although less than a quorum.

***Reports published by securities or industry analysts, including projections in those reports that exceed our actual results, could adversely affect our common stock price and trading volume.***

Securities research analysts, including those affiliated with our underwriters from this offering, establish and publish their own periodic projections for our business. These projections may vary widely from one another and may not accurately predict the results we actually achieve. Our stock price may decline if our actual results do not match securities research analysts' projections. Similarly, if one or more of the analysts who writes reports on us downgrades our stock or publishes inaccurate or unfavorable research about our business or if one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, our stock price or trading volume could decline. While we expect securities research analyst coverage to continue going forward, if no securities or industry analysts begin to cover us, the trading price for our stock and the trading volume could be adversely affected.

## ITEM 1B. UNRESOLVED STAFF COMMENTS

### Item 1B. Unresolved Staff Comments

None.

## ITEM 2. PROPERTIES

Our executive offices are located at 420 Lexington Avenue, 25th Floor, New York, NY 10170. We do not own any real property.

We are currently sharing approximately 3,011 square feet of laboratory and office space for our headquarters in Lexington Avenue, New York with Tiziana Therapeutics Inc. The lease is under Tiziana Therapeutics Inc.'s name and we are being charged for a portion of the space via a Shared Services agreement.

We believe that our facilities are adequate for our needs for the immediate future and that, should it be needed, suitable additional space will be available to accommodate expansion of our operations on commercially reasonable terms.

## ITEM 3. LEGAL PROCEEDINGS

We are not involved in any pending legal proceeding or litigation and, to the best of our knowledge, no governmental authority is contemplating any proceeding to which we are a party or to which any of our properties is subject, which would reasonably be likely to have a material adverse effect on us.

## ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES

**Market Information**

Our common shares are currently quoted on the OTCQB under the trading symbol "RASP". Our shares were previously quoted on the OTCQB Market from September 27, 2016 to April 21, 2017 and the OTCQX market from April 22, 2017 until October 5, 2018. Prior to September 27, 2016, our shares were quoted on the OTC Market under the trading symbol "ATVM".

Our transfer agent is Philadelphia Stock Transfer, Inc., 2320 Haverford Road, Ardmore, PA 19003.

**Holders of our Common Stock**

As of September 30, 2021, there were 60 registered stockholders of our issued and outstanding common stock.

**Dividend Policy**

We have never declared or paid any cash dividends on our common stock and we do not anticipate paying any dividends or making any other distributions in the foreseeable future. The payment by us of dividends, if any, in the future, rests within the discretion of our board of directors and will depend, among other things, upon our earnings, capital requirements and financial condition.

**Securities Authorized for Issuance Under Equity Compensation Plans**

The following table summarizes information about our equity compensation plans as of September 30, 2021.

| | Number of Shares of Common Stock to be Issued upon Exercise of Outstanding Options, Warrants and Rights | Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights | Number of Options Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) |
|---|---|---|---|
| Equity Compensation Plans Approved by Stockholders | 3,648,675 | $ 0.59 | — |
| Equity Compensation Plans Not Approved by Stockholders | 1,926,501 | $ 0.43 | — |
| Total | 5,575,176 | | — |

### ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

Not applicable.

**ITEM 7. MANAGEMENTS DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

**Forward-Looking Statements**

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the financial statements and the related notes and other information that are included elsewhere in this Form 10-K. This discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties, such as our plans, objectives, expectations and intentions. Actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of a number of factors, including those set forth under the cautionary note regarding "Forward-Looking Statements" contained elsewhere in this Form 10-K. Additionally, you should read the "Risk Factors" section of this Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

*Our audited financial statements are stated in United States dollars and are prepared in accordance with United States generally accepted accounting principles.*

*We assume no obligation to revise or publicly release the results of any revision to these forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.*

*Unless expressly indicated or the context requires otherwise, the terms "Rasna,"," the "Company," "we," "us," and "our" refer to Rasna Therapeutics, Inc., a Nevada corporation, and, where appropriate, its wholly owned subsidiaries.*

*Company Background*

***Overview***

To date, we have devoted substantially all of our resources to research and development efforts relating to our therapeutic candidates, including conducting clinical trials and developing manufacturing capabilities, in-licensing related intellectual property, protecting our intellectual property and providing general and administrative support for these operations. Since our inception, we have funded our operations primarily through the issuance of equity securities.

We anticipate that our expenses will increase substantially if and as we:

- continue enrollment in our ongoing clinical trials;
- initiate new clinical trials;
- seek to identify, assess, acquire and develop other products, therapeutic candidates and technologies;
- seek regulatory and marketing approvals in multiple jurisdictions for our therapeutic candidates that successfully complete clinical studies;
- establish collaborations with third parties for the development and commercialization of our products and therapeutic candidates;
- make milestone or other payments under our agreements pursuant to which we have licensed or acquired rights to intellectual property and technology seek to maintain, protect, and expand our intellectual property portfolio;
- seek to attract and retain skilled personnel;
- incur the administrative costs associated with being a public company and related costs of compliance;
- create additional infrastructure to support our operations as a commercial stage public company and our planned future commercialization efforts; and
- experience any delays or encounter issues with any of the above.

We expect to continue to incur significant expenses and increasing losses for at least the next several years. Accordingly, we anticipate that we will need to raise additional capital in addition to the net proceeds from this offering in order to obtain regulatory approval for, and the commercialization of our therapeutic candidates. Until such time that we can generate meaningful revenue from product sales, if ever, we expect to finance our operating activities through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any approved therapies or products or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially adversely affect our business, financial condition and results of operations.

We only have one segment of activity which is that of a clinical stage biotechnology company focused on targeted drugs to treat diseases in oncology and immunology, mainly focusing on the treatment of leukemia.

**Summary of significant accounting policies**

This discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States of America, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reported period. In accordance with US GAAP, we base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our audited consolidated financial statements appearing elsewhere in this Annual Report, we believe the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements.

***Basis of preparation***

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("US GAAP"). Any reference in these notes to applicable guidance is meant to refer to US GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

***Principles of Consolidation***

In accordance with ASC 810, *Consolidation,* the Company consolidates any entity in which it has a controlling financial interest. Further, the Company consolidates any variable interest entity that it is deemed to be the primary beneficiary of, and have the power to direct its significant activities. Upon review of the relationship between Rasna Therapeutics ("Rasna UK") and the Company, Management determined that the equity investment in Rasna UK was not sufficient to fund its operations. Accordingly, the Company is considered to be the primary beneficiary of the assets held within Rasna UK, which primarily consist of cash received from the Company to fund its operations, and has power to direct its significant activities. As a result, the Company consolidates this variable interest entity, which has minimal activity and has been liquidated.

The consolidated financial statements include the financial statements of the Company and its wholly owned subsidiary, Rasna Research Inc, and Rasna Research Inc's subsidiary, Arna Therapeutics Limited. All significant intercompany accounts and transactions have been eliminated in the preparation of the accompanying consolidated financial statements.

***Going Concern***

We are subject to a number of risks similar to those of other pre-commercial stage companies, including its dependence on key individuals, uncertainty of product development and generation of revenues, dependence on outside sources of capital, risks associated with research, development, testing, and obtaining related regulatory approvals of its pipeline products, suppliers and collaborators, successful protection of intellectual property, competition with larger, better-capitalized companies, successful completion of our development programs and, ultimately, the attainment of profitable operations are dependent on future events, including obtaining adequate financing to fulfill its development activities and generating a level of revenues adequate to support the Company's cost structure.

We have experienced net losses and significant cash outflows from cash used in operating activities over the past two years, and as of September 30, 2021, had an accumulated deficit of $23,443,563, a net loss for the year ended September 30, 2021 of $785,082 and net cash used in operating activities of $293,393. These conditions indicate that there is substantial doubt about our ability to continue as a going concern within the next twelve months from the filing date of this annual report on Form 10-K.

We expect to continue to incur net losses and have significant cash outflows for at least the next twelve months. We currently have sufficient funds to continue operating until the end of April 2022 , but will require significant additional cash resources to launch new development phases of existing products in its pipeline. Additional cash injections are expected from Panetta partners which is expected to enable the Company to continue our operations through at least March 2023, however in the event that we are unable to secure the necessary additional cash resources needed, we may need to slow current development phases or halt new development phases in order to mitigate the effects of the costs of development . The accompanying consolidated financial statements have been prepared assuming that we will continue as a going concern. This basis of accounting contemplates the recovery of our assets and the satisfaction of liabilities in the normal course of business. A successful transition to attaining profitable operations is dependent upon achieving a level of positive cash flows adequate to support our cost structure.

***Use of Estimates***

The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. We evaluate our estimates on an ongoing basis, including those related to the fair values of stock based compensation awards, the modification and extinguishment of debt, troubled debt restructuring, derivatives and valuations associated with derivatives, income taxes and contingent liabilities, among others . We base our estimates on historical experience and on various other assumptions that we believe to be reasonable, the results of which form the basis for making judgments about the carrying amounts of assets and liabilities. Actual results could differ from those estimates and such differences could be material to our consolidated financial position and results of operations.

***Goodwill and Intangible assets***

Intangible assets are made up of in-process research and development, ("IPR&D") and certain intellectual property ("IP"). The balance of IPR&D represents IPR&D acquired in 2013, which, at the time, was determined to have alternative future uses. IPR&D assets also represent the fair value assigned to acquired technologies in a business combination, which at the time of the business combination have not reached technological feasibility and have no alternative future use. IP assets represent the fair value assigned to technologies, which at the time of acquisition have reached technological feasibility, however, have not yet been put into service. Intangible assets are considered to have an indefinite useful life until the completion or abandonment of the associated research and development projects.

Goodwill represents the premium paid over the fair value of the net tangible and intangible assets acquired in business combinations. Goodwill is not amortized; rather, it is subject to a periodic assessment for impairment by applying a fair value based test. Goodwill is assessed for impairment on an annual basis or more frequently if events or changes in circumstances indicate that the asset might be impaired. An impairment charge is recognized only when the implied fair value of our reporting unit's goodwill is less than its carrying amount.

Management evaluates indefinite life intangible assets for impairment on an annual basis and on an interim basis if events or changes in circumstances between annual impairment tests indicate that the asset might be impaired. The ongoing evaluation for impairment of its indefinite life intangible assets requires significant management estimates and judgment. Management reviews definite life intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Goodwill and intangible assets were fully impaired as of September 30, 2020.

***Risks and Uncertainties***

We intend to operate in an industry that is subject to rapid change. Our operations will be subject to significant risk and uncertainties including financial, operational, technological, regulatory, and other risks associated with an early stage company, including the potential risk of business failure.

***Research and development***

Expenditure on research and development is charged to the statement of operations in the year in which it is incurred with the exception of expenditures incurred in respect of the development of major new products where the outcome of those projects is assessed as being reasonably certain in regards to viability and technical feasibility. Such expenditure is capitalized and amortized straight line over the estimated period of sale for each product, commencing in the year that sales of the product are first made. To date, we have not capitalized any such expenditures other than certain IPR&D & IP recorded in connection with certain acquisition or equity transactions.

***Income Taxes***

We account for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which the temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Management considers many factors when assessing the likelihood of future realization of deferred tax assets, including recent earnings experience by jurisdiction, expectations of future taxable income, and the carryforward periods available for tax reporting purposes, as well as other relevant factors. A valuation allowance may be established to reduce deferred tax assets to the amount that management believes is more likely than not to be realized. Due to inherent complexities arising from the nature of the business, future changes in income tax law and variances between actual and anticipated operating results, management makes certain judgments and estimates. Therefore, actual income taxes could materially vary from these estimates.

On December 22, 2017, The Tax Cuts and Jobs Act was signed into law and has resulted in significant change to the U.S corporate income tax system. These changes include a federal statutory rate reduction from 34% to 21%, a transition tax, which applies to the repatriation of foreign earnings and profits, the elimination or reduction of certain domestic deductions and credits and limitations on the deductibility of interest expense and executive compensation.

Changes in tax rates and tax laws are accounted for in the period of enactment.

We recognize in the financial statements the impact of a tax position, if that position is more likely than not to be sustained upon an examination, based on the technical merits of the position. We record a liability for the difference between the benefit recognized and measured and the tax position taken or expected to be taken on our tax return. To the extent that the assessment of such tax positions changes, the change in estimate is recorded in the period in which the determination is made. To the extent interest and penalties are not assessed with respect to uncertain tax positions, amounts accrued will be reduced and reflected as a reduction of the overall income tax provision.We have incurred no liability and, therefore, did not need to record interest and penalties during the year ended September 30, 2021 and 2020.

***Foreign Currency***

Items included in the financial statements are measured using their functional currency, which is the currency of the primary economic environment in which the company operates. The Company's consolidated financial statements are presented in United States Dollar ("USD"), which is the company's functional and presentational currency.

***Net Loss per Share***

Basic net loss per share is computed by dividing net loss available to common shareholders by the weighted average number of common shares outstanding during the period. Diluted net loss per share includes potentially dilutive securities such as outstanding options and warrants, using various methods such as the treasury stock or modified treasury stock method in the determination of dilutive shares outstanding during each reporting period.

The following table sets forth potential common shares issuable upon the exercise of outstanding options, the exercise of warrants and conversion of loan notes, all of which have been excluded from the computation of diluted weighted average shares outstanding as they would be anti-dilutive, including the impact on dilutive net loss per share of in-the-money warrants:

| | **September 30, 2021** | **September 30, 2020** |
|---|---|---|
| Stock options | 3,648,675 | 3,210,050 |
| Warrants | 1,926,501 | 1,926,501 |
| Convertible Notes | 82,487,678 | 1,562,319 |
| Total shares issuable upon exercise or conversion | 88,062,854 | 6,698,870 |

***Convertible Notes***

**Debt Discount**

The Company issued certain convertible notes that have certain embedded derivatives and/or required bifurcation. In connection with these features, the Company has recorded a discount to the debt that will be accreted to the face value of the note under the effective interest method over the term of the note.

***Fair Value of Financial Instruments***

Fair value is defined under FASB ASC Topic 820 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or the most advantageous market for an asset or liability in an orderly transaction between participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on the levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value. The levels are as follows:

● Level 1 - Quoted prices in active markets for identical assets or liabilities

● Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or corroborated by observable market data for substantially the full term of the assets or liabilities

● Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the value of the assets or liabilities.

The following is a listing of the Company's liabilities required to be measured at fair value on a recurring basis and where they are classified within the fair value hierarchy as of September 30, 2021:

| | Level 1 | Level 2 | Level 3 | Total |
| --- | --- | --- | --- | --- |
| Derivative Liability | $ — | $ — | $ 38,018 | $ 38,018 |

***Equity-Based Payments***

ASC Topic 718 "Compensation-Stock Compensation" requires companies to measure the cost of employee services received in exchange for the award of equity instruments based on the estimated fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. We account for shares of common stock, stock options and warrants issued to employees based on the fair value of the stock, stock option or warrant, if that value is more reliably measurable than the fair value of the consideration or services received.

We account for stock-based compensation awards issued to non-employees under Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") No. 718-10, *Compensation – Stock Compensation – Overall,* and uses the Black-Scholes Merton option-pricing model to determine the fair value of such awards. The Company values awards issued to non-employees on the grant date and has elected to estimate forfeitures as they occur and uses the simplified method to estimate the term of such awards. The Company recognizes stock-based compensation expense related to non-employee awards on a straight-line basis over the service period.

***Recent Accounting Pronouncements***

In August 2020, the FASB issued ASU 2020-06, which simplifies the guidance on the issuer's accounting for convertible debt instruments by removing the separation models for (1) convertible debt with a cash conversion feature and (2) convertible instruments with a beneficial conversion feature. As a result, entities will not separately present in equity an embedded conversion feature in such debt and will account for a convertible debt instrument wholly as debt, unless certain other conditions are met. The elimination of these models will reduce reported interest expense and increase reported net income for entities that have issued a convertible instrument that is within the scope of ASU 2020-06. Also, ASU 2020-06 requires the application of the if-converted method for calculating diluted earnings per share and treasury stock method will be no longer available. ASU 2020-06 is applicable for fiscal years beginning after December 15, 2021, with early adoption permitted no earlier than fiscal years beginning after December 15, 2020. The Company does not intend to early adopt and continues to evaluate the impact of the provisions of ASU 2020-06 on its consolidated financial statements.

In December 2019, the FASB issued ASU 2019 -12, Income Taxes - Simplifying the Accounting for Income Taxes ("ASU 2019-12"). Among other items, the amendments in ASU 2019-12 simplify the accounting treatment of tax law changes and year-to-date losses in interim periods. An entity generally recognizes the effects of a change in tax law in the period of enactment; however, there is an exception for tax laws with delayed effective dates. Under current guidance, an entity may not adjust its annual effective tax rate for a tax law change until the period in which the law is effective. This exception was removed under ASU 2019-12, thereby providing that all effects of a tax law change are recognized in the period of enactment, including adjustment of the estimated annual effective tax rate. Regarding year-to-date losses in interim periods, an entity is required to estimate its annual effective tax rate for the full fiscal year at the end of each interim period and use that rate to calculate its income taxes on a year-to-date basis. However, current guidance provides an exception that when a loss in an interim period exceeds the anticipated loss for the year, the income tax benefit is limited to the amount that would be recognized if the year-to-date loss were the anticipated loss for the full year. ASU 2019-12 removes this exception and provides that, in this situation, an entity would compute its income tax benefit at each interim period based on its estimated annual effective tax rate. ASU 2019-12 is effective for fiscal years beginning after December 15, 2020, including interim periods within those annual periods. Early adoption is permitted. The Company is currently evaluating the effect that this update will have on its financial statements and related disclosures.

The Company has determined that all other recently issued accounting pronouncements will not have a material impact on its consolidated financial position, results of operations and cash flows, or do not apply to its operations.

**Results of Operations**

The following paragraphs set forth our results of operations for the periods presented. The period-to-period comparison of financial results is not necessarily indicative of future results.

**Results of Operations for the years ended September 30, 2021 and 2020**

*Revenues*

There were no revenues for the year ended September 30, 2021, and 2020 because we do not have any commercial biopharmaceutical products.

*Operating Expenses*

Operating expenses consisting of consultancy fees, legal and professional fees and general and administrative expenses for the year ended September 30, 2021 decreased to $247,814 from $5,428,858 for the year ended September 30, 2020, a decrease of $5,181,044. The decrease is primarily attributable to the impairment and write off of goodwill and intangible assets of $4,872,354 offset by the pace of development of the LSD1 and NPM1 projects which decreased while the direction of the programs were being evaluated based on results achieved so far, along with a decrease in general administrative costs driven by our decreased activity.

*Net Loss*

Net loss for the year ended September 30, 2021 decreased to $785,082 from $5,346,672 for the year ended September 30, 2020, a decrease of $4,561,590. The decrease was due to the impairment and write off of goodwill and intangible assets of $4,872,354 offset by increases in costs due to the accretion of debt discount and other promissory note costs, decreases in the pace of development of the LSD1 and NPM1 projects which decreased while the direction of the programs are being evaluated, along with a decrease in general administrative costs driven by our decreased activity.

**Liquidity and Capital Resources**

On November 12, 2019 we entered into a 12% Convertible Promissory Note with a Holder pursuant to which we issued a Convertible Promissory Note to the Holder. The Holder provided us with $57,500 in cash, which we received in November 2019. As at the date of filing this note is in default. The Company is currently negotiating an extension to the maturity date along with amended terms.

On February 7, 2020, we entered into a 12% Convertible Promissory Note with a Holder pursuant to which we issued a Convertible Promissory Note to the Holder. The Holder provided us with $31,000 in cash, which we received in February 2020.

On March 20, 2020, we entered into a 12% Convertible Promissory Note with a Holder pursuant to which we issued a Convertible Promissory Note to the Holder. The Holder provided us with $20,000 in cash, which we received in March 2020.

On September 22, 2020, we entered into a 12% Convertible Promissory Note with a Holder pursuant to which we issued a Convertible Promissory Note to the Holder. The Holder provided us with $35,000 in cash, which we received in September 2020.

On October 21 2020, we entered into a 12% Convertible Promissory Note with a Holder pursuant to which we issued a Convertible Promissory Note to the Holder. The Holder provided us with $40,000 in cash, which we received in January 2021.

On January 12, 2021, we entered into a 12% Convertible Promissory Note with a Holder pursuant to which we issued a Convertible Promissory Note to the Holder. The Holder provided us with $60,000 in cash, which we received in January 2021.

On February 23, 2021, we entered into a 12% Convertible Promissory Note with a Holder pursuant to which we issued a Convertible Promissory Note to the Holder. The Holder provided us with $90,000 in cash, which we received in February 2021.

On May 25, 2021, we entered into a 1% Convertible Promissory Note with a Holder pursuant to which we issued a Convertible Promissory Note to the Holder. The Holder provided us with $100,000 in cash, which we received in May 2021.

We will be required to raise additional capital to continue the development and commercialization of current product candidates and to fund operations. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our shareholders may experience significant dilution. Any debt financing, if available, may (i) involve restrictive covenants that impact our ability to conduct, delay, scale back or discontinue the development and/or commercialization of one or more product candidates; (ii) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize its self on unfavorable terms.

*Capital Resources*

The following table summarizes total current assets, liabilities and working capital as of the periods indicated:

| | September 30, 2021 | September 30, 2020 | Change |
|---|---|---|---|
| Current assets | $ 44,577 | $ 32,630 | $ 11,947 |
| Current liabilities | $ 2,707,473 | $ 2,707,632 | $ (159) |
| Working capital deficiency | $ (2,662,896) | $ (2,675,002) | $ (12,106) |

We had a cash balance of $10,848 and $14,241 as of September 30, 2021 and September 30, 2020, respectively.

*Liquidity*

The following table sets forth a summary of our cash flows for the periods indicated:

| | For the year ended September 30, 2021 | For the year ended September 30, 2020 | Increase/ (Decrease) |
|---|---|---|---|
| Net cash used in operating activities | $ (293,393) | $ (251,327) | $ 42,066 |
| Net cash used in investing activities | $ — | $ — | $ — |
| Net cash provided by financing activities | $ 290,000 | $ 215,500 | $ 74,500 |

**Net Cash Used in Operating Activities**

Net cash used in operating activities was $293,393 for the year ended September 30, 2021 compared to $251,327 for the year ended September 30, 2020. The change is principally attributable to net loss of $785,082 excluding non-cash items such as share based compensation of $42,673, fee charges related to convertible notes of $123,718, Tiziana loan interest of $5,760, accretion of beneficial conversion feature and debt discount of $545,594, a gain on troubled debt restructuring of $11,773, a gain on the extinguishment of debt of $90,916 and changes in operating assets and liabilities of $123,682 for the year ended September 30, 2021 as compared to a net loss of $5,346,672 excluding non-cash items such as share based compensation of $134,632, an impairment of goodwill and intangible assets of $4,872,354 and changes in operating assets and liabilities of $48,320 for the year ended September 30, 2020

**Net Cash Provided by Financing Activities**

Net cash provided by financing activities consists of proceeds from the issuance of convertible notes of $290,000 during the year ended September 30, 2021 compared to proceeds from the issuance of a convertible notes and a related party loan payable of $215,500 during the year ended September 30, 2020.

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

*Capital Market Risk.*

We currently do not have any revenues because we do not have any commercial products and therefore depend on funds raised through other sources. One source of funding is through future debt or equity offerings. Our ability to raise funds in this manner depends upon, among other things, capital market forces affecting our stock price.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The full text of our audited financial statements as of September 30, 2021 and 2020, and for the years ended September 30, 2021 and 2020 begins on page F-1 of this Annual report on Form 10-K.

**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*

**Disclosure Controls and Procedures**

The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, have evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of September 30, 2021. Based on that evaluation, the Company's Chief Executive Officer and the Company's Chief Financial Officer have concluded that as of September 30, 2021, due to the existence of the material weaknesses in the Company's internal control over financial reporting described below, the Company's disclosure controls and procedures were not effective.

**Management's Annual Report on Internal Control over Financial Reporting**

The Company's management is responsible for establishing and maintaining adequate internal controls over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. The Company's internal control over financial reporting are a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles ("US GAAP").

Because of their inherent limitations, internal controls over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of management, the Company's Chief Executive Officer and the Company's Chief Financial Officer, the Company conducted an evaluation of the effectiveness of its internal control over financial over financial reporting based on the framework described in Internal Control-Integrated Framework issued by the Commission of Sponsoring Organizations of the Treadway Commission, as revised in 2013. Based on that evaluation, management has concluded that the Company did not maintain effective internal control over financial reporting as of the period ended September 30, 2021 due to the existence of the material weaknesses in internal control over financial reporting described below.

Material Weaknesses

A material weakness is a deficiency, or a combination of deficiencies, in internal controls over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

Management has determined that the Company did not maintain effective internal control over financial reporting as of the period ended September 30, 2021 due to the existence of the following material weaknesses identified by management:

Lack of Accounting Resources

The Company had a lack of accounting resources resulting in inadequate monitoring controls and other oversight procedures. Our management has determined that our disclosure controls and procedures and internal controls were ineffective due to weaknesses in our financial closing process, inadequate segregation of duties over authorization, review and recording of transactions, lack of accounting resources, as well as the financial reporting of such transactions.

Control Environment

The Company did not maintain an effective control environment. The control environment, which is the responsibility of senior management, sets the tone of the organization, influences the control consciousness of its people, and is the foundation for all other components of internal control over financial reporting. Our control environment was ineffective because:

- We did not implement a Whistleblower hotline in time for it to be effective;
- We developed an Insider Trading policy, which is within our code of ethics policy, but it should be a separate and more robust policy to include a definition of "insiders" versus "employees", "black-out periods", and how to contact the Compliance Officer if there are questions or concerns prior to executing a trade. In addition, it should be communicated and acknowledged by all employees, officers, and directors;

Remediation efforts to address the material weakness relating to the Control Environment

Management intends to remediate this item in the following manner:

i. Develop and implement the policies as listed herein. These policies will be approved by the Audit Committee and posted on the Company's website.

Accordingly, management has determined that these control deficiencies constitutes a material weakness. Management will begin implementing the Remediation Plan described herein and intends to continue working on it through the year ended September 30, 2021.

**Changes in internal control over financial reporting**

Other than as noted above, there have been no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15(d)-15(f) under the Exchange Act) during our most recently completed fiscal quarter that have materially effected, or a reasonably likely to materially effect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

**None.**

## PART III

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS OF THE REGISTRANT, AND CORPORATE GOVERNANCE

**Directors and Executive Officers**

The following persons are our executive officers and directors as of February 28, 2022 and hold the positions set forth opposite their respective names.

| Name | Age | Position |
|---|---|---|
| John Brancaccio | 73 | Director |
| Gary Jacob | 74 | Director |
| Willy Simon | 71 | Chairman |
| Keeren Shah | 46 | Finance Director |

*John Brancaccio*

*Director*

Mr. Brancaccio, retired CPA, is a financial executive with extensive international and domestic experience in pharmaceutical and biotechnology for privately and publicly held companies. From 2000 to 2002, Mr. Brancaccio was the Chief Financial Officer/Chief Operating Officer of Eline Group, an entertainment and media company. From May 2002 until March 2004, Mr. Brancaccio was the Chief Financial Officer of Memory Pharmaceuticals Corp., a biotechnology company. From April 2004 until May 2017, Mr. Brancaccio was the Chief Financial Officer of Accelerated Technologies, Inc., an incubator for medical device companies. Mr. Brancaccio is currently a director of Cardiff Oncology, Inc., Hepion Pharmaceuticals, Inc., OKYO Pharma Ltd., Accustem Sciences Inc and Tiziana Life Sciences plc.

*Gary Jacob*

*Director*

Dr. Jacob has over 35 years of extensive experience in the pharmaceutical and biotechnology industries across multiple disciplines, including research and development, operations, business development, capital financing activities and senior management expertise. He has developed broad and influential contacts throughout the biopharmaceutical, financial, banking and investor communities. Dr. Jacob is the Co-Founder and former CEO and Chairman of Synergy Pharmaceuticals. During his time at Synergy, he served as Chairman, Chief Executive Officer and Executive Chairman, and is the co-inventor of Synergy's FDA-approved drug Trulance® which is currently marketed in the U.S. by Bausch Health, Inc. to treat functional GI disorders. Dr. Jacob is also the former CEO and Managing Director of Immuron Inc., an Australian biotechnology company dual-listed on the Australian ASX exchange and on NASDAQ. Dr. Jacob currently is Chairman of the Board of Hepion Pharmaceuticals, Inc., a public NASDAQ listed company with a drug in clinical development to treat nonalcoholic steatohepatitis (NASH), Chief Executive Officer of OKYO Pharma Ltd, a UK Listed biopharmaceutical company developing next-generation therapeutics to improve the lives of patients with inflammatory eye diseases and chronic pain and is also on the Board of Directors of Cardiff Oncology, Inc., a NASDAQ listed public oncology company. He served as Chief Executive Officer and Director of Callisto Pharmaceuticals, Inc. from May 2003 until January 2013. Prior to his involvement with Callisto and Synergy, Dr. Jacob was at Monsanto/G.D. Searle, where he was Director of Glycobiology and a Monsanto Science Fellow, specializing in the field of Glycobiology and drug discovery. Dr. Jacob holds over 30 patents and is the co-inventor of two pharmaceutical drugs which are FDA approved. Dr. Jacob earned a B.S. *cum laude* in Chemistry from the University of Missouri – St. Louis and holds a Ph.D. in Biochemistry from the University of Wisconsin-Madison.

*Willy Simon*

*Chairman*

Willy Jules Simon is a banker and worked at Kredietbank N.V. and Citibank London before serving as an executive member of the Board of Generale Bank NL from 1997 to 1999 and as the chief executive of Fortis Investment Management from 1999 to 2002. He acted as chairman of Bank Oyens & van Eeghen from 2002 to 2004. Willy Simon has been the chairman of Bever Holdings, a company listed in Amsterdam, since 2006 and Chairman of Ducat Maritime since 2015. He also serves as a director OKYO Pharma Ltd., Accustem Sciences Inc and Tiziana Life Sciences plc.

*Keeren Shah*

*Finance Director*

Ms. Shah has been the Finance Director of our company since July 2020, having served as its financial controller since July 2016. Ms Shah has been the Finance Director of Tiziana Life Sciences since August 2020. She also serves as CFO for OKYO Pharma Ltd and Accustem Sciences Inc.

Our directors are appointed for a one-year term to hold office until the next annual general meeting of our shareholders or until removed from office in accordance with our bylaws. Our officers are appointed by our board of directors and hold office until removed by the board.

*Board Independence*

We currently have three directors serving on our board of directors. Our Board of Directors has adopted the definition of "independence" as described in NASDAQ Rules 4200 and 4350. Independent directors would not include anyone who, within the past three years, be employed by our Company or any parent or subsidiary of our company or any of their family members; or any director who is, or who has a family member who is, a controlling shareholder. Our Board of Directors has determined that a majority of our directors do meet the independence requirements.

*Family Relationships and Other Arrangements*

There are no family relationships among our directors and executive officers. There are no arrangements or understandings between or among our executive officers and directors pursuant to which any director or executive officer was or is to be selected as a director or executive officer.

*Audit Committee*

We have a separately designated standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. The Audit Committee's responsibilities include, among other things: (i) selecting and retaining an independent registered public accounting firm to act as our independent auditors, setting the compensation for our independent auditors, overseeing the work done by our independent auditors and terminating our independent auditors, if necessary, (ii) periodically evaluating the qualifications, performance and independence of our independent auditors, (iii) pre-approving all auditing and permitted non-audit services to be provided by our independent auditors, (iv) reviewing with management and our independent auditors our annual audited financial statements and our quarterly reports prior to filing such reports with the Securities and Exchange Commission, or the SEC, including the results of our independent auditors' review of our quarterly financial statements, and (v) reviewing with management and our independent auditors significant financial reporting issues and judgments made in connection with the preparation of our financial statements. The Audit Committee also prepares the Audit Committee report that is required to be included in our annual proxy statement pursuant to the rules of the SEC.

The Audit Committee currently consists of John P. Brancaccio, chairman of the Audit Committee and Willy Simon. Under the applicable rules and regulations of NASDAQ, each member of a company's audit committee must be considered independent in accordance with NASDAQ Listing Rule 5605(c)(2)(A)(i) and (ii) and Rule 10A-3(b)(1) under the Exchange Act. The Board has determined that Messrs. Brancaccio and Simon are "independent" as that term is defined under applicable NASDAQ and SEC rules. Mr. Brancaccio is our audit committee financial expert. The Board has adopted a written charter setting forth the authority and responsibilities of the Audit Committee.

*Compensation Committee*

The purpose of the Compensation Committee is to discharge the Board's responsibilities relating to compensation of our directors and executive officers. The Compensation Committee has responsibility for, among other things, (i) recommending to the Board for approval the overall compensation philosophy for our company and periodically reviewing the overall compensation philosophy for all employees to ensure it is appropriate and does not incentivize unnecessary and excessive risk taking, (ii) reviewing annually and making recommendations to the Board for approval, as necessary or appropriate, with respect to our compensation plans, (iii) based on an annual review, determining and approving, or at the discretion of the Compensation Committee, recommending to the Board for determination and approval, the compensation and other terms of employment of each of our officers, (iv) reviewing and making recommendations to the Board with respect to the compensation of directors, (v) overseeing our regulatory compliance with respect to compensation matters, (vi) reviewing and discussing with management, prior to the filing of our annual proxy statement or annual report on Form 10-K, our disclosure relating to executive compensation, including our Compensation Discussion and Analysis and executive and director compensation tables as required by SEC rules, and (vii) preparing an annual report regarding executive compensation for inclusion in our annual proxy statement or our annual report on Form 10-K. The Compensation Committee has the power to form one or more subcommittees, each of which may take such actions as may be delegated by the Compensation Committee.

The Compensation Committee currently consists of Willy Simon, Chairman of the Compensation Committee and Gary Jacob. The Board has determined that all of the members are "independent" under NASDAQ Listing Rule 5602(a)(2). The Board has adopted a written charter setting forth the authority and responsibilities of the Compensation Committee.

*Corporate Governance/Nominating Committee*

The Corporate Governance/Nominating Committee has responsibility for assisting the Board in, among other things, (i) effecting Board organization, membership and function, including identifying qualified board nominees, (ii) effecting the organization, membership and function of the committees of the Board, including the composition of the committees of the Board and recommending qualified candidates for the committees of the Board, (iii) evaluating and providing successor planning for the chief executive officer and our other executive officers, (iv) identifying and evaluating candidates for director in accordance with certain general and specific criteria, (v) developing and recommending to the Board Corporate Governance Guidelines and any changes thereto, setting forth the corporate governance principles applicable to us, and overseeing compliance with the our Corporate Governance Guidelines, and (vi) reviewing potential conflicts of interest involving directors and determining whether such directors may vote on issues as to which there may be a conflict. The Corporate Governance/Nominating Committee is responsible for identifying and evaluating candidates for director. Potential nominees are identified by the Board based on the criteria, skills and qualifications that are deemed appropriate by the Corporate Governance/Nominating Committee.

The Corporate Governance/Nominating Committee currently consists of Gary Jacob, chairman of the Corporate Governance/Nominating Committee and John P. Brancaccio. The Board has determined that all of the members are "independent" under NASDAQ Listing Rule 5605(a)(2). The Board has adopted a written charter setting forth the authority and responsibilities of the Corporate Governance/Nominating Committee.

*Code of Business Conduct and Ethics*

We have adopted a formal Code of Business Conduct and Ethics applicable to all Board members, officers and employees. That code is available on our corporate website www.rasna.com. A copy will also be provided free of charge upon request to:

Rasna Therapeutics Inc., 420 Lexington Ave, Suite 2525, New York, NY 10170.

## ITEM 11. EXECUTIVE COMPENSATION

### Summary Compensation Table

The following table sets forth summary information concerning the total compensation paid to our executive officers for the year ended September 30, 2021 for services to our company.

**Executive Compensation**

| Name | Fees Earned or Paid in Cash ($) | Option Awards ($) | Total ($) |
|---|---|---|---|
| Keeren Shah | 15,000 | — | — |

### Grants of Plan-Based Awards During Fiscal Year

No grants of plan-based awards to our executive officers for the year ended September 30, 2021.

### Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information for the named executive officers regarding the number of shares subject to both exercisable and unexercisable stock options, as well as the exercise prices and expiration dates thereof, as of September 30, 2021 Except for the options set forth in the table below, no other equity awards were held by any our named executive officers as of September 30, 2021.

| Name | Number of Securities Underlying Unexercised Options (#) | | Option Exercise Price ($) | Option Expiration Date |
|---|---|---|---|---|
| | Exercisable | Unexercisable | | |
| Keeren Shah | 2,500 | — | 4.00 | 9/1/2026 |

### Director Compensation

The following table sets forth summary information concerning the total compensation paid to our non-employee directors for the year ended September 30, 2021 for services to our company.

**Director Compensation**

| Name | Fees Earned or Paid in Cash ($) | Option Awards ($) | Total ($) |
|---|---|---|---|
| John Brancaccio | 25,000 | — | 25,000 |

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

The following tables set forth certain information regarding the ownership of our common stock as of January 11, 2022, by:

- each director;
- each person known by us to own beneficially 5% or more of our Common Stock;
- each executive officer; and
- all directors and executive officers as a group.

The amounts and percentages of common stock beneficially owned are reported on the basis of regulations of the Securities and Exchange Commission governing the determination of beneficial ownership of securities. Under the rules of the SEC, a person is deemed to be a "beneficial owner" of a security if that person has or shares "voting power," which includes the power to vote or to direct the voting of such security, or "investment power," which includes the power to dispose of or to direct the disposition of such security. A person is also deemed to be a beneficial owner of any securities of which that person has the right to acquire beneficial ownership within 60 days. Under these rules more than one person may be deemed a beneficial owner of the same securities and a person may be deemed to be a beneficial owner of securities as to which such person has no economic interest.

Unless otherwise indicated below, to the best of our knowledge each beneficial owner named in the table has sole voting and sole investment power with respect to all shares beneficially owned, subject to community property laws where applicable. Unless otherwise indicated, the address of each beneficial owner is c/o 420 Lexington Avenue, New York, NY 10170.

| Name of Beneficial Owner | Number of Shares Beneficially Owned | Percentage Beneficially Owned (1) |
|---|---|---|
| Executive Officers and Directors : | | |
| John Brancaccio | 100,000(2) | * |
| All executive officers and directors as a group (3 persons) | 164,899(3) | * |
| 4% or Greater Stockholders: | | |
| Panetta Partners Ltd. (4) | 39,640,069(5) | 36.52 |
| TES Pharma Srl (6) | 5,791,500(7) | 7.75 |
| Eurema Consulting Srl (8) | 5,791,500(7) | 7.75 |
| MS Investment Holding, Inc. (9) | 7,773,167 | 10.14 |
| Howard I. Freedberg Revocable Trust (10) | 6,758,188 | 8.93 |

* less than 1%

(1) Based on 68,908,003 shares of our common stock issued and outstanding as of September 30, 2021.
(2) Consists of shares of common stock issuable upon exercise of vested stock options.
(3) Includes 152,500 shares of common stock issuable upon exercise of vested stock options.
(4) Gabriele Cerrone is a director of Panetta Partners Ltd. and in such capacity holds voting and dispositive power over our securities held by such entity. Panetta Partners Ltd. address is, c/o Cooley Services Limited, Dashwood, 60 Old Broad Street, London EC2M 1QS
(5) Includes 529,000 shares of common stock issuable upon exercise of vested stock options held by Mr. Cerrone and 30,623,765 shares of common stock issuable upon the conversion of promissory notes.
(6) Dr. Roberto Pellicciari holds voting and dispositive power over securities of the company held by such entity.
(7) Includes 429,000 shares of common stock issuable upon exercise of vested stock options.
(8) Brunangelo Falini holds voting and dispositive power over securities of the company held by such entity.
(9) Morris Silverman holds voting and dispositive power over securities of the company held by such entity.
(10) Howard Freedberg is the trustee of the Howard I. Freedberg Revocable Trust and in such capacity holds voting and dispositive power over securities of the company held by such entity.

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

The following is a description of transactions or series of transactions since October 1, 2020, or any currently proposed transaction, to which we were or are to be a participant and in which the amount involved in the transaction or series of transactions exceeds $120,000, and in which any of our directors, executive officers or persons who we know hold more than five percent of our common stock, including their immediate family members, had or will have a direct or indirect material interest, other than compensation arrangements with our directors and executive officers.

*Eurema Consulting*

Eurema Consulting S.r.l. is a significant shareholder of the Company. During the years ended September 30, 2021 and 2020, Eurema Consulting did not supply the Company with consulting services. As of September 30, 2021, and September 30, 2020, the balance due to Eurema Consulting S.r.l. was $200,000 for past consultancy services.

*Gabriele Cerrone*

Gabriele Cerrone is the majority shareholder of Panetta Partners, one of the Company's principal shareholders. As of September 30, 2021, and September 30, 2020, the balance due to Gabriele Cerrone was $175,000 for past consultancy services. In March 2020, the Company entered into a 12% Convertible Promissory Note with Gabriele Cerrone for $20,000 with an extended maturity date of December 31, 2021. In February 2021, Gabriele Cerrone assigned the Note to Panetta Partners Ltd.

*Roberto Pellicciari and TES Pharma*

Roberto Pellicciari is the majority shareholder of TES Pharma Srl, one of the Company's principal shareholders. During the years ended September 30, 2021 and 2020, Roberto Pellicciari did not provide the Company with consulting services. As of September 30, 2021, and September 30, 2020, the balance due to Roberto Pellicciari was $175,000 for past consultancy services. At both September 30, 2021 and September 30, 2020, TES Pharma was owed $75,000.

*Tiziana Life Sciences ("Tiziana")*

As at September 30, 2021 the balance owed to Tiziana Life Sciences was $11,446. As at September 30, 2020, there was a balance owed by Tiziana Life Sciences of $748. As of the date these consolidated financial statements are issued, the related party payable had not been settled. Keeren Shah the Company's Finance Director is also Finance Director of Tiziana, and the Company's directors, Willy Simon and John Brancaccio are also non-executive directors of Tiziana.

The Company is party to a Shared Services agreement with Tiziana whereby the Company is charged for shared services such as the payroll and rent, see Note 11 for more details.

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

Set forth are the aggregate fees billed to the Company by Marcum LLP, the Company's former independent registered public accounting firm, for the indicated services for each of the last two fiscal years were as follows:

| | Year ended September 30, | |
|---|---|---|
| | **2021** | **2020** |
| Audit fees | $ 122,785 | $ 136,829 |
| Audit - related fees | — | — |
| Tax fees | — | — |
| All other fees | — | — |
| Total fees | $ 122,785 | $ 136,829 |

Audit fees consist of fees billed for services rendered for the audit of our financial statements and review of our financial statements included in our quarterly reports on Form 10-Q and services provided in connection with other statutory or regulatory filings.

Audit-related fees consist of fees billed for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements and not reported under Audit fees. No such fees were billed in fiscal 2021 or 2020.

Tax fees consist of fees billed for professional services related to the preparation of our U.S. federal and state income tax returns and tax advice. No such fees were billed by Marcum LLP in fiscal 2021 or 2020. The Audit Committee pre-approved all Audit-related fees. After considering the provision of services encompassed within the above disclosures about fees, the Audit Committee has determined that the provision of such services is compatible with maintaining Marcum's independence.

In addition, Mazars USA LLP has billed us $65,000 for the fiscal year ended September 30, 2021 for services rendered to us subsequent to September 30, 2021 as our independent registered public accounting firm.

## PART IV

### ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

**(a) (1) Financial Statements**

See Item 8.

**(a) (2) Financial Statement Schedules**

None.

**(b) Exhibits**

| Exhibit Number | Description |
|---|---|
| 3.1(a) | Amended and Restated Articles of Incorporation as filed with the Nevada Secretary of State on September 26, 2016 and effective September 20, 2016 (incorporated by reference to Exhibit 3.2 to Form 8-K filed on September 26, 2016) |
| 3.1(b) | Certificate of Change of Active With Me, Inc., as filed with the Nevada Secretary of State on September 19, 2016 and effective September 20, 2016 (incorporated by reference to Exhibit 3.1 to Form 8-K filed on September 26, 2016). |
| 3.2 | Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to Form 10-K filed on June 29, 2017). |
| 4.1* | 2016 Incentive Equity Plan (incorporated by reference to Exhibit 4.1 to Form 8-K filed on August 16, 2016). |
| 14 | Code of Business Conduct and Ethics (incorporated by reference to Exhibit 14 to Form 10-K filed on June 29, 2017). |
| 21 | List of Subsidiaries |
| 24 | Power of Attorney (included on signature page hereto) |
| 31.1 | Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 31.2 | Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 32.1 | Certification of Principal Executive Officer pursuant to Section 906 Certifications under Sarbanes-Oxley Act of 2002 |
| 32.2 | Certification of Principal Financial Officer pursuant to Section 906 Certifications under Sarbanes-Oxley Act of 2002 |
| 101.INS | Inline XBRL Instance Document. |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document. |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document. |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document. |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document. |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document. |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101). |

* Indicates a management contract or compensatory plan or arrangement.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 1, 2022

RASNA THERAPEUTICS, INC.

By: /s/ Willy Simon

**Willy Simon**
**Chairman**

**POWER OF ATTORNEY**

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

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

| Signature | Title(s) | Date |
| --- | --- | --- |
| /s/ Willy Simon<br>**Willy Simon** | Chairman<br>*(Principal Executive Officer)* | March 1, 2022 |
| /s/ Keeren Shah<br>**Keeren Shah** | Finance Director<br>*(Principal Accounting and Financial Officer)* | March 1, 2022 |
| /s/ John Brancaccio<br>**John Brancaccio** | Director | March 1, 2022 |
| /s/ Gary Jacob<br>**Gary Jacob** | Director | March 1, 2022 |

**RASNA THERAPEUTICS, INC.**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Rasna Therapeutics, Inc.

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheet of Rasna Therapeutics, Inc. (the "Company") as of September 30, 2020, the related consolidated statements of operations, changes in shareholders' equity/(deficit) and cash flows for the year ended September 30, 2020, 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 September 30, 2020, and the results of its operations and its cash flows for the year ended September 30, 2020, in conformity with accounting principles general accepted in the United States of America.

**Explanatory Paragraph – Going Concern**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully discussed in Note 3 to the financial statements, the Company has a significant working capital deficiency, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are described in Note 3. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Basis for Opinion**

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

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ Marcum LLP
Marcum LLP

We served as the Company's auditor from 2016 to 2021.

New York, NY
January 15, 2021

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheet of Rasna Therapeutics, Inc. (the "Company") as of September 30, 2021, the related consolidated statements of operations, stockholders' deficit, and cash flows, for the fiscal year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of September 30, 2021, and the results of its operations and its cash flows for the fiscal year then ended, in conformity with accounting principles generally accepted in the United States of America.

**Going Concern**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the financial statements, the Company has suffered recurring losses from operations, has a working capital deficiency, and an accumulated deficit that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 3. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Basis for Opinion**

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

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

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

**Critical Audit Matter**

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

***Modifications and Extinguishment of Debt***

During the fiscal year ended September 30, 2021, the Company modified several convertible notes. Management determined whether to account for these modifications as a debt modification or debt extinguishment. Management followed the guidance of Accounts Standards Codification ("ASC") 470-50, Debt Modifications and Extinguishments, ASC 815-15, Derivatives and Hedging. Per the guidance, management determined if the amended terms are substantially different, defined as the present value of the remaining cash flows after amendment differ by at least 10% of those prior to the amendment.

Given the significant estimates involved in determining if there is a debt modification or extinguishment, the related audit effort in evaluating both management's estimates in determining the total discount and the determination of whether the changes made the debt agreements a debt modification or debt extinguishment was extensive and required a high degree of auditor judgement.

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

We obtained an understanding over the Company's process to determine whether the modifications to the convertible notes are a modification or extinguishment. We reviewed the guidance in ASC 470-50, Modifications and Extinguishments, and ASC 815-15, Embedded Derivatives, and management's calculation of the present value of the cash flows prior to and after the amendments to see if there was more than a 10% change. We also recalculated the change in the present value of the remaining cash flows after the amendments for each of the amended convertible notes to determine if management applied the correct accounting treatment. We further considered the guidance in ASC 470-60, Troubled Debt Restructurings by Debtors, to determine if any of the amendments met the troubled debt restructuring criteria.

Additionally, we obtained an understanding over the Company's process to estimate the debt discounts including how the Company develops each of the estimates required. We applied the following audit procedures relating to testing the Company's estimates:

- We tested management's assumptions used for calculation of any modification and/or extinguishment for the fair value of the convertible notes before and after modification as well as any potential embedded derivatives.
- We recomputed management's calculation of the debt extinguishment on a lender-by-lender basis and verified the assumptions used and agreed them to the amended agreements.
- We considered how the Company should account for any contingent conversion option (redemption feature)
- We tested the assumptions used and recalculated the fair value of the embedded derivatives within the convertible note agreements.
- We reviewed the underlying agreements and assessed the terms in relating to the technical accounting guidance, testing of the completeness and accuracy of the underlying data and the calculations supporting the troubled debt restructuring.
- We tested and analyzed the debtor's effective borrowing rate on the restructured debt and compared this to the effective borrowing rate immediately before the restructuring to evaluate if this a troubled debt restructuring, including the concession assessment and the associated gain.

We have served as the Company's auditor since 2021.

/s/ Mazars USA LLP

Fort Washington, PA
March 1, 2022

**RASNA THERAPEUTICS, INC.**

**CONSOLIDATED BALANCE SHEETS**

| | As of September 30, | |
|---|---|---|
| | **2021** | **2020** |
| **ASSETS** | | |
| Current assets: | | |
| Cash | $ 10,848 | $ 14,241 |
| Prepayments and other receivables | 33,729 | 17,641 |
| Related party receivable | — | 748 |
| Total current assets | 44,577 | 32,630 |
| | | |
| Property and equipment, net | — | 314 |
| **Total assets** | $ 44,577 | $ 32,944 |
| | | |
| **LIABILITIES AND SHAREHOLDERS' DEFICIT** | | |
| | | |
| Liabilities: | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | $ 1,516,001 | $ 1,635,788 |
| Related party payables | 561,446 | 550,000 |
| Loan payable - related party | 80,640 | 74,880 |
| Derivative liabilities | 38,018 | — |
| Convertible notes payable - related party | 221,571 | 89,768 |
| Convertible notes payable | 289,797 | 357,196 |
| **Total Current liabilities** | 2,707,473 | 2,707,632 |
| | | |
| Commitments and contingencies (Note 12) | — | — |
| | | |
| Shareholders' deficit | | |
| Common stock, $0.001 par value, 200,000,000 shares authorized; 68,908,003 issued and outstanding at both 2021 and 2020 | 68,909 | 68,909 |
| Additional paid-in capital | 20,711,758 | 19,914,884 |
| Accumulated deficit | (23,443,563) | (22,658,481) |
| Total shareholders' deficit | (2,662,896) | (2,674,688) |
| **Total liabilities and shareholders' deficit** | $ 44,577 | $ 32,944 |

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

**RASNA THERAPEUTICS, INC.**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

| | Years ended September 30, | |
|---|---|---|
| | **2021** | **2020** |
| Revenue | $ — | $ — |
| Cost of revenue | — | — |
| Gross profit | — | — |
| | | |
| Operating expenses: | | |
| General and administrative | 247,814 | 556,504 |
| Research and development | — | — |
| Impairment of intangible assets | — | 2,149,369 |
| Impairment of goodwill | — | 2,722,985 |
| Total operating expenses | 247,814 | 5,428,858 |
| | | |
| Loss from operations | (247,814) | (5,428,858) |
| | | |
| Other income/(expense): | | |
| Expenses in connection with modification and extinguishment of convertible promissory notes | (123,718) | — |
| Interest expense | (515,907) | (41,438) |
| Gain on sale of asset | — | 120,000 |
| Gain on extinguishment of debt | 90,916 | — |
| Gain on troubled debt restructuring | 11,773 | — |
| Foreign currency transaction gain/(loss) | (332) | 590 |
| Other (expense)/income, net | (537,268) | 79,152 |
| | | |
| Loss before provision for income taxes | (785,082) | (5,349,706) |
| | | |
| Income tax benefit | - | (3,034) |
| | | |
| Net loss | $ (785,082) | $ (5,346,672) |
| | | |
| Basic and diluted loss per share attributable to common shareholders | $ (0.01) | $ (0.08) |
| | | |
| Basic weighted average common shares outstanding | 68,908,003 | 68,908,003 |

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

**RASNA THERAPEUTICS, INC.**

**CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY/(DEFICIT)**
**FOR THE YEARS ENDED SEPTEMBER 30, 2021, AND 2020**

| | Common Stock | | Additional Paid-In | Accumulated | Total Shareholders' Equity/ |
|---|---|---|---|---|---|
| | Shares | Amount | Capital | Deficit | (Deficit) |
| **Balance at October 1, 2019** | 68,908,003 | $ 68,909 | $ 19,780,252 | $ (17,311,809) | $ 2,537,352 |
| Share based compensation | — | — | 134,632 | — | 134,632 |
| Net loss | — | — | — | (5,346,672) | (5,346,672) |
| **Balance at September 30, 2020** | 68,908,003 | $ 68,909 | $ 19,914,884 | $ (22,658,481) | $ (2,674,688) |
| Share based compensation | — | — | 42,673 | — | 42,673 |
| Net loss | — | — | — | (785,082) | (785,082) |
| Fees relating to debt issuance | — | — | 123,718 | — | 123,718 |
| Beneficial conversion feature related to convertible notes | — | — | 630,483 | — | 630,483 |
| **Balance at September 30, 2021** | 68,908,003 | $ 68,909 | $ 20,711,758 | $ (23,443,563) | $ (2,662,896) |

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

**RASNA THERAPEUTICS, INC.**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

| | Years Ended September 30, | |
|---|---|---|
| | **2021** | **2020** |
| **CASH FLOWS FROM OPERATING ACTIVITIES:** | | |
| Net loss | $ (785,082) | $ (5,346,672) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Share-based compensation | 42,673 | 134,632 |
| Fees related to convertible notes | 123,718 | — |
| Depreciation | 314 | 1,635 |
| Deferred income tax benefit | — | (3,034) |
| Non-cash interest expense | 5,760 | 38,558 |
| Write off of related party receivable | — | 2,880 |
| Impairment of goodwill | — | 2,722,985 |
| Impairment of intangible assets | — | 2,149,369 |
| Gain on troubled debt restructuring | (11,773) | |
| Gain on debt extinguishment | (90,916) | |
| Accretion of debt discount | 545,594 | — |
| Changes in operating assets and liabilities: | | |
| Prepayments and other receivables | (16,088) | (10,463) |
| Related party receivable | 748 | 12,975 |
| Accounts payable and accrued expenses | (119,787) | 45,196 |
| Related party payables | 11,446 | 612 |
| Net cash used in operating activities | (293,393) | (251,327) |
| **CASH FLOWS FROM FINANCING ACTIVITIES:** | | |
| Proceeds from issuance of convertible notes | 290,000 | 143,500 |
| Proceeds from issuance of loan payable – related party | — | 72,000 |
| Net cash provided by financing activities | 290,000 | 215,500 |
| Net (decrease) in cash | (3,393) | (35,827) |
| Cash at beginning of year | 14,241 | 50,068 |
| Cash at end of year | $ 10,848 | $ 14,241 |
| **SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:** | | |
| Derivative liabilities in connection with debt extinguishments | $ 38,018 | $ — |
| Costs in connection with extinguishments of promissory notes | $ 123,718 | $ — |
| Beneficial conversion feature related to issuance of convertible notes | $ 630,483 | $ — |

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

**RASNA THERAPEUTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

## 1. GENERAL INFORMATION

Rasna Therapeutics, Inc. ( "Rasna Inc." or the "Company"), is a biotechnology company incorporated in the State of Delaware on March 28, 2016. The Company is engaged in modulating the molecular targets NPM1 and LSD1, which are implicated in the disease progression of leukemia and lymphoma.

These consolidated financial statements are presented in United States dollars ("USD") which is also the functional currency of the in which the Company operates.

## 2. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The principal accounting policies applied in the preparation of these consolidated financial statements are set out below. These policies have been applied consistently to all the periods presented unless otherwise stated.

***Basis of Presentation***

These consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("US GAAP") including all pronouncements of the U.S. Securities and Exchange Commission applicable to annual financial statements.

***Principles of Consolidation***

The consolidated financial statements include the financial statements of the Company and its wholly owned subsidiary, Rasna Research Inc, and Rasna Rasna Research Inc's subsidiary, Arna Therapeutics Limited. All significant intercompany accounts and transactions have been eliminated in the preparation of the accompanying consolidated financial statements.

***Use of Estimates***

The preparation of consolidated financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. The Company evaluates its estimates on an ongoing basis, including those related to the carrying amount of intangible assets, the fair values of stock based awards, the modification and extinguishment of debt, derivatives and valuations associated with derivatives, income taxes and contingent liabilities, among others. The Company bases its estimates on historical experience and on various other assumptions that the Company believes to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from those estimates and such differences could be material to the Company's consolidated financial position and results of operations.

***Fair Value of Financial Instruments***

Fair value is defined under FASB ASC Topic 820 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or the most advantageous market for an asset or liability in an orderly transaction between participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on the levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value. The levels are as follows:

- Level 1 - Quoted prices in active markets for identical assets or liabilities
- Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or corroborated by observable market data for substantially the full term of the assets or liabilities
- Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the value of the assets or liabilities.

The following is a listing of the Company's liabilities required to be measured at fair value on a recurring basis and where they are classified within the fair value hierarchy as of September 30, 2021:

| | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| Derivative Liability | $ — | $ — | $ 38,018 | $ 38,018 |

***Cash and Cash Equivalents***

The Company considers all short-term investments with an original maturity of three months or less to be cash equivalents.

***Risks and Uncertainties***

The Company intends to operate in an industry that is subject to rapid change. The Company's operations will be subject to significant risk and uncertainties including financial, operational, technological, regulatory, and other risks associated with an early stage company, including the potential risk of business failure.

In March 2020, the World Health Organization declared the outbreak of a novel coronavirus (COVID-19) as a pandemic, which continues to spread throughout the United States and the World. There is considerable uncertainty around the expected duration of this pandemic. The COVID-19 pandemic and the public health responses to contain it have resulted in global recessionary conditions. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on the Company's ability to access capital. Management continues to evaluate the impact of the COVID-19 pandemic and has concluded that while it is reasonably possible that the virus could have a negative effect on the Company's ability to raise capital, the specific impact is not readily determinable as of the date of these financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

***Research and development***

Expenditures for research and development are charged to operations in the year in which they are incurred with the exception of expenditures incurred in respect of the development of major new products where the outcome of those projects is assessed as being reasonably certain in regards to viability and technical feasibility. Such expenditures are capitalized and amortized straight line over the estimated period of sale for each product, commencing in the year that sales of the product are first made. To date, the Company has not capitalized any such expenditures other than certain IPR&D & intellectual property ("IP") recorded in connection with certain acquisition or equity transactions.

***Income Taxes***

The Company accounts for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which the temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. Management considers many factors when assessing the likelihood of future realization of deferred tax assets, including recent earnings experience by jurisdiction, expectations of future taxable income, and the carryforward periods available for tax reporting purposes, as well as other relevant factors. A valuation allowance may be established to reduce deferred tax assets to the amount that management believes is more likely than not to be realized. Due to inherent complexities arising from the nature of the business, future changes in income tax law and variances between actual and anticipated operating results, management makes certain judgments and estimates. Therefore, actual income taxes could materially vary from these estimates.

Changes in tax rates and tax laws are accounted for in the period of enactment.

The Company recognizes in the financial statements the impact of a tax position, if that position is more likely than not to be sustained upon an examination, based on the technical merits of the position. The Company records a liability for the difference between the benefit recognized and measured and the tax position taken or expected to be taken on the Company's tax return. To the extent that the assessment of such tax positions changes, the change in estimate is recorded in the period in which the determination is made. To the extent interest and penalties are not assessed with respect to uncertain tax positions, amounts accrued will be reduced and reflected as a reduction of the overall income tax provision. The Company incurred no liability and, therefore, did not need to record interest and penalties during the years ended September 30, 2021 and 2020.

***Reclassification***

Certain amounts in prior periods related to the classification of operating expenses have been reclassified to conform to current period presentation.

***Foreign Currency***

Items included in the financial statements are measured using their functional currency, which is the currency of the primary economic environment in which the company operates. The accompanying financial statements are presented in United States Dollar ("USD"), which is the Company's functional and presentational currency.

Foreign currency transactions are translated using the rate of exchange applicable at the date of the transaction. Foreign exchange gains and losses resulting from the settlement of such transactions and from the re-translation at the year-end of monetary assets and liabilities denominated in foreign currencies are recognized in the statements of operations.

***Net Loss per Share***

Basic net loss per share is computed by dividing net loss available to common shareholders by the weighted average number of common shares outstanding during the period. Diluted loss per share includes potentially dilutive securities such as outstanding options, warrants and convertible loan notes, using the if-converted method in the determination of dilutive shares outstanding during each reporting period.

The following table sets forth potential common shares issuable upon the exercise of outstanding options, the exercise of warrants and the conversion of notes and associated fees, all of which have been excluded from the computation of diluted weighted average shares outstanding as they would be anti-dilutive:

| | September 30, | |
|---|---|---|
| | **2021** | **2020** |
| Stock options | 3,648,675 | 3,210,050 |
| Warrants | 1,926,501 | 1,926,501 |
| Convertible notes & associated fees | 82,487,678 | 1,562,319 |
| Total shares issuable upon exercise or conversion | 88,062,854 | 6,698,870 |

The following is the computation of net loss per share for the following periods:

| | **For the Year Ended September 30, 2021** | **For the Year Ended September 30, 2020** |
|---|---|---|
| Net loss | $ (785,082) | $ (5,346,672) |
| Weighted average number of shares | 68,908,003 | 68,908,003 |
| Net loss per share (basic and diluted) | $ (0.01) | $ (0.08) |

***Equity-Based Payments***

The Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 718 "Compensation-Stock Compensation" requires companies to measure the cost of employee services received in exchange for the award of equity instruments based on the estimated fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. The Company accounts for shares of common stock, stock options and warrants issued to employees based on the fair value of the stock, stock option or warrant, if that value is more reliably measurable than the fair value of the consideration or services received.

The Company accounts for stock-based compensation awards issued to non-employees under ASC No. 718-10, *Compensation – Stock Compensation – Overall,* and uses the Black-Scholes Merton option-pricing model to determine the fair value of such awards. The Company values awards issued to non-employees on the grant date and has elected to estimate forfeitures as they occur and uses the simplified method to estimate the term of such awards. The Company recognizes stock-based compensation expense related to non-employee awards on a straight-line basis over the service period.

***Convertible Notes***

**Debt Discount**
The Company issued certain convertible notes that have certain embedded derivatives and/or required bifurcation. In connection with these features, the Company has recorded a discount to the debt that will be accreted to the face value of the note under the effective interest method over the term of the note.

***Recent Accounting Pronouncements***

In August 2020, the FASB issued ASU 2020-06, which simplifies the guidance on the issuer's accounting for convertible debt instruments by removing the separation models for (1) convertible debt with a cash conversion feature and (2) convertible instruments with a beneficial conversion feature. As a result, entities will not separately present in equity an embedded conversion feature in such debt and will account for a convertible debt instrument wholly as debt, unless certain other conditions are met. The elimination of these models will reduce reported interest expense and increase reported net income for entities that have issued a convertible instrument that is within the scope of ASU 2020-06. Also, ASU 2020-06 requires the application of the if-converted method for calculating diluted earnings per share and treasury stock method will be no longer available. ASU 2020-06 is applicable for fiscal years beginning after December 15, 2021, with early adoption permitted no earlier than fiscal years beginning after December 15, 2020. The Company does not intend to early adopt and continues to evaluate the impact of the provisions of ASU 2020-06 on its consolidated financial statements.

In December 2019, the FASB issued ASU 2019 -12, Income Taxes - Simplifying the Accounting for Income Taxes ("ASU 2019-12"). Among other items, the amendments in ASU 2019-12 simplify the accounting treatment of tax law changes and year-to-date losses in interim periods. An entity generally recognizes the effects of a change in tax law in the period of enactment; however, there is an exception for tax laws with delayed effective dates. Under current guidance, an entity may not adjust its annual effective tax rate for a tax law change until the period in which the law is effective. This exception was removed under ASU 2019-12, thereby providing that all effects of a tax law change are recognized in the period of enactment, including adjustment of the estimated annual effective tax rate. Regarding year-to-date losses in interim periods, an entity is required to estimate its annual effective tax rate for the full fiscal year at the end of each interim period and use that rate to calculate its income taxes on a year-to-date basis. However, current guidance provides an exception that when a loss in an interim period exceeds the anticipated loss for the year, the income tax benefit is limited to the amount that would be recognized if the year-to-date loss were the anticipated loss for the full year. ASU 2019-12 removes this exception and provides that, in this situation, an entity would compute its income tax benefit at each interim period based on its estimated annual effective tax rate. ASU 2019-12 is effective for fiscal years beginning after December 15, 2020, including interim periods within those annual periods. Early adoption is permitted. The Company is currently evaluating the effect that this update will have on its financial statements and related disclosures.

The Company has determined that all other recently issued accounting pronouncements will not have a material impact on its consolidated financial position, results of operations and cash flows, or do not apply to its operations.

**3. LIQUIDITY AND GOING CONCERN**

The Company is subject to a number of risks similar to those of other pre-commercial stage companies, including its dependence on key individuals, uncertainty of product development and generation of revenues, dependence on outside sources of capital, risks associated with research, development, testing, and obtaining related regulatory approvals of its pipeline products, suppliers and collaborators, successful protection of intellectual property, competition with larger, better-capitalized companies, successful completion of the Company's development programs and, ultimately, the attainment of profitable operations are dependent on future events, including obtaining adequate financing to fulfill its development activities and generating a level of revenues adequate to support the Company's cost structure.

The Company has experienced net losses and significant cash outflows from cash used in operating activities over the past two years, and as of September 30, 2021, had an accumulated deficit of $23,443,563, a net loss for the year ended September 30, 2021 of $785,082 and net cash used in operating activities of $293,393.

The Company expects to continue to incur net losses and have significant cash outflows for at least the next 12 months and will require significant additional cash resources to launch new development phases of existing products in its pipeline. In the event that the Company is unable to secure the necessary additional cash resources needed, the Company may slow current development phases or halt new development phases in order to mitigate the effects of the costs of development. These conditions, among others, raise substantial doubt about the Company's ability to continue as a going concern for a period of twelve months from the date these financial statements are issued. The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. This basis of accounting contemplates the recovery of the Company's assets and the satisfaction of liabilities in the normal course of business. A successful transition to attaining profitable operations is dependent upon achieving a level of positive cash flows adequate to support the Company's cost structure.

**4. ACCOUNTS PAYABLE AND ACCRUED EXPENSES**

The following table summarizes the Company's accounts payable and accrued expenses as of the following years :

| | September 30, | |
|---|---|---|
| | 2021 | 2020 |
| Accounts payable | $ 900,045 | $ 952,151 |
| Accrued expenses | 615,956 | 683,637 |
| | $ 1,516,001 | $ 1,635,788 |

Accounts payable is predominantly made up of unpaid invoices relating to research and development, accounting and professional fees. Included within the accrued expenses balance of $615,956 at September 30, 2021 is approximately $27,000 of accounting and professional fees, $208,000 of research and development fees, $309,000 for directors fees, and $72,000 for consultancy fees. Included within the accrued expenses balance of $683,637 at September 30, 2020 is approximately $110,000 of accrued legal, accounting and professional fees, $208,000 of research and development fees, $284,000 for directors fees, and $82,000 for consultancy fees.

**5. WARRANTS**

The Company had issued warrants to placement agents in lieu of fees for consultancy services and placement agent fees. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, "Derivatives and Hedging - Contracts in an Entity's Own Equity", the Company determined that all the warrants issued are classified as equity in additional paid in-capital.

The following table summarizes warrant activity for the years ended September 30, 2021 and 2020:

| | Number of Warrants | Weighted Average Exercise Price Per Option | Weighted Average remaining Contractual Life (years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding balance at October 1, 2019 | 1,926,501 | 0.43 | 6.86 | $ — |
| Granted | — | — | — | — |
| Forfeited | — | — | — | — |
| Outstanding balance at September 30, 2020 | 1,926,501 | 0.43 | 5.86 | $ — |
| Warrants exercisable at September 30, 2020 | 1,926,501 | 0.43 | 5.86 | $ — |
| Granted | — | — | — | — |
| Forfeited | — | — | — | — |
| Outstanding balance at September 30, 2021 | 1,926,501 | 0.43 | 4.86 | $ — |
| Warrants exercisable at September 30, 2021 | 1,926,501 | 0.43 | 4.86 | $ — |

**6. CONVERTIBLE NOTES**

The table below summarizes outstanding convertible notes as of September 30, 2021 and 2020:

| | |
| --- | --- |
| **Balance of non-related notes payable, net as of September 30, 2019** | **264,907** |
| Issuance of debt | 57,500 |
| Accrued Interest | 34,789 |
| **Balance of non-related notes payable, net as of September 30, 2020** | **357,196** |
| | |
| Issuance of debt | 100,000 |
| Beneficial conversion feature related to convertible notes issued | (370,413) |
| Derivative liability | (22,088) |
| Gain on extinguishment of debt | (82,200) |
| Gain on troubled debt restructuring | (11,773) |
| Accretion of debt discount | 319,075 |
| | |
| **Balance of non-related notes payable, net as of September 30, 2021** | **$ 289,797** |
| | |
| **Balance of related party notes payable, net as of September 30, 2019** | **-** |
| Issuance of debt | 86,000 |
| Accrued Interest | 3,768 |
| **Balance of related party notes payable, net as of September 30, 2020** | **89,768** |
| | |
| Issuance of debt | 190,000 |
| Beneficial conversion feature related to convertible notes issued | (260,070) |
| Derivative liability | (15,930) |
| Gain on extinguishment of debt | (8,716) |
| Gain on troubled debt restructuring | - |
| Accretion of debt discount | 226,519 |
| | |
| **Balance of related party notes payable, net as of September 30, 2021** | **$ 221,571** |

On October 21 2020, the Company entered into a seventh 12% Convertible Promissory Note with the Holder with a maturity date of October 21, 2021. The Holder provided the Company with $40,000 in cash. The Note provides the Holder with the right to convert, at any time, all or any part of the outstanding principal and accrued but unpaid interest into shares of the Company's common stock at a conversion price equal to the lower of (i) $0.05 per share or (ii) the price of the next equity financing, subject to adjustments noted within the Agreement. The number of shares issuable upon a conversion shall be determined by the quotient obtained by dividing (x) the outstanding principal amount of the Note to be converted by (y) the Conversion Price. The Note requires the Company to reserve and keep available out of its authorized and unissued shares of common stock the amount of shares that would be issued upon conversion of the Note, which includes the outstanding principal amount of the Note and interest accrued and to be accrued through the date of maturity.

On February 3, 2021, all outstanding notes were modified with amended expiry and conversion terms. The amended terms are as follows:

1. Conversion

The amended Notes provide the Holders with the right to convert, at any time, all or any part of the outstanding principal and accrued but unpaid interest into shares of the Company's common stock at a conversion price equal to the lower of (i) $0.01 per share or (ii) the price of the next equity financing, which raises at least US $1,000,000, subject to adjustments noted within the Agreement.

2. Expiry of the notes was amended to December 31, 2021.

The Company determined that the modification of the debt instruments added a substantive conversion option at the date of the modification or exchange. Prior to the Note Amendments, the lowest conversion price of any of the Notes was $0.05 and ranged up to $0.65 (out of the money for all). At the date of the modification the conversion option price was repriced to $0.01, resulting in the conversion option for all notes being in the money on the day of the modification. On the day of the modification the fair value of the underlying stock was $0.05. As such, the modification added a substantive conversion option as of the conversion date and the amendment would be considered substantial. The notes were deemed to be extinguished and require extinguishment accounting. Under extinguishment accounting, the debt was remeasured and recorded at fair value. The difference between the carrying value of the debt, prior to the extinguishment, and the new fair value of the debt, was recorded as a gain on debt extinguishment.

The Company noted short term nature of the note and the fact that the stock was thinly traded with any trading activity resulting in a disproportionate effect on the stock price. Therefore, a Black Scholes valuation was deemed to be inappropriate in this case. The fair value of the amended notes was calculated as the principal plus interest.

The fair value of the Notes on the extinguishment date was $509,416, resulting in a gain on extinguishment of $90,916.

On January 14, 2021, the Company entered into a 12% Convertible Promissory Note with Panetta Partners Ltd. (the "Holder") pursuant to which the Company issued a Convertible Promissory Note to the Holder. The Holder provided the Company with $60,000 in cash. The Company promised to pay the principal amount, together with guaranteed interest at the annual rate of 12%, with principal and accrued interest on the Note due and payable on December 31, 2021 (unless converted under terms and provisions as set forth within the Agreement). The Note provides the Holder with the right to convert, at any time, all or any part of the outstanding principal and accrued but unpaid interest into shares of the Company's common stock at a conversion price equal to the lower of (i) $0.01 per share or (ii) the price of the next equity financing, which raises at least US $1,000,000, subject to adjustments noted within the Agreement. The number of shares issuable upon a conversion shall be determined by the quotient obtained by dividing (x) the outstanding principal amount of the Note to be converted by (y) the Conversion Price. The Note requires the Company to reserve and keep available out of its authorized and unissued shares of common stock the amount of shares that would be issued upon conversion of the Note, which includes the outstanding principal amount of the Note and interest accrued and to be accrued through the date of maturity.

On February 10, 2021, the Company entered into another 12% Convertible Promissory Note with Panetta Partners Ltd. (the "Holder") pursuant to which the Company issued a Convertible Promissory Note to the Holder. The Holder provided the Company with $90,000 in cash. All other terms were the same as the note before.

On May 25, 2021, the Company entered into a 1% Convertible Promissory Note with Laura Fonda. (the "Holder") pursuant to which the Company issued a Convertible Promissory Note to the Holder. The Holder provided the Company with $100,000 in cash. All other terms were the same as the note before.

*Embedded Derivative Liability*

Under the promissory note agreement, the interest rate will reset upon the event of a default and an additional penalty of 6% will be accrued. The Company analyzed the conversion features of the note agreement for derivative accounting consideration under ASC 815, Derivatives and Hedging, and determined the interest rate resets met the definition of a derivative. It also noted that the Contingent Interest Rate feature required bifurcation from the host note contract and was to be accounted for at fair value. In accordance with ASC 815-15, the Company bifurcated the Contingent Interest Rate feature of the note and recorded a derivative liability.

The embedded derivatives for the notes are carried on the Company's balance sheet at fair value. The Company noted due to the short-term nature of the note in addition to the relatively small incremental increase in the interest rate in the event of default (6%) the maximum overall impact would be approximately $38,018 (calculated as the increase in interest rate multiplied by the principal balance). In addition, the Company assessed all Events of Default and concluded that they are generally within the Company's control and have a very low probability of occurrence.

The notes carry an embedded derivative liability of $38,018 which will be amortized over the life of the note. Management will continue to assess the valuation of the embedded derivative at each reporting period and will record any changes in value through other income and expenses.

*Beneficial Conversion Feature*

The conversion features for all notes issued are in the money as of the issuance date and accordingly a beneficial conversion feature was recorded upon issuance. As the intrinsic value of the Beneficial Conversion Feature exceeds the face value, the recorded Beneficial Conversion Feature will be limited to the gross proceeds less any debt discounts. As at September 30, 2021 this amounted to $630,483. This Beneficial Conversion Feature will be amortized on a straight line basis over the term of the note.

*Troubled Debt Restructuring*

On September 30, 2021, the interest rate for a Note was reduced to 1%. The company evaluated the reduction under ASC 470 and concluded that there were indicators of financial difficulty at this date and a concession had been granted. Therefore the amendment should be accounted for under the troubled debt restructuring model.

When a borrower has a troubled debt restructuring ("TDR") in which the terms of its debt are modified, it should analyze the future undiscounted cash flows to determine the appropriate accounting treatment. The recognition and measurement guidance for a TDR depends on whether the future undiscounted cash flows specified by the new terms are greater or less than the carrying value of the debt. The Company determined that the future undiscounted cash flows under the new terms were less than the adjusted net carrying value of the original debt, therefore a gain of $11,773 was recorded for the difference on the statement of operations,

**7. STOCK-BASED COMPENSATION**

**2016 EQUITY INCENTIVE PLAN**

On July 19, 2016, the Company adopted its 2016 Equity Incentive Plan (the "Equity Incentive Plan"). The Equity Incentive Plan was established to attract, motivate, retain and reward selected employees and other eligible persons. For the Equity Incentive Plan, employees, officers, directors and consultants who provide services to the Company or one of the Company's subsidiaries may be selected to receive awards. A total of 9,750,000 shares of the Company's common stock was authorized for issuance with respect to awards granted under the Equity Incentive Plan.

Stock-based compensation expense is the estimated fair value of options granted amortized on a straight-line basis over the requisite service period for the entire portion of the award less an estimate for anticipated forfeitures. The Company uses the "simplified" method to estimate the expected term of the options because the Company's historical share option exercise experience does not provide a reasonable basis upon which to estimate expected term. No options were granted during the years ended September 30, 2021 and 2020.

The Black-Scholes option pricing model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because the Company's stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of the Company's stock options.

The following table summarizes stock option activity for the years ended September 30, 2021 and September 30, 2020

| | Number of Options | Weighted Average Exercise Price Per Option | Weighted Average remaining Contractual Life (years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding balance at October 1, 2019 | 4,073,675 | 0.59 | 6.37 | $ |
| Granted | — | — | — | — |
| Exercised | — | — | — | — |
| Forfeited and Expired | (425,000) | (0.61) | — | — |
| Outstanding balance at September 30, 2020 | 3,648,675 | 0.59 | 5.28 | $ — |
| Options exercisable at September 30, 2020 | 3,210,050 | 0.54 | 5.11 | — |
| Granted | — | — | — | — |
| Exercised | — | — | — | — |
| Forfeited and Expired | — | — | — | — |
| Outstanding balance at September 30, 2021 | 3,648,675 | 0.59 | 4.28 | $ — |
| Options exercisable at September 30, 2021 | 3,648,675 | 0.59 | 4.28 | $ — |

There were no options exercised during the years ended September 30, 2021 and September 30, 2020. As of September 30, 2021, there was no unrecognized compensation cost related to stock options.

The charges related to share-based compensation to directors, officers and employees are included within the general and administrative expense category in the statement of operations. For the years ended September 30, 2021 and September 30, 2020, the charges were $42,673 and $134,632 respectively.

**8. INCOME TAXES**

The components of loss before income taxes consisted of the following:

| | Year Ended September 30, 2021 | Year Ended September 30, 2020 |
|---|---|---|
| US | $ (785,082) | $ (5,349,706) |
| Foreign | — | — |
| Total | $ (785,082) | $ (5,349,706) |

As of September 30, 2020, the Company is expected to have net operating loss carryforwards of approximately $7.7 million for federal tax purposes, which will expire in 2037. The utilization of these NOL's may be subject to limitations based on past and future changes in ownership of the Company pursuant to Internal Revenue Code section 382. The Company has determined that ownership changes may have occurred for Internal Revenue Code section 382 purposes and therefore, the ability of the Company to utilize its NOLs may be limited.

Income tax expenses attributable to income for continuing operations consists of:

| | Year Ended September 30, 2021 | Year Ended September 30, 2020 |
|---|---|---|
| Federal: | | |
| Current | — | — |
| Deferred | $ (191,652) | $ (169,925) |
| | | |
| Foreign: | | |
| Current | — | — |
| Deferred | — | — |
| | | |
| State and local: | | |
| Current | — | — |
| Deferred | (69,580) | (58,097) |
| | | |
| Change in valuation allowance | 261,232 | 224,988 |
| | | |
| Income tax (benefit)/expense | $ - | $ (3,034) |

Deferred income taxes reflect the net tax effects of temporary differences between the carrying value of the asset and liabilities for financial reporting purposes and amounts used for income tax purposes. The temporary differences that gave rise to the deferred tax assets and liabilities are as follows:

| | September 30, | |
|---|---|---|
| | 2021 | 2020 |
| Deferred tax assets: | | |
| Accrued Compensation | $ 89,385 | $ 81,861 |
| Stock Compensation | 441,240 | 454,507 |
| Net operating losses | 2,427,553 | 2,215,640 |
| R&D Credit carryforward | 268,715 | 208,715 |
| Fixed assets | 136 | 523 |
| Total gross deferred tax asset | 3,227,029 | 2,961,246 |
| | | |
| Less: valuation allowance | (3,271,021) | (3,009,789) |
| | | |
| Net deferred tax asset | (43,992) | (48,543) |
| | | |
| Deferred tax liabilities: | | |
| Intangible assets | 43,992 | 48,543 |
| Fixed assets | — | — |
| Total Deferred tax liabilities | 43,992 | 48,543 |
| | | |
| Net Deferred Income Tax | $ — | $ — |

At September 30, 2021 the Company had net operating loss carryforwards of approximately $8.4M for federal tax purposes.

In assessing the realizability of the deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, net operating loss carryback potential, and tax planning strategies in making these assessments.

Based upon the above criteria, the Company believes that it is more likely than not that the full amount of the remaining net deferred tax assets will not be realized. Accordingly, the Company has recorded a full valuation allowance of approximately $3.0 million against the deferred tax asset that is not expected to be realized.

The Company recognizes interest accrued to unrecognized tax benefits and penalties as income tax expense. The Company accrued no penalties or interest during the years ended September 30, 2021 and September 30, 2020.

A reconciliation of the statutory Federal Income tax rate and effective tax rate of the provision for income taxes is as follows:

| | Year ended September 30, 2021 | Year ended September 30, 2020 |
|---|---|---|
| Federal statutory rate | 21.00% | 21.00% |
| Permanent items | (0.02)% | (18.21)% |
| State taxes | 6.99% | 0.86% |
| Increase in valuation allowance | (33.35)% | (4.21)% |
| Impact of the change to Federal Statutory Tax | - | 1.12% |
| R$D Credit | 7.77% | - |
| Other | (2.39)% | (0.50)% |
| Effective income tax rate | 0.00% | 0.06% |

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which they operate. In the normal course of business, the Company is subject to examination by federal and foreign jurisdictions where applicable based on the statute of limitations that apply in each jurisdiction. As of September 30, 2021, open years related to the federal jurisdiction are fiscal years ending 2020, 2019, 2018, 2017 and 2016.

The Company has no open tax audits for the returns that were filed, with any tax authority as of September 30, 2021. Accordingly, there were no material uncertain tax positions in any of the jurisdictions that the Company operated in.

**9. RELATED PARTY TRANSACTIONS**

During the normal course of its business, the Company enters into various transactions with entities that are both businesses and individuals. The following is a summary of the related party transactions during the years ended September 30, 2021 and 2020.

*Eurema Consulting*

Eurema Consulting S.r.l. is a significant shareholder of the Company. During the years ended September 30, 2021 and 2020, Eurema Consulting did not supply the Company with consulting services. As of September 30, 2021, and September 30, 2020, the balance due to Eurema Consulting S.r.l. was $200,000 for past consultancy services.

*Gabriele Cerrone*

Gabriele Cerrone is the majority shareholder of Panetta Partners, one of the Company's principal shareholders. As of September 30, 2021, and September 30, 2020, the balance due to Gabriele Cerrone was $175,000 for past consultancy services. In March 2020, the Company entered into a 12% Convertible Promissory Note with Gabriele Cerrone for $20,000 with an extended maturity date of December 31, 2021. In February 2021, Gabriele Cerrone assigned the Note to Panetta Partners Ltd.

*Roberto Pellicciari and TES Pharma*

Roberto Pellicciari is the majority shareholder of TES Pharma Srl, one of the Company's principal shareholders. During the years ended September 30, 2021 and 2020, Roberto Pellicciari did not supply the Company with consulting services. As of September 30, 2021, and September 30, 2020, the balance due to Roberto Pellicciari was $175,000 for past consultancy services. At both September 30, 2021 and September 30, 2020, TES Pharma was owed $75,000.

*Tiziana Life Sciences ("Tiziana")*

The Company is party to a Shared Services Agreement with Tiziana, whereby the Company is charged for shared services and rent. Tiziana had previously agreed to waive all charges for shared services from October 2018 onwards, until further notice since the amounts due for such services are de minimis. Notice was given and recharges from October 1, 2020 were resumed. Keeren Shah the Company's Finance Director is also Finance Director of Tiziana, and the Company's directors, Willy Simon and John Brancaccio are also non-executive directors of Tiziana.

As of September 30, 2021, $11,446 was due to Tiziana under services charged under the shared services agreement. This is recorded as a related party payable in the accompanying consolidated balance sheets. As of September 30, 2020, the Company made payments on behalf of Tiziana of $748, which are recorded as a related party receivable in the accompanying consolidated balance sheets.

In March, 2020, Tiziana extended a loan facility to Rasna of $65,000. The loan is repayable within 18 months and is incurring an interest charge of 8% per annum. In April 2020, the loan facility was extended by a further $7,000, so the loan facility totals $72,000. As of September 30, 2021, the amounts due to Tiziana under this loan facility were $80,640. The amount due to Tiziana under this agreement as of September 30, 2020 was $74,880.

*Panetta Partners*

Panetta Partners Limited, a shareholder of Rasna, is a company in which Gabriele Cerrone is a major shareholder and also serves as a director. The Company has entered into numerous 12% Convertible Promissory Notes with Panetta Partners for a total of $256,000. The amount due for these notes as at September 30, 2021, with respect to the principal and accrued interest is $276,303. As at September 30, 2020 $68,501 was due with respect to notes issued.

Apart from the Convertible Promissory Notes, there is no interest charged on the balances with related parties,. There are no defined repayment terms and such amounts can be called for payment at any time.

**10. COMMITMENTS AND CONTINGENCIES**

*Consultancy Agreements*

On October 1, 2020 the Company entered into a consultancy agreement with Keeren Shah in which she agreed to serve as Finance Director for a fee of $15,000 per year. During the year to September 30, 2021, the Company incurred approximately $15,000 of consultancy expenses related to this agreement.

*Shared Services Agreement*

The Company has entered into a shared services agreement with Tiziana Life Sciences. Under the terms of this agreement, the Company will be charged for shared administrative services including payroll and rent for the London premises, on a monthly basis based on allocated costs incurred. This agreement is effective from January 1, 2017. As at September 30, 2021, $11,446 is due to Tiziana Life Sciences.

**11. SUBSEQUENT EVENTS**

The Company has evaluated subsequent events that occurred after the balance sheet date up to the date that the consolidated financial statements were issued. Other than as disclosed below, the Company did not identify any subsequent events that would have required adjustment or disclosure in the consolidated financial statements.

During November 2021, Panetta Partners Ltd advanced $85,000 to the Company. This advance was converted into promissory notes, the terms of which are the same as those of all the outstanding promissory notes, The expiration of the notes is December 31, 2023.

On December 31, 2021, the terms of all other outstanding promissory notes were extended to December 31, 2023.

**Exhibit 21**

Rasna Research, Inc., a Delaware corporation

**Exhibit 31.1**

**CERTIFICATION BY PRINCIPAL EXECUTIVE OFFICER, PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER**

I, Willy Simon, certify that:

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

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

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

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

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

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

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

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

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Dated: March 1, 2022

/s/ Willy Simon

Name: Willy Simon
Title: Chairman

**Exhibit 31.2**

**CERTIFICATION BY PRINCIPAL EXECUTIVE OFFICER, PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER**

I, Keeren Shah, certify that:

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

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

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

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

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

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

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

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

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Dated: March 1, 2022

/s/ Keeren Shah

Name: Keeren Shah
Title: Finance Director

**Exhibit 32.1**

**CERTIFICATION PURSUANT TO**
**18 U.S.C. SECTION 1350,**
**AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Interim Report of Rasna Therapeutics, Inc. (the "Company") on Form 10-K for the year ended September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Willy Simon, Executive Chairman of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Dated: March 1, 2022

/s/ Willy Simon
Name: Willy Simon
Title: Chairman

**Exhibit 32.2**

**CERTIFICATION PURSUANT TO**
**18 U.S.C. SECTION 1350,**
**AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Interim Report of Rasna Therapeutics, Inc. (the "Company") on Form 10-K for the year ended September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Keeren Shah, Finance Director of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Dated: March 1, 2022

/s/ Keeren Shah
Name: Keeren Shah
Title: Finance Director