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

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

Commission File Number 001-38174

Citius Pharmaceuticals, Inc.
(Exact name of Registrant as specified in its Charter)

Nevada	**27-3425913**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

11 Commerce Drive, First Floor, Cranford, NJ 07016
(Address of principal executive offices) (Zip Code)

(908) 967-6677
(Registrant's telephone number, including area code)

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	**CTXR**	**The NASDAQ Capital Market**
Warrants to purchase Common Stock	**CTXRW**	**The NASDAQ Capital Market**

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 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 Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act 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 Exchange Act). ☐ Yes ☒ No

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter (March 31, 2021) was approximately $218 million.

Affiliates for the purpose of this item refers to the issuer's executive officers and directors and/or any persons or firms (excluding those brokerage firms and/or clearing houses and/or depository companies holding issuer's securities as record holders only for their respective clients' beneficial interest) owning 10% or more of the issuer's common stock, both of record and beneficially.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date:

146,029,630 shares as of November 30, 2021, all of one class of common stock, $0.001 par value.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company's Proxy Statement for the Annual Meeting of Stockholders expected to be held on February 8, 2022 are incorporated by reference in Part III of this Report.

Citius Pharmaceuticals, Inc.

FORM 10-K
September 30, 2021

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NOTES

In this annual report on Form 10-K, and unless the context otherwise requires, the "Company," "we," "us" and "our" refer to Citius Pharmaceuticals, Inc. and its wholly-owned subsidiaries Citius Pharmaceuticals, LLC, Leonard-Meron Biosciences, Inc. and Citius Acquisition Corp., and its majority-owned subsidiary, NoveCite, Inc., taken as a whole.

Mino-Lok® is our registered trademark. All other trade names, trademarks and service marks appearing in this prospectus are the property of their respective owners. We have assumed that the reader understands that all such terms are source-indicating. Accordingly, such terms, when first mentioned in this report, appear with the trade name, trademark or service mark notice and then throughout the remainder of this report without trade name, trademark or service mark notices for convenience only and should not be construed as being used in a descriptive or generic sense.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements." Forward-looking statements include, but are not limited to, statements that express our intentions, beliefs, expectations, strategies, predictions or any other statements relating to our future activities or other future events or conditions. These statements are based on current expectations, estimates and projections about our business based, in part, on assumptions made by management. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may, and are likely to, differ materially from what is expressed or forecasted in the forward-looking statements due to numerous factors discussed from time to time in this report, including the risks described under Item 1A - "Risk Factors," and Item 7 - "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this report and in other documents which we file with the Securities and Exchange Commission ("SEC"). In addition, such statements could be affected by risks and uncertainties related to:

- the cost, timing and results of our pre-clinical and clinical trials;
- our ability to raise funds for general corporate purposes and operations, including our pre-clinical and clinical trials;
- our ability to apply for, obtain and maintain required regulatory approvals for our product candidates;
- the commercial feasibility and success of our technology and our product candidates;
- our ability to recruit qualified management and technical personnel to carry out our operations; and
- the other factors discussed in the "Risk Factors" section and elsewhere in this report.

Any forward-looking statements speak only as of the date on which they are made, and, except as may be required under applicable securities laws, we do not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the filing date of this report.

SUMMARY OF RISK FACTORS

An investment in our securities involves a high degree of risk. You should carefully consider the risks summarized in Item 1A, "Risk Factors" included in this report. These risks include, but are not limited to, the following:

- We have a history of net losses and expect to incur losses for the foreseeable future. We may never generate revenues or, if we are able to generate revenues, achieve profitability.
- We need to secure additional financing in the near future to complete the development of our current product candidates and support our operations. If we fail to raise additional funds, our operations and business will be significantly adversely affected.

- The COVID-19 pandemic has adversely impacted hospitals and medical facilities where we are currently conducting our Mino-Lok Phase 3 trial and may materially and adversely affect our clinical trial operations in the future, which could increase our operating expenses and the length of time to complete the trial and have a material adverse effect on our financial results.

- We cannot assure you that we will receive the approvals necessary to commercialize for sale any product candidates we are currently developing or that we may acquire or seek to develop in the future. Failure to obtain FDA approval of one or more of our product candidates could severely undermine our business by leaving us without saleable products, and therefore without any potential sources of revenues.

- The results of pre-clinical studies and completed clinical trials are not necessarily predictive of future results, and our current product candidates may not have favorable results in later studies or trials.

- If we are unable to file for approval of Mino-Lok or Halo-Lido under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, and thereby not be able to use existing, publicly available third party data regarding components of Mino-Lok or Halo-Lido, or if we are required to generate additional data related to safety and efficacy in order to obtain approval of Mino-Lok or Halo-Lido under Section 505 (b)(2), we may be unable to meet our anticipated development and commercialization timelines. Such a development would be costly and time consuming and adversely impact our operations and financial condition.

- Because our NoveCite product candidate is based on novel mesenchymal stem cell technologies, it is difficult to predict the regulatory approval process and the time, the cost and our ability to successfully initiate, conduct and complete clinical development, and obtain the necessary regulatory and reimbursement approvals, required for commercialization of our NoveCite product candidate.

- NoveCite has assumed that the biological capabilities of iPSCs and adult-donor derived cells are likely to be comparable. If it is discovered that this assumption is incorrect, the NoveCite product candidate research and development activities could be harmed.

- Currently, we do not have any sales, marketing or distribution capabilities. In order to generate sales of any product candidate that receives regulatory approval, we must either acquire or develop an internal marketing and sales force with technical expertise and with supporting distribution capabilities or make arrangements with third parties to perform these services for us.

- Physicians and patients might not accept and use any of our product candidates for which regulatory approval is obtained.

- Our ability to commercialize our product candidates will depend in part on the extent to which reimbursement will be available from government and health administration authorities, private health maintenance organizations and health insurers, and other healthcare payers. Our ability to generate product revenues will be diminished if any of our product candidates that may be approved sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.

- We are and will be dependent on third-party contract research organizations to conduct all of our clinical trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for any of our product candidates.

- We do not have and do not intend to establish our own manufacturing facilities. Consequently, we lack the physical plant to formulate and manufacture our product candidates, which are currently being manufactured entirely by commercial third-party manufacturers.

- We rely on the significant experience and specialized expertise of our executive management and other key personnel and the loss of any of our executive management or key personnel or our inability to successfully hire their successors could harm our business.

- We share some directors, officers and research staff with NoveCite. The dual roles of our employees, officers and directors who also serve in similar roles with NoveCite could create a conflict of interest, which could expose us to claims by our investors and creditors and could harm our results of operations.

- Our future success, competitive position and revenues, if any, depend in part on our ability and the abilities of our licensors to obtain and maintain patent protection for our product candidates, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties.

- If we fail to meet the continued listing requirements of Nasdaq it could result in a delisting of our common stock and certain warrants. We have twice failed to meet the listing standards, most recently between April 2020 and July 2020, but regained compliance. However, we cannot assure our future compliance with Nasdaq's listing requirements.

- You may experience dilution of your ownership interests because of the future issuance of additional shares of our common stock or securities convertible into common stock. As of September 30, 2021, there were 145,979,429 shares of common stock outstanding, 40,208,347 shares underlying warrants and 5,755,171 shares underlying options.

- Under our Certificate of Incorporation, our Board of Directors has the authority to issue up to 10,000,000 shares of preferred stock and to fix and determine the relative rights and preferences of any such preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of one or more series of preferred stock that would grant preferential rights over our common stock.

PART I

Item 1. Business

Overview

Citius Pharmaceuticals, Inc. (the "Company," "Citius" or "we"), headquartered in Cranford, New Jersey, is a specialty pharmaceutical company dedicated to the development and commercialization of first in class critical care products with a focus on anti-infective products in adjunct cancer care, unique prescription products and mesenchymal stem cell therapy. Our goal generally is to achieve leading market positions by providing therapeutic products that address unmet medical needs yet have a lower development risk than usually is associated with new chemical entities. New formulations of previously approved drugs with substantial existing safety and efficacy data are a core focus. We seek to reduce development and clinical risks associated with drug development, yet still focus on innovative applications. Our strategy centers on products that have intellectual property and regulatory exclusivity protection, while providing competitive advantages over other existing therapeutic approaches.

The Company was founded as Citius Pharmaceuticals, LLC, a Massachusetts limited liability company, on January 23, 2007. On September 12, 2014, Citius Pharmaceuticals, LLC entered into a Share Exchange and Reorganization Agreement, with Citius (formerly Trail One, Inc.), a publicly traded company incorporated under the laws of the State of Nevada. Citius Pharmaceuticals, LLC became a wholly-owned subsidiary of Citius. On March 30, 2016, Citius acquired Leonard-Meron Biosciences, Inc. ("LMB") as a wholly-owned subsidiary. LMB was a pharmaceutical company focused on the development and commercialization of critical care products with a concentration on anti-infectives. On September 11, 2020, we formed NoveCite, Inc. ("NoveCite"), a Delaware corporation, of which we own 75% of the issued and outstanding capital stock. NoveCite is focused on the development and commercialization of its proprietary mesenchymal stem cells for the treatment of acute respiratory disease syndrome ("ARDS"). On August 23, 2021, we formed Citius Acquisition Corp. as a wholly-owned subsidiary in conjunction with the acquisition of I/ONTAK, but no activity has occurred to date.

Since its inception, the Company has devoted substantially all of its efforts to business planning, acquiring our proprietary technology, research and development, recruiting management and technical staff, and raising capital. We are developing five proprietary products: Mino-Lok, an antibiotic lock solution used to treat patients with catheter-related bloodstream infections by salvaging the infected catheter; Mino-Wrap, a liquifying gel-based wrap for reduction of tissue expander infections following breast reconstructive surgeries; Halo-Lido, a corticosteroid-lidocaine topical formulation that is intended to provide anti-inflammatory and anesthetic relief to persons suffering from hemorrhoids; NoveCite, a mesenchymal stem cell therapy for the treatment of ARDS; and I/ONTAK, in-licensed in September 2021, a engineered IL-2 diphtheria toxin fusion protein, for the treatment of patients with persistent or recurrent cutaneous T-cell lymphoma ("CTCL"). We believe these unique markets for our products are large, growing, and underserved by the current prescription products or procedures.

Citius is subject to a number of risks common to companies in the pharmaceutical industry including, but not limited to, risks related to the development by Citius or its competitors of research and development stage products, market acceptance of its products that receive regulatory approval, competition from larger companies, dependence on key personnel, dependence on key suppliers and strategic partners, the Company's ability to obtain additional financing and the Company's compliance with governmental and other regulations.

I/ONTAK

Overview

In September 2021, the Company announced that it had entered into a definitive agreement with Dr. Reddy's Laboratories SA, a subsidiary of Dr. Reddy's Laboratories, Ltd. (collectively, "Dr. Reddy's"), to acquire its exclusive license of E7777 (denileukin diftitox), a late-stage oncology immunotherapy for the treatment of CTCL, a rare form of non-Hodgkin lymphoma. E7777, an engineered IL-2-diphtheria toxin fusion protein, is an improved formulation of oncology agent, ONTAK®, which was previously approved by the U.S. Food and Drug Administration ("FDA") for the treatment of patients with persistent or recurrent CTCL. We have renamed E7777 as I/ONTAK although we refer to it as E7777 at times in this report.

Phase 3 Trial

A global, multicenter, open label single arm pivotal clinical trial for the treatment of patients with persistent or recurrent CTCL was initiated in 2013. Inclusion criteria for the study were to evaluate patients in advanced stage CTCL (Mycosis Fungoides or Sézary Syndrome), who received at least one prior CTCL therapy.

The pivotal trial was divided into two phases, a lead-in phase with 21 subjects that evaluated dose finding, pharmacokinetics and immunogenicity, as well as assessing the Objective Response Rate (the "ORR"). An ORR is defined as a greater than 50% reduction in tumor burden.

The results of the lead-in study were:

- 9 mcg/kg/dose for 5 consecutive days in 21-day cycles which was selected for the main phase of the study based on safety, tolerability, and efficacy data.
- No new safety signals were identified compared to Ontak.
- An ORR of 38.1% in the intent to treat population and 44.4% in the efficacy evaluable populations.

The second phase to the pivotal trial was a 70-patient study administered at the 9 mcg/kg/dose rate for 5 consecutive days in 21-day cycles, The inclusion criteria was identical to the lead-in study and the primary objective was to evaluate the ORR.

Investigator Initiated Trials

A Phase 1 trial has been initiated at the University of Minnesota, Masonic Cancer Center. This study is a single-arm non-randomized trial which has an estimated enrollment of 30 participants who will be administered E7777 prior to tisagenlecleucel Chimeric Antigen Receptor, ("CAR-T") therapy. The Phase 1 study consists of two components: dose finding to establish a maximum tolerated dose ("MTD") of E7777 in combination with CART-T Therapy, and a small extension component to provide an estimate of efficacy at that MTD.

A second Phase 1 Study is planned to be initiated by March 2022 at the University of Pittsburg Medical Center, Hillman Cancer Center. This study will be investigating the safety and efficacy of a combined regimen of pembrolizumab with T-regulatory cell depletion and E7777 in patients diagnosed with recurrent or metastatic solid tumors in the second line setting.

Regulatory Development

In the 1990's, denileukin diftitox was developed at Boston University and the National Cancer Institute ("NCI") in collaboration with Seragen, Inc. In 1999, Ontak® (denileukin diftitox) was granted accelerated approval by the FDA for the treatment of persistent or recurrent CTCL with Ligand Pharmaceuticals, Inc. ("Ligand") acquiring the marketing rights in that same year. In 2006, Eisai Co., Ltd. ("Eisai") acquired the commercial rights to Ontak from Ligand.

In 2008, the FDA granted full approval to Ontak for CTCL.

In 2011, there was a commercial supply disruption due to manufacturing issues and a new formulation of denileukin diftitox was developed under the code name E7777. The FDA considered this a new product with a new IND being filed. In ensuing discussions, the FDA agreed to a development plan that included a single arm, open label study to conclude safety and efficacy of E7777 and a CMC development plan that demonstrates the new process results in a comparable drug product.

In 2011, the FDA Office of Orphan Products Development granted E7777 orphan drug designation status for the treatment of Peripheral T-Cell Lymphoma ("PTCL"). In 2013, the FDA Office of Orphan Products Development granted E7777 orphan drug designation status for the treatment of CTCL.

In 2013, the first patient was enrolled into the lead-in phase of the pivotal study for the E7777 U.S. CTCL clinical trial.

In 2014, commercial sales of Ontak were discontinued when the product was voluntarily withdrawn from the market due to manufacturing issues at the contract manufacturer.

In 2015, the last patient enrolled exited the lead-in phase of the E7777 U.S. CTCL clinical trial.

In March 2016, Dr. Reddy's Laboratories ("DRL") acquired the global rights to E7777 from Eisai, other than far east countries, with Eisai retaining the rights in those countries.

In June 2016, the first patient was enrolled in the Phase 3 pivotal study for E7777 CTCL in the U.S.

In March 2020, Eisai filed an NDA for E7777 in Japan for both CTCL and PTCL and in March 2021 received approvals in both CTCL and PTCL.

The last patient in the Phase 3 Pivotal study of E7777 has been enrolled and a biologics license application ("BLA") for E7777's first indication in CTCL is expected to be filed with the FDA by the end of 2022.

Market Opportunity

CTCL's are a heterogeneous subset of extranodal non-Hodgkin lymphomas ("NHL") of mature, skin-homing T-cells that are mainly localized to the skin. The most common types of CTCL are mycosis fungoides ("MF") and primary cutaneous CD30+ anaplastic large cell lymphoma (pcALCL), jointly representing an estimated 80–85% of all CTCL. Sézary Syndrome ("SS"), a very rare subtype (~2–5% of CTCL) characterized by diffuse inflammatory, often exfoliative, erythroderma and by leukemic and nodal involvement, displays a significant degree of clinical and biological overlap with MF and has long been considered a clinical variant of MF, although recent evidence suggests that it may be a separate entity. The rest is represented by extremely rare, generally more aggressive subtypes. In light of the overlap between MF and SS, and considering that many of the systemic therapy options for the two neoplasms are the same, some consider the treatment approach to MF and SS as if they were a single disease entity (MF/SS). However, some of the drugs currently in use, or in development, for MF/SS appear to be more effective in clearing different anatomical compartments (skin versus blood, for example) and therefore have differential efficacy in MF and SS.

Based on Surveillance Epidemiology and End Results (SEER) data from 2001–2007, the estimated incidence rate of MF/SS in the U.S. is 0.5/100,000 or about 2,500–3,000 new cases per year representing about 25% of all T-cell lymphomas.

The Company estimates that there are 30,000 – 40,000 patients living with CTCL in the U.S. with approximately 16,000 – 20,000 having mycosis fungoides. Of those, the Company further estimates that there are 10,000 patients with relapsed or refractory CTCL that require systemic therapy.

The Company also estimates that the addressable U.S. market is approximately $300,000,000 for patients with advanced stage relapsed or refractory CTCL.

Mino-Lok®

Overview

Mino-Lok is a patented solution containing minocycline, disodium ethylenediaminetetraacetic acid (edetate), and ethyl alcohol, all of which act synergistically to treat and salvage infected central venous catheters ("CVCs") in patients with catheter related bloodstream infections ("CRBSIs"). Mino-Lok breaks down biofilm barriers formed by bacterial colonies, eradicates the bacteria, and provides anti-clotting properties to maintain patency in CVCs.

The administration of Mino-Lok consists of filling the lumen of the catheter with 0.8 ml to 2.0 ml of Mino-Lok solution. The catheter is then "locked", meaning that the solution remains in the catheter without flowing into the vein. The lock is maintained for a dwell-time of two hours while the catheter is not in use. If the catheter has multiple lumens, all lumens may be locked with the Mino-Lok solution either simultaneously or sequentially. If patients are receiving continuous infusion therapy, the catheters alternate between being locked with the Mino-Lok solution and delivering therapy. The Mino-Lok therapy is two hours per day for at least five days, usually with two additional locks in the subsequent two weeks. After locking the catheter for two hours, the Mino-Lok solution is aspirated, and the catheter is flushed with normal saline. At that time, either the infusion will be continued, or will be locked with the standard-of-care lock solution until further use of the catheter is required. In a clinical study conducted by MD Anderson Cancer Center ("MDACC"), there were no serum levels of either minocycline or edetate detected in the sera of several patients who underwent daily catheter lock solution with minocycline and edetate ("M-EDTA") at the concentration level proposed in Mino-Lok treatment. Thus, it has been demonstrated that the amount of either minocycline or edetate that leaks into the serum is very low or none at all.

Phase 2b Results

From April 2013 to July 2014, 30 patients with CVC-related bloodstream infection were enrolled at MDACC in a prospective Phase 2b study. Patients received Mino-Lok therapy for two hours once daily for a minimum of five days within the first week, followed by two additional locks within the next two weeks. Patients were followed for one month post-lock therapy. Demographic information, clinical characteristics, laboratory data, therapy, as well as adverse events and outcome were collected for each patient. Median age at diagnosis was 56 years (range: 21-73 years). In all patients, prior to the use of lock therapy, systemic treatment with a culture-directed, first-line intravenous antibiotic was started. Microbiological eradication was achieved at the end of therapy in all cases. None of the patients experienced any serious adverse event related to the lock therapy.

The active arm, which is the Mino-Lok treated group of patients, was then compared to 60 patients in a matched cohort that experienced removal and replacement of their CVCs within the same contemporaneous timeframe. The patients were matched for cancer type, infecting organism, and level of neutropenia. All patients were cancer patients and treated at MDACC. The efficacy of Mino-Lok therapy was 100% in salvaging CVCs, demonstrating equal effectiveness to removing the infected CVC and replacing it with a new catheter.

The main purpose of the study was to show that Mino-Lok therapy was at least as effective as the removal and replacement of CVCs when CRBSIs are present, and that the safety was better, that is, the complications of removing an infected catheter and replacing with a new one could be avoided. In addition to having a 100% efficacy rate with all CVCs being salvaged, Mino-Lok therapy had no significant adverse events ("SAEs"), compared to an 18% SAE rate in the matched cohort where patients had the infected CVCs removed and replaced with a fresh catheter. There were no overall complication rates in the Mino-Lok arm group compared to 11 patients with events (18%) in the control group. These events included bacterial relapse (5%) at four weeks post-intervention, and a number of complications associated with mechanical manipulation in the removal or replacement procedure for the catheter (10%) or development of deep-seated infections such as septic thrombophlebitis and osteomyelitis (8%). As footnoted, six patients had more than one complication in the control arm group.

	Mino-Lok® Arm		**Control Arm**	
Parameter	**N**	**(%)**	**N**	**(%)%**
Patients	**30**	**(100)%**	**60**	**(100)%**
Cancer type				
- Hematologic	20	(67)	48	(80)
- Solid tumor	10	(33)	12	(20)
ICU Admission	**4**	**(13)**	**4**	**(7)**
Mech.Ventilator	**3**	**(10)**	**0**	**(0)**
Bacteremia				
- Gram+	17	(57)*	32	(53)
- Gram-	14	(47)*	28	(47)
Neutropenia (<500)	**19**	**(63)**	**36**	**(60)**
Microbiologic Eradication	**30**	**(100)**	**60**	**(100)**
- Relapse	0	(0)	3	(5)
Complications	**0**	**(0)**	**8**	**(13)**
SAEs related R&R	**0**	**(0)**	**6**	**(10)**
Overall Complication Rate	**0**	**(0)%**	**11****	**(18)%**

* 1 Polymicrobial patient had a Gram+ and a Gram- organism cultured

** 6 Patients had > 1 complication

Source: Dr. Issam Raad, Antimicrobial Agents and Chemotherapy, June 2016, Vol. 60 No. 6, Page 3429

Phase 3 Trial

In November 2016, the Company initiated site recruitment for Phase 3 clinical trials. From initiation through the first quarter of 2017, the Company received input from several sites related to the control arm as being less than standard-of-care for some of the respective institutions. The Company worked closely with the FDA with respect to the design of the Phase 3 trial and received feedback on August 17, 2017. The FDA stated that they recognized that there is an unmet medical need in salvaging infected catheters and agreed that an open label, superiority design would address the Company's concerns and would be acceptable to meet the requirements of a new drug application. The Company amended the Phase 3 study design to remove the saline and heparin placebo control arm and to use an active control arm that conforms with today's current standard-of-care. Patient enrollment commenced in February 2018.

The Mino-Lok Phase 3 Trial was originally planned to enroll 700 patients in 50 participating institutions, all located in the U.S. There were interim analyses at both the 50% and 75% points of the trial as measured by the number of patients treated. As of November 30, 2021, there are 21 active sites currently enrolling patients including such academic centers as MDACC, Henry Ford Health Center, Georgetown University Medical Center, and others. There are two additional medical centers in startup mode. There are no other remaining sites in feasibility.

In September 2019, the Company announced that the FDA agreed to a new primary efficacy endpoint of "time to catheter failure" in comparing Mino-Lok to the antibiotic lock control arm. This change in the trial design reduced the required patient sample size of the trial from 700 subjects to approximately 144 available subjects to achieve the pre-specified 92 catheter failure events needed to conclude the trial. Additionally, the Company submitted a response to the FDA that it would implement this change in the primary endpoint and expected it to result in less than 150 subjects needed in its Phase 3 trial. The new primary endpoints require that the time to catheter failure be at least 38 days for Mino-Lok versus 21 days for the standard of care antibiotic locks.

In October 2019, the FDA agreed that the patient sample size of approximately 144 patients was acceptable.

In October 2019, the Company announced that the Phase 3 trial had reached the 40% completion triggering an interim futility analysis by the data monitoring committee (the "DMC"). The DMC is an independent panel of experts that review progress regarding the safety and efficacy of drugs in clinical trials, and to determine if the trial may be futile in achieving its endpoints or if the trial should be modified in any way.

In December 2019, the DMC convened and recommended that the trial continue with no changes because the analysis showed a positive outcome, as it met the prespecified interim futility analysis criteria.

In May 2020, we announced that we are providing free access to Mino-Lok for healthcare providers under an Expanded Access protocol to ease the burden associated with the COVID-19 pandemic. Through the Expanded Access protocol, an infected central venous catheter can now be treated with Mino-Lok, potentially avoiding the need for the removal and replacement procedure.

In June 2020, we announced that we had received positive feedback from the FDA on our proposed catheter compatibility studies for Mino-Lok. The studies, if and when successfully completed, should allow Mino-Lok to be labeled for use with all commercially available CVCs and peripherally inserted central catheters (PICCs) on the U.S. market. We further assume that these studies will meet European and world standards. The ability to be labeled without restrictions with respect to catheter type would allow Mino-Lok unrestricted access to the full U.S. and world markets for an effective antibiotic lock therapy for central line associated blood stream infections ("CLABSIs").

In September 2020, we announced that another DMC meeting was held to review the data being generated and analyzed in the Mino-Lok Phase 3 trial based on progress to date, and to make recommendations to us as to any action that may be necessary regarding the study. After reviewing these data, the DMC members stated that they did not find any safety signals; and they also recommended continuing the trial without any modifications. The DMC further conducted an *ad hoc* meeting and agreed with the Company that a 75% interim analysis be conducted as planned in which superior efficacy is evaluated.

In September 2020, the Company announced that the three registration batches for all components of Mino Lok were manufactured and that clinical sites were resupplied with registration product.

In November 2020, the Company announced that the three components of Mino-Lok, minocycline, disodium edetate ("EDTA"), and ethanol, were superior to EDTA and ethanol in their ability to eradicate resistant staphylococcal biofilms.

The 75% interim analysis was completed in June 2021. In July 2021, the Company announced that following an unblinded data review of safety and efficacy, the independent DMC for the trial recommended proceeding with the trial as planned. The DMC did not identify any safety concerns and no modifications were recommended to the protocol-defined sample size or power to achieve the primary endpoint.

Fast Track Designation

In October 2017, the Company received official notice from FDA that the investigational program for Mino-Lok was granted "Fast Track" status. Fast Track is a designation that expedites FDA review to facilitate development of drugs which treat a serious or life-threatening condition and fill an unmet medical need. A drug that receives Fast Track designation is eligible for the following:

- More frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval;
- More frequent written correspondence from FDA about the design of the clinical trials;
- Priority review to shorten the FDA review process for a new drug from ten months to six months; and
- Rolling review, which means Citius can submit completed sections of its New Drug Application ("NDA") for review by FDA, rather than waiting until every section of the application is completed before the entire application can be submitted for review.

Mino-Lok International Study

In October 2017, data from an international study on Mino-Lok was presented at the Infectious Disease Conference, ("ID Week"), in San Diego, California. The 44-patient study was conducted in Brazil, Lebanon, and Japan and showed Mino-Lok therapy was an effective intervention to salvage long-term, infected CVCs in CRBSIs in patients who had cancer with limited vascular access. This study showed 95% effectiveness for Mino-Lok therapy in achieving microbiological eradication of the CVCs as compared to 83% for the control. The single failure in the Mino-Lok arm was due to a patient with *Burkholderia cepacia* that was resistant to all antibiotics tested.

Stability Patent Application for Mino-Lok

In October 2018, the U.S. Patent and Trademark Office ("USPTO") issued U.S. Patent No. 10,086,114, entitled "Antimicrobial Solutions with Enhanced Stability." On October 9, 2019, the European Patent Office ("EPO") granted European Patent No. 3370794, entitled "Antimicrobial Solutions with Enhanced Stability." The grant of this European patent strengthens the intellectual property protection for Mino-Lok through November of 2036. This invention overcomes limitations in mixing antimicrobial solutions in which components have precipitated because of physical and/or chemical factors, thus limiting the stability of the post-mix solutions. The scientists and technologists at MDACC have been able to improve the stability of the post-mixed solutions through adjustments of the post-mixed pH of the solution. This may allow for longer storage time of the ready-to-use solution. Citius holds the exclusive worldwide license which provides access to this patented technology for development and commercialization of Mino-Lok.

Market Opportunity

In spite of best clinical practice, catheters contribute to approximately 70% of blood stream infections that occur in the intensive care unit or are associated with hemodialysis or cancer patients (approximately 470,000 per year). Bacteria enter the catheter either from the skin or intraluminally through the catheter hub. Once in the catheter, bacteria tend to form a protective biofilm on the interior surface of the catheter that is resistant to most antimicrobial solutions. The most frequently used maintenance flush, heparin, actually stimulates biofilm formation. Heparin is widely used as a prophylactic lock solution, in spite of the evidence that it contributes to the promotion of biofilm formation. The formation of bacterial biofilm usually precedes CRBSIs.

The standard of care in the management of CRBSI patients consists of removing the infected CVC and replacing it with a new catheter at a different vascular access site. However, in cancer and hemodialysis patients with long-term surgically implantable silicone catheters, removal of the CVC and reinsertion of a new one at a different site might be difficult, or even impossible, because of the unavailability of other accessible vascular sites and the need to maintain infusion therapy. Furthermore, critically ill patients with short-term catheters often have underlying coagulopathy, which makes reinsertion of a new CVC at a different site, in the setting of CRBSIs, risky in terms of mechanical complications, such as pneumothorax, misplacement, or arterial puncture. Studies have also revealed that CRBSI patients may be associated with serious complications, including septic thrombosis, endocarditis and disseminated infection, particularly if caused by *Staphylococcus aureus* or *Candida* species. Furthermore, catheter retention in patients with CRBSIs is associated with a higher risk of relapse and poor response to antimicrobial therapy.

According to Maki et al., published in the *Mayo Clinic Proceedings* in 2006, there are approximately 250,000 CRBSIs annually in the U.S. Subsequent to this study, our estimates have ranged upwards to over 450,000 CLABSIs annually (see analysis in the table below). CRBSIs are associated with a 12% to 35% mortality rate and an attributable cost of $35,000 to $56,000 per episode.

We estimate that the potential market for Mino-Lok in the U.S. to be approximately $500 million to $1 billion as shown in the table below based on a target price of up to $300 per dose of each salvage flush treatment.

	Short-Term CVC	Long-Term CVC	Total
No. of Catheters	3 million	4 million	7 million
Avg. Duration (Days)	12	100	N/A
Catheter Days	36 million	400 million	436 million
Infection Rate	2/1,000 days	1/1,000 days	N/A
Catheters Infected	72,000	400,000	472,000
Flushes/Catheter	5	7	6.7
Total Salvage Flushes	360,000	2,800,000	3,160,000

Sources: Ann Intern Med 2000; 132:391-402, Clev Clin J Med 2011; 78(1):10-17, JAVA 2007; 12(1):17-27, J Inf Nurs 2004;27(4):245-250, Joint Commission website Monograph, CLABSI and Internal Estimates.

Under various plausible pricing scenarios, we believe that Mino-Lok would be cost-saving to the healthcare system given that the removal of an infected CVC and replacement of a new catheter in a different venous access site is estimated by us to cost between $8,000 and $10,000. Furthermore, there are potential additional medical benefits, a reduction in patient discomfort and avoidance of serious adverse events with the Mino-Lok approach since the catheter remains in place and is not subject to manipulation. We believe there will be an economic argument to enhance the adoption of Mino-Lok by infection control committees at acute care institutions.

In January of 2017, we commissioned a primary market research study with MEDACore, a subsidiary of Leerink, a healthcare focused network with more than 35,000 healthcare professionals, including key opinion leaders, experienced practitioners and other healthcare professionals throughout North America, Europe, Asia and other locations around the world. This network includes approximately 55 clinical specialties, 21 basic sciences and 20 business specialties. As part of this market research project, we commissioned a third-party survey of 31 physicians to qualify the need for catheter salvage in patients with infected, indwelling central venous lines, especially when the catheter is a tunneled or an implanted port. There were 19 infectious disease experts and 12 intensivists surveyed who all agreed that salvage would be preferable to catheter exchange to avoid catheter misplacements, blood clots, or vessel punctures that can potentially occur during reinsertion. Most were also concerned that viable venous access may not be available in patients who were vitally dependent on a central line.

Mino-Wrap

Overview

On January 2, 2019, we entered into a patent and technology license agreement with the Board of Regents of the University of Texas System on behalf of MDACC, whereby we in-licensed exclusive worldwide rights to the patented technology for any and all uses relating to breast implants, specifically the Mino-Wrap technology. This includes rights to U.S. Patent No. 9,849,217, which was issued on December 16, 2017. We intend to develop Mino-Wrap as a liquefying, gel-based wrap containing minocycline and rifampin for the reduction of infections associated with breast implants following breast reconstructive surgeries. We are required to use commercially reasonable efforts to commercialize Mino-Wrap under several regulatory scenarios and achieve milestones associated with these regulatory options leading to an approval from the FDA. Mino-Wrap will require pre-clinical development prior to any regulatory pathway. In July 2019, we announced that we intend to pursue the FDA's Investigational New Drug ("IND") regulatory pathway for the development of Mino-Wrap. On August 4, 2020, we announced that we had submitted a briefing package to the FDA for a pre-IND consultation on Mino-Wrap.

In December 2020, the Company announced the receipt of a written response and guidance from the FDA Division of Anti-Infective Products to the Company's Pre-IND consultation request for its Mino-Wrap briefing package. The briefing package contained information regarding pre-clinical data and a clinical development plan, along with questions for the FDA regarding safety and efficacy data that would be required to advance Mino-Wrap into clinical trials. The FDA granted a Written Response Only meeting regarding guidance and direction on our Mino-Wrap development plan. The FDA indicated that bio absorption simulation studies may provide information to support the development of Mino-Wrap and made suggestions on what should be provided relative to non-clinical support. The FDA provided guidance on the design of the drug elution studies and agreed that a large animal pharmacology study would be appropriate. They also agreed that a 28-day toxicology study appears appropriate and that microbiology support through existing data is acceptable. We are pursuing these studies and anticipate filing an IND for Mino-Wrap in 2022.

Market Opportunity

Breast cancer is the most frequent cancer in women worldwide representing 25% of all cancer diagnoses with the exception of non-melanoma skin cancer. In the United States, the overall rate of mastectomies, combining single and double mastectomies, has increased 36% from 2005 to 2013. Additionally, the incidence of post-mastectomy breast reconstruction, following breast cancer treatment, has been increasing on an annual basis.

In 2017, the American Society of Plastic Surgeons reported that over 105,000 women in the United States underwent a post-mastectomy breast reconstructive procedure. Approximately 30% of these breast reconstructions occur simultaneously with mastectomy, with most reconstructions occurring weeks later.

The current standard of care in post-mastectomy breast reconstruction is the use of a Tissue Expander ("TE"), which is a temporary implant that is placed below the pectoralis muscle within the mastectomy space. Once a sufficiently large soft tissue envelope has been created, the TE is then replaced by a permanent breast implant. Approximately 80% of the time, a TE is used in breast reconstructions.

The rate of infection following a mastectomy with a TE is 2.4 to 24% with an estimated mean of 12-14%. Once the implant becomes infected, the patient is usually hospitalized requiring approximate two weeks of IV and/or oral antimicrobials. In addition, the TE is removed, leading to a delay of lifesaving chemo-radiation therapy, and a more complex reconstruction in the future.

Currently, preventive measures are used to decrease the rate of TE infections with include a systemic perioperative antimicrobial agent with the perioperative immersion of the implant or irrigation of the surgical pocket with an antimicrobial solution prior to insertion of the device. This is also administered with immediate postoperative oral antimicrobials.

Based on the in vitro preclinical laboratory work, Mino-Wrap appears to have the characteristics necessary for advancement in the protection of human implants from subsequent infection.

Halo-Lido

Overview

Halo-Lido is a topical formulation of halobetasol propionate, a corticosteroid, and lidocaine that is intended for the treatment of hemorrhoids. To our knowledge, there are currently no FDA-approved prescription drug products for the treatment of hemorrhoids. Some physicians are known to prescribe topical steroids for the treatment of hemorrhoids. In addition, there are various topical combination prescription products containing halobetasol propionate along with lidocaine or pramoxine, each a topical anesthetic, that are prescribed by physicians for the treatment of hemorrhoids. These products contain drugs that were in use prior to the start of the Drug Efficacy Study Implementation ("DESI") program and are commonly referred to as DESI drugs. However, none of these single-agent or combination prescription products have been clinically evaluated for safety and efficacy and approved by the FDA for the treatment of hemorrhoids. Further, many hemorrhoid patients use over the counter ("OTC") products as their first line therapy. OTC products contain any one of several active ingredients including glycerin, phenylephrine, pramoxine, white petrolatum, shark liver oil and/or witch hazel, for symptomatic relief.

Development of Hemorrhoids Drugs

Hemorrhoids are a common gastrointestinal disorder, characterized by anal itching, pain, swelling, tenderness, bleeding and difficulty defecating. In the U.S., hemorrhoids affect nearly 5% of the population, with approximately 10 million persons annually admitting to having symptoms of hemorrhoidal disease. Of these persons, approximately one third visit a physician for evaluation and treatment of their hemorrhoids. The data also indicate that for both sexes a peak of prevalence occurs from age 45 to 65 years with a subsequent decrease after age 65 years. Caucasian populations are affected significantly more frequently than African Americans, and increased prevalence rates are associated with higher socioeconomic status in men but not women. Development of hemorrhoids before age 20 is unusual. In addition, between 50% and 90% of the general U.S., Canadian and European population will experience hemorrhoidal disease at least once in life. Although hemorrhoids and other anorectal diseases are not life-threatening, individual patients can suffer from agonizing symptoms which can limit social activities and have a negative impact on the quality of life.

Hemorrhoids are defined as internal or external according to their position relative to the dentate line. Classification is important for selecting the optimal treatment for an individual patient. Accordingly, physicians use the following grading system referred to as the Goligher's classification of internal hemorrhoids:

Grade I Hemorrhoids not prolapsed but bleeding.

Grade II Hemorrhoids prolapse and reduce spontaneously with or without bleeding.

Grade III Prolapsed hemorrhoids that require reduction manually.

Grade IV Prolapsed and cannot be reduced including both internal and external hemorrhoids that are confluent from skin tag to inner anal canal.

Development Activities to Date

In the fall of 2015, we completed dosing patients in a double-blind dose ranging placebo-controlled Phase 2a study where six different formulations containing hydrocortisone and lidocaine in various strengths were tested against the vehicle control. The objectives of this study were to: (1) demonstrate the safety and efficacy of the formulations when applied twice daily for two weeks in subjects with Grade I or II hemorrhoids, and (2) assess the potential contribution of lidocaine hydrochloride and hydrocortisone acetate, alone or in combination for the treatment of symptoms of Goligher's Classification Grade I or II hemorrhoids.

Symptom improvement was observed based on a global score of disease severity ("GSDS") and based on some of the individual signs and symptoms of hemorrhoids, specifically itching and overall pain and discomfort. Within the first few days of treatment, the combination products (containing both hydrocortisone and lidocaine) were directionally favorable versus the placebo and their respective individual active treatment groups (e.g., hydrocortisone or lidocaine alone) in achieving 'almost symptom free' or 'symptom free' status according to the GSDS scale. These differences suggest the possibility of a benefit for the combination product formulation.

Overall, results from adverse event reporting support the safety profile of all test articles evaluated in this study and demonstrate similar safety profiles as compared to the vehicle. The safety findings were unremarkable. There was a low occurrence of adverse events and a similar rate of treatment related adverse events across all treatment groups. The majority of adverse events were mild and only one was severe. None of the adverse events were an SAE and the majority of adverse events were recovered/resolved at the end of the study. There were only two subjects who were discontinued from the study due to adverse events.

In addition to the safety and dose-ranging information, information was obtained relating to the use of the GSDS as an assessment tool for measuring the effectiveness of the test articles. Individual signs and symptoms were also assessed but can vary from patient to patient. Therefore, the goal of the GSDS was to provide an assessment tool that could be used for all patients regardless of which signs and symptoms they are experiencing. The GSDS proved to be a more effective tool for assessing the severity of the disease and the effectiveness of the drug when compared to the assessment of the individual signs and symptoms. Citius believes that we can continue to develop this assessment tool as well as other patient reported outcome endpoints for use in the next trials and in the pivotal trial.

Information was also obtained about the formulation of the drug and the vehicle. As a result of this study, we believe that the performance of the active arms of the study relative to the vehicle could be improved by re-formulating our topical preparation. Therefore, we initiated work on vehicle formulation and evaluation of higher potency steroids.

In June and July 2016, we engaged the Dominion Group, a leading provider of healthcare and pharmaceutical marketing research services. The primary market research was conducted to understand the symptoms that are most bothersome to patients better in order to develop meaningful endpoints for the clinical trials. We also learned about the factors that drive patients to seek medical attention for hemorrhoids in an effort to understand the disease impact on quality of life. The results of this survey are able to help us develop patient reported outcome evaluation tools. These tools can be used in clinical trials to evaluate the patients' conditions and to assess the performance of the test articles.

In March 2018, we announced that we had selected a higher potency corticosteroid in our steroid/anesthetic topical formulation program for the treatment of hemorrhoids. The original topical preparation, which we referred to as Hydro-Lido or CITI-001, which was used in the Phase 2a study, was a combination of hydrocortisone acetate and lidocaine hydrochloride. The new formulation, CITI-002, which we refer to as Halo-Lido, combine lidocaine with the higher potency corticosteroid halobetasol propionate for symptomatic relief of the pain and discomfort of hemorrhoids.

We held a Type C meeting with the FDA in December 2017 to discuss the results of the Phase 2a study and to obtain the FDA's view on development plans to support the potential formulation change for the planned Phase 2b study. We also requested the FDA's feedback on our Phase 2b study design, including target patient population, inclusion/exclusion criteria, and efficacy endpoints. The pre-clinical and clinical development programs for CITI-002 are planned to be similar to those conducted for the development of CITI-001 to support the design for a planned Phase 3 clinical trial. We anticipate filing an IND in December 2021 and beginning a Phase 2b clinical study by March 2022.

Market Opportunity

The current market for OTC and topical prescription ("Rx") products for the symptomatic treatment of hemorrhoids is highly fragmented, and includes approximately 20 million units of OTC and over 4 million prescriptions. None of the Rx products have received FDA approval and are only available due to the DESI program, which started decades ago after enactment of the 1962 Kefauver-Harris Drug Amendments. These DESI products have no FDA reviewed evidence of efficacy or safety, and may be subject to withdrawal if an approved product were to be introduced. Several topical combination prescription products for the treatment of hemorrhoids are available containing hydrocortisone in strengths ranging from 0.5% to 3.0%, combined with lidocaine in strengths ranging from 1.0% to 3.0%. The various topical formulations include creams, ointments, gels, lotions, enemas, pads, and suppositories. The most commonly prescribed topical combination gel is sold as a branded generic product and contains 2.5% hydrocortisone and 3.0% lidocaine.

We believe there are currently no FDA-approved prescription drug products for the treatment of hemorrhoids. Although there are numerous Rx and OTC products commonly used to treat hemorrhoids, none possess proven safety and efficacy data generated from rigorously conducted clinical trials. We believe that a novel topical formulation of halobetasol propionate and lidocaine designed to provide anti-inflammatory and anesthetic relief and which has an FDA-approved label specifically claiming the treatment of hemorrhoids will become an important treatment option for physicians who want to provide their patients with a therapy that has demonstrated safety and efficacy in treating this uncomfortable and often recurring disease. We believe that our Halo-Lido product represents an attractive, low-risk product opportunity with meaningful upside potential.

Market Exclusivity

We believe that we will be the first company to conduct rigorous clinical trials and receive FDA approval of a topical corticosteroid-lidocaine combination product for the treatment of hemorrhoids. If we receive FDA approval, we will qualify for three years of market exclusivity for our dosage strength and formulation. In addition, we will also be the only product on the market specifically proven to be safe and effective for the treatment of hemorrhoids. Generally, if a company conducts clinical trials and receives FDA approval of a product for which there are similar, but non FDA-approved, prescription products on the market, the manufacturers of the unapproved but marketed products are required to withdraw them from the market. However, the FDA has significant latitude in determining how to enforce its regulatory powers in these circumstances. We have not had any communication with the FDA regarding this matter and cannot predict what action, if any, the FDA will take with respect to the unapproved products.

We believe that should Halo-Lido demonstrate, proven safety and efficacy data and receive FDA approval, and if Halo-Lido obtains three years of market exclusivity based on our dosage strength and formulation, we are likely to have a meaningful advantage in our pursuit of achieving a significant position in the market for topical combination prescription products for the treatment of hemorrhoids.

NoveCite

Overview

In October 2020, we, through our subsidiary, NoveCite, signed an exclusive agreement with Novellus Therapeutics Limited ("Novellus") to license iPSC-derived mesenchymal stem cells (iMSCs). Under this worldwide exclusive license, we are focused on developing cellular therapies. Specifically, we are seeking to develop and commercialize the NoveCite mesenchymal stem cells ("NC-*i*MSCs") to treat acute respiratory conditions with a near term focus on ARDS.

NC-*i*MSCs are the next generation mesenchymal stem cell therapy. We believe them to be differentiated and superior to donor-derived MSCs. Human donor-derived MSCs are sourced from human bone marrow, adipose tissue, placenta, umbilical tissue, etc. and have significant challenges (e.g., variable donor and tissue sources, limited supply, low potency, inefficient and expensive manufacturing). NC-iMSCs overcome these challenges because they:

- Are more potent and secrete exponentially higher levels of immunomodulatory proteins;
- Have practically unlimited supply for high doses and repeat doses;
- Are from a single donor and clonal so they are economically produced at scale with consistent quality and potency, as well as being footprint free (compared to viral reprogramming methods); and
- Have a significantly higher expansion capability.

Several cell therapy companies using donor-derived MSC therapies in treating ARDS have demonstrated that MSCs reduce inflammation, enhance clearance of pathogens and stimulate tissue repair in the lungs. Almost all these positive results are from early clinical trials or under the FDA's emergency authorization program.

In December 2020, the Company announced interim data from a proof-of-concept ("POC") large animal study of its proprietary NC-iMSC therapy. The available results of NC-iMSC therapy in the study show improvement in critical parameters, such as improved oxygenation, less systemic shock, and reduced lung injury, compared to the control group. The study was conducted in a widely accepted large animal model.

In the third quarter 2021, the Company completed the characterization and expansion of its NC-iMSC accession cell bank (ACB) at Waisman Biomanufacturing at the University of Wisconsin-Madison to create a cGMP master cell bank (MCB).

In July 2021, Novellus was acquired by Brooklyn ImmunoTherapeutics, Inc. ("Brooklyn"). Pursuant to this transaction, the NoveCite license was assumed by Brooklyn with all of the original terms and conditions in the exclusive license agreement.

Market Opportunity

Globally, there are 3 million cases of ARDS every year, out of which approximately 200,000 cases are in the United States. The COVID-19 pandemic has added significantly to the number of ARDS cases. Once the COVID-19 patients advance to ARDS, they are put on mechanical ventilators. Death rate among patients on ventilators can be as high as 50% depending on associated co-morbidities. There are no approved treatments for ARDS, and the current standard of care only attempts to provide symptomatic relief.

Sales and Marketing

We are primarily focused on identifying opportunities within the critical care and cancer care market segments. In our product acquisition criteria, we concentrate on markets that are highly influenced by key opinion leaders, commonly referred to as KOLs, and in which products are prescribed by a relatively small number of physicians, yet provide opportunities for growth and market share. This strategy allows for a manageable commercialization effort for our Company in terms of resources and capital. We also seek to provide cost-effective therapies that would be endorsed by payers, patients, and providers. We believe that we will be able to commercialize products within the scope of these criteria ourselves, and that we can create marketing synergies by having a common narrow audience for our marketing efforts ("several products in the bag for the same customer").

For our product candidates that fall out of the narrow scope criteria, we have identified pharmaceutical companies with large sales forces, experienced sales and marketing management teams, direct-to-consumer capabilities, significantly larger resources than ours, and non-competing product portfolios that we believe would make excellent sales and marketing partners. We intend to license our mass audience, non-specialty product candidates to such companies for sales and marketing.

Intellectual Property

We rely on a combination of patent, trade secret, copyright, and trademark laws, as well as confidentiality, licensing and other agreements, to establish and protect our proprietary rights. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our current product candidates and any future product candidates both in the U.S. and abroad. However, patent protection may not provide us with complete protection against competitors who seek to circumvent our patents. To help protect our proprietary know-how that is not patentable, and for inventions for which patents may be difficult to enforce, we currently rely and will in the future rely on trade secret protection and confidentiality agreements to protect our interests.

I/ONTAK Intellectual Property

On September 3, 2021, we, through our subsidiary, Citius Acquisition Corp., acquired the exclusive license of E7777 (denileukin diftitox), a late-stage oncology immunotherapy for the treatment of CTCL, a rare form of non-Hodgkin lymphoma. E7777, an engineered IL-2-diphtheria toxin fusion protein, is an improved formulation of oncology agent, ONTAK®, which was previously FDA-approved for the treatment of patients with persistent or recurrent CTCL, from Dr. Reddy's. We refer to the agent as I/ONTAK. The exclusive license, which was amended as part of the transaction, is with Eisai and includes rights to develop and commercialize I/ONTAK in all markets except for Japan and certain parts of Asia. Additionally, we have an option on the right to develop and market the product in India.

Under the license agreement, Eisai is to receive a $6 million development milestone payment upon initial approval by the FDA of I/ONTAK for the CTCL indication (which increases to $7 million in the event we have exercised our option to add India to the licensed territory prior to FDA approval) and an aggregate of up to $22 million related to the achievement of net product sales thresholds. We also are required to reimburse Eisai for up to $2.65 million of its costs to complete the ongoing Phase 3 pivotal clinical trial for I/ONTAK for the CTCL indication and reimburse Eisai for all reasonable costs associated with the preparation of a BLA for I/ONTAK.

Pursuant to the terms of the license agreement, Eisai is responsible for completing the current CTCL clinical trial, and chemistry, manufacturing and controls development activities through the production of the BLA that we will file with the FDA while we are responsible for the costs of correcting any major deficiencies in the BLA as well as the costs of any necessary companion diagnostic or pediatric study. We are responsible for development costs associated with potential additional indications.

The term of the license agreement will continue until (i) if there has not been a commercial sale of a licensed product in the territory, until the 10-year anniversary of the original license effective date, March 30, 2016, or (ii) if there has been a first commercial sale of a licensed product in the territory within the 10-year anniversary of the original license effective date, the 10-year anniversary of the first commercial sale on a country-by-country basis. The term of the license may be extended for additional 10-year periods for all countries in the territory by notifying Eisai and paying an extension fee equal to $10 million. Either party may terminate the license agreement upon written notice if the other party is in material breach of the agreement, subject to cure within the designated time periods. Either party also may terminate the license agreement immediately upon written notice if the other party files for bankruptcy or takes related actions or is unable to pay its debts as they become due. Additionally, either party will have the right to terminate the agreement if the other party directly or indirectly challenges the patentability, enforceability or validity of any licensed patent.

We are responsible for preparing, filing, prosecuting and maintaining all patent applications and patents included in the licensed patents that we intend to pursue within the territory.

Under the terms of the agreement with Dr. Reddy's, we are obligated to pay up to an aggregate of $40 million related to CTCL approvals in the U.S. and other markets, up to $70 million in development milestones for additional indications, and up to $300 million for commercial sales milestones. We also must pay on a fiscal quarter basis tiered royalties equal to low double-digit percentages of net product sales. The royalties will end on the earlier of (i) the 15-year anniversary of the first commercial sale of the latest indication that received regulatory approval in the applicable country and (ii) the date on which a biosimilar product results in the reduction of net sales in the applicable product by 50% in two consecutive quarters, as compared to the four quarters prior to the first commercial sale of the biosimilar product. We will also pay to Dr. Reddy's an amount equal to a low-thirties percentage of any sublicense upfront consideration or milestone payments (or the like) received by us and the greater of (i) a low-thirties percentage of any sublicensee sales-based royalties or (ii) a mid-single digit percentage of such licensee's net sales.

Also under the agreement with Dr. Reddy's, we are required to (i) use commercially reasonable efforts to make commercially available products in the CTCL indication, peripheral T-cell lymphoma indication and immuno-oncology indication, (ii) initiate two investigator initiated immuno-oncology trials, (iii) use commercially reasonable efforts to achieve each of the approval milestones, and (iv) to complete each specified immuno-oncology investigator trial on or before the four-year anniversary of the effective date of the definitive agreement. Additionally, we are required to commercially launch a product in a territory within six months of receiving regulatory approval for such product in each such jurisdiction.

Mino-Lok Intellectual Property

In May 2014, our subsidiary LMB entered into a patent and technology license agreement with Novel Anti-Infective Therapeutics, Inc. ("NAT"), who licensed the intellectual property from MDACC, to develop and commercialize Mino-Lok on an exclusive, worldwide (except for South America), sub-licensable basis. LMB incurred a one-time license fee in May 2014. On March 20, 2017, LMB entered into an amendment to the license agreement that expanded the licensed territory to include South America, providing LMB with worldwide rights. We are obligated to pay annual maintenance fees that increase annually until reaching a designated amount, which we must pay until the first sale of product. We also must pay up to an aggregate of approximately $1.1 million in milestone payments, depending on the achievement of various regulatory and commercial milestones. Under the terms of the license agreement, we also must pay a royalty equal to mid-single digit percentages to low-double digit percentages of net sales, depending on the level of sales in that year, and subject to downward adjustment to lower- to mid-single digit percentages in the event there is no valid patent for the product in the country of sale at the time of sale. After the first sale of product, we will owe an annual minimum royalty payment that will increase annually until reaching a designated amount, which we must pay for the duration of the term. We will be responsible for all patent expenses for the term of the agreement although MDACC is responsible for filing, prosecution and maintenance of all patents.

Unless earlier terminated by NAT based on the failure to achieve certain development or commercial milestones, the license agreement remains in effect until the date that all patents licensed under the agreement have expired and all patent applications within the licensed patent rights have been cancelled, withdrawn or expressly abandoned. The license agreement will terminate in the event we breach any of our payment or reporting obligations or NAT breaches any of its obligations under the agreement. NAT will have the right to terminate the agreement if we bring or participate in an action to challenge NAT's ownership of any of the licensed patent rights. We may terminate the license agreement upon 180 days' notice. The license agreement may also be terminated upon our and NAT's mutual consent.

Mino-Lok is covered in relation to the composition by issued U.S. patent No. 7,601,731, entitled "Antimicrobial Flush Solutions," which was issued on October 13, 2009. Mino-Lok is further covered in relation to its method of use by issued U.S. Patent No. 9,078,441, which was issued on July 14, 2015. The patents provide intellectual property protection until June 7, 2024. There are corresponding patents granted in Europe and Canada (European Patent No. EP 1644024, and Canadian Patent No. 2528522).

Stability Patent Application for Mino-Lok

In October 2018, the U.S. Patent and Trademark Office ("USPTO") issued U.S. Patent No. 10,086,114 (the "114 patent"), entitled "Antimicrobial Solutions with Enhanced Stability." On October 9, 2019, the European Patent Office ("EPO") granted European Patent No. 3370794, which corresponds to the '114 patent. The grant of these patents strengthens the intellectual property protection for Mino-Lok through November 2036. While the original patents for Mino-Lok (discussed above) cover the basic composition, this invention overcomes limitations in mixing antimicrobial solutions in which components have precipitated because of physical and/or chemical factors, thus limiting the stability of the post-mix solutions. The scientists and technologists at MDACC have been able to improve the stability of the post-mixed solutions through adjustments of the post-mixed pH of the solution. This may allow for longer storage time of the ready-to-use solution. As such, the patents claiming the enhanced stability may effectively extend patent protection for Mino-Lok beyond the 2024 expiration of the original patents since it is expected that the compositions providing enhanced stability would be preferred over any non-stabilized versions that a competitor may introduce after June 7, 2024. Citius holds the exclusive worldwide license which provides access to this patented technology for development and commercialization of Mino-Lok.

Mino-Lok has received a Qualified Infectious Disease Product ("QIDP") designation. The QIDP designation provides New Drug Applications an additional five years of market exclusivity, which together with the potential three years of exclusivity for the new strength and formulation of Mino-Lok, would result in a combined total of eight years of market exclusivity regardless of patent protection.

Mino-Wrap Intellectual Property

In January 2019, we entered into a patent and technology license agreement with MDACC to develop and commercialize Mino-Wrap on an exclusive worldwide basis, with no rights to sub-license. We paid a one-time upfront licensing fee upon execution of the agreement. Under the agreement, we are required to use commercially reasonable efforts to commercialize Mino-Wrap under several regulatory scenarios and achieve milestones that are associated with these regulatory options leading to an approval from the FDA. We are obligated to pay annual maintenance fees that increase annually until reaching a designated amount, which we must pay until the first sale of product. We also must pay up to an aggregate of $2.1 million in milestone payments, depending on the achievement of various regulatory and commercial milestones. Under the terms of the license agreement, we also must pay a royalty equal to mid- to upper-single digit percentages of net sales, depending on the level of sales in that year, and subject to downward adjustment to lower- to mid-single digit percentages in the event there is no valid patent for the product in the United States at the time of sale. After the first sale of product, we will owe an annual minimum royalty payment that will increase annually for the duration of the term. We will be responsible for all patent expenses incurred by MDACC for the term of the agreement although MDACC is responsible for filing, prosecution and maintenance of all patents.

The term of the license agreement will end on the later of the expiration of all licensed patents, or the fifteenth anniversary of the agreement. MDACC may terminate the license agreement at any time after four years in any country if we have not commercialized or are not actively attempting to commercialize a product in such country. The license agreement will terminate in the event we breach any of our payment or reporting obligations or MDACC breaches any of its obligations under the agreement. MDACC will have the right to terminate the agreement if we bring or participate in an action to challenge MDACC's ownership of any of the licensed patent rights. We may terminate the license agreement upon 180 days' notice. The license agreement may also be terminated upon our and MDACC's mutual consent.

In December 2017, the USPTO issued U.S. Patent No. 9,849,217, entitled "Antimicrobial Wraps for Medical Implants." This invention overcomes limitations in breast reconstruction utilizing tissue expanders and implants following mastectomies by providing, in certain aspects, biodegradable antimicrobial film that may be wrapped around a medical implant such as a breast implant prior to the insertion into a subject such as a human patient. The scientists and technologists at MDACC have developed a biodegradable covering for a medical implant comprising a highly plasticized gelatin and at least one drug to reduce infection. Citius holds the exclusive worldwide license, which provides access to this patented technology for development and commercialization of Mino-Wrap.

Halo-Lido Intellectual Property

We are developing Halo-Lido to have a unique combination of excipients as well as unique concentrations of the active ingredients. The goal is to have a product that is optimized for stability and activity. Once the formulation development is completed and data is obtained, we intend to apply for a patent on this new topical formulation.

We seek to achieve approval for Halo-Lido by utilizing the FDA's 505(b)(2) pathway. This pathway allows an applicant to file an NDA that contains full reports of investigations of safety and effectiveness, but where at least some of the information required for approval comes from prior studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference to such prior third-party studies. This pathway would provide three years of market exclusivity.

NoveCite Intellectual Property

In October 2020, we, through our subsidiary NoveCite, Inc., entered into a license agreement with Novellus Therapeutics Limited ("Licensor"), whereby NoveCite acquired an exclusive, worldwide license, with the right to sublicense, to develop and commercialize a stem cell therapy based on the Licensor's patented technology for the treatment of acute pneumonitis of any etiology in which inflammation is a major agent in humans. The patented technology consists of mesenchymal stem cells ("MSCs") derived from an induced pluripotent stem cell line that is made by Licensor using the mRNA cell reprogramming methods in the patents covering the licensed technology.

Upon execution of the license agreement, NoveCite paid an upfront payment of $5,000,000 and issued to Licensor shares of Novecite's common stock representing 25% of Novecite's currently outstanding equity. We own the other 75% of NoveCite's currently outstanding equity.

NoveCite is obligated to pay Licensor up to an aggregate of $51,000,000 in milestone payments upon the achievement of various regulatory and developmental milestones. NoveCite also must pay on a fiscal quarter basis a royalty equal to low double-digit percentages of net sales, commencing upon the first commercial sale of a licensed product. This royalty is subject to downward adjustment on a product-by-product and country-by-country basis to an upper-single digit percentage of net sales in any country in the event of the expiration of the last valid patent claim or if no valid patent claim exists in that country. The royalty will end on the earlier of (i) the date on which a biosimilar product is first marketed, sold, or distributed by Licensor or any third party in the applicable country or (ii) the 10-year anniversary of the date of expiration of the last-to-expire valid patent claim in that country. In the case of a country where no licensed patent ever exists, the royalty will end on the later of (i) the date of expiry of such licensed product's regulatory exclusivity and (ii) the 10-year anniversary of the date of the first commercial sale of the licensed product in the applicable country. In addition, NoveCite will pay to Licensor an amount equal to a mid-twenties percentage of any sublicensee fees it receives.

During the term of the license agreement, NoveCite is required to use commercially reasonable efforts to make commercially available at least one product in at least two markets: the United States and either the United Kingdom, France, Germany, China or Japan. Additionally, NoveCite shall (i) on or before the five-year anniversary of the date of the license agreement, file an IND for a licensed product in the field of acute pneumonitis treatment and (ii) receive regulatory approval for a licensed product in the field of acute pneumonitis treatment in the United States or in a major market country on or before the ten-year anniversary of the date of the license agreement.

Pursuant to the terms of the license agreement, NoveCite has been granted a right of first negotiation to exclusively license the rights to any new products developed or acquired by Licensor which cannot include MSC's, that may be used within the field of acute pneumonitis treatment. After receiving notice from the Licensor of the new product opportunity, NoveCite has 30 days to notify Licensor of its desire to negotiate a license agreement for the new product. If such notice is given by NoveCite, the parties shall then have a period of 150 days from the date of Licensor's notice to NoveCite to negotiate, exclusively and in good faith, the terms and conditions for the new product license agreement.

The term of the license agreement will continue on a country-by-country and licensed product-by-licensed product basis until the expiration of the last-to-expire royalty term for any and all licensed products unless earlier terminated in accordance with its terms. Either party may terminate the license agreement upon written notice if the other party is in material default or breach of the agreement, subject to cure within the designated time periods. Either party also may terminate the license agreement if the other party files for bankruptcy or takes related actions or is unable to pay its debts as they become due, subject to cure within the designated time period. Additionally, Licensor will have the right to terminate the agreement if NoveCite directly or indirectly challenges the patentability, enforceability or validity of any licensed patent. NoveCite may terminate the license agreement at any time without cause upon 90 days prior written notice.

Licensor will be responsible for preparing, filing, prosecuting and maintaining all patent applications and patents included in the licensed patents in the territory. Provided however, that if Licensor decides that it is not interested in maintaining a particular licensed patent or in preparing, filing, or prosecuting a licensed patent, it will promptly advise NoveCite in writing and NoveCite will have the right, but not the obligation, to assume such responsibilities in the territory at NoveCite's sole cost and expense.

During the term of the license agreement, Licensor is prohibited from commercializing or exploiting (directly or indirectly) any product that includes mesenchymal stem cells for any purpose in acute pneumonitis treatment (subject to certain sponsored research exceptions), or exploiting (directly or indirectly) or enabling a third party to exploit, for any purpose in acute pneumonitis treatment or otherwise, the original licensed cell banks line or any GMP-grade cell banks of a cell line derived therefrom and that can be used as starting material for the manufacture of products derived from the licensed technology. During the term of the license agreement, each party is prohibited from soliciting any employee of the other party, subject to certain exceptions.

In July 2021, Novellus was acquired by Brooklyn. Pursuant to this transaction, the NoveCite license was assumed by Brooklyn with all of its original terms and conditions.

Competition

We operate in a highly competitive and regulated industry which is subject to rapid and frequent changes. We face significant competition from organizations that are pursuing drugs that would compete with the drug candidates that we are developing and the same or similar products that target the same conditions we intend to treat. Due to our limited resources, we may not be able to compete successfully against these organizations, which include many large, well-financed and experienced pharmaceutical and biotechnology companies, as well as academic and research institutions and government agencies.

Mino-Lok Competition

Currently, the only alternative to Mino-Lok in the treatment of infected CVCs in CRBSI/CLABSI patients of which we are aware, is the standard of care of removing the culprit CVC and replacing a new CVC at a different vascular site. Citius is not aware of any INDs for a salvage antibiotic lock solution and does not expect any to be forthcoming due to the difficulty of meeting the necessary criteria to be effective and practical.

At this time, there are no pharmacologic agents approved in the U.S. for the prevention or treatment of CRBSIs or CLABSIs in central venous catheters. Citius is aware that there are several agents in development for prevention but none for salvage. The most prominent of these appear to be Defencath from CorMedix Inc. and B-Lock from Great Lakes Pharmaceuticals, Inc. ("GLP"). Neither of these lock solutions have been shown to be effective in salvaging catheters in bacteremic patients as Mino-Lok is intended to do, and Citius does not expect that either would be pursued for this indication.

Defencath™ (CorMedix Inc.)

Defencath is a formulation of Taurolidine 1.35%, Citrate 3.5%, and Heparin 1000 units/mL. Neutrolin is an anti-microbial catheter lock solution being developed by CorMedix to prevent CRBSIs and to prevent clotting. In January 2015, the FDA granted Fast Track and QIDP designations for Defencath. In December 2015, CorMedix initiated its Phase 3 clinical trial in hemodialysis patients in the United States. On June 20, 2018, CorMedix announced that it had completed its review and source-verification of the data required for the interim analysis of the Phase 3 LOCK-IT-100 study for Neutrolin. The data was then locked and transferred to the independent biostatistician for un-blinding and analysis, who then provided the results to the Data and Safety Monitoring Board ("DSMB") for its review.

On July 25, 2018, CorMedix announced that the DSMB had completed its review of the interim analysis of the data from the currently ongoing Phase 3 LOCK-IT-100 study for Neutrolin. Because the pre-specified level of statistical significance was reached and efficacy had been demonstrated, the DSMB recommended the study be terminated early. No safety concerns were reported by the DSMB based on the interim analysis.

CorMedix submitted its NDA for Defencath to the FDA, which accepted the NDA in August 2020. The FDA set a target review date of February 28, 2021. In March 2021, CorMedix reported that the FDA, in its Complete Response Letter ("CRL"), informed CorMedix that the FDA could not approve the NDA for DefenCath in its present form. The FDA noted concerns at the third-party manufacturing facility after a review of records requested by the FDA and provided by the contract manufacturer ("CMO"). Additionally, the FDA is requiring a manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from the vials despite an existing in-process control to demonstrate fill volume within specifications. In April 2021, CorMedix and the CMO met with the FDA to discuss proposed resolutions for the deficiencies identified in the CRL and the Post-Application Action Letter received by the CMO from the FDA for the NDA for DefenCath. There was an agreed upon protocol for the manual extraction study identified in the CRL, which has been successfully completed. Addressing the FDA's concerns regarding the qualification of the filling operation necessitated adjustments in the process and generation of additional data on operating parameters for the manufacture of DefenCath. CorMedix and the CMO determined that additional process qualification is needed with subsequent validation to address these issues. The FDA stated that the review timeline would be determined when the NDA resubmission is received and that it expected all corrections to facility deficiencies to be complete at the time of resubmission so that all corrective actions may be verified during an onsite evaluation of the manufacturing facility in the next review cycle, if the FDA determines it will do an onsite evaluation. Satisfactory resolution of these issues is required for FDA approval of the DefenCath NDA.

B-Lock™ (Great Lakes Pharmaceuticals, Inc.)

B-Lock is a triple combination of trimethoprim, EDTA and ethanol from Great Lakes Pharmaceuticals, Inc. ("GLP"). On July 24, 2012, GLP announced the initiation of a clinical study of B-Lock. We are unaware as to the progress or results of these studies. In addition, we are not aware of any IND being filed in the U.S. for B-Lock, nor are we aware of any clinical studies to support salvage of infected catheters in bacteremic patients.

There has been no further public information available on GLP. GLP's web site and phone number are no longer active and the Company believes that they have ceased operations.

Mino-Wrap Competition

The primary competition for Mino-Wrap would be the existing standard of care treatment, which includes a systemic perioperative antimicrobial agent with the perioperative immersion of the implant or irrigation of the surgical pocket with an antimicrobial solution prior to insertion of the tissue expander device. This is also administered with immediate postoperative oral antimicrobials.

Halo-Lido Competition

The primary competition in the hemorrhoid market is non-prescription OTC products. If approved by the FDA, Halo-Lido will be the only prescription product for the treatment of hemorrhoids.

NoveCite Competition

There are multiple participants in the cell therapy field both in the United States and abroad. We believe that the following companies most directly compete with NoveCite in our licensed field of acute pneumonitis treatment.

Cynata Therapeutics Limited develops and commercializes a proprietary mesenchymal stem cell technology under the Cymerus brand for human therapeutic use in Australia. The company's lead therapeutic product candidate is CYP-001, which has completed a Phase 1 clinical trial for the treatment of graft versus host disease. Cynata also develops products for the treatment of asthma, heart attack, diabetic wounds, coronary artery disease, acute respiratory distress syndrome, brain cancer, melanoma, sepsis, osteoarthritis, and critical limb ischemia, which are in a preclinical model.

Athersys, Inc. is a biotechnology company that focuses on the research and development activities in the field of regenerative medicine. Its clinical development programs are focused on treating neurological conditions, cardiovascular diseases, inflammatory and immune disorders, and pulmonary and other conditions. The company's lead platform product includes MultiStem cell therapy, an allogeneic stem cell product, which has an ongoing Phase 2/3 clinical trial for the treatment of ARDS and has an ongoing clinical trial on Japan for the treatment of RDS. The MultiStem therapy also is in a Phase 3 clinical study for the treatment of patients suffering from neurological damage from an ischemic stroke, as well as in a Phase 2 clinical study for the treatment of patients with acute myocardial infarction, and has completed a Phase 1 clinical study for the treatment of patients suffering from leukemia or various other blood-borne cancers. The company has license and collaboration agreements with Healios K.K. to develop and commercialize MultiStem cell therapy for ischemic stroke, acute respiratory distress syndrome, and ophthalmological indications, as well as for the treatment of liver, kidney, pancreas, and intestinal tissue diseases; and the University of Minnesota to develop MultiStem cell therapy platform.

Pluristem Therapeutics Inc. operates as a bio-therapeutics company in Israel. It focuses on the research, development, clinical trial, and manufacture of placental expanded (PLX) based cell therapeutic products and related technologies for the treatment of various ischemic, inflammatory, and hematologic conditions, as well as autoimmune disorders. A Phase 2 study of PLX cells as a treatment for severe COVID-19 cases complicated by acute respiratory distress syndrome has been initiated in the U.S. as well as in Europe and Israel.

Mesoblast Limited is a biopharmaceutical company that develops and commercializes allogeneic cellular medicines. The company offers products in the areas of cardiovascular, spine orthopedic disorder, oncology, hematology, and immune-mediated and inflammatory diseases. Its proprietary regenerative medicine technology platform is based on specialized cells known as mesenchymal lineage adult stem cells. In April 2020, Mesoblast initiated a Phase 3 trial using mesenchymal stromal cells for the treatment of moderate to severe COVID-19 acute respiratory distress syndrome. The trial was halted in December 2020 after the Data Safety Monitoring Board (DSMB) performed a third interim analysis on the trial's first 180 patients, noting that the trial was not likely to meet the 30-day mortality reduction endpoint at the planned 300 patient enrolment. The trial was powered to achieve a primary endpoint of 43% reduction in mortality at 30 days for treatment with remestemcelL on top of maximal care. The DSMB recommended that the trial complete with the enrolled 222 patients, and that all be followed-up as planned. At follow-up through day 60, remestemcel-L showed a positive but non-significant trend in overall mortality reduction across the entire population of treated patients (n=217). In the pre-specified population of patients under age 65 (n=123), remestemcel-L reduced mortality through day 60 by 46%, but not in patients 65 or older (n=94). In an exploratory analysis through day 60, remestemcelL reduced mortality by 75% and increased days alive off mechanical ventilation in patients under age 65 when combined with dexamethasone, in comparison with controls on dexamethasone.

I/ONTAK Competition

The following products are approved for the systemic treatment of advanced CTCL.

Mogamulizumab, sold under the brand name Poteligeo, is a humanized, afucosylated monoclonal antibody targeting CC chemokine receptor 4. The FDA approved it for treatment of relapsed or refractory mycosis fungoides and Sézary disease.

Brentuximab vedotin, sold under the brand name Adcetris, is an antibody-drug conjugate medication used to treat relapsed or refractory Hodgkin lymphoma and systemic anaplastic large cell lymphoma, a type of T-cell non-Hodgkin lymphoma. It selectively targets tumor cells expressing the CD30 antigen, a defining marker of Hodgkin lymphoma and ALC.

Romidepsin sold under the brand name Istodax, is a histone deacetylase ("HDAC") inhibitor indicated for the treatment of CTCL in adult patients who have received at least one prior systemic therapy.

Vorinostat sold under the brand name Zolinza, is a HDAC inhibitor indicated for the treatment of cutaneous manifestations in patients with CTCL who have progressive, persistent or recurrent disease on or following two systemic therapies.

There are limitations in these targeted therapies, which often are discontinued due to toxicity and adverse events as well as a limited duration of response due to resistance over time.

Supply and Manufacturing

We do not currently have and we do not intend to set up our own manufacturing facilities. We expect to use approved contract manufacturers for manufacturing our product candidates in all stages of development after we file for FDA approval. Each of our domestic and foreign contract manufacturing establishments, including any contract manufacturers we may decide to use, must be listed in the NDA or the BLA, as applicable, and must be registered with the FDA. Also, the FDA imposes substantial annual fees on manufacturers of branded products.

In general, our suppliers purchase raw materials and supplies on the open market. Substantially all such materials are obtainable from a number of sources so that the loss of any one source of supply would not have a material adverse effect on us.

If we elect to conduct product development and manufacturing, we will be subject to regulation under various federal and state laws, including the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, the Controlled Substances Act and other present and potential future federal, state or local regulations.

We have contracted with proven suppliers and manufacturers for active pharmaceutical ingredient, development and packaging. We are confident that all materials meet or will meet specifications discussed at the chemistry, manufacturing and controls meeting with the FDA.

Regulation

United States Government Regulation

The research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing, among other things, of our product candidates are extensively regulated by governmental authorities in the United States and other countries. All of our current product candidates are considered drugs. Consequently, we intend to submit an NDA to the FDA for each of Mino-Lok, Halo-Lido, Mino-Wrap and a BLA to the FDA for each of I/ONTAK and NoveCite.

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act and the agency's implementing regulations. If we fail to comply with the applicable United States requirements at any time during the product development process, including clinical testing, as well as at any time before and after the approval process, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning letters, adverse publicity, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any agency enforcement action could have a material adverse effect on our company and its operations.

Before any of our drug product candidates may be marketed in the United States, it must be approved by the FDA. The steps required before a drug may be approved for marketing in the United States generally include:

- preclinical laboratory and animal tests, and formulation studies;
- the submission to the FDA of an IND application for human clinical testing that must become effective before human clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each indication for which approval is sought;
- the submission to the FDA of an NDA or a BLA and the FDA's acceptance of the NDA or BLA for filing;
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the product is to be produced to assess compliance with the FDA's current Good Manufacturing Practices ("cGMP"); and
- FDA review and approval of the NDA or BLA.

Foreign Regulation

We and any of our collaborative partners may be subject to widely varying foreign regulations, which may be different from those of the FDA, governing clinical trials, manufacture, product registration and approval and pharmaceutical sales. Whether or not FDA approval has been obtained, we or our collaboration partners must obtain a separate approval for a product by the comparable regulatory authorities of foreign countries prior to the commencement of product marketing in such countries. In certain countries, regulatory authorities also establish pricing and reimbursement criteria. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. In addition, under current United States law, there are restrictions on the export of products not approved by the FDA, depending on the country involved and the status of the product in that country.

Employees

As of September 30, 2021, we had fifteen employees and various consultants providing support. Through our consulting and collaboration arrangements, and including our Scientific Advisory Board, we have access to more than 30 additional professionals, who possess significant expertise in business development, legal, accounting, regulatory affairs, clinical operations and manufacturing. We also rely upon a network of consultants to support our clinical studies and manufacturing efforts.

Executive Officers of Citius

Myron Holubiak, President, Chief Executive Officer and Director – Mr. Holubiak, 74, was appointed President, Chief Executive Officer and Director in March 2016. He previously served as a Director of Citius since October 2015 and was the founder and Chief Executive Officer and President of Leonard-Meron Biosciences, Inc., an acquired subsidiary of Citius, from March 2013 until March 2016.

Leonard Mazur, Executive Chairman and Secretary – Mr. Mazur, 76, has been a member of the Board since September 2014. Mr. Mazur previously served as Chief Executive Officer, President, and Chief Operating Officer from September 2014 until March 2016.

Jaime Bartushak, Chief Financial Officer and Principal Financial Officer – Mr. Bartushak, 54, was appointed as Chief Financial Officer in November 2017. Previously, he was one of the founders and Chief Financial Officer of Leonard-Meron Biosciences, Inc., an acquired subsidiary of Citius.

Myron Czuczman, Chief Medical Officer and Executive Vice President – Dr. Czuczman, 62 was appointed as Chief Medical Officer and Executive Vice President in July 2020. Dr. Czuczman previously served as Vice President, Global Clinical Research and Development, Therapeutic Head of Lymphoma/CLL at Celgene Corporation.

Other Information

We make available, free of charge through our website, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports as soon as is reasonably practicable after such material is electronically filed with or furnished to the SEC pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The SEC maintains an Internet site that contains these reports at www.sec.gov.

Our website address is *http://www.citiuspharma.com*. The information contained in, or that can be accessed through, our website is not part of this report.

Item 1A. Risk Factors

This report contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed in this report. Factors that could cause or contribute to these differences include, but are not limited to, those discussed below and elsewhere in this report.

If any of the following risks, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our securities could decline, and stockholders may lose all or part of their investment.

Risks Related to Our Business and our Industry

We have a history of net losses and expect to incur losses for the foreseeable future. We may never generate revenues or, if we are able to generate revenues, achieve profitability.

We were formed in 2007 and since our inception have incurred a net loss in each of our previous operating years. Our ability to become profitable depends upon our ability to obtain marketing approval for and generate revenues from sales of our product candidates. We have been focused on product development, have not received approval for any of our product candidates, and have not generated any revenues to date. We have incurred losses in each period of our operations, and we expect to continue to incur losses for the foreseeable future. These losses are likely to continue to adversely affect our working capital, total assets and stockholders' equity. The process of developing our product candidates requires significant clinical development, laboratory testing and clinical trials. In addition, commercialization of our product candidates will require that we obtain necessary regulatory approvals and establish sales, marketing and manufacturing capabilities, either through internal hiring or through contractual relationships with others. We expect to incur substantial losses for the foreseeable future as a result of anticipated increases in our research and development costs, including costs associated with conducting preclinical testing and clinical trials, and regulatory compliance activities. We incurred net losses of $23,054,434 and $17,548,085 for the years ended September 30, 2021 and 2020, respectively. At September 30, 2021, we had stockholders' equity of $132,182,353 and an accumulated deficit of $96,047,821. Our net cash used in operating activities was $24,250,414 and $16,930,658 for the years ended September 30, 2021 and 2020, respectively.

Our ability to generate revenues and achieve profitability will depend on numerous factors, including success in:

- developing and testing product candidates;
- receiving regulatory approvals for our product candidates;
- commercializing our product candidates that receive regulatory approval;
- manufacturing commercial quantities of our product candidates at acceptable cost levels;
- obtaining medical insurance coverage for any approved product candidate; and
- establishing a favorable competitive position for any approved product candidates.

Many of these factors will depend on circumstances beyond our control. We cannot assure you that any of our product candidates will be approved by the FDA or any foreign regulatory body or obtain medical insurance coverage, that we will successfully bring any approved product to market or, if so, that we will ever become profitable.

Ability to continue as a going concern.

At September 30, 2021, we estimated that we have sufficient capital to continue our operations through March 2023. You should not rely on our consolidated balance sheet as an indication of the amount of proceeds that would be available to satisfy claims of creditors, and potentially be available for distribution to stockholders, in the event of liquidation.

The Company has generated no operating revenue to date and has principally raised capital through the issuance of debt and equity instruments to finance its operations. However, the Company's continued operations beyond March 2023, including its development plans for Mino-Lok, Mino-Wrap, Halo-Lido, Novecite and I/ONTAK, will depend on its ability to obtain regulatory approval to market Mino-Lok and generate substantial revenue from the sale of Mino-Lok and on its ability to raise additional capital through various potential sources, such as equity and/or debt financings, strategic relationships, or out-licensing of its product candidates. However, the Company can provide no assurances on the approval, commercialization or future sales of Mino-Lok or that financing or strategic relationships will be available on acceptable terms, or at all. If the Company is unable to raise sufficient capital, find strategic partners or generate substantial revenue from the sale of Mino-Lok, there would be a material adverse effect on its business. Further, the Company expects in the future to incur additional expenses as it continues to develop its product candidates, including seeking regulatory approval, and protecting its intellectual property.

We need to secure additional financing in the future to complete the development of our current product candidates and support our operations.

We anticipate that we will incur operating losses for the foreseeable future as we continue developing our product candidates. The amount and timing of our future funding requirements will depend on many factors, including, but not limited to:

- the rate of progress and cost of our trials and other product development programs for our current product candidates;
- the costs and timing of obtaining licenses for additional product candidates or acquiring other complementary technologies;
- the timing of any regulatory approvals of any of our product candidates;
- the costs of establishing or contracting for sales, marketing and distribution capabilities for our product candidates; and
- the status, terms and timing of any collaborative, licensing, co-promotion or other arrangements.

We will need to access the capital markets in the future for additional capital for research and development and for operations. As of the date of this report, we do not anticipate seeking additional capital until sometime in 2023. Traditionally, pharmaceutical companies have funded their research and development expenditures through raising capital in the equity markets. Declines and uncertainties in these markets over the past several years have severely restricted raising new capital and have affected companies' abilities to continue to expand or fund existing research and development efforts. The COVID-19 pandemic could also adversely impact future fundraising activities. If the COVID-19 pandemic and related and/or other economic conditions continue or become worse, our future cost of equity or debt capital and access to the capital markets could be adversely affected. If we are not successful in securing additional financing, we may be required to significantly delay, reduce the scope of or eliminate one or more of our research or development programs, downsize our general and administrative infrastructure, or seek alternative measures to avoid insolvency, including arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies or product candidates.

We are primarily a late-stage development company with an unproven business strategy and may never achieve commercialization of our therapeutic product candidates or profitability.

We have no approved products. All of our current product candidates are in the pre-clinical or clinical stage. We rely on third parties to conduct the research and development activities for our product candidates. Further, we have no sales or marketing capability at this time. Even if we decide to use collaborative partners to assist us in the commercialization of our product candidates, our product commercialization capabilities are unproven. Our success will depend upon our ability to develop such capabilities on our own or to enter into collaboration agreements on favorable terms and to select an appropriate commercialization strategy for each product candidate that we choose to pursue and that receive approval, whether on our own or in collaboration. If we are not successful in implementing our strategy to commercialize our product candidates, we may never achieve, maintain or increase profitability. Our ability to successfully commercialize any of our product candidates will depend, among other things, on our ability to:

- successfully complete pre-clinical and clinical trials for our product candidates;
- receive marketing approvals from the FDA and similar foreign regulatory authorities for our product candidates;
- establish commercial manufacturing arrangements with third-party manufacturers for our product candidates;
- produce, through a validated process, sufficiently large quantities of our drug compound(s) to permit successful commercialization of our product candidates;
- build and maintain strong sales, distribution and marketing capabilities sufficient to launch commercial sales of any approved products or establish collaborations with third parties for such commercialization;
- secure acceptance of any approved products from physicians, health care payers, patients and the medical community; and
- manage our spending as costs and expenses increase due to clinical trials, regulatory applications and development and commercialization activities.

There are no guarantees that we will be successful in completing these tasks. If we are unable to successfully complete these tasks, we may not be able to commercialize any of our product candidates in a timely manner, or at all, in which case we may be unable to generate sufficient revenues to sustain and grow our business. If we experience unanticipated delays or problems, our development costs could substantially increase and our business, financial condition and results of operations will be adversely affected.

We have a limited operating history upon which to evaluate our ability to successfully commercialize our product candidates.

We are a clinical stage company and our success is dependent upon our ability to obtain regulatory approval for and commercialize our product candidates and we, as a company, have not demonstrated an ability to perform the functions necessary for the approval or successful commercialization of any product candidates. While various members of our executive management and key employees have significant prior experience in pharmaceutical development, as a company we have to date not successfully completed any late-stage clinical trials nor undertaken any commercialization activities. Our operations have been limited primarily to business planning, acquiring our proprietary technology, research and development, recruiting management and technical staff, and raising capital. These operations provide a limited basis for you to assess our ability to successfully commercialize our product candidates and the advisability of investing in our securities.

The COVID-19 pandemic may materially and adversely affect our clinical trial operations and our financial results.

The COVID-19 pandemic has adversely impacted hospitals and medical facilities where we are currently conducting our Mino-Lok phase 3 trial. The full extent to which COVID-19 may impact this trial is not known at this time, but it has slowed the estimated completion date for the trial, which we now expect to be in 2022. This same risk applies to planned clinical trials for our other product candidates. The exact duration of the delay and any other impact will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the severity of COVID-19, or the effectiveness of actions to contain and treat for COVID-19. The continued spread of COVID-19 also could adversely impact our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, which could further negatively impact the Mino-Lok trial. In addition, if the FDA elects to delay face-to-face meetings for an extended period of time due to COVID-19, it could have a material adverse effect on our Mino-Lok trial and our other product candidates. Any or all of these events could increase our operating expenses and the length of time to complete the trial and have a material adverse effect on our financial results.

We may choose not to continue developing any of our product candidates at any time during development, which would reduce or eliminate our potential return on investment for those product candidates.

At any time, we may decide to discontinue the development of any of our product candidates for a variety of reasons, including inadequate financial resources, the appearance of new technologies that render our product candidates obsolete, competition from a competing product or changes in or failure to comply with applicable regulatory requirements. If we terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to allocate those resources to potentially more productive uses.

As an example, on July 1, 2016, we announced that we were discontinuing the development of Suprenza, which was our first commercial product candidate, for strategic reasons and not due to safety or regulatory concerns, in order to focus our management and cash resources on the Phase 3 development of Mino-Lok and the Phase 2b development of Halo-Lido. The resources expended on Suprenza therefore did not provide us any benefit.

We face significant risks in our product candidate development efforts.

Our business depends on the successful development and commercialization of our product candidates. We are not permitted to market any of our product candidates in the United States until we receive approval from the FDA, or in any foreign jurisdiction until we receive the requisite approvals from such jurisdiction. The process of developing new drugs and/or therapeutic products is inherently complex, unpredictable, time-consuming, expensive and uncertain. We must make long-term investments and commit significant resources before knowing whether our development programs will result in products that will receive regulatory approval and achieve market acceptance. Product candidates that appear to be promising at some or all stages of development may not receive approval or reach the market for a number of reasons that may not be predictable based on results and data of the clinical program. Product candidates may be found ineffective or may cause harmful side effects during clinical trials, may take longer to progress through clinical trials than had been anticipated, may not be able to achieve the pre-defined clinical endpoints due to statistical anomalies even though clinical benefit may have been achieved, may fail to receive necessary regulatory approvals, may prove impracticable to manufacture in commercial quantities at reasonable cost and with acceptable quality, or may fail to achieve market acceptance.

We cannot predict whether or when we will obtain regulatory approval to commercialize our product candidates that are under development and we cannot, therefore, predict the timing of any future revenues from these product candidates, if any. The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example, the FDA:

- could determine that we cannot rely on Section 505(b)(2) for Mino-Lok or Halo-Lido or any future product candidate whose composition includes components previously approved by the FDA;
- could determine that the information provided by us was inadequate, contained clinical deficiencies or otherwise failed to demonstrate the safety and effectiveness of any of our product candidates for any indication;
- may not find the data from clinical trials sufficient to support the submission of an NDA or BLA or to obtain marketing approval in the United States, including any findings that the clinical and other benefits of our product candidates outweigh their safety risks;
- may disagree with our trial design or our interpretation of data from preclinical studies or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our trials;
- may determine that we have identified the wrong reference listed drug or drugs or that approval of a Section 505(b)(2) application for any of our product candidates is blocked by patent or non-patent exclusivity of the reference listed drug or drugs;
- may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the manufacture of our product candidates;
- may approve our product candidates for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials;
- may change its approval policies or adopt new regulations that could adversely impact our product candidate development programs; or
- may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates, or may require labeling claims that impair the potential market acceptance of our product candidates.

These same risks are generally applicable to the regulatory process in foreign countries. Any failure to obtain regulatory approval of our product candidates would significantly limit our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues.

While our business strategy generally is to focus on the development of late-stage product candidates to lessen the development risk, there is still significant risk to successfully developing a product candidate.

Our goal in generally pursuing late-stage therapeutic product candidates with what we believe is a promising pre-clinical and early clinical stage track record is to avoid the risk of failure at the pre-clinical and early clinical stages. However, there is still significant risk to obtaining regulatory approval and successfully commercializing any late-stage product candidate that we pursue. All of the risks inherent in drug development of initial stage product candidates also apply to late-stage candidates. We cannot assure you that our business strategy will be successful.

The results of pre-clinical studies and completed clinical trials are not necessarily predictive of future results, and our current product candidates may not have favorable results in later studies or trials.

Pre-clinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a product candidate in the general population, but rather to test initial safety, to study pharmacokinetics and pharmacodynamics, to study limited efficacy in a small number of study patients in a selected disease population, and to identify and attempt to understand the product candidate's side effects at various doses and dosing schedules. Success in pre-clinical studies or completed clinical trials does not ensure that later studies or trials, including continuing pre-clinical studies and large-scale clinical trials, will be successful nor does it predict future results. Favorable results in early studies or trials may not be repeated in later studies or trials, and product candidates in later stage trials may fail to show acceptable safety and efficacy despite having progressed through earlier trials. In addition, the placebo rate in larger studies may be higher than expected.

We may be required to demonstrate through large, long-term outcome trials that our product candidates are safe and effective for use in a broad population prior to obtaining regulatory approval. This would increase the duration and cost of any such trial.

There is typically a high rate of attrition from the failure of product candidates proceeding through clinical trials. In addition, certain subjects in our clinical trials may respond positively to placebo treatment - these subjects are commonly known as "placebo responders" - making it more difficult to demonstrate efficacy of the trial drug compared to placebo. This effect is likely to be observed in the treatment of hemorrhoids, which could negatively impact the development program for Halo-Lido.

If any of our product candidates fail to demonstrate sufficient safety and efficacy in any clinical trial, we will experience potentially significant delays and cost increases in, or may decide to abandon development of, that product candidate. If we abandon or are delayed, or experience increased costs, in our development efforts related to any of our product candidates, we may not have sufficient resources to continue or complete development of that product candidate or any other product candidates. We may not be able to continue our operations and clinical studies, or generate any revenue or become profitable. Our reputation in the industry and in the investment community would likely be significantly damaged. Further, it might not be possible for us to raise funds in the public or private markets, and our stock price would likely decrease significantly.

If we are unable to file for approval of Mino-Lok or Halo-Lido under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or if we are required to generate additional data related to safety and efficacy in order to obtain approval of Mino-Lok or Halo-Lido under Section 505(b)(2), we may be unable to meet our anticipated development and commercialization timelines.

Our current plans for filing NDAs or BLAs for our product candidates include efforts to minimize the data we will be required to generate in order to obtain marketing approval for certain of our product candidates and therefore possibly reduce the time and cost of development of a product candidate and obtain a shortened review period for the application. The timeline for filing and review of our planned NDA for each of Mino-Lok and Halo-Lido is based upon our plan to submit each such NDA under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, wherein we will rely in part on data generated by third parties and that is in the public domain or elsewhere. Depending on the data that may be required by the FDA for approval, some of the data may be related to products already approved by the FDA. If the data relied upon is related to products already approved by the FDA and covered by third-party patents, we would be required to certify that we do not infringe the listed patents or that such patents are invalid or unenforceable. As a result of the certification, the third party would have 45 days from notification of our certification to initiate an action against us. In the event that an action is brought in response to such a certification, the approval of our NDA could be subject to a stay of up to 30 months or more while we defend against such a suit. Approval of any product candidate under Section 505(b)(2) may therefore be delayed until patent exclusivity expires or until we successfully challenge the applicability of those patents applicable to our product candidates. Alternatively, we may elect to generate sufficient additional clinical data so that we no longer rely on data which triggers a potential stay of the approval of any product candidate. Even if no exclusivity periods apply to an application under Section 505(b)(2), the FDA has broad discretion to require us to generate additional data on the safety and efficacy of our product candidates to supplement third-party data on which we may be permitted to rely. In either event, we could be required, before obtaining marketing approval for such product candidate, to conduct substantial new research and development activities beyond those in which we currently plan to engage in order to obtain approval of that product candidate. Such additional new research and development activities would be costly and time consuming.

We may not be able to obtain shortened review of our applications where available, and in any event the FDA may not agree that any of our product candidates qualify for marketing approval. If we are required to generate additional data to support approval, we may be unable to meet our anticipated development and commercialization timelines, may be unable to generate the additional data at a reasonable cost, or at all, and may be unable to obtain marketing approval of that product candidate. In addition, notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) application that we submit.

Two of our product candidates, Mino-Lok and Halo-Lido, are combination products consisting of components that have each been separately approved by the FDA for other indications and which are commercially available and marketed by other companies. Our approval under Section 505(b)(2), if received, would not preclude physicians, pharmacists and patients from obtaining individual drug products and titrating the dosage of these drug products as close to our approved dose as possible.

Our Mino-Lok solution contains minocycline, disodium ethylenediaminetetraacetic acid (edetate), and ethyl alcohol, all of which have been separately approved by the FDA for other indications, or are used as excipients in other parenteral products. Assuming FDA approval as a branded pharmaceutical product, we would need to obtain hospital formulary acceptance to generate sales of Mino-Lok. Additionally, we may encounter reluctance by the infectious disease physician community to vary from the existing standard of care to remove and replace an infected catheter. Currently, hospitals are reimbursed for the treatment of CRBSIs by the Center for Medicare and Medicare Services ("CMS") through a Diagnosis Related Group ("DRG") classification or code. Commercial insurance plans reimburse for CRBSIs in a similar manner. With Mino-Lok being priced as a branded FDA-approved pharmaceutical product, this could result in the participating hospital retaining a lower share of CMS or commercial reimbursement which may impact the acceptance and use of Mino-Lok by these institutions.

Our Halo-Lido product candidate for the treatment of hemorrhoids is a combination product consisting of two drugs, halobetasol propionate, a corticosteroid, and lidocaine, that have each been separately approved by the FDA for other indications and which are commercially available and marketed by other companies. Halobetasol propionate cream is available in a 0.05% strength, and lidocaine creams are also available in strengths up to 5%. From our market analysis and discussions with a limited number of physicians, we know that patients sometimes obtain two separate cream products and co-administer them as prescribed, giving them a combination treatment which could be very similar to what we intend to study and seek approval for. As a branded, FDA-approved product with safety and efficacy data, we intend to price our product substantially higher than the generically available individual creams. We will then have to convince third-party payers and pharmacy benefit managers of the advantages of our product and justify our premium pricing. We may encounter resistance from these entities and will then be dependent on patients' willingness to pay the premium and not seek alternatives. In addition, pharmacists often suggest lower cost prescription treatment alternatives to both physicians and patients. If approved, our Section 505(b)(2) approval and the market exclusivity we may receive will not guarantee that such alternatives will not exist, that substitution will not occur, or that there will be immediate or any acceptance to our pricing by payer formularies**.**

Any fast track designation or grant of priority review status by the FDA may not actually lead to a faster development or regulatory review or approval process, nor will it assure FDA approval of our product candidates. Additionally, our product candidates may treat indications that do not qualify for priority review vouchers.

We have received fast track designation for Mino-Lok to treat and salvage infected central venous catheters in patients with CRBSIs. We may seek fast track designation for some of our other product candidates or priority review of applications for approval of our product candidates for certain indications. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for the FDA fast track designation. If a product candidate offers major advances in treatment, the FDA may designate it eligible for priority review. The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular product candidate is eligible for these designations, we cannot assure you that the FDA would decide to grant them. Even with the fast track designation for Mino-Lok and if we do receive fast track designation or priority review for any other product candidate, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation from Mino-Lok or any other product candidate to be so designated if it believes that the designation is no longer supported by data from our clinical development program.

We do not own NoveCite, Inc. outright and will share any benefits from the development of its NoveCite product candidate with the other stockholder.

As of November 30, 2021, we owned 75% of the outstanding common stock of NoveCite. As a result, we will only be entitled to a portion of any benefits that flow from the development by NoveCite of its NoveCite product candidate or any other product candidates that it might develop. In the event that NoveCite issues additional equity securities in the future this would likely reduce our percentage ownership, unless we were to increase our investment, which would further reduce the portion of any benefit that might be derived from the NoveCite drug candidate's successful development.

Any FDA programs related to the development and approval of treatments for COVID-19 and its symptoms may not be available to us or actually lead to a faster development or regulatory review or approval process for NoveCite, our proposed treatment for ARDS, nor will it assure FDA approval of such a treatment.

We intend to develop NoveCite under the FDA's Coronavirus Treatment Acceleration Program, or CTAP. The CTAP program was designed to accelerate the development of COVID-19 treatments via faster communications and regulatory review protocols. In late April 2020, we made a pre-IND submission to the FDA for this treatment and requested the FDA's feedback to support the most expeditious pathway for clinical development of the therapy. The CTAP program has only recently begun and the FDA has broad discretion in administering the CTAP program and therefore we cannot assure you what the FDA might decide. Even though we believe that the response from the FDA was favorable, we did not specifically request guidance on the CTAP program we may encounter problems at a later date under the CTAP program, or with the therapy itself, and we may not experience a faster development process, review or approval compared to conventional FDA procedures.

Because our NoveCite product candidate is based on novel technologies, it is difficult to predict the regulatory approval process and the time, the cost and our ability to successfully initiate, conduct and complete clinical development, and obtain the necessary regulatory and reimbursement approvals, required for commercialization of our NoveCite product candidate.

NoveCite's cell programming technology and platform for generating cell therapy products using allogenic mesenchymal stem cells derived from iPSCs represent novel therapeutic approaches, and to our knowledge there are currently no iPSC-derived cell products approved anywhere in the world for commercial sale. As such, it is difficult to accurately predict the type and scope of challenges that NoveCite may incur during development of its NoveCite product candidate, and it faces uncertainties associated with the preclinical and clinical development, manufacture and regulatory requirements for the initiation and conduct of clinical trials, regulatory approval, and reimbursement required for successful commercialization of its NoveCite product candidate. In addition, because NoveCite's iPSC-derived cell product candidate is in the pre-clinical stage, NoveCite is currently assessing safety in humans and have not yet been able to assess the long-term effects of treatment. Animal models and assays may not accurately predict the safety and efficacy of our product candidate in our target patient populations, and appropriate models and assays may not exist for demonstrating the safety and purity of the NoveCite product candidate, as required by the FDA and other regulatory authorities for ongoing clinical development and regulatory approval.

The pre-clinical and clinical development, manufacture, and regulatory requirements for approval of the NoveCite product candidate may be more expensive and take longer than for other more well-known or extensively studied pharmaceutical or biopharmaceutical product candidates due to a lack of prior experiences on the side of both developers and regulatory agencies. Additionally, due to the uncertainties associated with the pre-clinical and clinical development, manufacture, and regulatory requirements for approval of the NoveCite product candidate, NoveCite may be required to modify or change its pre-clinical and clinical development plans or its manufacturing activities and plans, or be required to meet stricter regulatory requirements for approval. Any such modifications or changes could delay or prevent NoveCite's ability to develop, manufacture, obtain regulatory approval or commercialize its NoveCite product candidate, which would adversely affect NoveCite's and our business, financial condition and results of operations.

Cellular immunotherapies, and stem cell therapies and iPSC-derived cell therapies in particular, represent relatively new therapeutic areas, and the FDA has cautioned consumers about potential safety risks associated with cell therapies. To date, there are relatively few approved cell therapies. As a result, the regulatory approval process for a product candidate such as NoveCite is uncertain and may be more expensive and take longer than the approval process for product candidates based on other, better known or more extensively studied technologies and therapeutic approaches. For example, there are currently no FDA approved products with a label designation that supports the use of a product to treat and reduce the severity of ARDS in patients with COVID-19, which makes it difficult to determine the clinical endpoints and data required to support an application or regulatory approval, and the time and cost required to obtain regulatory approval in the United States for our product candidate.

Regulatory requirements in the United States governing cell therapy products have changed frequently and the FDA or other regulatory bodies may change the requirements, or identify different regulatory pathways, for approval of the NoveCite product candidate. For example, within the FDA, the Center for Biologics Evaluation and Research, or CBER, restructured and created a new Office of Tissues and Advanced Therapies to better align its oversight activities with FDA Centers for Drugs and Medical Devices. It is possible that over time new or different divisions may be established or be granted the responsibility for regulating cell and/or gene therapy products, including iPSC-derived cell products, such as the NoveCite product candidate. As a result, NoveCite may be required to change its regulatory strategy or to modify its applications for regulatory approval, which could delay and impair its ability to complete the pre-clinical and clinical development and manufacture of, and obtain regulatory approval for, its NoveCite product candidate. Changes in regulatory authorities and advisory groups, or any new requirements or guidelines they promulgate, may lengthen the regulatory review process, require NoveCite to perform additional studies, increase its development and manufacturing costs, lead to changes in regulatory pathways, positions and interpretations, delay or prevent approval and commercialization of the NoveCite product candidate or lead to significant post-approval limitations or restrictions. As NoveCite advances its NoveCite product candidate, NoveCite will be required to consult with the FDA and other regulatory authorities, and its NoveCite product candidate will likely be reviewed by an FDA advisory committee. NoveCite also must comply with applicable requirements, and if it fails to do so, it may be required to delay or discontinue development of its NoveCite product candidate. Delays or unexpected costs in obtaining, or the failure to obtain, the regulatory approval necessary to bring the NoveCite product candidate to market could impair NoveCite's and our ability to generate sufficient product revenues to maintain our respective businesses.

NoveCite has assumed that the biological capabilities of iPSCs and adult-donor derived cells are likely to be comparable. If it is discovered that this assumption is incorrect, the NoveCite product candidate research and development activities could be harmed.

NoveCite anticipates that its research and development for its NoveCite product candidate will involve iPSCs, rather than adult-donor derived cells. With respect to iPSCs, NoveCite believes that scientists are still somewhat uncertain about the clinical utility, life span, and safety of such cells, and whether such cells differ in any clinically significant ways from adult-donor derived cells. If NoveCite discovers that iPSCs will not be useful for whatever reason for its NoveCite product candidate program, this would negatively affect NoveCite's ability to develop a marketable product and it and we may never become profitable, which would have an adverse effect on our respective businesses, prospects, financial condition and results of operations.

Even if we receive regulatory approval to commercialize a product candidate, our ability to generate revenues from any resulting product will be subject to a variety of risks, many of which are out of our control.

Even if one of our product candidates obtains regulatory approval, that product may not gain market acceptance among physicians, patients, healthcare payers or the medical community. The indication may be limited to a subset of the population or we may implement a distribution system and patient access program that is limited. Coverage and reimbursement of our product candidates by third-party payers, including government payers, generally is also necessary for commercial success. We believe that the degree of market acceptance and our ability to generate revenues from any approved product candidate or acquired approved product will depend on a number of factors, including:

- prevalence and severity of any side effects;
- results of any post-approval studies of the product;
- potential or perceived advantages or disadvantages over alternative treatments;
- availability of coverage and reimbursement from government and other third-party payers;

- the willingness of patients to pay out of pocket in the absence of government or third-party coverage;
- the relative convenience and ease of administration and dosing schedule;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- strength of sales, marketing and distribution support;
- price of any future products, if approved, both in absolute terms and relative to alternative treatments;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- the effect of current and future healthcare laws on any approved products;
- patient access programs that require patients to provide certain information prior to receiving new and refill prescriptions; and
- requirements for prescribing physicians to complete certain educational programs for prescribing drugs.

If approved, any product candidate may fail to achieve market acceptance or generate significant revenue to achieve or sustain profitability. In addition, our efforts to educate the medical community and third-party payers on the benefits of any product candidate may require significant resources and may never be successful.

Even if approved for marketing by applicable regulatory bodies, we will not be able to create a market for any of our product candidates if we fail to establish marketing, sales and distribution capabilities, either on our own or through arrangements with third parties.

Our strategy with our product candidates is to outsource to third parties all or most aspects of the product development process, and possibly marketing, sales and distribution activities. Currently, we do not have any sales, marketing or distribution capabilities. In order to generate sales of any product candidate that receives regulatory approval, we must either acquire or develop an internal marketing and sales force with technical expertise and with supporting distribution capabilities or make arrangements with third parties to perform these services for us. The acquisition or development of a sales and distribution infrastructure would require substantial resources, which may divert the attention of our management and key personnel and defer our product development efforts. To the extent that we enter into marketing and sales arrangements with other companies, our revenues will depend on the efforts of others. These efforts may not be successful. If we fail to develop sales, marketing and distribution channels, or enter into arrangements for such with third parties, we will experience delays in product launch and sales and incur increased costs.

The markets in which we operate are highly competitive and we may be unable to compete successfully against new entrants or established companies.

Competition in the pharmaceutical and medical products industries is intense and is characterized by costly and extensive research efforts and rapid technological progress. We are aware of several pharmaceutical companies also actively engaged in the development of therapies or products for at least some of the same conditions we are targeting. Many of these companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human resources than we do. In addition, many of these companies have significantly greater experience than us in undertaking pre-clinical testing, clinical trials and other regulatory approval procedures. Our competitors may develop technologies and products that are more effective than those we are researching and developing. Such developments could render our product candidates, if approved, less competitive or possibly obsolete. We are also competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have no current capabilities and in which we have no experience as a company, although our executive officers do have commercialization experience. However, that experience might not translate into the successful development and launch of any of our product candidates. Mergers, acquisitions, joint ventures and similar events may also significantly increase the competition we face. In addition, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical and medical technology industries at a rapid pace. These developments may render our product candidates obsolete or noncompetitive. Compared to us, many of our potential competitors have substantially greater as well as access to strategic partners and capital resources.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we can or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop products that are more effective, more useful and less costly than ours and may also be more successful in manufacturing and marketing their products. In addition, our competitors may be more effective than us in commercializing their products and as a result, our business and prospects might be materially harmed.

Physicians and patients might not accept and use any of our product candidates for which regulatory approval is obtained.

Even if the FDA approves one of our product candidates, physicians and patients might not accept and use it. Acceptance and use of our approved product candidates will depend upon a number of factors, including:

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of any of our product candidates;
- perceptions by members of the health care community, including physicians, about the use of our product candidates versus the then respective standards of care for the disease or problem that we seek to address with our product candidates;
- cost-effectiveness of our product candidates relative to competing products or therapies;
- availability of reimbursement for our product candidates from government or other healthcare payers; and
- effective marketing and distribution efforts by us and/or our licensees and distributors, if any.

If any of our current product candidates are approved, we expect their sales to generate substantially all of our revenues for the foreseeable future, and as a result, the failure of any of these product candidates to find market acceptance would harm our business and would require us to seek additional financing.

Our ability to generate product revenues will be diminished if any of our product candidates that may be approved sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.

Our ability to commercialize our product candidates, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from:

- government and health administration authorities;
- private health maintenance organizations and health insurers; and
- other healthcare payers.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs. Even if our product candidates are approved by the FDA, insurance coverage might not be available, and reimbursement levels might be inadequate, to cover our products. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for our products, once approved, market acceptance of such products could be reduced. We cannot predict whether federal or state legislation will be passed that may impact reimbursement policies nor what the impact of any such legislation would be on the healthcare industry in general or on our business specifically.

Health administration authorities in countries other than the U.S. may not provide reimbursement for our products at rates sufficient for us to achieve profitability, or at all. Like the U.S., these countries have considered health care reform proposals and could materially alter their government-sponsored health care programs by reducing reimbursement rates. Any reduction in reimbursement rates under Medicare or foreign health care programs could negatively affect the pricing of our product candidates. If we are not able to charge a sufficient amount for our product candidates, then our margins and our profitability will be adversely affected.

We are and will be dependent on third-party contract research organizations to conduct all of our clinical trials.

We are and will be dependent on third-party research organizations to conduct all of our clinical trials with respect to our product candidates, including any candidates that we may develop in the future. If we are unable to obtain any necessary testing services on acceptable terms, we may not complete our product development efforts in a timely or cost-effective manner or at all. If we rely on third parties for human trials, we may lose some control over these activities and become too dependent upon these parties. These third parties may not complete testing activities on schedule or when we so request. We may not be able to secure and maintain suitable research organizations to conduct our human trials. We are responsible for confirming that each of our clinical trials is conducted in accordance with the trial's general plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for any of our product candidates.

We rely exclusively on third parties to formulate and manufacture our product candidates.

We do not have and do not intend to establish our own manufacturing facilities. Consequently, we lack the physical plant to formulate and manufacture our product candidates, which are currently being manufactured entirely by commercial third-party manufacturers. If any product candidate we might develop or acquire in the future receives FDA approval, we will rely on one or more third-party contractors to manufacture our products. If, for any reason, we become unable to rely on our current source or any future source or sources to manufacture our product candidates, either for pre-clinical or clinical trials or for commercial quantities, then we would need to identify and contract with additional or replacement third-party manufacturers to manufacture compounds for preclinical, clinical and commercial purposes. We might not be successful in identifying additional or replacement third-party manufacturers, or in negotiating acceptable terms with any that we do identify. If we are unable to secure and maintain third-party manufacturing capacity, the development and sales of our product candidates and our financial performance might be materially and adversely affected.

In addition, before any of our collaborators can begin to commercially manufacture our product candidates, each must obtain regulatory approval of the manufacturing facility and process. Manufacturing of drugs for clinical and commercial purposes must comply with the FDA's good manufacturing practice, or cGMP, and applicable non-U.S. regulatory requirements. The cGMP requirements govern quality control and documentation policies and procedures. Complying with cGMP and non-U.S. regulatory requirements will require that we expend time, money, and effort in production, recordkeeping, and quality control to assure that the product meets applicable specifications and other requirements. Our contracted manufacturing facilities must also pass a pre-approval inspection prior to FDA approval. Failure to pass a pre-approval inspection might significantly delay FDA approval of our product candidates. If any of our collaborators fails to comply with these requirements, we would be subject to possible regulatory action which could limit the jurisdictions in which we are permitted to sell our product candidates. As a result, our business, financial condition, and results of operations might be materially harmed.

Our reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We might be unable to identify manufacturers for commercial supply on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would generally require compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our product candidates after receipt of FDA approval, if any;

- Our third-party manufacturers might be unable to formulate and manufacture our product candidates in the volume and of the quality required to meet our clinical and commercial needs, if any;

- Our contract manufacturers might not perform as agreed or might not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our product candidates for commercialization;

- Currently, our contract manufacturer for our clinical supplies is foreign, which increases the risk of shipping delays, adds the risk of import restrictions and adds the risk of political and environmental uncertainties that might affect those countries;

- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards;

- If any third-party manufacturer makes improvements in the manufacturing process for our product candidates, we might not own, or might have to share, the intellectual property rights to the innovation with our licensors;

- Operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including a bankruptcy of the manufacturer or supplier or a natural disaster or a pandemic such as COVID-19; and

- We might compete with other companies for access to these manufacturers' facilities and might be subject to manufacturing delays if the manufacturers give other clients higher priority than us.

Each of these risks could delay our clinical trials or the approval, if any, of our product candidates by the FDA or any foreign regulatory agency or the commercialization of our product candidates and could result in higher costs or deprive us of potential product revenues. As a result, our business, financial condition, and results of operations might be materially harmed.

If we materially breach or default under any of our license agreements, the licensor party to such agreement will have the right to terminate the license agreement, which termination may materially harm our business.

Our commercial success will depend in part on the maintenance of our current and any future license agreements. Our license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. For example, under our current license agreements, we are required to use commercially reasonable diligence to develop and commercialize a product and to satisfy specified payment obligations. If we fail to comply with our obligations under our current license agreements or any future license agreements with any party, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license. Each of our license agreements provides the licensor with a right to terminate the license agreement for our material breach or default under the agreement, including the failure to make any required milestone or other payments. Should the licensor under any of our license agreements exercise such a termination right, we would lose our right to the intellectual property under the respective license agreement, which loss may materially harm our business.

Any termination, or breach by, or conflict with our strategic partners could harm our business.

If we or any of our current or future collaborators fail to renew or terminate any of our collaboration agreements or if either party fails to satisfy its obligations under any of our collaboration or license agreements or complete them in a timely manner, we could have difficulty completing the development of any of our product candidates and potentially lose significant sources of revenue, which could result in an adverse impact on our operations and financial condition as well as volatility in any future revenue. In addition, our agreements with our collaborators may have provisions that give rise to disputes regarding the rights and obligations of the parties. These and other possible disagreements could lead to termination of the agreement or delays in collaborative research, development, supply or commercialization of our product candidates, or could require or result in litigation or arbitration. Any such conflicts with our collaborators could reduce our ability to obtain future collaboration agreements and could have a negative impact on our relationship with existing collaborators, adversely affecting our business and revenues. Finally, any of our collaborations may prove to be unsuccessful.

We plan to grow and develop our business through acquisitions of or investment in new or complementary businesses, products or technologies, and the failure to manage these acquisitions or investments, or the failure to integrate them with our existing business, could have a material adverse effect on us.

Our business strategy is based on the acquisition of additional product candidates. This is evidenced by our in-licensing of NoveCite in October 2020 and I/ONTAK in September 2021. We might consider opportunities to acquire or invest in other technologies, products and businesses that might enhance our capabilities or complement our current product candidates. Potential and completed acquisitions and strategic investments involve numerous risks, including potential problems or issues associated with the following:

- assimilating the acquired technologies, products or business operations, as we are currently engaged in for I/ONTAK;
- maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with the acquisition or investment;
- diversion of our management's attention from our preexisting business;
- maintaining or obtaining the necessary regulatory approvals or complying with regulatory standards; and
- adverse effects on existing business operations.

We have no current commitments with respect to any acquisition or investment in other technologies or businesses. We do not know if we will identify other suitable acquisitions, whether we will be able to successfully complete any acquisitions, or whether we will be able to successfully integrate any acquired product, technology or business into our business operations or retain key personnel, suppliers or collaborators.

Our ability to successfully develop our business through acquisitions including the recent in-licensing of I/ONTAK, will depend on our ability to identify, negotiate, complete and integrate suitable target businesses or technologies and obtain any necessary financing. These efforts could be expensive and time consuming and might disrupt our ongoing operations. If we are unable to efficiently integrate any acquired business, technology or product into our business operations, our business and financial condition might be adversely affected.

We rely on the significant experience and specialized expertise of our executive management and other key personnel and the loss of any of our executive management or key personnel or our inability to successfully hire their successors could harm our business.

Our performance is substantially dependent on the continued services and on the performance of our executive management and other key personnel, who have extensive experience and specialized expertise in our business. Our President and Chief Executive Officer, Myron Holubiak, our Executive Chairman, Leonard Mazur, and our Chief Medical Officer and Executive Vice President, Myron Czuczman, in particular have significant experience in the running of pharmaceutical companies and/or drug development itself. In addition, Matt Angel, a director of NoveCite, is serving as a technical consultant to that company and was instrumental in the discovery and development to date of NoveCite. This depth of experience is of significant benefit to us, especially given the small size of our management team and our company, including our subsidiaries. The loss of the services of any of Mr. Holubiak, Mr. Mazur, Dr. Czuczman or Dr. Angel, as well as any other member of our executive management or any key employees, including those at NoveCite, could harm our ability to attract capital and develop and commercialize our product candidates. Neither we nor NoveCite has key man life insurance policies.

If we are unable to retain or hire additional qualified personnel, our ability to grow our business might be harmed.

We utilize the services of a clinical management team on a part-time basis to assist us in managing our ongoing Phase 2 and Phase 3 trials and intend to do so for future preclinical and clinical trials. While we believe this will provide us with sufficient staffing for our current and future development efforts, we will need to hire or contract with additional qualified personnel with expertise in preclinical testing, clinical research and testing, government regulation, formulation and manufacturing and sales and marketing in connection with the continued development, regulatory approval and commercialization of our product candidates. We compete for qualified individuals with numerous pharmaceutical and biopharmaceutical companies, universities and other research institutions.

Competition for these individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success. In addition, we may be unable to attract and retain those qualified officers, directors and members of board committees required to provide for effective management. If we are unable to attract and retain qualified employees, officers and directors, the management and operation of our business could be adversely affected.

We expect to need to increase the size of our organization to further develop our product candidates, and we may experience difficulties in managing growth.

We will need to manage our anticipated growth and increased operational activity, including as a result of the in-licensing of I/ONTAK in September 2021. Our personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy will require that we:

- manage our research and development activities and our regulatory trials effectively;
- attract and motivate sufficient numbers of talented employees or consultants;
- manage our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors, collaborators and other third parties;
- develop internal sales and marketing capabilities or establish collaborations with third parties with such capabilities;
- commercialize our product candidates; and
- improve our operational, financial and management controls, reporting systems and procedures.

This planned future growth could place a strain on our administrative and operational infrastructure and may require our management to divert a disproportionate amount of its attention away from our day-to-day activities. We may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel, which may result in weaknesses in our infrastructure, and give rise to operational mistakes, loss of business opportunities, loss of employees and consultants and reduced productivity among remaining employees and consultants. We may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate or increase our revenues could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to effectively manage any future growth.

Conflicts of interest may arise from our relationship with NoveCite.

As of November 30, 2021, we beneficially owned 75% of the voting power of NoveCite's outstanding common stock; Novellus owns the other 25%. As a result of our partial ownership, our relationship with NoveCite could give rise to certain conflicts of interest that could have an impact on our and NoveCite's respective research and development programs, business opportunities, and operations generally.

- Even though we utilize different technologies than NoveCite, we could find ourselves in competition with it for research scientists, financing and other resources, licensing, manufacturing, and distribution arrangements.

- NoveCite will engage for its own business in research and product development programs, investments, and business ventures, and we will not be entitled to participate or to receive an interest in those programs, investments, or business ventures other than to the extent as a stockholder in NoveCite. NoveCite will not be obligated to present any particular research and development, investment, or business opportunity to us, even if the opportunity would be within the scope of our research and development plans or programs, business objectives, or investment policies. These opportunities may include, for example, opportunities to acquire businesses or assets, including but not limited to patents and other intellectual property that could be used by us or by NoveCite.

- Each conflict of interest will be resolved by our respective boards of directors in keeping with their fiduciary duties and such policies as they may implement from time to time.

- There is overlap among our board of directors, senior management and research staffs and that of NoveCite. Two of our directors, Myron Holubiak and Leonard Mazur, also serve as directors of NoveCite. In addition, Myron Holubiak serves as Chief Executive Officer and Jaime Bartushak serves as Chief Financial Officer of both Citius and NoveCite. These overlapping positions could interfere with the duties owed by such individuals to Citius.

Risks Related to Our Regulatory and Legal Environment

We might not obtain the necessary U.S. or foreign regulatory approvals to commercialize any product candidates.

We cannot assure you that we will receive the approvals necessary to commercialize for sale any product candidates we are currently developing or that we may acquire or seek to develop in the future. We will need FDA approval to commercialize our product candidates in the U.S. In order to obtain FDA approval of any product candidate, we must submit to the FDA an NDA or a BLA demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research, pre-clinical studies, and clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in products that the FDA considers safe for humans and effective for their indicated uses. The FDA has substantial discretion in the product approval process and might require us to conduct additional pre-clinical and clinical testing, perform post-marketing studies or otherwise limit or impose conditions on any additional approvals we obtain. The approval process might also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our product candidate's regulatory review. Delays in obtaining regulatory approvals might:

- delay commercialization of, and our ability to derive product revenues from, our product candidates;

- impose costly procedures on us; and

- diminish any competitive advantages that we might otherwise enjoy.

Even if we comply with all FDA requests, the FDA might ultimately reject one or more of our NDAs or BLAs. Even if we are able to obtain regulatory approval for a particular product candidate, the approval might limit the indicated medical uses for the product, limit our ability to promote, sell, and distribute the product, require that we conduct costly post-marketing surveillance, and/or require that we conduct ongoing post-marketing studies. We cannot be sure that we will ever obtain regulatory clearance for any of our product candidates. Failure to obtain FDA approval of one or more of our product candidates could severely undermine our business by leaving us without saleable products, and therefore without any potential sources of revenues, until another product candidate could be developed or obtained and successfully developed, approved and commercialized. Foreign jurisdictions impose similar regulatory approval processes and we will face the same risks if we seek foreign approval for any of our product candidates. There is no guarantee that we will ever be able to successfully develop or acquire any product candidate.

Following any regulatory approval of any product candidate, we will be subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize our other product candidates.

If one of our product candidates is approved by the FDA or by a foreign regulatory authority, we will be required to comply with extensive regulations for product manufacturing, labeling, packaging, adverse event reporting, storage, distribution, advertising, promotion and record keeping. Regulatory approvals may also be subject to significant limitations on the indicated uses or marketing of the products or to whom and how we may distribute an approved product. Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. For example, the label ultimately approved for any of our product candidates, if any, may include restrictions on use. If so, we may be subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize that product candidate. The FDA could also require a registry to track the patients utilizing the product or implement a Risk Evaluation and Mitigation Strategy, or REMS, that could restrict access to the product, which would reduce our revenues and/or increase our costs. Potentially costly post-marketing clinical studies may be required as a condition of approval to further substantiate safety or efficacy, or to investigate specific issues of interest to the regulatory authority. Similar risks apply in foreign jurisdictions.

Manufacturers of pharmaceutical products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Similar regulatory programs exist in foreign jurisdictions. Further, regulatory agencies must approve these manufacturing facilities before they can be used to manufacture our future approved products, if any, and these facilities are subject to ongoing regulatory inspections. In addition, regulatory agencies subject a pharmaceutical product, its manufacturer and the manufacturer's facilities to continual review and inspections. The subsequent discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, may result in restrictions on the marketing of that product, up to and including, withdrawal of the product from the market. If the manufacturing facilities of our suppliers fail to comply with applicable regulatory requirements, it could result in regulatory action and additional costs to us. Failure to comply with applicable FDA and other regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions.

In addition, the law or regulatory policies governing pharmaceutical products may change. New statutory requirements may be enacted or additional regulations may be enacted that could prevent or delay regulatory approval of our product candidates. Contract manufacturing organizations, or CMOs, and their vendors or suppliers may also face changes in regulatory requirements from governmental agencies in the U.S. and other countries. We cannot predict the likelihood, nature, extent or effects of government regulation that may arise from future legislation or administrative action, either in the U.S. or elsewhere. If we are not able to maintain regulatory compliance, we might not be permitted to market any future approved products and our business could suffer.

We could be forced to pay substantial damage awards if product liability claims that may be brought against us are successful.

The use of any of our product candidates in pre-clinical and clinical trials, and the sale of any approved products, may expose us to liability claims and financial losses resulting from the use or sale of our product candidates. We have obtained limited product liability insurance coverage for our pre-clinical and clinical trials of $5.0 million per occurrence and in the aggregate, subject to a deductible of $25,000 per bodily injury and property damage occurrence, and a medical expense per person limit of $25,000. There can be no assurance that our existing insurance coverage will extend to any other product candidates in the future. Any product liability insurance coverage may not be sufficient to satisfy all liabilities resulting from product liability claims. A successful claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable terms, if at all. Even if a claim is not successful, defending such a claim would be time consuming and expensive, may damage that product's and our reputations in the marketplace, and would likely divert management's attention, any of which could have a material adverse effect on our Company.

Risks Related to Our Intellectual Property

Our business depends on protecting our intellectual property.

Without the intellectual property rights we have already obtained, as well as the further rights we are also pursuing, our competitors would have opportunity to take advantage of our research and development efforts to develop competing products. Our success, competitive position and future revenues, if any, depend in part on our ability and the abilities of our licensors to obtain and maintain patent protection for our product candidates, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties. We anticipate filing additional patent applications both in the U.S. and in other countries, as appropriate. However, the patent process is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- Our patent rights might be challenged, invalidated, or circumvented, or otherwise might not provide any competitive advantage;
- Our competitors, many of which have substantially greater resources than we do and many of which might make significant investments in competing technologies, might seek, or might already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our product candidates either in the U.S. or in international markets;
- Countries other than the U.S. might have less restrictive patent laws than those upheld by U.S. courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products; and
- As a matter of public policy regarding worldwide health concerns, there might be significant pressure on the U.S. government and other international governmental bodies to limit the scope of patent protection both inside and outside the U.S. for product candidates that prove successful.

In addition, the U.S. Patent and Trademark Office and patent offices in other jurisdictions have often required that patent applications concerning pharmaceutical and/or biotechnology-related inventions be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Thus, even if we or our licensors are able to obtain patents, the patents might be substantially narrower than anticipated.

Because the time period from filing a patent application to the issuance, if ever, of the patent is often more than three years and because any regulatory approval and marketing for a pharmaceutical product often occurs several years after the related patent application is filed, the resulting market exclusivity afforded by any patent on our drug candidates and technologies will likely be substantially less than 20 years. For example, the U.S. patent on the original Mino-Lok composition expires in June 2024, and the U.S. patent on the stabilized Mino-Lok composition expires in November 2036. Since we anticipate significant additional time before FDA approval could be obtained, the maximum market exclusivity afforded by the statutory term of the currently issued patents would be less than 17 years. In the United States, the European Union and some other jurisdictions, patent term extensions are available for certain delays in either patent office proceedings or marketing and regulatory approval processes. However, due to the specific requirements for obtaining these extensions, there is no assurance that our patents will be granted extensions even if we encounter significant delays in patent office proceedings or marketing and regulatory approval.

Additionally, patent law is subject to change and varies among the U.S. and foreign countries. Depending on decisions by the United States Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' abilities to obtain new patents or to enforce existing patents we and our licensors or partners may obtain in the future.

Patent and other intellectual property protection is crucial to the success of our business and prospects, and there is a substantial risk that such protections will prove inadequate. Our business and prospects will be harmed if these protections prove insufficient.

We rely on trade secret protections through confidentiality agreements with our employees and other parties, and the breach of these agreements could adversely affect our business and prospects.

We rely on trade secrets, which we seek to protect, in part, through confidentiality and non-disclosure agreements with our employees, collaborators, suppliers, and other parties. There can be no assurance that these agreements will not be breached, that we would have adequate remedies for any such breach or that our trade secrets will not otherwise become known to or independently developed by our competitors. We might be involved from time to time in litigation to determine the enforceability, scope and validity of our proprietary rights. Any such litigation could result in substantial cost and divert management's attention from our operations.

If we infringe the rights of third parties we might have to forego developing and/or selling any approved products, pay damages, or defend against litigation.

If our product candidates, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we might have to:

- obtain licenses, which might not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate;
- redesign our product candidates or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others;
- pay damages; and/or
- defend litigation or administrative proceedings which might be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

Any of these events could substantially harm our earnings, financial condition and operations.

The U.S. government could have "march-in rights" to certain of our intellectual property.

If at any time federal monies are used in support of the research and development activities at MDACC that resulted or in the future result in certain of our issued pending U.S. patent applications, the federal government retains what are referred to as "march-in rights" to patents that are granted on these applications. Our license agreements for Mino-Lok and Mino-Wrap each provide that in the event of such governmental funding, our rights are subject to the government's prior rights, if any. In addition, the license agreements provide that we will comply with the requirements of any agreement between MDACC and the governmental funding entity. If applicable, this could require us to grant the U.S. government either a nonexclusive, partially exclusive or exclusive license to the patented invention in any field of use, upon terms that are reasonable for a particular situation. Circumstances that could trigger march-in rights generally would be set out in the agreement between MDACC and the funding governmental entity and could include, for example, failure to take, within a reasonable time, effective steps to achieve practical application of the invention in a field of use, failure to satisfy the health and safety needs of the public and failure to meet requirements of public use specified by federal regulations. A funding governmental entity could elect to exercise these march-in rights on their own initiative or at the request of a third party; however, the exercise of such march-in rights has been historically rare when the patent holder (or its licensee) is practicing the patent invention although there can be no assurance that such rights would not be exercised. This same risk would apply to any other license into which we enter if the licensor receives government funding for the product candidate that is the subject of the license.

Risks Related to Our Securities

If we fail to meet the continued listing requirements of Nasdaq it could result in a delisting of our common stock and certain warrants.

Our common stock and certain outstanding warrants are currently listed for trading on The Nasdaq Capital Market, and the continued listing of our common stock on The Nasdaq Capital Market is subject to our compliance with a number of listing standards. These listing standards include the requirement for avoiding sustained losses, maintaining a minimum level of stockholders' equity and maintaining a minimum stock price. The failure to meet any listing standard would subject us to potential loss of listing.

If our common stock were no longer listed on The Nasdaq Capital Market, investors might only be able to trade on one of the over-the-counter markets, including the OTC Bulletin Board ® or in the Pink Sheets ® (a quotation medium operated by Pink Sheets LLC). This would impair the liquidity of our common stock not only in the number of shares that could be bought and sold at a given price, which might be depressed by the relative illiquidity, but also through delays in the timing of transactions and reduction in media coverage. In addition, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- a limited amount of news and analyst coverage for us; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

We have twice failed to meet the listing standards between October 2019 and January 2020 and between April 2020 and July 2020 because the closing bid price for our common stock has fallen below $1.00 per share for 30 consecutive business days, as a result of which we did not comply with the $1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market under Rule 5550(a)(2) of the Nasdaq Listing Rules. Pursuant to Nasdaq Marketplace Rule 5810(c)(3)(A). In each instance, we regained compliance within the time period allowed by Nasdaq.

In the event of a future delisting, we would take actions to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

If our common stock were delisted and determined to be a "penny stock," a broker-dealer may find it more difficult to trade our common stock and an investor may find it more difficult to acquire or dispose of our common stock in the secondary market.

If our common stock were removed from listing with The Nasdaq Capital Market, it may be subject to the so-called "penny stock" rules. The SEC has adopted regulations that define a "penny stock" to be any equity security that has a market price per share of less than $5.00, subject to certain exceptions, such as any securities listed on a national securities exchange, which is the exception on which we currently rely. For any transaction involving a "penny stock," unless exempt, the rules impose additional sales practice requirements on broker-dealers, subject to certain exceptions. If our common stock were delisted and determined to be a "penny stock," a broker-dealer may find it more difficult to trade our common stock and an investor may find it more difficult to acquire or dispose of our common stock on the secondary market.

You may experience dilution of your ownership interests because of the future issuance of additional shares of our common stock or securities convertible into common stock.

For the foreseeable future, to finance our operations, including possible acquisitions or strategic transactions, we expect to issue equity securities, resulting in the dilution of the ownership interests of our present stockholders. We are currently authorized to issue an aggregate of 400,000,000 shares of common stock and 10,000,000 shares of preferred stock. As of September 30, 2021, there were 145,979,429 shares of common stock outstanding, 40,208,347 shares underlying warrants with a weighted average exercise price of $1.695 per share and 5,755,171 shares underlying options with a weighted average exercise price of $2.13 per share. We may also issue additional shares of our common stock or other securities that are convertible into or exercisable for common stock in connection with hiring or retaining employees, or for other business purposes. The future issuance of any such additional shares of common stock or common stock equivalents may create downward pressure on the trading price of our common stock or publicly traded warrants.

Our Certificate of Incorporation allows for our Board of Directors to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of the common stock.

Our Board of Directors has the authority to issue up to 10,000,000 shares of preferred stock and to fix and determine the relative rights and preferences of any such preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of one or more series of preferred stock that would grant preferential rights to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the preferred shares, together with a premium, prior to the redemption of the common stock. In addition, our Board of Directors could authorize the issuance of a series of preferred stock that has greater voting power than the common stock or that is convertible into our common stock, which could decrease the relative voting power of the common stock or result in dilution to our existing stockholders.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

We lease our offices at 11 Commerce Drive, Cranford, New Jersey 07016. The lease runs until October 31, 2025.

Item 3. Legal Proceedings

We are not involved in any litigation that we believe could have a material adverse effect on our financial position or results of operations. There is no action, suit, proceeding, inquiry or investigation before or by any court, public board, government agency, self-regulatory organization or body pending or, to the knowledge of our executive officers, threatened against or affecting our company or our officers or directors in their capacities as such.

In the future, we might from time to time become involved in litigation relating to claims arising from our ordinary course of business.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

The information regarding our equity compensation plans required by this Item is found in Item 12 of this report.

Market Information

Our common stock and certain warrants to purchase common stock trade on The Nasdaq Capital Market under the symbol "CTXR" and "CTXRW," respectively.

Holders of Common Stock

As November 30, 2021, we had approximately 96 stockholders of record of our common stock.

Dividends

We have never paid dividends on our common stock. We intend to follow a policy of retaining earnings, if any, to finance the growth of our business and do not anticipate paying any cash dividends in the foreseeable future. The declaration and payment of future dividends on the common stock will be at sole discretion of our Board of Directors and will depend on our profitability and financial condition, capital requirements, statutory and contractual restrictions, future prospects and other factors deemed relevant by the Board.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

We did not make any purchases of our common stock during the three months ended September 30, 2021, which is the fourth quarter of our fiscal year.

Item 6. [Reserved]

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

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and related notes included elsewhere in this annual report on Form 10-K. Management's discussion and analysis contains forward-looking statements, such as statements of our plans, objectives, expectations and intentions. Any statements that are not statements of historical fact are forward-looking statements. When used, the words "believe," "plan," "intend," "anticipate," "target," "estimate," "expect" and the like, and/or future tense or conditional constructions ("will," "may," "could," "should," etc.), or similar expressions, identify these forward-looking statements. These forward-looking statements are subject to risks and uncertainties including those under "Risk Factors" in Item 1A in this Form 10-K that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several factors. We do not undertake any obligation to update forward-looking statements to reflect events or circumstances occurring after the filing date of this report.

Historical Background

We are a specialty pharmaceutical company dedicated to the development and commercialization of critical care products targeting unmet needs with a focus on anti-infectives, cancer care and unique prescription products. On September 12, 2014, we acquired Citius Pharmaceuticals, LLC as a wholly-owned subsidiary.

On March 30, 2016, we acquired all of the outstanding stock of Leonard-Meron Biosciences, Inc. ("LMB") by issuing shares of our common stock. We acquired identifiable intangible assets of $19,400,000 related to in-process research and development and recorded goodwill of $9,346,796 for the excess of the purchase consideration over the net assets acquired.

On September 11, 2020, we formed NoveCite, Inc. ("NoveCite"), a Delaware corporation, of which we own 75% of the issued and outstanding capital stock.

On August 23, 2021, we formed Citius Acquisition Corp., a wholly owned subsidiary.

In-process research and development of $19,400,000 represents the value of LMB's leading drug candidate (Mino-Lok), which is an antibiotic solution used to treat catheter-related bloodstream infections and is expected to be amortized on a straight-line basis over a period of eight years commencing upon revenue generation. Goodwill of $9,346,796 represents the value of LMB's industry relationships and its assembled workforce. Goodwill will not be amortized but will be tested at least annually for impairment. In-process research and development of $40,000,000 represents the value of our September 2021 acquisition of an exclusive license for E7777 (denileukin diftitox), a late-stage oncology immunotherapy for the treatment of CTCL, a rare form of non-Hodgkin lymphoma and is expected to be amortized on a straight-line basis over a period of twelve years commencing upon revenue generation.

Through September 30, 2021, we have devoted substantially all of our efforts to product development, raising capital, building infrastructure through strategic alliances and coordinating activities relating to our proprietary products. We have not yet realized any revenues from its operations.

Patent and Technology License Agreements

Mino-Lok® - LMB has a patent and technology license agreement with Novel Anti-Infective Therapeutics, Inc. ("NAT") to develop and commercialize Mino-Lok on an exclusive, worldwide sub-licensable basis, as amended. Since May 2014, LMB has paid an annual maintenance fee, which began at $30,000 and that increased over five years to $90,000, where it will remain until the commencement of commercial sales of a product subject to the license. LMB will also pay annual royalties on net sales of licensed products, with royalties ranging from the mid-single digits to the low double digits. In limited circumstances in which the licensed product is not subject to a valid patent claim and a competitor is selling a competing product, the royalty rate is in the low single digits. After a commercial sale is obtained, LMB must pay minimum aggregate annual royalties that increase in subsequent years. LMB must also pay NAT up to $1,100,000 upon achieving specified regulatory and sales milestones. Finally, LMB must pay NAT a specified percentage of payments received from any sub licensees.

Mino-Wrap - On January 2, 2019, we entered into a patent and technology license agreement with the Board of Regents of the University of Texas System on behalf of the University of Texas M. D. Anderson Cancer Center ("Licensor"), whereby we in-licensed exclusive worldwide rights to the patented technology for any and all uses relating to breast implants. We intend to develop a liquefying gel-based wrap containing minocycline and rifampin for the reduction of infections associated with breast implants following breast reconstructive surgeries. We are required to use commercially reasonable efforts to commercialize Mino-Wrap under several regulatory scenarios and achieve milestones associated with these regulatory options leading to an approval from the FDA.

Under the license agreement, we paid a nonrefundable upfront payment of $125,000. We are obligated to pay an annual maintenance fee of $30,000, commencing in January 2020 that increases annually by $15,000 per year up to a maximum of $90,000. Annual maintenance fees cease on the first sale of product. We also must pay up to an aggregate of $2.1 million in milestone payments, contingent on the achievement of various regulatory and commercial milestones. Under the terms of the license agreement, we also must pay a royalty of mid- to upper-single digit percentages of net sales, depending on the amount of annual sales, and subject to downward adjustment to lower- to mid-single digit percentages in the event there is no valid patent for the product in the United States at the time of sale. After the first sale of product, we will owe an annual minimum royalty payment of $100,000 that will increase annually by $25,000 for the duration of the term. We will be responsible for all patent expenses incurred by Licensor for the term of the agreement although Licensor is responsible for filing, prosecution and maintenance of all patents.

NoveCite – On October 6, 2020, our subsidiary NoveCite entered into a license agreement with Novellus Therapeutics Limited ("Licensor"), whereby NoveCite acquired an exclusive, worldwide license, with the right to sublicense, to develop and commercialize a stem cell therapy based on the Licensor's patented technology for the treatment of acute pneumonitis of any etiology in which inflammation is a major agent in humans. Upon execution of the license agreement, NoveCite paid an upfront payment of $5,000,000 to Licensor and issued to Licensor shares of Novecite's common stock representing 25% of NoveCite's currently outstanding equity. We own the other 75% of NoveCite's currently outstanding equity.

In July 2021, Novellus was acquired by Brooklyn. Pursuant to this transaction, the NoveCite license was assumed by Brooklyn with all original terms and conditions.

As part of the Novellus and Brooklyn merger transaction, the 25% non-dilutive position as per the subscription agreement between Novellus and NoveCite was removed.

Under the license agreement, NoveCite is obligated to pay Licensor up to an aggregate of $51,000,000 in regulatory and developmental milestone payments. NoveCite also must pay a royalty equal to low double-digit percentages of net sales, commencing upon the first commercial sale of a licensed product. This royalty is subject to downward adjustment on a product-by-product and country-by-country basis to an upper-single digit percentage of net sales in any country in the event of the expiration of the last valid patent claim or if no valid patent claim exists in that country. The royalty will end on the earlier of (i) date on which a biosimilar product is first marketed, sold, or distributed by Licensor or any third party in the applicable country or (ii) the 10-year anniversary of the date of expiration of the last-to-expire valid patent claim in that country. In the case of a country where no licensed patent ever exists, the royalty will end on the later of (i) the date of expiry of such licensed product's regulatory exclusivity and (ii) the 10-year anniversary of the date of the first commercial sale of the licensed product in the applicable country. In addition, NoveCite will pay to Licensor an amount equal to a mid-twenties percentage of any sublicensee fees it receives.

Under the terms of the license agreement, in the event that Licensor receives any revenue involving the original cell line included in the licensed technology, then Licensor shall remit to NoveCite 50% of such revenue.

I/ONTAK/E7777 - In September 2021 the Company announced that it had entered into a definitive agreement with Dr. Reddy's to acquire its exclusive license of E7777 (denileukin diftitox), a late-stage oncology immunotherapy for the treatment of CTCL, a rare form of non-Hodgkin lymphoma.

Under the terms of this agreement, Citius acquired Dr. Reddy's exclusive license of E7777 from Eisai and other related assets owned by Dr. Reddy's. Citius's exclusive license rights include rights to develop and commercialize E7777 in all markets except for Japan and certain parts of Asia. Additionally, Citius has an option on the right to develop and market the product in India. Eisai retains exclusive development and marketing rights for the agent in Japan and Asia. Dr. Reddy's received a $40 million upfront payment and is entitled to up to $40 million in development milestone payments related to CTCL approvals in the U.S. and other markets, up to $70 million in development milestones for additional indications, as well as commercial milestone payments and low double-digit tiered royalties on net product sales. Eisai is to receive a $6 million development milestone payment upon initial approval and additional commercial milestone payments related to the achievement of net product sales thresholds. Eisai will be responsible for completing the current CTCL clinical trial, and chemistry, manufacturing and controls (CMC) activities through the filing of a BLA for E7777 with the FDA. Citius will be responsible for development costs associated with potential additional indications.

Results of Operations for Year Ended September 30, 2021 compared to Year Ended September 30, 2020

	Year Ended September 30, 2021	Year Ended September 30, 2020
Revenues	$ -	$ -
Operating expenses:		
Research and development	12,240,503	8,812,810
General and administrative	9,836,412	8,094,614
Stock-based compensation – general and administrative	1,454,979	803,261
Total operating expenses	23,531,894	17,710,685
Operating loss	(23,531,894)	(17,710,685)
Interest income	261,825	68,066
Gain on forgiveness of note payable - Paycheck Protection Program and accrued interest	166,557	-
Other income	59,917	110,207
Interest expense	(10,839)	(15,673)
Net loss	$ (23,054,434)	$ (17,548,085)

Revenues

We did not generate any revenues for the years ended September 30, 2021 and 2020.

Research and Development Expenses

For the year ended September 30, 2021, research and development expenses were $12,240,503 as compared to $8,812,810 for the year ended September 30, 2020, an increase of $3,427,693. Research and development costs for Mino-Lok® decreased by $2,679,768 to $3,527,250 for the year ended September 30, 2021 as compared to $6,207,018 for the year ended September 30, 2020 driven primarily by a decrease in the cost of registration batches produced in the year ended September 30, 2021. Research and development costs for our Halo-Lido product candidate decreased by $783,870 to $862,173 for the year ended September 30, 2021 as compared to $1,646,043 for the year ended September 30, 2020 due to a reduction in costs associated with manufacturing development as well as our patient reported outcome tool for the year ended September 30, 2021. Research and development costs for our Mino-Wrap product candidate increased by $51,990 to $165,507 for the year ended September 30, 2021 as compared to $113,517 during the year ended September 30, 2020. During the year ended September 30, 2021, research and development costs for our proposed novel cellular therapy for acute respiratory distress syndrome (ARDS) were $6,946,365 as compared to $846,232 for the year ended September 30, 2020. The increase of $6,100,133 was primarily due to the $5,000,000 license fee paid to Novellus. We also incurred $739,208 in research and development expenses for our proposed product candidate related to the E7777 license.

We expect that research and development expenses will continue to increase in fiscal 2022 as we continue to focus on our Phase 3 trial for Mino-Lok, progress the Halo-Lido product candidate, and accelerate our research and development efforts related to ARDS, Mino-Wrap and E7777.

General and Administrative Expenses

For the year ended September 30, 2021, general and administrative expenses were $9,836,412 as compared to $8,094,614 for the year ended September 30, 2020 an increase of $1,741,798. The primary reason for the increase was additional compensation costs for new employees and performance bonuses. General and administrative expenses consist primarily of compensation costs, consulting fees incurred for financing activities and corporate development services, and investor relations expenses.

Stock-based Compensation Expense

For the year ended September 30, 2021, stock-based compensation expense was $1,454,979 as compared to $803,261 for the year ended September 30, 2020. Stock-based compensation expense includes options granted to directors, employees and consultants. For the year ended September 30, 2021, stock-based compensation includes $83,555 in expense for the NoveCite stock option plan that was adopted in November 2020. Stock-based compensation expense increased by $651,718 in comparison to the prior year due to new grants made by Citius and the expense for the NoveCite stock plan. In fiscal year 2012, we granted options to our new employees and additional options to other employees, our directors and consultants. At September 30, 2021, unrecognized total compensation cost related to unvested options for Citius common stock of $3,012,685 is expected to be recognized over a weighted average period of 2.34 years and unrecognized total compensation cost related to unvested options for NoveCite common stock of $316,444 is expected to be recognized over a weighted average period of 2.42 years

Other Income (Expense)

During the year ended September 30, 2021, the Company earned $261,825 of interest income compared to $68,066 of interest income during the year ended September 30, 2020. The increase was due to our investment of most of the 2021 equity offerings and common stock warrant exercises proceeds in money market accounts.

The Company recorded a gain of $166,557 for the principal and accrued interest on the Paycheck Protection Program loan that was forgiven on July 28, 2021.

Other income for the year ended September 30, 2021 consists of accrued interest of $59,917 on notes payable – related parties that was forgiven in June 2021.

In November 2019, we received a $110,207 refund from the FDA for 2016 product and establishment fees because the fees paid by the Company exceeded the costs of the FDA's review of the associated applications. The Company recorded the $110,207 as other income during the year ended September 30, 2020.

Interest expense for the year ended September 30, 2021 was $10,839 as compared to $15,673 for the year ended September 30, 2020. Interest expense for both years is primarily for the notes payable to related parties that were acquired in the acquisition of LMB. We also accrued interest expense on the COVID-19 related Small Business Administration ("SBA") Paycheck Protection Program loan received on April 15, 2020. At September 30, 2021, there were no outstanding notes payable.

Net Loss

For the year ended September 30, 2021, we incurred a net loss of $23,054,434 compared to a net loss of $17,548,085 for the year ended September 30, 2020. The $5,506,349 increase in the net loss was primarily due to the $3,427,693 increase in research and development expenses and the $1,741,798 increase in general and administrative expenses, which increases were primarily associated with NoveCite.

LIQUIDITY AND CAPITAL RESOURCES

Liquidity and Working Capital

Citius has incurred operating losses since inception and incurred net losses of $23,054,434 and $17,548,085 for the years ended September 30, 2021 and 2020, respectively. At September 30, 2021, Citius had an accumulated deficit of $96,047,821. Citius' net cash used in operations during the years ended September 30, 2021 and 2020 was $24,250,414 and $16,930,658, respectively.

As a result of our common stock offerings and common stock warrant exercises in fiscal year 2021, the Company had working capital of approximately $68,800,000 at September 30, 2021. We expect that we will have sufficient funds to continue our operations through March 2023. At September 30, 2021, Citius had cash and cash equivalents of $70,072,946 available to fund its operations. The Company's only source of cash flow since inception has been from financing activities. During the years ended September 30, 2021 and 2020, the Company received net proceeds of $120,643,020 and $22,733,850, respectively, from the issuance of equity. We also received $164,583 from the COVID-related SBA paycheck protection program loan received on April 15, 2020. Our primary uses of operating cash were for in-licensing of intellectual property, product development and commercialization activities, employee compensation, consulting fees, legal and accounting fees, insurance and investor relations expenses.

Financing Activities

In December 2019, 1,060,615 of the September 2019 Offering Pre-Funded Unit Warrants were exercised at $0.0001 per share for net proceeds of $106.

In January 2020, investors who participated in the September 2019 Offering exercised 1,315,715 warrants at $0.77 per share resulting in net proceeds of $1,013,101 to the Company.

On February 14, 2020, the Company entered into a warrant exercise agreement for 3,712,218 shares of common stock having an exercise price of $0.77 and 2,586,455 shares of common stock at a reduced exercise price of $1.02. The offering closed on February 19, 2020 and net proceeds were $5,013,930 after placement agent fees and offering expenses.

On May 18, 2020, the Company closed a registered direct offering for the sale of 7,058,824 shares of common stock at $1.0625 per share for gross proceeds of $7,500,001. The Company also issued 3,529,412 unregistered immediately exercisable warrants to the investors with an exercise price of $1.00 per share and a term of five and one-half years. Net proceeds from the offering were $6,877,100.

On June 26, 2020, 1,129,412 of the May 2020 Registered Direct Offering Investor Warrants were exercised at $1.00 per share for net proceeds of $1,129,412.

On August 10, 2020, the Company closed an underwritten public offering of 9,159,524 shares of common stock at $1.05 per share for gross proceeds of $9,617,500. The Company paid the underwriter a fee of 7% of the gross proceeds totaling $673,225 and issued the underwriter 641,166 immediately exercisable warrants with an exercise price of $1.3125 per share and a term of five years. The Company also reimbursed the placement agent for $135,000 in expenses and incurred $109,074 in other expenses. Net proceeds from the offering were $8,700,201.

On January 27, 2021, the Company closed a private placement for 15,455,960 common shares and warrants to purchase 7,727,980 common shares, at a purchase price of $1.294 per share of common stock and accompanying warrant, for gross proceeds of $20,000,012. Net proceeds from the offering were $18,450,410.

On February 19, 2021, the Company closed a registered direct offering for 50,830,566 common shares and warrants to purchase 25,415,283 common shares, at a purchase price of $1.505 per share and accompanying warrant, for gross proceeds of $76,500,002. Net proceeds from the offering were $70,979,842.

During the year ended September 30, 2021, we received $31,130,134 in proceeds from the exercise of common stock warrants and $82,634 in proceeds from the exercise of common stock options.

Based on our cash and cash equivalents at September 30, 2021, we expect that we will have sufficient funds to continue our operations through March 2023. We may need to raise additional capital in the future to support our operations beyond March 2023. There is no assurance, however, that we will be successful in raising the needed capital or that the proceeds will be received in an amount or in a timely manner to support our operations.

While the COVID-19 pandemic has adversely impacted the progress of our clinical trials and operations, as of the date of this report, the Company has been able to access the capital markets and successfully complete financing transactions. However, we cannot be certain that any future impact of COVID-19 on our operations will not negatively impact our ability to raise capital.

Inflation

Our management believes that inflation has not had a material effect on our results of operations.

Off Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

CRITICAL ACCOUNTING POLICIES

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and related disclosure of contingent assets and liabilities. We review our estimates on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe to be reasonable under the circumstances. Actual results may differ from these estimates. We believe the judgments and estimates required by the following accounting policies to be critical in the preparation of our financial statements.

Research and Development

Research and development costs, including upfront fees and milestones paid to collaborators who are performing research and development activities under contractual agreement with us, are expensed as incurred. We defer and capitalize our nonrefundable advance payments that are for research and development activities until the related goods are delivered or the related services are performed. When we are reimbursed by a collaboration partner for work we perform, we record the costs incurred as research and development expenses and the related reimbursement as a reduction to research and development expenses in our statement of operations. Research and development expenses primarily consist of clinical and non-clinical studies, materials and supplies, third-party costs for contracted services, and payments related to external collaborations and other research and development related costs.

In-process Research and Development and Goodwill

In-process research and development of $19,400,000 represents the value of LMB's leading drug candidate, Mino-Lok, an antibiotic lock solution in Phase 3 clinical development, which if approved, would be used to treat catheter-related bloodstream infections and is expected to be amortized on a straight-line basis over a period of eight years commencing upon revenue generation. In-process research and development of $40,000,000 represents the value of our September 2021 acquisition of an exclusive license for E7777 (denileukin diftitox), a late-stage oncology immunotherapy for the treatment of CTCL, a rare form of non-Hodgkin lymphoma and is expected to be amortized on a straight-line basis over a period of twelve years commencing upon revenue generation.

Goodwill represents the value of LMB's industry relationships and its assembled workforce. Goodwill will not be amortized and will be tested at least annually for impairment.

The Company reviews intangible assets annually to determine if any adverse conditions exist or a change in circumstances has occurred that would indicate impairment or a change in the remaining useful life of any intangible asset. If the carrying value of an asset exceeds its undiscounted cash flows, the Company writes down the carrying value of the intangible asset to its fair value for the period identified. No impairments have occurred since the acquisitions of our intangible assets through September 30, 2021.

The Company evaluates the recoverability of goodwill annually or more frequently if events or changes in circumstances indicate that the carrying value of an asset might be impaired, in accordance with Accounting Standard Update ("ASU") 2017-04, *Intangibles – Goodwill and Other (Topic 350): Simplifying the Accounting for Goodwill Impairment*. Goodwill is first qualitatively assessed to determine whether further impairment testing is necessary. Factors that management considers in this assessment include macroeconomic conditions, industry and market considerations, overall financial performance (both current and projected), changes in management and strategy and changes in the composition or carrying amount of net assets. If this qualitative assessment indicates that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, a one-step test is then performed in accordance with ASU 2017-04. Under the simplified model, a goodwill impairment is calculated as the difference between the carrying amount of the reporting unit and its fair value.

The Company performed a qualitative assessment for its 2021 analysis of goodwill. Based on this assessment, management does not believe that it is more likely than not that the carrying value of the reporting unit exceeds its fair value. Accordingly, no further testing was performed as management believes that there are no impairment issues with respect to goodwill as of September 30, 2021.

Income Taxes

We follow accounting guidance regarding the recognition, measurement, presentation and disclosure of uncertain tax positions in the financial statements. Tax positions taken or expected to be taken in the course of preparing our tax returns are required to be evaluated to determine whether the tax positions are "more-likely-than-not" of being sustained by the applicable tax authorities. Tax positions not deemed to meet a more-likely-than-not threshold would be recorded in the financial statements.

We recognize deferred tax assets and liabilities based on differences between the financial reporting and tax basis of assets and liabilities using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. We provide a valuation allowance for deferred tax assets for which we do not consider realization of such assets to be more likely than not.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not required.

Item 8. Financial Statements and Supplementary Data

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of Citius Pharmaceuticals, Inc.:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Citius Pharmaceuticals, Inc. (the "Company") as of September 30, 2021 and 2020, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively, 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 2020, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

Critical Audit Matters

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

/s/ Wolf & Company, P.C.

We have served as the Company's auditor since 2014.

Boston, Massachusetts
December 15, 2021

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
SEPTEMBER 30, 2021 AND 2020

	2021	2020
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 70,072,946	$ 13,859,748
Prepaid expenses	2,741,404	122,237
Total Current Assets	72,814,350	13,981,985
Property and equipment, net	7,023	1,577
Operating lease right-of-use asset, net	822,828	986,204
Other Assets:		
Deposits	38,062	57,093
In-process research and development	59,400,000	19,400,000
Goodwill	9,346,796	9,346,796
Total Other Assets	68,784,858	28,803,889
Total Assets	$ 142,429,059	$ 43,773,655
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,277,095	$ 1,856,235
Accrued expenses	621,960	164,040
Accrued compensation	1,906,000	1,654,919
Accrued interest	—	89,970
Notes payable – related parties	—	172,970
Operating lease liability	177,237	158,999
Total Current Liabilities	3,982,292	4,097,133
Note payable – paycheck protection program	—	164,583
Deferred tax liability	4,985,800	4,985,800
Operating lease liability – non current	678,234	855,471
Total Liabilities	9,646,326	10,102,987
Commitments and Contingencies		
Stockholders' Equity:		
Preferred stock - $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock - $0.001 par value; 400,000,000 shares authorized; 145,979,429 and 55,576,996 shares issued and outstanding at September 30, 2021 and 2020, respectively	145,979	55,577
Additional paid-in capital	228,084,195	104,208,958
Accumulated deficit	(96,047,821)	(70,593,867)
Total Citius Pharmaceuticals, Inc. Stockholders' Equity	132,182,353	33,670,668
Non-controlling interest	600,380	—
Total Equity	132,782,733	33,670,668
Total Liabilities and Equity	$ 142,429,059	$ 43,773,655

See accompanying report of independent registered public accounting firm and notes to the consolidated financial statements.

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED SEPTEMBER 30, 2021 AND 2020

	2021	2020
Revenues	$ —	$ —
Operating Expenses:		
Research and development	12,240,503	8,812,810
General and administrative	9,836,412	8,094,614
Stock-based compensation – general and administrative	1,454,979	803,261
Total Operating Expenses	23,531,894	17,710,685
Operating Loss	(23,531,894)	(17,710,685)
Other Income (Expense):		
Interest income	261,825	68,066
Gain on forgiveness of note payable - Paycheck Protection Program and accrued interest	166,557	
Other income	59,917	110,207
Interest expense	(10,839)	(15,673)
Total Other Income, Net	477,460	162,600
Net Loss	(23,054,434)	(17,548,085)
Deemed dividend on warrant extension	1,450,876	—
Net Loss Applicable to Common Stockholders	$ (24,505,310)	$ (17,548,085)
Net Loss Per Share Applicable to Common Stockholders - Basic and Diluted	$ (0.23)	$ (0.45)
Weighted Average Common Shares Outstanding		
Basic and diluted	108,599,080	39,165,248

See accompanying report of independent registered public accounting firm and notes to the consolidated financial statements.

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED SEPTEMBER 30, 2021 AND 2020

	Preferred Stock	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Citius Pharmaceuticals, Inc. Shareholder's Equity	Non-Controlling Interest	Total Equity
		Shares	Amount					
Balance, October 1, 2019	$ —	28,930,493	$ 28,930	$ 80,169,724	$ (53,045,782)	$ 27,152,872	$ —	$ 27,152,872
Issuance of common stock upon exercise of warrants	—	9,804,415	9,804	7,146,745	—	7,156,549	—	7,156,549
Issuance of common stock for services	—	623,740	624	528,146	—	528,770	—	528,770
Issuance of common stock in registered direct offering, net of costs of $622,900	—	7,058,824	7,059	6,870,041	—	6,877,100	—	6,877,100
Issuance of common stock in underwritten offering, net of costs of $917,299	—	9,159,524	9,160	8,691,041	—	8,700,201	—	8,700,201
Stock-based compensation expense	—	—	—	803,261	—	803,261	—	803,261
Net loss	—	—	—	—	(17,548,085)	(17,548,085)	—	(17,548,085)
Balance, September 30, 2020	—	55,576,996	55,577	104,208,958	(70,593,867)	33,670,668	—	33,670,668
Issuance of NoveCite common stock	—	—	—	1,799,640	(2,399,520)	(599,880)	600,380	500
Issuance of common stock in private placement offering, net of costs of $1,549,602	—	15,455,960	15,456	18,434,954	—	18,450,410	—	18,450,410
Issuance of common stock in registered direct offering, net of costs of $5,520,160	—	50,830,566	50,830	70,929,012	—	70,979,842	—	70,979,842
Issuance of common stock upon exercise of warrants	—	23,995,907	23,996	31,106,138	—	31,130,134	—	31,130,134
Issuance of common stock for services	—	50,000	50	67,950	—	68,000	—	68,000
Issuance of common stock upon exercise of stock options	—	70,000	70	82,564	—	82,634	—	82,634
Stock-based compensation expense	—	—	—	1,454,979	—	1,454,979	—	1,454,979
Net loss	—	—	—	—	(23,054,434)	(23,054,434)	—	(23,054,434)
Balance, September 30, 2021	$ —	145,979,429	$145,979	$228,084,195	$ (96,047,821)	$ 132,182,353	$ 600,380	$132,782,733

See accompanying report of independent registered public accounting firm and notes to the consolidated financial statements.

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED SEPTEMBER 30, 2021 AND 2020

	2021	2020
Cash Flows From Operating Activities:		
Net loss	$ (23,054,434)	$ (17,548,085)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,454,979	803,261
Issuance of common stock for services	68,000	528,770
Amortization of operating lease right-of-use asset	163,376	151,520
Depreciation	1,492	844
Gain from forgiveness of notes payable – paycheck protection program and accrued interest	(166,557)	—
Changes in operating assets and liabilities:		
Prepaid expenses	(2,619,167)	(74,126)
Deposits	19,031	—
Accounts payable	(579,140)	(857,307)
Accrued expenses	457,920	(82,185)
Accrued compensation	251,081	254,231
Accrued interest	(87,996)	15,673
Operating lease liability	(158,999)	(123,254)
Net Cash Used In Operating Activities	(24,250,414)	(16,930,658)
Cash Flows From Investing Activities:		
Purchase of property and equipment	(6,938)	(1,831)
Purchase of in-process research and development	(40,000,000)	—
Net Cash Used In Investing Activities	(40,006,938)	(1,831)
Cash Flows From Financing Activities:		
Proceeds from notes payable – paycheck protection program	—	164,583
Principal paid on notes payable – related parties	(172,970)	—
Proceeds from sale of NoveCite, Inc. common stock	500	—
Proceeds from common stock warrant exercises	31,130,134	7,156,549
Proceeds from common stock option exercises	82,634	—
Net proceeds from underwritten offerings	—	8,700,201
Net proceeds from private placement	18,450,410	—
Net proceeds from registered direct offerings	70,979,842	6,877,100
Net Cash Provided By Financing Activities	120,470,550	22,898,433
Net Change in Cash and Cash Equivalents	56,213,198	5,965,944
Cash and Cash Equivalents – Beginning of Year	13,859,748	7,893,804
Cash and Cash Equivalents – End of Year	$ 70,072,946	$ 13,859,748
Supplemental Disclosures of Cash Flow Information and Non-cash Activities:		
Operating lease right-of-use asset and liability recorded upon adoption of ASC 842	$ —	$ 1,137,724

See accompanying report of independent registered public accounting firm and notes to the consolidated financial statements.

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Business

Citius Pharmaceuticals, Inc. ("Citius," the "Company" or "we") is a specialty pharmaceutical company dedicated to the development and commercialization of critical care products targeting unmet needs with a focus on anti-infectives, cancer care and unique prescription products.

On March 30, 2016, Citius acquired Leonard-Meron Biosciences, Inc. ("LMB") as a wholly-owned subsidiary. The Company acquired all of the outstanding stock of LMB by issuing shares of its common stock. The net assets acquired included identifiable intangible assets of $19,400,000 related to in-process research and development. The Company recorded goodwill of $9,346,796 for the excess of the purchase price over the net assets acquired.

On September 11, 2020, we formed NoveCite, Inc. ("NoveCite"), a Delaware corporation, of which we own 75% of the issued and outstanding capital stock.

On August 23, 2021, we formed Citius Acquisition Corp., a wholly owned subsidiary in conjunction with the acquisition of I/ONTAK, but no activity has occurred to date.

In-process research and development ("IPR&D) consists of i) $19,400,000 acquisition value of of LMB's leading drug candidate (Mino-Lok), which is an antibiotic solution used to treat catheter-related bloodstream infections and is expected to be amortized on a straight-line basis over a period of eight years commencing upon revenue generation, and ii) $40,000,000 acquisition value of the exclusive license for E7777 (denileukin diftitox), a late-stage oncology immunotherapy for the treatment of CTCL, a rare form of non-Hodgkin lymphoma and is expected to be amortized on a straight-line basis over a period of twelve years commencing upon revenue generation. Goodwill of $9,346,796 represents the value of LMB's industry relationships and its assembled workforce. Goodwill will not be amortized but will be tested at least annually for impairment.

Since its inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, and raising capital. Citius is subject to a number of risks common to companies in the pharmaceutical industry including, but not limited to, risks related to the development by Citius or its competitors of research and development stage products, market acceptance of its products, competition from larger companies, dependence on key personnel, dependence on key suppliers and strategic partners, the Company's ability to obtain additional financing and the Company's compliance with governmental and other regulations.

Basis of Presentation

The accompanying consolidated financial statements include the operations of Citius Pharmaceuticals, Inc., and its wholly-owned subsidiaries, Citius Pharmaceuticals, LLC, LMB and Citius Acquisition Corp., and its majority-owned subsidiary NoveCite. NoveCite, was inactive until October 2020. Citius Acquisition Corp. was inactive at September 30, 2021. All significant inter-company balances and transactions have been eliminated in consolidation.

2. LIQUIDITY AND MANAGEMENT'S PLAN

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company experienced negative cash flows from operations of $24,250,414 and $16,930,658, for the years ended September 30, 2021 and 2020, respectively. As a result of the Company's common stock offerings and common stock warrant exercises during the year ended September 30, 2021, the Company had working capital of approximately $68,800,000 at September 30, 2021. The Company estimates that its available cash resources will be sufficient to fund its operations through March 2023.

The Company has generated no operating revenue to date and has principally raised capital through the issuance of debt and equity instruments to finance its operations. However, the Company's continued operations beyond March 2023, including its development plans for Mino-Lok, Mino-Wrap, Halo-Lido, Novecite and E7777, will depend on its ability to obtain regulatory approval to market Mino-Lok and generate substantial revenue from the sale of Mino-Lok and on its ability to raise additional capital through various potential sources, such as equity and/or debt financings, strategic relationships, or out-licensing of its product candidates. However, the Company can provide no assurances on regulatory approval, commercialization or future sales of Mino-Lok or that financing or strategic relationships will be available on acceptable terms, or at all. If the Company is unable to raise sufficient capital, find strategic partners or generate substantial revenue from the sale of Mino-Lok, there would be a material adverse effect on its business. Further, the Company expects in the future to incur additional expenses as it continues to develop its product candidates, including seeking regulatory approval, and protecting its intellectual property.

3. PATENT AND TECHNOLOGY LICENSE AGREEMENTS

Patent and Technology License Agreement – Mino-Lok

LMB has a patent and technology license agreement with Novel Anti-Infective Therapeutics, Inc. ("NAT") to develop and commercialize Mino-Lok® on an exclusive, worldwide sub licensable basis, as amended. LMB pays an annual maintenance fee each June until commercial sales of a product subject to the license commence. The Company recorded an annual maintenance fee expense of $90,000 in 2021 and 2020.

LMB will also pay annual royalties on net sales of licensed products, with royalties ranging from the mid-single digits to the low double digits. In limited circumstances in which the licensed product is not subject to a valid patent claim and a competitor is selling a competing product, the royalty rate is in the low- to mid-single digits. After a commercial sale is obtained, LMB must pay minimum aggregate annual royalties of $100,000 in the first commercial year which is prorated for a less than 12-month period, increasing $25,000 per year to a maximum of $150,000 annually. LMB must also pay NAT up to $1,100,000 upon achieving specified regulatory and sales milestones. Finally, LMB must pay NAT a specified percentage of payments received from any sub-licensees.

Unless earlier terminated by NAT, based on the failure to achieve certain development and commercial milestones, the license agreement remains in effect until the date that all patents licensed under the agreement have expired and all patent applications within the licensed patent rights have been cancelled, withdrawn or expressly abandoned.

Patent and Technology License Agreement – Mino-Wrap

On January 2, 2019, we entered into a patent and technology license agreement with the Board of Regents of the University of Texas System on behalf of the University of Texas M. D. Anderson Cancer Center ("Licensor"), whereby it in-licensed exclusive worldwide rights to the patented technology for any and all uses relating to breast implants. We intend to develop a liquefying gel-based wrap containing minocycline and rifampin for the reduction of infections associated with breast implants following breast reconstructive surgeries ("Mino-Wrap"). We are required to use commercially reasonable efforts to commercialize Mino-Wrap under several regulatory scenarios and achieve milestones associated with these regulatory options leading to an approval from the U.S. Food and Drug Administration (the "FDA").

Under the license agreement, we paid a nonrefundable upfront payment of $125,000 which was recorded as research and development expense during the year ended September 30, 2019. We paid annual maintenance fees of $45,000 and $30,000 in January 2021 and 2020, respectively. The annual maintenance fee increases by $15,000 per year up to a maximum of $90,000 and ceases on the first sale of product. We also must pay up to an aggregate of $2.1 million in milestone payments, contingent on the achievement of various regulatory and commercial milestones. Under the terms of the license agreement, we also must pay a royalty of mid- to upper-single digit percentages of net sales, depending on the amount of annual sales, and subject to downward adjustment to lower- to mid-single digit percentages in the event there is no valid patent for the product in the United States at the time of sale. After the first sale of product, we will owe an annual minimum royalty payment of $100,000 that will increase annually by $25,000 for the duration of the term. We will be responsible for all patent expenses incurred by Licensor for the term of the agreement although Licensor is responsible for filing, prosecution and maintenance of all patents. The agreement expires on the later of the expiration of the patents or January 2, 2034.

License Agreement with Novellus

On March 31, 2020, we entered into an option agreement with a subsidiary of Novellus, Inc. ("Novellus") whereby we had the opportunity to in-license from Novellus on a worldwide basis, a novel cellular therapy for acute respiratory distress syndrome (ARDS). The option exercise period ran for six months and the option agreement contained the agreed upon financial terms for the license. In April 2020 we paid Novellus $100,000 for the option and recorded it as a research and development expense.

Our Board Chairman Leonard Mazur, who is also our largest stockholder, was a director and significant shareholder of Novellus at this time and until the acquisition of Novellus by Brooklyn ImmunoTherapeutics, Inc. ("Brooklyn") in July 2021. As required by our Code of Ethics, the Audit Committee of our Board of Directors approved the entry into the option agreement with Novellus, as did the disinterested members of our Board of Directors.

On October 6, 2020, our subsidiary, NoveCite, exercised the option and signed an exclusive license agreement with Novellus. Upon execution of the agreement, we paid $5,000,000 to Novellus, which was charged to research and development expense during the year ended September 30, 2021, and issued Novellus shares of NoveCite's common stock representing 25% of the outstanding equity. We own the other 75% of NoveCite's outstanding equity. Pursuant to the terms of the original stock subscription agreement between Novellus and NoveCite, if NoveCite issued additional equity, subject to certain exceptions, NoveCite had to maintain Novellus's ownership at 25% by issuing additional shares to Novellus.

Citius is responsible for the operational activities of NoveCite and bears all costs necessary to operate NoveCite. Citius's officers are also the officers of NoveCite and oversee the business strategy and operations of NoveCite. As such, NoveCite is accounted for as a consolidated subsidiary with a noncontrolling interest.

Novellus has no contractual rights in the profits or obligations to share in the losses of NoveCite, and the Company has not allocated any losses to the noncontrolling interest.

NoveCite is obligated to pay Novellus up to $51,000,000 upon the achievement of various regulatory and developmental milestones. NoveCite also must pay a royalty equal to low double-digit percentages of net sales, commencing upon the sale of a licensed product. This royalty is subject to downward adjustment to an upper-single digit percentage of net sales in any country in the event of the expiration of the last valid patent claim or if no valid patent claim exists in that country. The royalty will end on the earlier of (i) date on which a biosimilar product is first marketed, sold, or distributed in the applicable country or (ii) the 10-year anniversary of the date of expiration of the last-to-expire valid patent claim in that country. In the case of a country where no licensed patent ever exists, the royalty will end on the later of (i) the date of expiry of such licensed product's regulatory exclusivity and (ii) the 10-year anniversary of the date of the first commercial sale of the licensed product in the applicable country. In addition, NoveCite will pay to Novellus an amount equal to a mid-twenties percentage of any sublicensee fees it receives.

Under the terms of the license agreement, in the event that Novellus receives any revenue involving the original cell line included in the licensed technology, then Novellus shall remit to NoveCite 50% of such revenue.

The term of the license agreement will continue on a country-by-country and licensed product-by-licensed product basis until the expiration of the last-to-expire royalty term. Either party may terminate the license agreement upon written notice if the other party is in material default. NoveCite may terminate the license agreement at any time without cause upon 90 days prior written notice.

Novellus will be responsible for preparing, filing, prosecuting and maintaining all patent applications and patents included in the licensed patents in the territory, provided however, that if Novellus decides that it is not interested in maintaining a particular licensed patent or in preparing, filing, or prosecuting a licensed patent, NoveCite will have the right, but not the obligation, to assume such responsibilities in the territory at NoveCite's sole cost and expense.

In July 2021, Novellus was acquired by Brooklyn. In connection with that transaction, the stock subscription agreement between Novellus and NoveCite was amended to assign to Brooklyn all of Novellus's right, title, and interest in the stock subscription agreement and delete the anti-dilution protection and replace it with a right of first refusal whereby Brooklyn will have the right to purchase all or a portion of the securities that NoveCite intends to sell or in the alternative, at the option of NoveCite, Brooklyn may purchase that amount of the securities proposed to be sold by NoveCite to allow Brooklyn to maintain its then percentage ownership.

License Agreement with Eisai

In September 2021, the Company entered into a definitive agreement with Dr. Reddy's Laboratories SA, a subsidiary of Dr. Reddy's Laboratories, Ltd. (collectively, "Dr. Reddy's") to acquire its exclusive license of E7777 (denileukin diftitox), a late-stage oncology immunotherapy for the treatment of CTCL, a rare form of non-Hodgkin lymphoma.

Under the terms of this agreement, Citius acquired Dr. Reddy's exclusive license of E7777 from Eisai Co., Ltd. ("Eisai") and other related assets owned by Dr. Reddy's. Citius's exclusive license include rights to develop and commercialize E7777 in all markets except for Japan and certain parts of Asia. Additionally, Citius retained an option on the right to develop and market the product in India. Eisai retains exclusive development and marketing rights for the agent in Japan and Asia. Citius paid $40 million upfront payment which represents the acquisition date fair value of the in-process research and development acquired from Dr. Reddy's. Dr. Reddy's is entitled to up to $40 million in development milestone payments related to CTCL approvals in the U.S. and other markets, up to $70 million in development milestones for additional indications, as well as commercial milestone payments and low double-digit tiered royalties on net product sales, and up to $300 million for commercial sales milestones. We also must pay on a fiscal quarter basis tiered royalties equal to low double-digit percentages of net product sales. The royalties will end on the earlier of (i) the 15-year anniversary of the first commercial sale of the latest indication that received regulatory approval in the applicable country and (ii) the date on which a biosimilar product results in the reduction of net sales in the applicable product by 50% in two consecutive quarters, as compared to the four quarters prior to the first commercial sale of the biosimilar product. We will also pay to Dr. Reddy's an amount equal to a low-thirties percentage of any sublicense upfront consideration or milestone payments (or the like) received by us and the greater of (i) a low-thirties percentage of any sublicensee sales-based royalties or (ii) a mid-single digit percentage of such licensee's net sales.

Under the license agreement, Eisai is to receive a $6.0 million development milestone payment upon initial approval and additional commercial milestone payments related to the achievement of net product sales thresholds (which increases to $7 million in the event we have exercised our option to add India to the licensed territory prior to FDA approval) and an aggregate of up to $22 million related to the achievement of net product sales thresholds. We also are required to reimburse Eisai for up to $2.65 million of its costs to complete the ongoing Phase 3 pivotal clinical trial for I/ONTAK for the CTCL indication and reimburse Eisai for all reasonable costs associated with the preparation of a BLA for I/ONTAK. Eisai will be responsible for completing the current CTCL clinical trial, and chemistry, manufacturing and controls (CMC) activities through the filing of a BLA for E7777 with the FDA. Citius will be responsible for development costs associated with potential additional indications.

The term of the license agreement will continue until (i) if there has not been a commercial sale of a licensed product in the territory, until the 10-year anniversary of the original license effective date, March 30, 2016, or (ii) if there has been a first commercial sale of a licensed product in the territory within the 10-year anniversary of the original license effective date, the 10-year anniversary of the first commercial sale on a country-by-country basis. The term of the license may be extended for additional 10-year periods for all countries in the territory by notifying Eisai and paying an extension fee equal to $10 million. Either party may terminate the license agreement upon written notice if the other party is in material breach of the agreement, subject to cure within the designated time periods. Either party also may terminate the license agreement immediately upon written notice if the other party files for bankruptcy or takes related actions or is unable to pay its debts as they become due. Additionally, either party will have the right to terminate the agreement if the other party directly or indirectly challenges the patentability, enforceability or validity of any licensed patent.

Also under the agreement with Dr. Reddy's, we are required to (i) use commercially reasonable efforts to make commercially available products in the CTCL indication, peripheral T-cell lymphoma indication and immuno-oncology indication, (ii) initiate two investigator initiated immuno-oncology trials, (iii) use commercially reasonable efforts to achieve each of the approval milestones, and (iv) to complete each specified immuno-oncology investigator trial on or before the four-year anniversary of the effective date of the definitive agreement. Additionally, we are required to commercially launch a product in a territory within six months of receiving regulatory approval for such product in each such jurisdiction.

4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

A summary of the significant accounting policies followed by the Company in the preparation of the consolidated financial statements is as follows:

Use of Estimates

The process of preparing financial statements in conformity with accounting principles generally accepted in the United States of America ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates having relatively higher significance include the accounting for in-process research and development and goodwill impairment, stock-based compensation, valuation of warrants, and income taxes. Actual results could differ from those estimates and changes in estimates may occur.

Cash and Cash Equivalents

The Company considers all highly liquid instruments with maturities of less than three months at the time of purchase to be cash equivalents. From time to time, the Company may have cash balances in financial institutions in excess of insurance limits. The Company has never experienced any losses related to these balances.

Research and Development

Research and development costs, including upfront fees and milestones paid to collaborators who are performing research and development activities under contractual agreements with the Company, are expensed as incurred. The Company defers and capitalizes its nonrefundable advance payments that are for research and development activities until the related goods are delivered or the related services are performed. When the Company is reimbursed by a collaboration partner for work the Company performs, it records the costs incurred as research and development expenses and the related reimbursement as a reduction to research and development expenses in its consolidated statement of operations. Research and development expenses primarily consist of clinical and non-clinical studies, materials and supplies, third-party costs for contracted services, and payments related to external collaborations and other research and development related costs.

In-process Research and Development and Goodwill

In-process research and development of $19,400,000 represents the value of LMB's leading drug candidate (Mino-Lok), which is an antibiotic solution used to treat catheter-related bloodstream infections and is expected to be amortized on a straight-line basis over a period of eight years commencing upon revenue generation.

In-process research and development of $40,000,000 represents the value of our September 2021 acquisition of an exclusive license for E7777 (denileukin diftitox), a late-stage oncology immunotherapy for the treatment of CTCL, a rare form of non-Hodgkin lymphoma and is expected to be amortized on a straight-line basis over a period of twelve years commencing upon revenue generation. Included in the IPR&D is the historical know-how, formula protocols, designs, and procedures expected to be needed to complete Phase 3. In addition, the contracts acquired in connection with Dr. Reddy's transaction with the clinical research and manufacturing organization are at market rates and could be provided by multiple vendors in the marketplace Therefore, there is no fair value associated with the contracts acquired.

Incremental costs incurred on IPR&D after the acquisition date are expensed as incurred, unless there is an alternative future use.

The Company reviews intangible assets annually to determine if any adverse conditions exist or a change in circumstances has occurred that would indicate impairment or a change in the remaining useful life of any intangible asset. If the carrying value of an asset exceeds its undiscounted cash flows, the Company writes down the carrying value of the intangible asset to its fair value in the period identified. No impairment has occurred since the acquisitions through September 30, 2021.

Goodwill represents the value of LMB's industry relationships and its assembled workforce. Goodwill is not amortized but it is tested at least annually for impairment.

The Company evaluates the recoverability of goodwill annually or more frequently if events or changes in circumstances indicate that the carrying value of an asset might be impaired, in accordance with Accounting Standard Update ("ASU") 2017-04, *Intangibles – Goodwill and Other (Topic 350): Simplifying the Accounting for Goodwill Impairment* issued by the Financial Accounting Standards Bureau ("FASB"). Goodwill is first qualitatively assessed to determine whether further impairment testing is necessary. Factors that management considers in this assessment include macroeconomic conditions, industry and market considerations, overall financial performance (both current and projected), changes in management and strategy and changes in the composition or carrying amount of net assets. If this qualitative assessment indicates that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, a one-step test is then performed in accordance with ASU 2017-04. Under the simplified model, a goodwill impairment is calculated as the difference between the carrying amount of the reporting unit and its fair value.

The Company performed a qualitative assessment for its 2021 analysis of goodwill. Based on this assessment, management does not believe that it is more likely than not that the carrying value of the reporting unit exceeds its fair value. Accordingly, no further testing was performed as management believes that there are no impairment issues with respect to goodwill as of September 30, 2021.

Patents and Trademarks

Certain costs of outside legal counsel related to obtaining trademarks for the Company are capitalized. Patent costs are amortized over the legal life of the patents, generally twenty years, starting at the patent issuance date. There are no capitalized patents and trademarks as of September 30, 2021.

The costs of unsuccessful and abandoned applications are expensed when abandoned. The costs of maintaining existing patents are expensed as incurred.

Stock-Based Compensation

The Company recognizes compensation costs resulting from the issuance of stock-based awards to employees and directors as an expense in the consolidated statement of operations over the requisite service period based on the fair value for each stock award on the grant date. The fair value of each option grant is estimated as of the date of grant using the Black-Scholes option pricing model. The Company estimates volatility using the trading activity of its common stock. Because the Company's stock options have characteristics significantly different from those of traded options, and because changes in the input assumptions can materially affect the fair value estimate, the existing model may not necessarily provide a reliable single measure of fair value of the Company's stock options.

The Company recognizes compensation costs resulting from the issuance of stock-based awards to non-employees as an expense in the consolidated statement of operations over the service period based on the measurement of fair value for each stock award and records forfeitures as they occur.

Income Taxes

The Company follows accounting guidance regarding the recognition, measurement, presentation and disclosure of uncertain tax positions in the consolidated financial statements. Tax positions taken or expected to be taken in the course of preparing the Company's tax returns are required to be evaluated to determine whether the tax positions are "more-likely-than-not" of being sustained by the applicable tax authorities. Tax positions not deemed to meet a more-likely-than-not threshold would be recorded in the consolidated financial statements. There are no uncertain tax positions that require accrual or disclosure as of September 30, 2021. Any interest or penalties are charged to expense. During the years ended September 30, 2021 and 2020, the Company did not recognize any interest and penalties. Tax years subsequent to September 30, 2017 are subject to examination by federal and state authorities.

The Company recognizes deferred tax assets and liabilities based on differences between the financial reporting and tax basis of assets and liabilities, and operating loss and tax credit carry forwards. Deferred tax assets and liabilities are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The Company provides a valuation allowance, if necessary, for deferred tax assets for which it does not consider realization of such assets to be "more-likely-than-not." The deferred tax benefit or expense for the period represents the change in the deferred tax asset or liability from the beginning to the end of the period.

Basic and Diluted Net Loss per Common Share

Basic and diluted net loss per common share applicable to common stockholders is computed by dividing net loss applicable to common stockholders in each period by the weighted average number of shares of common stock outstanding during such period. For the periods presented, common stock equivalents, consisting of options and warrants were not included in the calculation of the diluted loss per share because they were anti-dilutive.

Segment Reporting

The Company currently operates as a single segment.

Concentrations of Credit Risk

The Company has no significant off-balance-sheet concentration of credit risk such as foreign exchange contracts, option contracts or other hedging arrangements.

Recently Adopted Accounting Standards

In May 2021, the FASB issued ASU 2021-04 *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options (a consensus of the FASB Emerging Issues Task Force)*. The amendments in this update are effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early application is permitted, including in an interim period as of the beginning of the fiscal year that includes that interim period. The Company adopted the provisions of ASU 2021-04 in the quarter beginning April 1, 2021.

Recently Issued Accounting Standards

In August 2020, FASB issued ASU 2020-06, *Debt — Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which, among other things, provides guidance on how to account for contracts on an entity's own equity. This ASU eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. It also amends the accounting for certain contracts in an entity's own equity that are currently accounted for as derivatives because of specific settlement provisions. In addition, this ASU modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the diluted EPS computation. The amendments in this ASU are effective for the public companies for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. The Company is currently evaluating the impact of ASU 2020-06 on its consolidated financial statements.

In October 2021, the FASB issued ASU No. 2021-08, *Business Combinations (Topic 805): Accounting for Acquired Contract Assets and Contract Liabilities.* Under the new guidance (ASC 805-20-30-28), the acquirer should determine what contract assets and/or contract liabilities it would have recorded under ASC 606 (the revenue guidance) as of the acquisition date, as if the acquirer had entered into the original contract at the same date and on the same terms as the acquiree. The recognition and measurement of those contract assets and contract liabilities will likely be comparable to what the acquiree has recorded on its books under ASC 606 as of the acquisition date. ASU 2021-08 is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. ASU 2021-08 is effective for the Company in the first quarter of fiscal 2024. Early adoption is permitted, including in an interim period, for any period for which financial statements have not yet been issued. However, adoption in an interim period other than the first fiscal quarter requires an entity to apply the new guidance to all prior business combinations that have occurred since the beginning of the annual period in which the new guidance is adopted. The Company is currently evaluating the adoption date of ASU 2021-08 and the impact, if any, adoption will have on its financial position and results of operations.

5. NOTES PAYABLE

Notes Payable – Related Parties

The aggregate principal balance consisted of notes payable held by our Chairman, Leonard Mazur, in the amount of $160,470 and notes payable held by our Chief Executive Officer, Myron Holubiak, in the amount of $12,500. Notes with an aggregate principal balance of $104,000 accrued interest at the prime rate plus 1.0% per annum and notes with an aggregate principal balance of $68,970 accrued interest at 12% per annum.

In June 2021, we repaid the $172,970 principal balance of these notes and paid accrued interest of $38,917. Accrued interest of $59,917 was forgiven and has been recorded as other income during the year ended September 30, 2021.

Interest expense on notes payable – related parties for the years ended September 30, 2021 and 2020 was $9,606 and $14,932, respectively.

Paycheck Protection Program

On April 12, 2020, due to the business disruption caused by the COVID-19 health crisis, the Company applied for a forgivable loan through the Small Business Association's Paycheck Protection Program (the "PPP"). In accordance with the provisions of the PPP, the loan accrued interest at a rate of 1% and a portion of the loan may be forgiven if it is used to pay qualifying costs such as payroll, rent and utilities. Amounts that are not forgiven will be repaid two years from the date of the loan. On April 15, 2020, the Company received $164,583 from the PPP through its bank.

Interest expense on the PPP loan was $1,233 and $741 for the years ended September 30, 2021 and 2020, respectively.

On July 28, 2021, the Small Business Administration ("SBA") gave full forgiveness of the PPP loan. The Company recorded a gain from debt extinguishment of $166,557 consisting of the principal balance and related accrued interest expense.

6. COMMON STOCK, STOCK OPTIONS AND WARRANTS

Authorized Common Stock

On June 21, 2021, our stockholders approved an amendment to our Articles of Incorporation to increase the authorized number of shares of capital stock from 210,000,000 to 410,000,000 and the authorized number of common shares from 200,000,000 to 400,000,000.

Common Stock Issued for Services

On November 4, 2019, the Company issued 186,566 shares of common stock for strategic consulting and corporate development services and expensed the $100,000 fair value of the common stock issued.

On February 10, 2020, the Company issued 150,000 shares of common stock for investor relations services and 136,000 shares of common stock for general advisory and business development advisory services. The Company expensed the $306,020 fair value of the common stock issued.

On April 6, 2020, the Company issued 50,000 shares of common stock for strategic consulting and corporate development services and expensed the $22,750 fair value of the common stock issued.

On September 8, 2020, the Company issued 101,174 shares of common stock for investor relations services and expensed the $100,000 fair value of the common stock issued.

On February 12, 2021, the Company issued 50,000 shares of common stock for investor relations services and expensed the $68,000 fair value of the common stock issued.

Common Stock Offerings

On May 18, 2020, the Company closed a registered direct offering with several institutional and accredited investors for the sale of 7,058,824 shares of common stock at $1.0625 per share for gross proceeds of $7,500,001. The Company also issued 3,529,412 unregistered immediately exercisable warrants to the investors with an exercise price of $1.00 per share and a term of five and one-half years. The Company paid the placement agent for the offering a fee of 7% of the gross proceeds totaling $525,000 and issued the placement agent 494,118 immediately exercisable warrants with an exercise price of $1.3281 per share and a term of five years. The Company also reimbursed the placement agent for $85,000 in expenses and incurred $12,901 in other expenses. Net proceeds from the offering were $6,877,100. The estimated fair value of the 3,529,412 warrants issued to the investors was $2,138,998 and the estimated fair value of the 494,118 warrants issued to the placement agent was $275,724.

On August 10, 2020, the Company closed an underwritten public offering of 9,159,524 shares of common stock at a price of $1.05 per share for gross proceeds of $9,617,500. The Company paid the underwriter a fee of 7% of the gross proceeds totaling $673,225 and issued the underwriters 641,166 immediately exercisable warrants with an exercise price of $1.3125 per share and a term of five years. The Company also reimbursed the placement agent for $135,000 in expenses and incurred $109,074 in other expenses. Net proceeds from the offering were $8,700,201. The estimated fair value of the 641,166 warrants issued to the underwriter was $569,426.

On January 27, 2021, the Company closed a private placement for 15,455,960 common shares and warrants to purchase 7,727,980 common shares, at a purchase price of $1.294 per common share and accompanying warrant, for gross proceeds of $20,000,012. The 7,727,980 warrants are immediately exercisable at $1.231 per common share for a term of five and one-half years. The Company paid the placement agent a fee of 7% of the gross proceeds totaling $1,400,001 and issued the placement agent 1,081,917 immediately exercisable warrants at $1.6175 per common share for a term of five and one-half years. The Company also reimbursed the placement agent for $85,000 in expenses and incurred $64,601 in other expenses. Net proceeds from the offering were $18,450,410. The estimated fair value of the 7,727,980 warrants issued to the investors was approximately $7,582,000 and the estimated fair value of the 1,081,917 warrants issued to the placement agent was approximately $1,025,000.

On February 19, 2021, the Company closed a registered direct offering for 50,830,566 common shares and warrants to purchase up to 25,415,283 common shares, at a purchase price of $1.505 per share of common stock and accompanying warrant, for gross proceeds of $76,500,002. The 25,415,283 warrants are immediately exercisable at $1.70 per common share for a term of five years. The Company paid the placement agent a fee of 7% of the gross proceeds totaling $5,355,000 and issued the placement agent 3,558,140 immediately exercisable warrants at $1.881 per common share for a term of five years. The Company also reimbursed the placement agent for $85,000 in expenses and incurred $80,160 in other expenses. Net proceeds from the offering were $70,979,842. The estimated fair value of the 25,415,283 warrants issued to the investors was approximately $42,322,000 and the estimated fair value of the 3,558,140 warrants issued to the placement agent was approximately $5,850,000.

Stock Option Plans

Pursuant to its 2014 Stock Incentive Plan, we reserved 866,667 shares of common stock for issuance to employees, directors and consultants. As of September 30, 2021, there were options to purchase 855,171 shares outstanding, options to purchase 4,829 shares were exercised, options to purchase 6,667 shares expired, and no shares were available for future grants.

On February 7, 2018, our stockholders approved the 2018 Omnibus Stock Incentive Plan and we reserved 2,000,000 shares of common stock for issuance to employees, directors and consultants. As of September 30, 2021, there were options to purchase 1,820,000 shares outstanding, options to purchase 70,000 shares were exercised and the remaining 110,000 shares were transferred to the 2020 Omnibus Stock Incentive Plan ("2020 Plan").

On February 10, 2020, our stockholders approved the 2020 Plan and we reserved 3,110,000 common shares. As of September 30, 2021, there were options to purchase 1,870,000 shares outstanding and the remaining 1,240,000 shares were transferred to the 2021 Omnibus Stock Incentive Plan ("2021 Stock Plan").

On May 24, 2021, our stockholders approved the 2021 Stock Plan and we reserved 8,740,000 shares. The 2021 Stock Plan provides incentives to employees, directors, and consultants through options, SARs, dividend equivalent rights, restricted stock, restricted stock units, or other rights. As of September 30, 2021, options to purchase 1,210,000 shares were outstanding and there were 7,530,000 shares available for future grants.

The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option pricing model. Volatility is estimated using the trading activity of our common stock. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected term assumption. The expected term of stock options granted to employees and directors, all of which qualify as "plain vanilla," is based on the average of the contractual term (generally 10 years) and the vesting period. For non-employee options, the expected term is the contractual term.

The following assumptions were used in determining the fair value of stock option grants for the years ended September 30, 2021 and 2020:

	2021	2020
Risk-free interest rate	0.32 – 0.89%	0.26 – 1.66%
Expected dividend yield	0.00%	0.00%
Expected term	6.50 – 10 years	6.50 – 10 years
Expected volatility	111 – 112%	107 – 117%

A summary of option activity under the plans (excluding the NoveCite Stock Plan) is presented below:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at September 30, 2020	3,390,171	$ 2.51	8.00 years	$ 440,336
Granted	2,435,000	1.57		
Exercised	(70,000)	1.18		$ 101,866
Forfeited or expired	—	9.0		
Outstanding at September 30, 2021	5,755,171	$ 2.13	8.02 years	$ 3,589,392
Exercisable at September 30, 2021	2,499,635	$ 3.10	6.56 years	$ 1,429,358

The weighted average grant date fair value of the options granted during the year ended September 30, 2020 was estimated at $0.76 per share. All of these options vest over terms of 12 to 36 months and have a term of 10 years.

The weighted average grant date fair value of the options granted during the year ended September 30, 2021 was estimated at $1.34 per share. All of these options vest over terms of 12 to 36 months and have a term of 10 years.

Stock-based compensation expense for the years ended September 30, 2021 and 2020 was $1,454,979 (including $83,555 for the NoveCite Stock Plan) and $803,261, respectively.

At September 30, 2021, unrecognized total compensation cost related to unvested awards under the Citius stock plans of $3,012,685 is expected to be recognized over a weighted average period of 2.34 years.

On November 5, 2020, the stockholders of NoveCite, Inc., approved NoveCite's Stock Plan and under which 2,000,000 common shares of NoveCite were reserved. The NoveCite Stock Plan provides incentives to employees, directors, and consultants through grants of options, SARs, dividend equivalent rights, restricted stock, restricted stock units, or other rights. As of September 30, 2021, there were options outstanding to purchase 2,000,000 common shares of NoveCite and no common shares of NoveCite available for future grants.

During the year ended September 30, 2021, NoveCite granted options to purchase 2,000,000 common shares to employees at a weighted average exercise price of $0.24 per share, of which none are exercisable as of September 30, 2021. The weighted average grant date fair value of the options granted during the year ended September 30, 2021 was estimated at $0.20 per share. All of these options vest over 36 months and have a term of 10 years. The weighted average remaining contractual term of options outstanding under the NoveCite Stock Plan is 9.39 years. At September 30, 2021, unrecognized total compensation cost related to unvested awards under the NoveCite Stock Plan of $316,445 is expected to be recognized over a weighted average period of 2.42 years.

Warrants

The Company has reserved 40,208,347 shares of common stock for the exercise of outstanding warrants. The following table summarizes the warrants outstanding at September 30, 2021:

	Exercise price	Number	Expiration Dates
LMB Warrants	$ 7.50	53,110	March 24 – April 29, 2022
2016 Offering Warrants	4.13	140,819	November 23, 2021 – February 27, 2022
2017 Public Offering Investors	4.13	1,622,989	August 2, 2022
2017 Public Offering Underwriter	4.54	65,940	February 2, 2023
December 2017 Registered Direct/Private Placement Offering Investors	4.63	640,180	June 19, 2023
December 2017 Registered Direct/Private Placement Offering Placement Agent	5.87	89,625	December 19, 2022
March 2018 Registered Direct/Private Placement Offering Investors	2.86	218,972	October 2, 2023
March 2018 Registered Direct/Private Placement Offering Placement Agent	3.73	46,866	March 28, 2023
August 2018 Offering Investors	1.15	3,921,569	August 14, 2023
August 2018 Offering Agent	1.59	189,412	August 8, 2023
April 2019 Registered Direct/Private Placement Offering Investors	1.42	1,294,498	April 5, 2024
April 2019 Registered Direct/Private Placement Offering Placement Agent	1.93	240,130	April 5, 2024
September 2019 Offering Investors	0.77	2,793,297	September 27, 2024
September 2019 Offering Underwriter	1.12	194,358	September 27, 2024
February 2020 Exercise Agreement Placement Agent	1.28	138,886	August 19, 2025
May 2020 Registered Direct Offering Investors	1.00	1,670,588	November 18, 2025
May 2020 Registered Direct Offering Placement Agent	1.33	155,647	May 14, 2025
August 2020 Underwriter	1.31	201,967	August 10, 2025
January 2021 Registered Direct Offering Investors	1.23	3,091,192	July 27, 2026
January 2021 Registered Direct Offering Agent	1.62	351,623	July 27, 2026
February 2021 Offering Investors	1.70	20,580,283	February 19, 2026
February 2021 Offering Agent	1.88	2,506,396	February 19, 2026
		40,208,347	

In December 2019, 1,060,615 of the September 2019 Offering Pre-Funded Unit Warrants were exercised at $0.0001 per share for net proceeds of $106.

In January 2020, 1,315,715 of the September 2019 Offering Investor Warrants were exercised at $0.77 per share for net proceeds of $1,013,101.

On February 14, 2020, the Company entered into a warrant exercise agreement for an aggregate of 3,712,218 shares of common stock having an existing exercise price of $0.77 and 2,586,455 shares of common stock at a reduced exercise price of $1.02. In consideration for the exercise of the warrants for cash, the exercising holders received new unregistered warrants to purchase 6,298,673 shares of common stock at an exercise price of $1.02 per share, exercisable six months after issuance and which have a term of exercise equal to five years. The offering closed on February 19, 2020 and net proceeds were $5,013,930 after placement agent fees and offering expenses. The Company also issued warrants to purchase 440,907 shares to the placement agent. The placement agent warrants have identical terms to the investor warrants except that the exercise price is $1.275 per share. The estimated fair value of the 6,298,673 warrants issued to the investors was $5,360,465 and the estimated fair value of the 440,907 warrants issued to the placement agent was $367,022.

On June 26, 2020, 1,129,412 of the May 2020 Registered Direct Offering Investor Warrants were exercised at $1.00 per share for net proceeds of $1,129,412.

In April 2021, we extended the term by three years to April 5, 2024 for 1,294,498 warrants for common stock with an exercise price of $1.42 per share and 240,130 warrants with an exercise price of $1.93 per share. We recorded a deemed dividend of $1,450,876 based on the excess of the fair value of the modified warrants over the fair value of the warrants before the modification, the effect of which was an increase in the net loss attributable to common shareholders in the statement of operations for the year ended September 30, 2021.

During the year ended September 30, 2021, we received $31,130,134 in proceeds from the exercise of common stock warrants.

At September 30, 2021, the weighted average remaining life of all of the outstanding warrants is 3.74 years, all warrants are exercisable, and the aggregate intrinsic value for the warrants outstanding was $19,903,185.

Common Stock Reserved

A summary of common stock reserved for future issuances as of September 30, 2021 is as follows:

Stock plan options outstanding	5,755,171
Stock plan shares available for future grants	7,530,000
Warrants outstanding	40,208,347
Total	53,493,518

7. RELATED PARTY TRANSACTIONS

The Company had outstanding debt due to Leonard Mazur (Chairman of the Board) and Myron Holubiak (Chief Executive Officer) (see Note 5).

Mr. Mazur was a director and significant shareholder of Novellus, Inc. until July 2021. On October 6, 2020, the Company, through its subsidiary NoveCite, entered into an exclusive agreement with Novellus to develop cellular therapies (see Note 3).

In April 2021, we extended the term by three years for 1,294,498 warrants held by our Chairman and our Chief Executive Officer (see Note 6).

8. EMPLOYMENT AND CONSULTING AGREEMENTS

Employment Agreements

On October 19, 2017, the Company and its Chairman of the Board, Leonard Mazur, entered into an employment agreement with a three-year term. Upon expiration, the agreement automatically renews for successive periods of one-year unless terminated pursuant to its terms. Under the terms of the agreement, the Company is required to pay base compensation plus incentives over the employment term plus severance benefits upon the occurrence of certain events as described in the agreement.

On March 30, 2016, the Company entered into a three-year employment agreement with Myron Holubiak to serve as Chief Executive Officer. Upon expiration, the agreement automatically renews for successive periods of one-year unless terminated pursuant to its terms. The agreement requires the Company to pay base compensation plus incentives over the employment term plus severance benefits upon the occurrence of certain events as described in the agreement.

On July 13, 2020, Citius entered into an employment agreement with Myron Czuczman, M.D. to serve as Executive Vice President, Chief Medical Officer. The agreement requires the Company to pay base compensation plus incentives over the employment term plus severance benefits upon the occurrence of certain events as described in the agreement. Dr. Czuczman was granted an option to purchase 500,000 shares of common stock.

The Company has employment agreements with certain other employees that require the Company to pay base compensation plus incentives over the employment term plus severance benefits upon the occurrence of certain events as described in the agreement.

Consulting Agreements

Effective September 1, 2014, the Company entered into three consulting agreements. Two of the agreements were for financial services including accounting, preparation of financial statements and filings with the SEC. The third agreement was for financing activities, product development strategies and corporate development. The agreements may be terminated by the Company or the consultant with 90 days written notice. A consulting agreement for financial services ended in February 2019 and the agreement for financing activities, product development strategies and corporate development ended in December 2020.

Consulting expense under the agreements for the years ended September 30, 2021 and 2020 was $144,000 and $324,000, respectively.

9. FDA REFUND

In November 2019, the Company received a $110,207 refund from the FDA for 2016 product and establishment fees because the fees paid by the Company exceeded the costs of the FDA's review of the associated applications. The Company recorded the $110,207 as other income during the year ended September 30, 2020.

10. COMMITMENTS AND CONTINGENCIES

Operating Lease

Effective July 1, 2019, Citius entered into a 76-month lease for office space in Cranford, NJ. Citius will pay its proportionate share of real estate taxes and operating expenses in excess of the base year expenses. These costs are considered to be variable lease payments and are not included in the determination of the lease's right-of-use asset or lease liability.

The Company identified and assessed the following significant assumptions in recognizing its right-of-use assets and corresponding lease liabilities:

- As the Company's Cranford lease does not provide an implicit rate, the Company estimated the incremental borrowing rate in calculating the present value of the lease payments. The Company has estimated its incremental borrowing rate based on the remaining lease term as of the adoption date.

- Since the Company elected to account for each lease component and its associated non-lease components as a single combined component, all contract consideration was allocated to the combined lease component.

- The expected lease terms include noncancelable lease periods.

The elements of lease expense are as follows:

Lease cost	Year Ended September 30, 2021	Year Ended September 30, 2020
Operating lease cost	$ 238,824	$ 228,828
Variable lease cost	194	—
Total lease cost	$ 239,018	$ 228,828
Other information		
Weighted-average remaining lease term - operating leases	4.1 Years	5.1 Years
Weighted-average discount rate - operating leases	8.0%	8.0%

Maturities of lease liabilities due under the Company's non-cancellable leases are as follows:

Year Ending September 30,	
2022	$ 239,306
2023	244,165
2024	249,024
2025	253,883
Thereafter	21,460
Total lease payments	1,007,838
Less: interest	(152,367)
Present value of lease liabilities	$ 855,471

Leases	Classification	September 30, 2021	September 30, 2020
Assets			
Lease asset	Operating	$ 822,828	$ 986,204
Total lease assets		$ 822,828	$ 986,204
Liabilities			
Current	Operating	$ 177,237	$ 158,999
Non-current	Operating	678,234	855,471
Total lease liabilities		$ 855,471	$ 1,014,470

Interest expense on the lease liability was $75,448 and $87,303 for the years ended September 30, 2021 and 2020, respectively.

Legal Proceedings

The Company is not involved in any litigation that it believes could have a material adverse effect on its financial position or results of operations. There is no action, suit, proceeding, inquiry or investigation before or by any court, public board, government agency, self-regulatory organization or body pending or, to the knowledge of the Company's executive officers, threatened against or affecting the Company or its officers or directors in their capacities as such.

11. INCOME TAXES

There was no provision for federal or state income taxes for the years ended September 30, 2021 and 2020 due to the Company's operating losses and the valuation reserve on deferred tax assets.

The income tax benefit differs from the amount of income tax determined by applying the U.S. federal income tax rate to pretax income for the years ended September 30, 2021 and 2020 due to the following:

	2021	2020
Computed "expected" tax benefit	(21.0)%	(21.0)%
Increase (decrease) in income taxes resulting from:		
State taxes, net of federal benefit	(6.3)%	(6.3)%
Permanent differences	0.7%	0.7%
Increase in the valuation reserve	26.6%	26.6%
	0.0%	0.0%

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities are as follows:

	September 30, 2021	September 30, 2020
Deferred tax assets:		
Net operating loss carryforward	$ 25,508,000	$ 14,498,000
Stock-based compensation	1,105,000	915,000
Other	2,564,000	1,507,000
Valuation allowance on deferred tax assets	(29,177,000)	(16,920,000)
Total deferred tax assets	—	—
Deferred tax liabilities:		
In-process research and development	(4,985,800)	(4,985,800)
Total deferred tax liability	(4,985,800)	(4,985,800)
Net deferred tax liability	$ (4,985,800)	$ (4,985,800)

The Company has recorded a valuation allowance against deferred tax assets as the utilization of the net operating loss carryforward and other deferred tax assets is uncertain. During the years ended September 30, 2021 and 2020, the valuation allowance increased by $12,257,000 and $3,591,000, respectively. The increase in the valuation allowance during the years ended September 30, 2021 and 2020 was primarily due to the Company's net operating loss. At September 30, 2021, the Company has a federal net operating loss carryforward of approximately $88,000,000. Federal net operating loss carryforwards of approximately $35,000,000 begin expiring in 2034 and carryforwards of approximately $53,000,000 generated in tax years beginning after 2017 may be carried forward indefinitely.

As of September 30, 2021, the Company also has estimated federal research and development credits of $2,044,000 to offset future income taxes. The tax credit carryforwards will begin to expire in 2036.

The Company accounts for uncertain tax positions in accordance with the guidance provided in ASC 740, "Accounting for Income Taxes." This guidance describes a recognition threshold and measurement attribute for the financial statement disclosure of tax positions taken or expected to be taken in a tax return and requires recognition of tax benefits that satisfy a more-likely-than-not threshold. ASC 740 also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods and disclosure. There have been no reserves for uncertain tax positions recorded by the Company to date.

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

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to provide reasonable assurance that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the specified time periods and accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding disclosure.

Our Chief Executive Officer (who is our principal executive officer) and Chief Financial Officer (who is our principal financial officer and principal accounting officer), evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Exchange Act) as of September 30, 2021, the end of our fiscal year. In designing and evaluating disclosure controls and procedures, we recognize that any disclosure controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objective. As of September 30, 2021, based on the evaluation of these disclosure controls and procedures, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining effective internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. Because of its inherent limitations, internal control over financial reporting is not intended to provide absolute assurance that a misstatement of our financial statements would be prevented or detected. Under the supervision of our Chief Executive Officer and Chief Financial Officer, the Company conducted an evaluation of the effectiveness of our internal control over financial reporting as of September 30, 2021 using the criteria established in Internal Control—*Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") (2013 Framework).

Based on this evaluation, management has concluded that our internal controls were effective and that we maintained effective controls over our financial reporting as of September 30, 2021.

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

Changes in Internal Controls over Financial Reporting

There were no changes in our internal controls over financial reporting during the fourth quarter of fiscal 2021 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

We have adopted a written Code of Ethics and Business Conduct that applies to our directors, officers and all employees. We intend to disclose any amendments to, or waivers from, our code of ethics and business conduct that are required to be publicly disclosed pursuant to rules of the SEC by filing such amendment or waiver with the SEC. This code of ethics and business conduct can be found in the "Investors - Corporate Governance" section of our website, *www.citiuspharma.com*.

The other information required by this Item concerning our directors and executive officers is incorporated by reference to the section captioned "Proposal No. 1—Election of Directors" and "Corporate Governance" to be contained in our proxy statement related to the 2022 Annual Meeting of Stockholders (the "Proxy Statement"), which information is expected to be filed with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K. The information required by this Item concerning compliance with Section 16(a) of the Exchange Act by our directors, executive officers and persons who own more than 10% of our outstanding common stock is incorporated by reference from the section captioned "Section 16(a) Beneficial Ownership Reporting Compliance" to be contained in the Proxy Statement.

Item 11. Executive Compensation

The information required by this Item concerning directors and executive compensation is incorporated by reference from the sections captioned "Director Compensation" and "Executive Compensation", respectively, to be contained in the Proxy Statement.

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

The following table sets forth the indicated information as of September 30, 2021 with respect to our equity compensation plans:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders			
2014 Stock Incentive Plan	855,171	$ 6.65	—
2018 Omnibus Stock Incentive Plan	1,820,000	1.08	—
2020 Omnibus Stock Incentive Plan	1,870,000	1.13	—
2021 Omnibus Stock Incentive Plan	1,210,000	2.07	7,530,000
Total	5,755,171	$ 2.13	7,530,000

Our equity compensation plans consist of the Citius Pharmaceuticals, Inc. 2021 Omnibus Stock Incentive Plan, 2020 Omnibus Stock Incentive Plan, 2018 Omnibus Stock Incentive Plan and 2014 Stock Incentive Plan, which were all approved by our stockholders. We do not have any equity compensation plans or arrangements that have not been approved by our stockholders.

We no longer may grant awards under the 2014 Stock Incentive Plan, the 2018 Omnibus Stock Incentive Plan or 2020 Omnibus Stock Incentive Plan.

The other information required by this Item is incorporated by reference to the information under the section captioned "Security Ownership of Certain Beneficial Owners and Management" to be contained in the Proxy Statement.

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

The information required by this Item is incorporated by reference to the information under the section captioned "Certain Relationships and Related Transactions" and "Proposal No. 1—Election of Directors" to be contained in the Proxy Statement.

Item 14. Principal Accountant Fees and Services

The information required by this Item is incorporated by reference to the information under the section captioned "Auditor and Audit Committee Matters" to be contained in the Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
3.1	Amended and Restated Articles of Incorporation of Citius Pharmaceuticals, Inc.	8-K	9/18/2014	3.1	
3.2	Certificate of Amendment to the Amended and Restated Articles of Incorporation of Citius Pharmaceuticals, Inc., effective September 16, 2016.	8-K	9/21/2016	3.1	
3.3	Certificate of Amendment to the Amended and Restated Articles of Incorporation of Citius Pharmaceuticals, Inc., effective June 9, 2017.	8-K	6/8/2017	3.1	
3.4	Certificate of Amendment to the Articles of Incorporation of Citius Pharmaceuticals Inc., dated June 21, 2021.	8-K/A	6/22/2021	3.1	
3.5	Amended and Restated Bylaws of Citius Pharmaceuticals, Inc.	8-K	2/9/2018	3.1	
4.1	Form of Registration Rights Agreement between the Purchasers named therein and Citius Pharmaceuticals Holdings, Inc., dated September 12, 2014.	8-K	9/18/2014	10.2	
4.2	Form of Investor Warrant, dated September 12, 2014.	8-K	9/18/2014	10.3	
4.3	Form of Common Stock Purchase Warrant, dated May 10, 2017.	10-Q	5/15/2017	10.4	
4.4	Form of Representative's Warrant, dated August 3, 2017.	8-K	8/4/2017	4.2	
4.5	Form of Investor Warrant, dated December 15, 2017.	8-K	12/19/2017	4.1	
4.6	Form of Placement Agent Warrant, dated December 15, 2017.	8-K	12/19/2017	4.2	
4.7	Form of Investor Warrant, dated March 28, 2018.	8-K	3/29/2018	4.1	
4.8	Form of Placement Agent Warrant, dated March 28, 2018.	8-K	3/29/2018	4.2	
4.9	Form of Common Stock Purchase Warrant, dated August 13, 2018.	8-K	8/13/2018	4.1	
4.10	Form of Pre-Funded Common Stock Purchase Warrant, dated August 13, 2018.	8-K	8/13/2018	4.2	
4.11	Form of Underwriter's Common Stock Purchase Warrant, dated August 13, 2018.	8-K	8/13/2018	4.3	
4.12	Form of Investor Warrant issued April 3, 2019.	8-K	4/03/2019	4.1	
4.13	Form of Placement Agent Warrant issued April 3, 2019.	8-K	4/03/2019	4.2	
4.14	Form of Common Stock Purchase Warrant issued September 27, 2019.	8-K	9/27/2019	4.1	
4.15	Form of Underwriters Common Stock Purchase Warrant issued September 27, 2019.	8-K	9/27/2019	4.3	
4.16	Form of Investor Warrant issued on February 19, 2020.	8-K	2/19/2020	4.1	
4.17	Form of Placement Agent Warrant issued on February 19, 2020.	8-K	2/19/2020	4.2	
4.18	Form of Investor Warrant issued May 18, 2020.	8-K	5/18/2020	4.1	
4.19	Form of Placement Agent Warrant issued May 18, 2020.	8-K	5/18/2020	4.2	
4.20	Form of Underwriter Warrant issued August 10, 2020.	8-K	8/10/2020	4.1	
4.21	Form of investor warrant issued January 27, 2021.	8-K	1/27/2021	4.1	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
4.22	Form of placement agent warrant issued January 27, 2021.	8-K	1/27/2021	4.2	
4.23	Form of Registration Rights Agreement, dated January 24, 2021, by and between Citius Pharmaceuticals, Inc. and the purchasers signatory thereto.	8-K	1/27/2021	4.3	
4.24	Form of investor warrant issued February 19, 2021.	8-K	2/19/2021	4.1	
4.25	Form of placement agent warrant issued February 19, 2021	8-K	2/19/2021	4.2	
10.1	Citius Pharmaceuticals, Inc. 2014 Stock Incentive Plan.	10-Q	8/15/2016	10.1	
10.2	Form of Citius Pharmaceuticals, Inc. 2014 Stock Incentive Plan Nonqualified Stock Option.	10-Q	8/15/2016	10.2	
10.3	Employment Agreement between Myron Holubiak and Citius Pharmaceuticals, Inc., executed March 30, 2016, effective March 1, 2016.	8-K	4/5/2016	10.1	
10.4	Second Amendment to the Patent and Technology License Agreement between Novel Anti-Infective Technologies, LLC and Leonard-Meron Biosciences, Inc., dated March 20, 2017.	10-Q	5/15/2017	10.8	
10.5	Future Advance Convertible Promissory Note between Leonard Mazur and Citius Pharmaceuticals, Inc., dated May 10, 2017.	10-Q	5/15/2017	10.1	
10.6	Amended and Restated Demand Convertible Promissory Note between Leonard Mazur and Citius Pharmaceuticals, Inc., dated May 10, 2017.	10-Q	5/15/2017	10.3	
10.7	Warrant Agent Agreement between VStock Transfer, LLC and Citius Pharmaceuticals, Inc., dated August 3, 2017.	8-K	8/4/2017	4.1	
10.8	Amended and Restated Employment Agreement between Leonard Mazur and Citius Pharmaceuticals, Inc., dated October 19, 2017.	10-K	12/11/2018	10.23	
10.9	Employment Agreement between Jaime Bartushak and Citius Pharmaceuticals, Inc., dated November 27, 2017.	8-K	12/1/2017	10.1	
10.10	Form of Securities Purchase Agreement between Citius Pharmaceuticals, Inc. and the purchasers named therein, dated December 15, 2017.	8-K	12/19/2017	10.1	
10.11	Citius Pharmaceuticals, Inc. 2018 Omnibus Stock Incentive Plan	10-Q	2/14/2018	10.2	
10.12	Form of Securities Purchase Agreement between Citius Pharmaceuticals, Inc. and the purchasers named therein, dated March 28, 2018.	8-K	3/29/2018	10.1	
10.13+	Patent and Technology License Agreement, dated January 2, 2019, between the Board of Regents of the University of Texas System on behalf of the University of Texas M. D. Anderson Cancer Center and Citius Pharmaceuticals, Inc.	10-Q	2/14/2019	10.1	
10.14	First Amendment, dated October 15, 2015, to Patent and Technology License Agreement, dated May 14, 2014, between Novel Anti-Infective Technologies, LLC and Leonard-Meron Biosciences, Inc.	10-Q	2/14/2019	10.2	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
10.15+	Patent and Technology License Agreement, dated May 14, 2014, between Novel Anti-Infective Technologies, LLC and Leonard-Meron Biosciences, Inc.	10-Q	2/14/2019	10.3	
10.16	Form of Securities Purchase Agreement, dated April 1, 2019, by and between Citius Pharmaceuticals, Inc. and the purchasers named therein.	8-K	4/03/2019	10.1	
10.17	Citius Pharmaceuticals, Inc. 2020 Omnibus Stock Incentive Plan.	Schedule 14A	12/20/2019	Appendix A	
10.18	Form of Notice of Stock Option Grant and Stock Option Award Agreement.	10-Q	2/13/2020	10.2	
10.19	Form of Warrant Exercise Agreement, dated February 14, 2020, by and between Citius Pharmaceuticals, Inc. and the investor signatory thereto.	8-K	2/19/2020	10.1	
10.20	Form of Warrant Exercise Agreement, dated February 14, 2020, by and between Citius Pharmaceuticals, Inc. and the investor signatory thereto.	8-K	2/19/2020	10.2	
10.21	Form of Securities Purchase Agreement, dated May 14, 2020, by and between Citius Pharmaceuticals, Inc. and the purchasers signatory thereto.	8-K	5/18/2020	10.1	
10.22	Engagement letter, dated February 14, 2020, between Citius Pharmaceuticals, Inc. and the purchasers signatory thereto.	8-K	5/18/2020	10.2	
10.23	Employment Agreement, effective as of July 14, 2020, between Citius Pharmaceuticals, Inc. and Myron Czuczman.	10-Q	8/14/2020	10.3	
10.24	License Agreement, dated October 6, 2020, between NoveCite, Inc. and Novellus Therapeutics, Limited.+	10-K	12/16/2020	10.24	
10.25	Form of Securities Purchase Agreement, dated January 24, 2021, by and between Citius Pharmaceuticals, Inc. and the purchasers signatory thereto.	8-K	1/27/2021	10.1	
10.26	Engagement letter, dated January 23, 2021, between Citius Pharmaceuticals, Inc. and H. C. Wainwright & Co., LLC	8-K	1/27/2021	10.2	
10.27	Form of Securities Purchase Agreement, dated February 16, 2021, by and between Citius Pharmaceuticals, Inc. and the purchasers signatory thereto.	8-K	2/19/2021	10.1	
10.28	Citius Pharmaceuticals, Inc. 2021 Omnibus Incentive Stock Plan.	Schedule 14A	4/12/2021	Appendix B	
10.29	Form of Notice of Stock Option Grant and Stock Option Award Agreement.				X
10.30+	Asset Purchase Agreement, dated as of September 1, 2021, between Dr. Reddy's Laboratories S.A. and Citius Pharmaceuticals, Inc.				X
10.31+	Amended and Restated License, Development and Commercialization Agreement, dated as of February 26, 2018, between Eisai, Ltd. and Dr. Reddy's Laboratories S.A.				X

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
10.32+	Amendment to Amended and Restated License, Development and Commercialization Agreement, dated as of August 9, 2018, between Eisai, Ltd. and Dr. Reddy's Laboratories S.A.				X
10.33+	Amendment No. 2 to Amended and Restated License, Development and Commercialization Agreement, dated as of August 31, 2021, between Eisai, Ltd. and Dr. Reddy's Laboratories S.A.				X
21	Subsidiaries.	--	--	--	X
23.1	Consent of Independent Registered Public Accounting Firm.	--	--	--	X
31.1	Certification of the Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a).	--	--	--	X
31.2	Certification of the Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a).	--	--	--	X
32.1	Certification of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.	--	--	--	X
101.INS	Inline XBRL Instance Document	--	--	--	X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	--	--	--	X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	--	--	--	X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	--	--	--	X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	--	--	--	X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	--	--	--	X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).	--	--	--	X

+ Portions of this exhibit have been omitted pursuant to Item 601(b)10 of Regulation S-K.

Item 16. Form 10-K Summary.

Not applicable.

SIGNATURES

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

CITIUS PHARMACEUTICALS, INC.

Date: December 15, 2021

By: /s/ Myron Holubiak
Myron Holubiak
President and Chief Executive Officer
(Principal Executive Officer)

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	Date
/s/ Leonard Mazur Leonard Mazur	Executive Chairman of the Board of Directors	December 15, 2021
/s/ Myron Holubiak Myron Holubiak	President and Chief Executive Officer and Director (Principal Executive Officer)	December 15, 2021
/s/ Jaime Bartushak Jaime Bartushak	Chief Financial Officer and Chief Accounting Officer (Principal Financial Officer and Principal Accounting Officer)	December 15, 2021
/s/ Suren Dutia Suren Dutia	Director	December 15, 2021
/s/ Carol Webb Carol Webb	Director	December 15, 2021
/s/ William Kane William Kane	Director	December 15, 2021
/s/ Howard Safir Howard Safir	Director	December 15, 2021
/s/ Eugene Holuka Eugene Holuka	Director	December 15, 2021

CITIUS PHARMACEUTICALS, INC.
2021 OMNIBUS STOCK INCENTIVE PLAN

NOTICE OF STOCK OPTION GRANT

_____

_____

_____

(Grantee name and address)

You have been granted an option to purchase shares of the Common Stock of Citius Pharmaceuticals, Inc. (the "**Company**") as follows, subject to the terms of the Citius Pharmaceuticals, Inc. 2021 Omnibus Stock Incentive Plan (the "**Plan**") and the attached Stock Option Award Agreement.

Date of Grant: _____

Vesting Commencement Date: _____

Exercise Price per Share: _____

Total Number of Shares Subject to Option: _____

Total Exercise Price: _____

Type of Option: _____ Incentive Stock Option (ISO)

_____ Non-Statutory Stock Option (NSO)

Note: If the Option is designated a Non-Statutory Stock Option above, or if the Option otherwise fails to qualify as an incentive stock option pursuant to Section 422 of the Code, then this Option will not be treated as an incentive stock option within the meaning of Section 422 of the Code.

Term/Expiration Date: 10 Years/ _____

Vesting Schedule: Subject to the Plan and the Stock Option Award Agreement, this Option may be exercised, in whole or in part, in accordance with the following schedule:

[EXAMPLE FOR EMPLOYEES: The Option will vest as to 1/36th of the shares subject to the Option on the last day of each month for a period of thirty-six (36) months beginning with the month after the Vesting Commencement Date, provided that Grantee provides Continuous Service to the Company or a Related Entity as of each such vesting date.]

[DIRECTOR VESTING: The Option will vest as to on first anniversary of the Vesting Commencement Date, provided that Grantee provides Continuous Service to the Company or a Related Entity as of each such vesting date.]

[IF NOT USING STANDARD VESTING, PROVIDE CUSTOM LANGUAGE: _____]

Exercise Period: The Option may be exercised for up to three months after the termination of Continuous Service to the Company or a Related Entity, except as set out in Section 4 of the Stock Option Award Agreement (but in no event later than the Expiration Date); provided that upon a termination for Cause the Option will be immediately terminated.

[SIGNATURE PAGE FOLLOWS]

By your signature and the signature of the Company's representative below, you and the Company agree that this Option is granted under and governed by the terms and conditions of the Plan and the Stock Option Agreement, all of which are attached and made a part of this document.

COMPANY:

Citius Pharmaceuticals, Inc.

By: _____
Name: _____
Title: _____

Address: _____
_____
_____

GRANTEE:

[GRANTEE NAME]

_____

Address: _____
_____

CITIUS PHARMACEUTICALS, INC.
2021 OMNIBUS STOCK INCENTIVE PLAN

STOCK OPTION AWARD AGREEMENT

This Stock Option Award Agreement (this "**Agreement**") is made by and between Citius Pharmaceuticals, Inc. (the "**Company**") and _____ ("**Grantee**") effective as of the Date of Grant shown on the accompanying Notice of Stock Option Grant (the "**Grant Notice**"). Capitalized terms not explicitly defined in this Agreement or the Grant Notice but defined in the Company's 2021 Omnibus Stock Incentive Plan (the "**Plan**") will have the same definition and meaning as in the Plan.

1. Grant of Option. The Company has granted to Grantee an option to purchase, on the terms and conditions set forth in the Plan and this Agreement, all or any part of the number of Shares described in the Grant Notice, at the Exercise Price set forth in the Grant Notice (the "**Option**"), subject to adjustment as set forth in Section 13 of the Plan.

2. Vesting. Subject to the terms and conditions set forth in the Plan and this Agreement, the Option will vest as provided in the Grant Notice, provided that vesting will cease upon the termination of Grantee's Continuous Service.

3. Forfeiture; Expiration. Any unvested portion of the Option will be forfeited immediately, automatically, and without consideration upon a termination of Grantee's Continuous Service for any reason. In the event Grantee's Continuous Service is terminated for Cause, the vested portion of the Option will also be forfeited immediately, automatically, and without consideration upon that termination for Cause. Any unexercised vested portion of the Option will expire on the Expiration Date set forth in the Grant Notice.

4. Period of Exercise. Subject to the terms and conditions set forth in the Plan and this Agreement, Grantee may exercise all or any part of the vested portion of the Option at any time prior to the earliest to occur of:

(a) the Expiration Date indicated in the Grant Notice;

(b) the effective date of the termination of Grantee's Continuous Service for Cause;

(c) the date that is 12 months after the termination of Grantee's Continuous Service due to his or her death or Disability, provided, however, that in the event Grantee dies within such 12 month period after the termination of Grantee's Continuous Service due to his or her Disability, the period for exercise will be extended until the date twelve (12) months after his or her death (but in no event later than the Expiration Date); or

(d) the date that is three months after the termination of Grantee's Continuous Service for any reason other than Cause, Disability or death; provided however, that in the event that Grantee dies within such three-month period, the period for exercise will be extended until the date 12 months after his or her death (but in no event later than the Expiration Date).

5. Exercise of Option. Grantee or, in the case of Grantee's death or Disability, Grantee's representative, may exercise all or any part of the vested portion of the Option by delivering to the Company at its principal office a written notice of exercise in the form attached as Exhibit A or any other form that the Administrator may permit (such notice, a "**Notice of Exercise**"). The Notice of Exercise will be signed by the person exercising the Option. In the event that the Option is being exercised by Grantee's representative, the Notice of Exercise will be accompanied by proof (satisfactory to the Administrator) of the representative's right to exercise the Option. In addition, any exercise of the Option, whether in whole or in part, is subject to the following conditions:

(a) Grantee (or Grantee's representative, if applicable) will deliver to the Company, at the time of giving the Notice of Exercise, payment in a form permissible under Section 6 below for the full amount of the Purchase Price.

(b) Grantee (or Grantee's representative, if applicable) may exercise the Option only for whole Shares.

(c) Grantee (or Grantee's representative, if applicable) may not exercise the Option unless the tax withholding obligations of the Company and/or any Related Entity, as described in Section 9 below, are satisfied.

(d) In the event that Grantee is an employee eligible for overtime compensation under the Fair Labor Standards Act of 1938, as amended (sometimes referred to as a "non-exempt employee"), then he or she may not exercise the Option until he or she has completed at least six months of Continuous Service measured from the Date of Grant specified in the Grant Notice, notwithstanding any other provision of the Option.

6. Payment for Shares. The "**Purchase Price**" will be the Exercise Price multiplied by the number of Shares with respect to which the Option is being exercised. The Purchase Price may be paid as follows:

(a) in cash;

(b) by check or money order;

(c) by surrender to the Company (either by actual delivery or attestation) of already-owned shares of Common Stock that are owned by Grantee free and clear of any liens, claims, encumbrances or security interests, with a Fair Market Value on the date of surrender or attestation equal to the Purchase Price (provided that Grantee may not exercise the Option by tender to the Company of Common Stock to the extent such tender would violate the provisions of any law, regulation or agreement restricting the redemption of the Company's stock);

(d) through a formal "net exercise" arrangement adopted by the Company pursuant to which the Grantee may exercise the Option and receive the net number of Shares equal to (i) the number of Shares as to which the Option is being exercised, multiplied by (ii) a fraction, the numerator of which is the Fair Market Value per Share (on such date as is determined by the Administrator) less the Exercise Price per Share, and the denominator of which is such Fair Market Value per Share;

(e) through a broker-dealer sale and remittance procedure pursuant to which the Grantee (i) provides written instructions to a Company designated brokerage firm to effect the immediate sale of some or all of the purchased Shares and remit to the Company sufficient funds to cover the aggregate Exercise Price payable for the purchased Shares and (ii) provides written directives to the Company to deliver the certificates (or other evidence satisfactory to the Company to the extent that the Shares are uncertificated) for the purchased Shares directly to such brokerage firm in order to complete the sale transaction; or

(f) through any combination of the foregoing methods of payment.

7. Securities Law Compliance. No Shares will be issued pursuant to this Agreement unless and until all then applicable requirements imposed by federal and state securities and other laws, rules and regulations and by any regulatory agencies having jurisdiction, and by any exchanges upon which the Shares may be listed, have been fully met. The Company may impose such conditions on any Shares issuable pursuant to this Agreement as it may deem advisable, including, without limitation, restrictions under the Securities Act of 1933, as amended, under the requirements of any exchange upon which shares of the same class are then listed and under any blue sky or other securities laws applicable to those Shares.

8. Tax Consequences. Set forth below is a brief summary as of the date of this Option of some of the U.S. federal income tax consequences of exercise of this Option and disposition of the Shares issued as a result of the exercise thereof. THIS SUMMARY IS NECESSARILY INCOMPLETE, AND THE TAX LAWS AND REGULATIONS ARE SUBJECT TO CHANGE. THIS SUMMARY DOES NOT INCLUDE ANY DISCUSSION OF STATE, LOCAL, OR FOREIGN TAX CONSEQUENCES OR ANY FEDERAL TAX CONSEQUENCES OTHER THAN INCOME TAX. BESIDES THE INCOME TAX ITEMS SUMMARIZED BELOW, EMPLOYMENT OR SELF-EMPLOYMENT TAXES MAY ALSO APPLY WITH RESPECT TO THE OPTION. GRANTEE SHOULD CONSULT HIS OR HER PERSONAL TAX ADVISOR BEFORE EXERCISING THIS OPTION OR DISPOSING OF THE SHARES.

(a) Exercise of ISO. If this Option qualifies as an ISO, there will be no regular federal income tax liability upon the exercise of the Option, although the excess, if any, of the fair market value of the Shares on the date of exercise over the Purchase Price will be treated as an item of adjustment to the alternative minimum tax for federal tax purposes in the year of exercise and may subject Grantee to the alternative minimum tax.

(b) Exercise of Non-Statutory Stock Option. If this Option does not qualify as an ISO, there may be a regular federal income tax liability upon the exercise of the Option. Grantee will be treated in such event as having received compensation income (taxable at ordinary income tax rates) equal to the excess, if any, of the fair market value of the Shares on the date of exercise over the Purchase Price. If Grantee is an employee, the Company will generally be required to withhold from Grantee's compensation or collect from Grantee and pay to the applicable taxing authorities an amount equal to a percentage of this compensation income at the time of exercise (see Section 9 below).

(c) Disposition of Shares. In the case of an NSO, if Shares are held for more than one year after the date of the taxable compensation event, under current law any gain realized on disposition of the Shares will generally be treated as long-term capital gain for federal income tax purposes. In the case of an ISO, if Shares transferred pursuant to the Option are held for more than one year after exercise and are disposed of more than two years after the Date of Grant, any gain realized on disposition of the Shares will generally also be treated as long-term capital gain for federal income tax purposes. If Shares purchased under an ISO are disposed of within the later of (1) the date two years after the Date of Grant, or (2) the date one year after the date of exercise (such disposition a "**Disqualifying Disposition**"), any gain realized on such disposition will be treated as compensation income (taxable at ordinary income rates) in an amount equal to the excess of (1) the lesser of (A) the fair market value of the Shares on the date of exercise, or (B) the sale price of the Shares over (2) the Purchase Price paid for those Shares. The gain realized in excess of such amount, if any, will generally be eligible for capital gains treatment (either short-term or long-term, depending upon the length of time the Shares were held prior to disposition).

(d) Notice of Disqualifying Disposition of ISO Shares. If the Option is designated as an ISO, then in the event of a Disqualifying Disposition, Grantee will immediately, and in any event not later than fifteen (15) days after such disposition, notify the Company in writing of such disposition.

9. Withholding Obligations. Grantee may incur Tax Obligations under federal, state, local, and/or foreign law, in connection with the grant, vesting, or exercise of the Option, the ownership of the Shares, and other actions taken pursuant to this Agreement, and the Company may be required to satisfy by withholding from Grantee's compensation or otherwise collect from Grantee. Grantee agrees that the Company (or a Related Entity) may condition the exercise of the Option upon the satisfaction of such withholding tax obligations, and may satisfy such withholding obligations by any of the following means or by a combination of such means, in the Administrator's discretion: (i) withholding from any compensation otherwise payable to Grantee by the Company; (ii) causing Grantee to tender a cash payment; or (iii) withholding from the Shares otherwise issuable to Grantee upon exercise of the Option the number of Shares with a Fair Market Value (measured as of the date the tax withholding obligations are to be determined) equal to the amount of such tax withholding; provided, however, that the number of such Shares so withheld will not exceed the amount necessary to satisfy the Company's required tax withholding obligations using the statutory withholding rates for federal, state, local and foreign tax purposes, including payroll taxes, that are applicable to supplemental taxable income (or such lesser amount as may be necessary to avoid classification of the Shares as a liability for financial accounting purposes). Grantee understands that all matters with respect to the total amount of taxes to be withheld in respect of such compensation income will be determined by the Administrator in its reasonable discretion. Grantee further understands that, although the Company will pay withheld amounts to the applicable taxing authorities, Grantee remains responsible for payment of all taxes due as a result of income arising under the Agreement.

10. Rights as a Stockholder. Neither Grantee nor anyone claiming through him/her will have any rights as a stockholder of the Company with respect to any Shares subject to the Option until the Grantee has exercised the Option as described herein and the Shares are delivered (as evidenced by delivery of a certificate for such Shares or the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company).

11. Transferability. The Option may not be sold, pledged, assigned, hypothecated, transferred, except by will or by the laws of descent and distribution, and is exercisable during Grantee's life only by Grantee. Notwithstanding the foregoing, by delivering written notice to the Company, in a form satisfactory to the Administrator, Grantee may designate a third party who, in the event of Grantee's death, will thereafter be entitled to exercise the Option.

12. Option not a Service Contract. Neither the Option nor this Agreement is an employment or service contract, and nothing in this Agreement or the Grant Notice creates or will be deemed to create in any way whatsoever any obligation on Grantee's part to continue in the service of the Company or a Related Entity, or of the Company or a Related Entity to continue Grantee's service.

13. Governing Plan Document. This Option is subject to all the provisions of the Plan, the provisions of which are hereby made a part of this Agreement, and is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan. Grantee acknowledges receipt of a copy of the Plan. In the event of any conflict between the provisions of this Agreement and those of the Plan, the provisions of the Plan will control.

14. Miscellaneous.

(a) Notices. Any notice, demand or request required or permitted to be given pursuant to the terms of this Agreement will be in writing and will be deemed given when delivered personally, one day after deposit with a recognized international delivery service (such as FedEx), or three days after deposit in the U.S. mail, first class, certified or registered, return receipt requested, with postage prepaid, in each case addressed to the parties at the addresses of the parties set forth in the Grant Notice or such other address as a party may designate by notifying the other in writing.

(b) Successors and Assigns. The provisions of this Agreement will inure to the benefit of, and be binding upon, the Company and its successors and assigns and upon the Grantee, Grantee's executor, personal representative(s), distributees, administrators, permitted transferees, permitted assignees, beneficiaries, and legatee(s), as applicable, whether or not any such person will have become a party to this Agreement and have agreed in writing to be joined herein and be bound by the terms hereof.

(c) Severability. The provisions of this Agreement are severable, and if any one or more provisions are determined to be illegal or otherwise unenforceable, in whole or in part, then the remaining provisions will nevertheless be binding and enforceable.

(d) Amendment. Except as otherwise provided in the Plan, this Agreement will not be amended unless the amendment is agreed to in writing by both Grantee and the Company.

(e) Choice of Law. This Agreement will be construed and enforced in accordance with and governed by the laws of the State of Nevada, without giving effect to the choice of law rules of any jurisdiction.

(f) Entire Agreement. This Agreement, along with the Grant Notice and the Plan, constitutes the entire agreement between the parties hereto with regard to the subject matter hereof, and supersedes any other agreements, representations or understandings (whether oral or written and whether express or implied) that relate to such subject matter.

EXHIBIT A

CITIUS PHARMACEUTICALS, INC.
2021 OMNIBUS STOCK INCENTIVE PLAN

NOTICE OF EXERCISE

Citius Pharmaceuticals, Inc.

_____

_____

Attention: President

Date of Exercise: _____

1. Exercise of Option. This constitutes notice to Citius Pharmaceuticals, Inc. (the "**Company**") that, pursuant to the Citius Pharmaceuticals, Inc. 2021 Omnibus Stock Incentive Plan (the "**Plan**") and the Stock Option Award Agreement, dated _____, 20__ (the "**Award Agreement**"), I elect to purchase the number of Shares set forth below for the price set forth below.

Number of Shares as to which Option is exercised (the "**Optioned Shares**"):	_____
Exercise Price per Share:	_____
Total Purchase Price:	_____

2. Delivery of Payment. With this notice, I hereby deliver to the Company the full Purchase Price for the Optioned Shares, in a form permitted by the Award Agreement.

3. Representations. By signing and delivering this notice to the Company, I acknowledge that I am the holder of the Option exercised by this notice and have full power and authority to exercise the Option. I further represent that I have received, read, and understood the Plan and the Award Agreement, and I confirm my agreement to abide by and be bound by their terms and conditions. Capitalized terms used and not otherwise defined in this notice will have the meanings ascribed to those terms in the Award Agreement.

4. Compliance with Securities Laws. Notwithstanding any other provision of the Award Agreement to the contrary, the exercise of any rights to purchase any Optioned Shares is expressly conditioned upon compliance with the Securities Act of 1933, as amended (the "**Securities Act**"), all applicable state securities laws and all applicable requirements of any stock exchange or over the counter market on which the Company's Common Stock may be listed or traded at the time of exercise and transfer. I agree to cooperate with the Company to ensure compliance with such laws. I further understand that the Optioned Shares cannot be resold and must be held indefinitely unless they are registered under the Securities Act or unless an exemption from such registration is available and that the certificate(s) representing the Optioned Shares may bear a legend to that effect. I understand that the Company is under no obligation to register the Optioned Shares and that an exemption may not be available or may not permit me to transfer Optioned Shares in the amounts or at the times I may desire.

5. Tax Withholding. I acknowledge that my exercise of the Option may result in Tax Obligations which require the Company to withhold certain amounts to satisfy federal, state, local, and/or foreign taxes. I agree to satisfy such tax withholding obligations as described in Section 9 of the Award Agreement.

6. Rights as Stockholder. While the Company will endeavor to process this notice in a timely manner, I acknowledge that, until the issuance of the Optioned Shares (or, in the Company's discretion, in un-certificated form, upon the books of the Company's transfer agent) and my satisfaction of any other conditions imposed by the Company pursuant to the Plan or as set forth in the Award Agreement, no right to vote or receive dividends or any other rights as a stockholder will exist with respect to the Optioned Shares, notwithstanding the exercise of my Option. No adjustment will be made for a dividend or other right for which the record date is prior to the date of issuance of the Optioned Shares.

7. Tax Consultation. I understand that I may experience adverse tax consequences as a result of my exercise of the Option or my disposition of the Optioned Shares. I represent that I have consulted with any tax consultants I deem advisable in connection with the exercise of the Option and/or the disposition of the Optioned Shares and that I am not relying on the Company or its agents for any tax advice.

8. Interpretation. Any dispute regarding the interpretation of this notice will be resolved by the Administrator in its discretion, and the Administrator's determination will be final and binding on all parties.

9. Entire Agreement. The Plan and the Award Agreement under which the Optioned Shares were granted are incorporated herein by reference and, together with this notice, constitute the entire agreement of the parties with respect to the subject matter of this notice.

GRANTEE:

_____

Print Name: _____

Address: _____

_____

_____

Exhibit 10.30

* Information in this exhibit marked [***] has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such information is not material and is the type of information that the registrant treats as private or confidential.

ASSET PURCHASE AGREEMENT

BY AND BETWEEN

DR. REDDY'S LABORATORIES S.A.,

AS SELLER

AND

CITIUS PHARMACEUTICALS, INC.,

AS PURCHASER

DATED AS OF

September 1, 2021

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List of Exhibits and Schedules

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Exhibit H	Transition Services Agreement
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Schedule 2.01(g)	Proration Schedule

ASSET PURCHASE AGREEMENT

This Asset Purchase Agreement (this "**Agreement**") dated as of September 1, 2021 (the "**Effective Date**") by and between Dr. Reddy's Laboratories S.A., a company incorporated under the laws of Switzerland and having its principal place of business located at Elisabethenanlage 11, CH - 4051, Basel, Switzerland (the "**Seller**") and Citius Pharmaceuticals, Inc., a Nevada corporation having its principal place of business located at 11 Commerce Drive, First Floor, Cranford, New Jersey 07016 (the "**Purchaser**"). The Seller and the Purchaser may be collectively referred to herein as the "**Parties**" and each, individually, as a "**Party**".

RECITALS

WHEREAS, the Seller desires to sell, transfer and assign to the Purchaser, and the Purchaser desires to acquire from the Seller, all of the Purchased Assets and Assumed Liabilities, all as more specifically, and subject to the terms and conditions, provided herein;

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements contained herein, the Parties, intending to be legally bound hereby, do agree as follows:

ARTICLE I
DEFINITIONS AND INTERPRETATION

Section 1.01 Defined Terms. Capitalized terms used in this Agreement have the meanings specified in Schedule 1.01, or as otherwise defined within this Agreement.

Section 1.02 Other Definitional and Interpretive Provisions.

(a) The words "hereof", "herein", "hereto" and "hereunder" and words of similar import, when used in this Agreement, shall refer to this Agreement as a whole and not to any particular provision of this Agreement.

(b) The terms defined in the singular shall have a comparable meaning when used in the plural and vice versa.

(c) The terms "dollars" and "$" shall mean United States of America dollars.

(d) The term "including" (and with correlative meaning "include") shall mean "including, without limitation."

(e) Reference to any Person includes such Person's successors and assigns but, if applicable, only if such successors and assign are permitted by this Agreement, and reference to a Person in a particular capacity excludes such Person in any other capacity.

(f) Reference to any agreement (including this Agreement), document or instrument means such agreement, document or instrument as amended, modified or supplemented and in effect from time to time in accordance with the terms thereof and, if applicable, the terms hereof.

(g) When a reference is made in this Agreement to an Article, a Section, an Exhibit or a Schedule, such reference shall be to an Article of, a Section of, an Exhibit to or a Schedule to, this Agreement unless otherwise indicated.

(h) The Parties acknowledge that: (i) this Agreement is the result of negotiations between the Parties and shall not be deemed or construed as having been drafted by any one Party; (ii) each Party and its counsel have reviewed and negotiated the terms and provisions of this Agreement (including any exhibits, schedules, and disclosure schedules attached hereto) and have contributed to its revision; (iii) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (iv) the terms and provisions of this Agreement shall be construed fairly as to all Parties and not in favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

ARTICLE II
PURCHASE AND SALE; LICENSE GRANTS

Section 2.01 Purchase and Sale of Purchased Assets.

(a) Purchased Assets. Upon the terms and subject to the conditions set forth in this Agreement, at the Closing, the Seller shall (and shall cause each of its Affiliates to) sell, convey, transfer and assign to the Purchaser, and the Purchaser shall purchase and acquire from the Seller and its Affiliates, all of the Seller's and its Affiliates' right, title, and interest in the Purchased Assets, free from any Encumbrances except for Permitted Encumbrances.

(b) Excluded Assets. Other than the Purchased Assets, the Purchaser expressly understands and agrees that it is not purchasing or acquiring, and the Seller is not selling, conveying, transferring, or assigning, any other assets or properties of the Seller (or any of the Seller's Affiliates), and all such other assets and properties shall be excluded from the Purchased Assets (the "**Excluded Assets**"). For the avoidance of doubt, the Excluded Assets include all books and records of the Seller and its Affiliates (other than books and records that constitute Regulatory Documentation or are otherwise specifically included in the definition of Purchased Assets); provided, however, that Purchaser shall have the right to make copies of any portions of such retained books and records that expressly relate to any of the Purchased Assets.

(c) Assumed Liabilities. Upon the terms and subject to the conditions set forth in this Agreement, the Purchaser shall, effective upon the Closing, assume (and shall pay, perform and discharge when due) all Assumed Liabilities.

(d) Excluded Liabilities. Except for the Assumed Liabilities, the Purchaser will not acquire any interest in, or obligations in respect of, any Liabilities of the Seller or any of the Seller's Affiliates (the "**Excluded Liabilities**"). Notwithstanding anything to the contrary, all Liabilities arising out of or relating to any breach of an Acquired Contract by Seller or any of its Affiliates prior to the Closing, or any unauthorized use or disclosure of Eisai's confidential information by Seller or any of its Affiliates, shall be Excluded Liabilities and not Assumed Liabilities.

(e) Consents.

(i) Notwithstanding any other provision of this Agreement, this Agreement does not constitute an agreement to sell, convey, assign, assume, transfer or deliver any interest in any Acquired Contract that would be a Purchased Asset (other than the Acquired Contracts listed on Schedule 2.01(e), any required Consents with respect to which shall be obtained prior to Closing), or any claim or right of any benefit arising thereunder or resulting therefrom, if an attempted direct or indirect assignment thereof, or agreement to sell, convey, assign, assume, transfer or deliver any such Acquired Contract, without the Consent of any Third Party, (A) would violate applicable Laws or constitute a breach or other contravention of the rights of such Third Party (including any Governmental Authority), or (B) would be ineffective with respect to any party to such Acquired Contract (each such Acquired Contract, other than those listed on Schedule 2.01(e)), a "**Non-Assignable Contract**"). If any direct or indirect transfer or assignment or agreement to do so by the Seller (and/or the Seller's Affiliates, as applicable) of, or any direct or indirect assumption by the Purchaser of, any interest in, or liability, obligation or commitment under, any Non-Assignable Contract requires the Consent of a Third Party, then such transfer, assignment or assumption or agreement to do so shall be made subject to such Consent being obtained.

(ii) The Purchaser acknowledges that certain Consents to the transactions contemplated by this Agreement may be required from counterparties to Non-Assignable Contracts and that such Consents may not be obtained prior to Closing. In the event that such required Consent is not obtained with respect to a Non-Assignable Contract, notwithstanding any other provision to the contrary set forth in this Agreement, the Purchaser agrees that the Seller shall not have any Liability whatsoever arising out of or relating to the failure to obtain such Consent that may have been or may be required with respect to such Non-Assignable Contract in connection with the transactions contemplated by this Agreement, provided that Seller complies with its obligations under in Section 2.01(e)(iii). The Purchaser further agrees that, provided that Seller complies with its obligations under in Section 2.01(e)(iii), no representation, warranty or covenant of the Seller contained herein shall be breached or deemed breached, and no condition to the Purchaser's obligations to close the transactions contemplated by this Agreement shall be deemed not satisfied, as a result of (i) the failure to obtain any such Consent with respect to a Non-Assignable Contract; or (ii) any Legal Proceeding commenced or threatened by or on behalf of any Person arising out of or relating to the failure to obtain any Consent with respect to a Non-Assignable Contract.

(iii) If any Consent referred to in Section 2.01(e)(i) is not obtained prior to the Closing with respect to a Non-Assignable Contract, the Closing shall nonetheless take place without any adjustment of the Purchase Price on account thereof, and thereafter each of the Seller and the Purchaser shall use commercially reasonable efforts (A) to endeavor to obtain such Consent (provided that neither the Seller nor the Purchaser shall be required to expend money, commence, defend or participate in any litigation or offer or grant any accommodation (financial or otherwise) to any Third Party), and (B) to cooperate, upon written request of the Purchaser, in endeavoring to obtain for the Purchaser, at no cost to the Seller, an arrangement to provide to the Purchaser, in compliance with Law, substantially comparable benefits thereof. Upon obtaining the requisite Consent, such Non-Assignable Contract shall be transferred and assigned to the Purchaser hereunder, for no additional consideration.

(f) Transfer of Purchased Assets. As soon as practicable following the Closing (and in no event later than [***] ([***]) Business Days after the Closing), the Seller shall make available to the Purchaser electronically all Purchased Assets held electronically. Within [***] ([***]) Business Days after the Closing, the Seller shall make available to the Purchaser all tangible Purchased Assets for pick-up at the Seller's facilities, at the Purchaser's sole cost, expense and risk; provided, that if the Seller finds, locates, discovers or otherwise becomes aware that it possesses any Purchased Assets after the Closing, the Seller shall reasonably promptly notify the Purchaser in writing and make such Purchased Assets available for pick-up at the Seller's facilities, at the Purchaser's sole cost, expense and risk.

(g) Proration Schedule. Schedule 2.01(g) (the "**Proration Schedule**") sets forth certain deposits and other prepaid items, which includes certain expenses that Seller or its respective Affiliates have paid or that are required to be paid by the Seller (or their applicable Affiliates) by Law or contractual obligation, and which shall be prorated as of the Effective Date. At the Closing, the Purchaser shall pay to the Seller an amount equal to the Purchaser's Prorated Portion, which amount is set forth on the Proration Schedule. Any amounts set forth in the Proration Schedule that are owed to a Third Party that have not been paid by the Seller prior to the Closing Date will be paid by the Seller following the Closing Date and shall remain the Liability of the Seller.

Section 2.02 Further Expenses and Studies; Other Commitments. After the Closing, the Purchaser shall be responsible for any and all of its further developmental activities relating to Products and the Compound, including the Proof of Concept Plan and all expenses relating thereto.

ARTICLE III
PURCHASE PRICE

Section 3.01 Purchase Price.

(a) Amount. The aggregate consideration for the purchase of the Purchased Assets to be paid by the Purchaser (the "**Purchase Price**") shall be:

(i) A non-refundable, non-creditable amount equal to Forty Million Dollars ($40,000,000.00) in respect of the Purchased Assets (the "**Upfront Payment**") and the assumption of the Assumed Liabilities;

(ii) the Milestone Payments, as and to the extent provided in Section 3.01(b); and

(iii) the Quarterly Earn-Out Payment(s), as and to the extent provided in Section 3.01(c) (including as adjusted pursuant to Section 3.01(c)(iv)(A));

(iv) any Licensee Consideration Payments, as and to the extent provided in Section 3.01(c)(iv)(B); and

(v) the Purchaser's Prorated Portion.

(b) Milestone Payments. As consideration for the purchase of the Purchased Assets, in addition to the Cash Consideration, the assumption of the Assumed Liabilities, the Quarterly Earn-Out Payments and the Licensee Consideration Payments, and subject to this Section 3.01(b), the Purchaser shall pay to the Seller the following non-refundable, non-creditable amounts (each, a "**Milestone Payment**") upon the achievement by or on behalf of the Purchaser or its Affiliates, Licensees or Transferees, if any, of the following events (each, a "**Milestone Event**"):

Table 3.01(b)

No.	Milestone Event	Milestone Payment
1.	Upon Regulatory Approval of the first Product by the FDA in a CTCL Indication	$[***]
2.	Upon a European Approval of the first Product in a CTCL Indication	$[***]
3.	Upon Regulatory Approval of the first Product by the Health Canada in a CTCL Indication	$[***]
4.	Upon Regulatory Approval of the first Product by the FDA in a PTCL Indication	$[***]
5.	Upon a European Approval of the first Product in a PTCL Indication	$[***]
6.	Upon Successful Proof of Concept	$[***]
7.	Upon Regulatory Approval by the FDA of the first Product in an I/O Indication	$[***]
8.	Upon the achievement of $[***] in cumulative Net Sales.	$[***]
9.	Upon the achievement of $[***] in cumulative Net Sales.	$[***]

Each Milestone Payment set forth in this Section 3.01(b) is payable only once (*i.e.*, the first time the Milestone Event is achieved) and is non-refundable once paid. Notwithstanding anything to the contrary, for the purposes of calculating Milestone No. 8 and Milestones No. 9 above, Licensee Net Sales shall not be included in such calculation (other than in cases where Purchaser has granted a Licensee generating such Licensee Net Sales a license to all rights with respect to the Purchased Assets and all Products throughout (A) [***] or (B) [***] (an "**Entire Rights License**")).

(c) Quarterly Earn-Out Payments; Licensee Consideration Payments.

(i) As consideration for the purchase of the Purchased Assets, in addition to the Cash Consideration, the assumption of the Assumed Liabilities, the Milestone Payments and the Licensee Consideration Payments, and subject to this Section 3.01(c), commencing on the Effective Date, each Quarter for the duration of the Earn-Out Term for a given Product in a given country of the Territory, Purchaser shall pay to the Seller non-refundable, non-creditable amounts with respect to such Product in such country, based upon the cumulative Net Sales of each Product in the applicable countries of the Territory in the applicable Calendar Year to which such Quarter relates (each payment a "**Quarterly Earn-Out Payment**"). Such Quarterly Earn-Out Payment shall be calculated: (A) in the case of Licensee Net Sales, in accordance with Section 3.01(c)(iv)(A) below; and (B) in the case of any Net Sales of Products other than Licensee Net Sales, by multiplying the applicable rate set forth in Table 3.01(c) below (the "**Quarterly Earn-Out Rate**") by the aggregate Net Sales (other than Licensee Net Sales) of Product in the applicable countries of the Territory in an applicable Quarter; and, in each case (for both of the preceding clauses (A) and (B)), applying any applicable reductions under Section 3.01(c)(v) below:

Table 3.01(c)

No.	Aggregate Annual Net Sales (other than Licensee Net Sales)	Quarterly Earn-Out Rate
1.	For that portion of Net Sales (other than Licensee Net Sales) of Products in a Calendar Year up to and including [***] Dollars ($[***])	[***] Percent ([***]%)
2.	For that portion of Net Sales (other than Licensee Net Sales) of Products in a Calendar Year that is greater than [***] Dollars ($[***])	[***] Percent ([***]%)

(ii) Quarterly Earn-Out Payments and Licensee Consideration Payments shall be paid pursuant to Section 3.01(c)(i) as from the Effective Date and until the earlier to occur of (as determined on a Product-by-Product, country-by-country basis): (a) the fifteen (15) year anniversary of the First Commercial Sale of the latest to be received Regulatory Approval of an Indication of such Product in the applicable country, and (b) the date on which Biosimilar Entry with respect to a Product (for any Indication) occurs in such country (the "**Earn-Out Term**"). For clarity, each time a Product is approved for a new Indication in a given country, the fifteen (15) year period described in clause (a) of the definition of Earn-Out Term for such Product and country shall reset based on the date of the First Commercial Sale of such Product in such country following the Regulatory Approval for such new Indication. For the avoidance of doubt, the Purchaser shall be liable to make a Quarterly Earn-Out Payment pursuant to Section 3.01(c)(i), for the Quarter during which such event terminating the obligation to make such Quarterly Earn-Out Payment occurs as long as the Product is sold in such Quarter. Notwithstanding anything otherwise to the contrary, no amounts shall be counted more than once in the calculation of the Quarterly Earn-Out Payments or the Licensee Consideration Payments.

(iii) Blended Rate. The Parties acknowledge and agree that, the Quarterly Earn-Out Rates agreed upon by the Parties for the Product(s) have been blended to take into consideration, the Purchased Know-How, the Quarterly Earn-Out Rate that could be applied to Products prior to the expiration of any Valid Claims, the Quarterly Earn-Out Rate that could be applied after the expiration of any Valid Claims and the Quarterly Earn-Out Rate that could be applied if no Valid Claims Cover the Product. The Parties recognize that the differing Quarterly Earn-Out Rates that could apply to such periods could last for differing time periods. Therefore the Parties have determined to use the blended Quarterly Earn-Out Rate in this Agreement for reasons of convenience, and the use of such blended Quarterly Earn-Out Rate is advantageous to both Parties.

(iv) Sales of Product by Licensees; Licensee Net Sales; Licensee Consideration.

(A) Licensee Sales. Notwithstanding anything to the contrary, the Quarterly Earn-Out Payment with respect to any sales of Product(s) by or on behalf of a Licensee in an applicable Quarter during the Earn-Out Term for such Product in such country shall be an amount equal to the greater of (1) [***] ([***]%) of all Licensee Sales-Based Royalties that are paid to Purchaser and/or its Affiliates with respect to such sales of Product(s) by or on behalf of a Licensee and (2) [***] percent ([***]%) of such Licensee Net Sales. In the event that Purchaser or its Affiliates enters into any agreement pursuant to which Licensee Net Sales may occur, Purchaser shall provide notice to Seller that it has entered into such arrangement, and provide a copy of such agreement to the Seller (which agreement shall be deemed to be the Confidential Information of Purchaser in accordance with Section 7.01).

(B) Licensee Consideration Payments. As consideration for the purchase of the Purchased Assets, in addition to the Cash Consideration, the assumption of the Assumed Liabilities, the Milestone Payments and the Quarterly Earn-Out Payments, Purchaser shall pay to the Seller [***] percent ([***]%) of any Licensee Consideration received with respect to a given Product in a given country of the Territory during the Earn-Out Term for such Product in such country (such [***]% portion of such Licensee Consideration, the "**Licensee Consideration Payments**"). Such Licensee Consideration Payments shall be paid to the Seller within [***] ([***]) days that such Licensee Consideration is received by the Purchaser, and are non-creditable and non-refundable once paid. The Purchaser shall provide a notice to the Seller of the occurrence of an event giving rise to a Licensee Consideration Payment prior to, or no later than on, the date of the payment of the corresponding Licensee Consideration Payment.

(v) License Stacking. If Purchaser or any of its Affiliates (A) determines it is required to obtain a license or other right to a Third Party's Intellectual Property (in the event such license or other right is not otherwise granted to Purchaser under the Eisai Agreement upon the transfer of the Eisai Agreement to Purchaser at Closing) in order to Exploit a Product in the Territory and (B) enters into an agreement with a Third Party in order to obtain a license or other right under such Third Party's Intellectual Property in order to Exploit a Product (a "**Third Party License**"), the Quarterly Earn-Out Payments with respect to such Product (on a Product-by-Product Basis) shall be reduced by [***] percent ([***]%) of any amounts actually paid to such Third Party with respect to such Third Party License; provided, however, that in no event will such reduction reduce a Quarterly Earn-Out Payment for a given Calendar Quarter for such Product by more than [***] percent ([***]%). [***]. For the avoidance of doubt, Purchaser shall only be permitted to reduce the amounts payable hereunder to the extent such payments to a Third Party for a Third Party License relate to a Product or any component thereof, which are necessary for making, using, selling or otherwise Exploiting the Product in the Territory, and not to other components or products that are not necessary for making, using, selling or otherwise Exploiting a Product in the Territory.

Section 3.02 Payment Terms; Transfer Taxes.

(a) Payment of the Purchase Price.

(i) The Purchaser shall pay the Cash Consideration to the Seller at Closing, by wire transfer of immediately available funds to an account designated in writing by the Seller.

(ii) Each Milestone Payment due and payable under Section 3.01(b) shall be paid by the Purchaser to the Seller within [***] ([***]) days following the occurrence of the corresponding Milestone Event; provided, however, that [***]. The Purchaser shall provide a notice to the Seller of the occurrence of the Milestone Event set forth in Section 3.01(b) prior to, or no later than on, the date of the payment of the corresponding Milestone Payment.

(iii) Each of the Quarterly Earn-Out Payments due and payable under Section 3.01(c) shall be paid by the Purchaser to the Seller promptly (but no more than [***] ([***]) days) following the end of the Quarter to which they relate to; *provided*, that (x) notwithstanding the foregoing, Quarterly Earn-Out Payments payable under Section 3.01(c)(iv)(A) with respect to sales of Product by or on behalf of Licensees) shall be payable by Purchaser to Seller on [***] of (1) [***] and (2) the [***] ([***]) day following the end of the applicable Quarter to such Quarterly Earn-Out Payment relates and (y) Purchaser shall [***]. The Purchaser shall provide a notice to the Seller prior to, or no later than on, the date such of payment, which notice shall provide sufficient details to permit confirmation by the Seller of the accuracy of the payments made.

(iv) Any payments to be made to the Seller under this Agreement shall be made to the Seller without deduction, setoff or counterclaim by the Purchaser for any taxes, fees, duties (except for any withholding required by applicable Tax Laws). Each Party shall use reasonable efforts to provide the other Party with such reasonable assistance as the other Party may request from time to time to minimize any such taxes, fees or duties arising at any time in connection with the Exploitation of the Products, Compound or Purchased Assets in the Territory. Upon written request, Seller shall deliver to the Purchaser a properly completed W-8BEN-E Internal Revenue Service Form which may be required by Purchaser in order for Purchaser not to withhold tax under the Double Tax Avoidance Treaty. The Parties agree that as of the Effective Date, no payments under this Agreement are subject to deduction or withholding tax, including the Upfront Payment. Notwithstanding anything herein to the contrary, if, in connection with an actual or proposed change in Tax Law applicable to the payment of any amounts from the Purchaser or its Affiliates to the Seller hereunder, either Party reasonably believes that actual or proposed change in Tax Law may result in the Purchaser withholding any amounts hereunder due to any Tax Law, at the time amounts become due under this Agreement, the Parties shall confer and discuss in good faith any amendments of changes to this Agreement that might reduce the impact of such change in Tax Law.

(b) Mode of Payment. All payments to the Seller under this Agreement shall be made by way of direct wire transfer of immediately available funds, in Dollars, in the requisite amount to such bank account as the Seller may from time to time designate by notice to the Purchaser.

(c) Transfer Taxes. All transfer, documentary, sales, use, valued-added, gross receipts, stamp, registration or other similar transfer Taxes (collectively, "**Transfer Taxes**") incurred in connection with the transfer and sale of the Purchased Assets as contemplated by the terms of this Agreement, including all recording or filing fees and other similar costs of the Closing, that may be imposed, payable, collectible or incurred, shall be borne by the Purchaser. The Parties hereto agree to reasonably cooperate with each other to claim any applicable exemption from, or reduction of, any applicable Transfer Taxes.

Section 3.03 Additional Covenants relating to the Milestone Payments and Quarterly Earn-Out Payments.

(a) The Purchaser shall, and shall cause its Affiliates, and any Licensees and Transferees of rights to Exploit any Product, to keep reasonable, correct and complete books, records and documents (whether in hardcopy, electronic or other form) substantiating the achievement (or non-achievement) of the Milestone Event set forth in Section 3.01(b) and the Net Sales amounts recognized in each Calendar Year for each Product in each country of the Territory, as related to the Quarterly Earn-Out Payments (the "**Milestone and Earn-Out Information**") and shall maintain such Milestone and Earn-Out Information until the [***] ([***]) year following the end of the Calendar Year to which such Milestone and Earn-Out Information relates.

(b) Commencing with First Commercial Sale of the first Product, and until the first Calendar Year following the Calendar Year in which the Seller has received all Milestone Payments and Quarterly Earn-Out Payments, the Purchaser shall provide the Seller, (i) on a quarterly basis, not later than [***] ([***]) days after the end of each Quarter other than the Quarter ended December 31, the quarterly Sales Reports; and (ii) on an annual basis, not later than [***] ([***]) days after the end of each Calendar Year, the annual Sales Report. "**Sales Reports**" shall mean reasonably detailed quarterly and annual reports of the aggregate gross sales and Net Sales of the Product in each applicable country of the Territory, for such Quarter or Calendar Year, as applicable. All Sales Reports shall also include separate line items for the gross sales and the Net Sales of the Product, in each case per applicable country of the Territory.

(c) From the Closing until the Seller has received all Milestone Payments and Quarterly Earn-Out Payments, an independent, national or global third party auditing firm that is reasonably acceptable to Purchaser (and who is subject to the obligations of confidentiality as set forth herein) shall have reasonable access to, and shall be able to review and audit, once every [***] ([***]) months upon no less than [***] ([***]) days written notice and during normal business hours, the books, records, documents (whether in hardcopy, electronic or other form), personnel, work papers and operations) of the Purchaser to the extent necessary to permit the auditor to verify compliance of Purchaser with its obligations under Section 3.01(b), Section 3.01(c) and Section 3.03(a) and the Sales Reports. The Purchaser agrees to reasonably assist such auditing firm in connection with the exercise of the audit rights granted by this Section 3.03(c). All expenses and costs associated with the review and audit in this Section 3.03(c) shall be borne solely by the Seller; provided that in the event that such review and audit results in a finding and determination that a Milestone Payment or Quarterly Earn-Out Payment payable was not otherwise paid or that the amount paid was lower by more than [***] percent ([***]%) than the amount that should have been paid, then the reasonable expenses and costs charged by such audit firm for such review and audit (including reasonable attorney's fees) shall be borne and paid by the Purchaser. The results of such audit will be binding on the Parties, absent manifest error. All amounts due to the Seller as shown by the audit (that have not been previously paid by Purchaser to Seller) shall be paid within [***] ([***]) days following the receipt by Purchaser of a copy of the final audit report. Purchaser will include in all sublicenses granted with respect to the Compound and/or Product, an audit provision substantially similar to the foregoing requiring such sublicensee to keep full and accurate books and records relating to the Compound and/or Product and granting such independent third party auditing firm the right to audit the accuracy of the information reported by any sublicensee in connection therewith in accordance with terms and conditions substantially similar to those provided in this Section above.

(d) From the Closing until the Seller has received all Milestone Payments and Quarterly Earn-Out Payments, the Purchaser and its Affiliates shall not without the prior written consent of the Seller, sell, assign, or otherwise transfer (excluding, for clarity, grant of a license other than an Entire Rights License) any of the Purchased Assets to any Person or grant an Entire Rights License to any Person; provided that, no such consent shall be required for such sale, assignment, transfer or Entire Rights License to any Person who agrees in writing to be bound by the terms of, and to assume all applicable obligations of Purchaser and its Affiliates under this Agreement and the other Transaction Documents, including obligations under ARTICLE III of this Agreement. For the avoidance of doubt, "applicable obligations" shall mean all obligations of Purchaser and its Affiliates under this Agreement and the other Transaction Documents directly or indirectly relating to such Purchased Assets or Product(s) (or rights to such Purchased Assets or Product(s), as applicable) that are the subject of such sale, assignment or transfer. Nothing contained herein shall release the Purchaser from its obligations under this Agreement or any other Transaction Document after any sale, license, assignment or transfer of any Purchased Assets or Assumed Liabilities and Purchaser hereby expressly agrees that it shall remain liable under this Agreement and the other Transaction Documents following any assignment or license for the full and complete performance of all obligations arising hereunder or thereunder. The Parties will reasonably cooperate to maximize efficiency with respect to payments to be made under this Agreement.

Section 3.04 Additional Covenants relating to Milestone Events.

(a) From the Closing and until the Seller has received all Milestone Payments and Quarterly Earn-Out Payments, the Purchaser and its Affiliates or Licensees or Transferees, as applicable, shall use Commercially Reasonable Efforts in order to develop, launch, commercialize, sell and market Products in the Territory in each of the CTCL Indication, the PTCL Indication and the I/O Indication. The Purchaser shall not take any actions with the intent to avoid the achievement of any of the Milestone Events (except that the applicable efforts to achieve the Milestone Events shall be subject to Section 3.04(c) and (d)) or Quarterly Earn-Out Payments or reduce the amount of any of the Quarterly Earn-Out Payments, including, without limitation, intentionally delaying sales or incentivizing customers to delay placing orders. Notwithstanding the foregoing, Purchaser shall launch each Product in a jurisdiction within the Territory on or before the six (6) month anniversary of the date such Product receives Regulatory Approval for such jurisdiction.

(b) With respect to the CTCL Approval Milestones, the PTCL Approval Milestones, the I/O Approval Milestones (collectively, the "**Approval Milestones**") commencing on the Effective Date and continuing until such time as all Approval Milestones have been achieved, Purchaser and its Affiliates or Licensees or Transferees, as applicable, shall use their Commercially Reasonable Efforts to achieve each of the Approval Milestones (the "**Approval Efforts**").

(c) Commencing on the Effective Date, Purchaser and its Affiliates or Licensees or Transferees, as applicable, shall use their Commercially Reasonable Efforts to achieve a Successful Proof of Concept (the "**Proof of Concept Efforts**"). The Purchaser and its Affiliates or Licensees or Transferees, as applicable, shall complete the Proof of Concept Plan (unless the Proof of Concept Plan must be discontinued or delayed for safety reasons or reasons outside Purchaser's reasonable control (and not directly or indirectly caused by Purchaser, its Affiliates (or their permitted transferees, licensees or sublicensees)), which shall include taking the actions set forth in Annex A within the timetable set forth therein (provided that if Purchaser does not comply with such timetable due to delays outside of Purchaser's reasonable control, such timetable shall be automatically extended on a day-for-day basis for so long as such event out of Purchaser's reasonable control is existing and preventing the Purchaser to proceed on such applicable activities). Purchaser shall not cease the Proof of Concept Plan prior to its completion without the prior written consent of the Seller (such consent not to be unreasonably withheld, conditioned or delayed), unless the Proof of Concept Plan or Proof of Concept Efforts must be discontinued for safety reasons or reasons outside of Purchaser's reasonable control; *provided*, that Purchaser shall promptly provide notice to the Seller (in accordance with Section 10.02) that Purchaser has discontinued the Proof of Concept Plan activities and the reasons for such discontinuance. In the event that the Purchaser is required to delay the Proof of Concept Plan prior to its completion due to delays outside of Purchaser's reasonable control (which delays are not directly or indirectly caused by Purchaser, its Affiliates or their permitted transferees, licensees or sublicensees, Purchaser shall provide notice (in accordance with Section 10.02) to Seller of such delay and the events contributing to such delay. Purchaser and its Affiliates shall consult with Seller in connection with the Proof of Concept Efforts and consider in good faith the suggestions of Seller with respect thereto.

(d) The Parties acknowledge that Purchaser may suspend or discontinue development of the Product for a particular Indication and/or a particular jurisdiction within the Territory, to the extent such suspension or discontinuation would be consistent with the exercise of Commercially Reasonable Efforts. Without limiting the foregoing, Purchaser may suspend or discontinue development of the Product for the I/O Indication if, based on the results of the Proof of Concept Plan, such suspension or discontinuation would be consistent with the exercise of Commercially Reasonable Efforts. For the avoidance of doubt, in the event that the Purchaser, its Affiliates or Licensees or Transferees, as applicable, suspends or abandons any of the Approval Efforts, but later continues or revives the program with respect to the Approval Milestones, the Purchaser's obligation to pay the applicable Milestone Payment with respect to each then applicable Approval Milestone shall remain in the event such Milestone Payment had not been earlier paid hereunder to Seller and remains outstanding under Section 3.01(b).

(e) Information Rights.

(i) Subject to 3.01(e)(iii), within [***] ([***]) calendar days of the end of each Calendar Year until all Approval Milestones have been achieved (other than any Approval Milestones for which the applicable Approval Efforts have been properly discontinued in accordance with Section 3.04(c) and (d)), if requested by Seller, Purchaser shall meet and confer with Seller and update Seller on the status of the Approval Milestones. [***] ([***]) calendar days prior to such meeting, Purchaser shall deliver to Seller a written report in reasonable detail setting forth the preceding Calendar Year's Approval Efforts and an update on the status of all Approval Milestones.

(ii) Subject to 3.01(e)(iii), within [***] ([***]) calendar days of the end of each Quarter until the Proof of Concept Plan has been completed (or the Proof of Concept Plan has been discontinued in accordance with Section 3.04(c) and (d)), if requested by Seller, Purchaser shall meet and confer with Seller and update Seller on the status of the Proof of Concept Plan. [***] ([***]) calendar days prior to such meeting, Purchaser shall deliver to Seller a written report in reasonable detail setting forth for the preceding Quarter's Proof of Concept Efforts and an update on the status of the Proof of Concept Plan.

(iii) Notwithstanding anything to the contrary herein, Purchaser shall provide written notification (in accordance with Section 10.02) to the Seller ("**Discontinuation Notice**") upon its determination to discontinue of any of the Approval Efforts, which discontinuance shall be in accordance with Section 3.04(c) and Section 3.04(d). Upon receipt of a Discontinuation Notice, Seller and Purchaser shall meet and confer over the discontinuation of such Approval Efforts within forty-five (45) days. Thirty (30) calendar days prior to such meeting, Purchaser shall deliver to Seller a written report in reasonable detail setting forth for the reasons for such discontinuance, and the efforts undertaken with respect to such Approval Effort.

ARTICLE IV
CLOSING

Section 4.01 Closing. The consummation of the transactions contemplated in this Agreement (the "**Closing**") shall take place remotely, via the exchange of electronic copies of the agreements, documents, certificates and other instruments set forth in Section 4.02. The Closing shall be deemed to be effective as of 12:00:01 a.m. eastern time on the Effective Date, and the date in which the Closing occurs shall be deemed the "Closing Date".

Section 4.02 Closing Deliverables.

(a) At the Closing, the Seller shall deliver or cause to be delivered to the Purchaser the following:

(i) the Bill of Sale & Assignment and Assumption Agreement, duly executed by authorized officers of the Seller and any applicable Affiliate of Seller;

(ii) the Eisai Assignment and Assumption Agreement, duly executed by an authorized officer of the Seller and an authorized officer of Eisai;

(iii) assignments of Acquired Contracts not assigned pursuant to the Eisai Assignment or Bill of Sale & Assignment and Assumption Agreement, if any, duly executed by an authorized officer of Seller and any applicable Affiliate of Seller;

(iv) the Transition Services Agreement, duly executed by an authorized officer of the Seller;

(v) the Assignment of Patents, duly executed by an authorized officer of the Seller and any applicable Affiliate of Seller;

(vi) such other documents as the Purchaser may reasonably request to give effect to this Agreement.

(b) At the Closing, the Purchaser shall deliver to the Seller the following:

(i) the payment of the Cash Consideration in accordance with Section 3.02(b);

(ii) the Bill of Sale & Assignment and Assumption Agreement, duly executed by an authorized officer of the Purchaser;

(iii) the Eisai Assignment and Assumption Agreement, duly executed by an authorized officer of the Purchaser;

(iv) the Transition Services Agreement, duly executed by an authorized officer of the Purchaser;

(v) the Assignment of Patents, duly executed by an authorized officer of the Purchaser;

(vi) such other documents as the Seller may reasonably request to give effect to this Agreement.

(c) Transition Services Agreement. At Closing, the Purchaser and the Seller will enter into a Transition Services Agreement, in the form attached hereto as Exhibit H (the "**Transition Services Agreement**").

(d) Inventory Letter. At the Closing, the Seller shall assign to the Purchaser all of the Seller's rights and interest in the Inventory Letter pursuant to the Eisai Assignment and Assumption Agreement.

ARTICLE V
REPRESENTATIONS AND WARRANTIES OF SELLER

Except as set forth in the disclosure schedules attached hereto (the "**Seller Disclosure Schedules**"), but subject to the immediately following sentence, the Seller represents and warrants to the Purchaser that the statements contained in this ARTICLE V are true and correct as of the date hereof (unless in each case the particular statement speaks expressly as of a particular date, in which case it is true and correct only as of such date). Notwithstanding the foregoing, it is expressly understood and acknowledged that any information disclosed in the Seller Disclosure Schedule under any numbered or lettered schedule, section, or subsection shall be deemed to relate to and qualify such schedule, section or subsection, as well as any other schedule, sections or subsections of the Seller Disclosure Schedule, but only where the relevance of such disclosure to such other schedule, section or subsection is reasonably apparent from the text of such disclosure.

Section 5.01 Organization and Authority of the Seller. The Seller is a company duly organized, validly existing and in good standing under the Laws of Switzerland. The Seller has the requisite power and authority to own and operate the Purchased Assets that it owns or operates. The Seller is duly qualified to do business and in good standing in each jurisdiction where the ownership of the Purchased Assets requires such qualification, except where the failure to be so qualified or in such good standing will not prevent or delay the ability of Seller to consummate the transactions contemplated by this Agreement and the other Transaction Documents.

Section 5.02 Authority, Non-Contravention, Required Filings.

(a) The Seller has the requisite power and authority to execute and deliver this Agreement and the other Transaction Documents to which the Seller is a Party and to perform its obligations hereunder and thereunder and to consummate the transactions contemplated hereby and thereby (including, but not limited to, the power and authority to cause each Affiliate of Seller who has any rights with respect to any Purchased Asset to sell, convey, transfer and assign such Purchased Asset to Purchaser in accordance with this Agreement). The execution and delivery of this Agreement and the other Transaction Documents and the performance by the Seller of its obligations hereunder and thereunder and the consummation by the Seller of the transactions contemplated hereby and thereby, has been duly authorized by all necessary company action on the part of the Seller and its Affiliates.

(b) This Agreement and the other Transaction Documents to which the Seller is a Party have been duly executed and delivered by the Seller, and constitutes a legal, valid and binding obligation of the Seller, enforceable against it in accordance with its respective terms, in each case subject to: (i) the effects of bankruptcy, insolvency, fraudulent conveyance, reorganization, moratorium and other similar Laws relating to or affecting the enforcement of creditors' rights generally; and (ii) general equitable principles (whether considered in a proceeding in equity or at Law).

(c) The execution and delivery by the Seller of this Agreement and the other Transaction Documents to which the Seller is a Party, the performance by the Seller of its obligations hereunder and thereunder, and the consummation by the Seller of the transactions contemplated hereby and thereby do not and will not (i) contravene any provision of the Organizational Documents of the Seller or any of its Affiliates, (ii) constitute a material breach, materially violate the terms, conditions or provisions of, or result in a material default under, or give to others any rights of termination, amendment, acceleration or cancellation of, or notice with regard to, any agreement to which the Seller or an of its Affiliates is a party or is otherwise bound, (iii) result in the creation of any Encumbrance (except for Permitted Encumbrances) upon the Purchased Assets or (iv) violate any provision of any Laws.

(d) No Permit, Consent, waiting period expiration or termination, approval or authorization of, or designation, declaration or filing with, any Governmental Authority on the part of the Seller or any of its Affiliates is required in connection with the execution or delivery by the Seller of this Agreement, or the consummation of the transactions contemplated hereby.

Section 5.03 Purchased Assets. The Seller and/or its applicable Affiliate(s) are the sole and exclusive owners of all right, title and interest in and to all of the Purchased Assets, free and clear of all Encumbrances other than Permitted Encumbrances; and to the Knowledge of the Seller, no Person is infringing or otherwise violating any of the Purchased Assets. Upon Closing, good and marketable title to the Purchased Assets will pass to Purchaser, free and clear of all Encumbrances other than Permitted Encumbrances.

Section 5.04 Acquired Contracts.

(a) Each Acquired Contract is a valid and binding obligation of the Seller or an Affiliate of Seller who is a party thereto (and, to the Knowledge of the Seller, each other party thereto) and is enforceable against the Seller or the Affiliate of Seller who is a party thereto (and, to the Knowledge of the Seller, each other party thereto) in accordance with its terms, and is in full force and effect, subject to (i) the effects of bankruptcy, insolvency, fraudulent conveyance, reorganization, moratorium and other similar Laws relating to or affecting the enforcement of creditors' rights generally and (ii) general equitable principles (whether considered in a proceeding in equity or at Law).

(b) Neither Seller nor any Affiliate of Seller is in violation, breach or default in any material respect under any Acquired Contract to which it is a party, and to the Knowledge of the Seller no event has occurred that will (with or without notice or lapse of time) result in a violation, breach or default in any material respect by the Seller or any Affiliate of Seller under any Acquired Contract to which it is a party. To the Knowledge of the Seller, there is no violation, breach, or default in any material respect under any Acquired Contract by any other party to such Acquired Contracts. No party to any Acquired Contract has cancelled or withdrawn any such Acquired Contract, nor, to the Knowledge of the Seller, has any party threatened in writing to do so.

(c) All Consents required for the sale, conveyance, transfer and delivery of the Acquired Contracts to Purchaser pursuant to this Agreement have been obtained.

Section 5.05 Compliance with Law; Permits; Regulatory Matters.

(a) The Seller's and its Affiliates' use of the Purchased Assets has been and is being conducted in compliance in all material respects with all applicable Laws.

(b) To the Knowledge of the Seller, the Existing Product is being and has been developed in material compliance with applicable Law, including those requirements relating to good manufacturing practice, good laboratory practice and good clinical practice. Neither the Seller nor any of its Affiliates have received (and, to the Knowledge of the Seller, neither Eisai nor any of its Affiliates has received) any (i) written notice from the FDA or any other Governmental Authority, including the Office of Inspector General, any United States Attorney, the Department of Justice or any attorney general of any jurisdiction, alleging that the Seller, Eisai or any of their respective Affiliates has been or is in violation of any Applicable Healthcare Industry Laws or other applicable Laws, or commencing or indicating an intention to conduct an investigation, audit, or review, in each case, in connection with the conduct of the Business or the Purchased Assets; (ii) written notice of inspectional observation (including those recorded on form FDA 483), warning letter, penalty, fine, sanction, request for recall or other remedial action in connection with the conduct of the Business or the Purchased Assets; or (iii) other written documents issued by the FDA or any other Governmental Authority alleging lack of compliance with any Applicable Healthcare Industry Laws or other applicable Laws by the Seller, Eisai or any of their respective Affiliates, or any Person engaged by the Seller, Eisai or any of their respective Affiliates, to provide any service with respect to any Existing Product or otherwise in connection with the conduct of the Business or the Purchased Assets.

(c) Seller holds all Permits which are required by the Seller to conduct the Business as it currently being conducted, except where failure to hold any Permit would not reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect.

(d) Neither the Seller nor any of its Affiliates (nor, to the Knowledge of the Seller, Eisai or any Affiliate of Eisai) has made an untrue statement or fraudulent statement of material fact to the FDA or any other Governmental Authority or to any physician or customer, failed to disclose a material fact required to be disclosed to the FDA or any other Governmental Authority or to any physician or customer, or committed any material act, made any material statement, or failed to make any material statement, that would reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Fact, Bribery, and Illegal Gratuities", set forth in FDA's Compliance Policy Guide Sec. 120.100 (CPG 7150.09) with respect to the Existing Product. Neither the Seller (nor any of its Affiliates or its or their respective directors, officers or employees who has been involved in the development of the Existing Product) nor, to the Knowledge of the Seller, Eisai or any Affiliate of Eisai (or any officers, employees, or agents of any of the foregoing) or any agent of the Seller has (i) been convicted of any crime or engaged in any conduct that would reasonably be expected to result in, or that has resulted in, debarment, disqualification or exclusion by any Governmental Authority or under applicable Law, including 21 U.S.C. §335a, or (ii) any knowledge of facts that would lead to a false claim, or debarment, and there are no proceedings pending or threatened that would result in criminal liability or debarment or disqualification by any Governmental Authority.

(e) Neither the Seller, nor, to the Knowledge of the Seller, any Affiliate, director, manager, officer, equity holder or employee of the Seller has (i) used any funds for contributions, gifts, entertainment or other expenses in violation in any material respect of applicable Law, (ii) paid any bribe, kickback or other similar payment, directly or indirectly, to any foreign government official or employee in violation of the Foreign Corrupt Practices Act of 1977 or other applicable Law, (iii) made any other payment of any kind in violation of any Law, to secure any improper advantage for the Purchased Assets or the Seller or any of its Affiliates, or (iv) knowingly incorrectly recorded any transactions in any of the foregoing categories on the books and records of the Seller or any of its Affiliates. No claims, actions or proceedings or, to the Knowledge of the Seller, actual or threatened investigations that would be reasonably expected to result in such a debarment, disqualification or exclusion are pending or to the Knowledge of the Seller, threatened, against the Seller or its Affiliates, Eisai or its Affiliates or any of their respective officers, employees or agents.

(f) All ongoing and completed preclinical studies and clinical trials conducted by the Seller or its Affiliates or, to the Knowledge of the Seller, Eisai or any of its Affiliates, or by third-party vendors on behalf of any of them, with respect Products have been conducted in all material respects in accordance with the applicable Good Clinical Practice regulations described in 21 CFR Parts 50, 54, 56 and 312, and applicable Good Laboratory Practice regulations as described in 21 CFR Part 58 and comparable applicable Law solely to the extent the foregoing are applicable to such studies and/or trials.

(g) Seller has made available to Purchaser (or its agents) true, correct and complete copies of (i) the IND relating to the Existing Product and (ii) any other material documents received from the FDA or equivalent non-US regulatory agency in the possession or control of Seller or any of its Affiliates, including documents that indicate or suggest lack of compliance with the regulatory requirements of the FDA or other regulatory agencies, in each case to the extent related to any Product (or the development or approval of any Product) or any Purchased Asset. Seller has made available to Purchaser for review all material correspondence to or from the FDA, material minutes of meetings, including material documents concerning communications to or from the FDA or other regulatory agencies, or prepared by the FDA or other regulatory agency or which bear on the ability to obtain approval of the Existing Product or compliance with regulatory requirements with respect to any of the foregoing, each of the foregoing, to the extent in the possession or control of Seller or any of its Affiliates.

(h) To the Knowledge of the Seller and without making any due inquiry, the Seller is unaware of any material correspondence to or from the FDA on the one hand, and Eisai or its Affiliates on the other hand, that indicate a lack of compliance with the regulatory requirements of the FDA with respect to the Existing Product in the Territory, or which bear in any material respect on the ability to obtain approval of the Existing Product in the Territory, which (i) are not part of the IND relating to the Existing Product that has been made available to Purchaser, or (ii) has not otherwise been made available to Purchaser.

Section 5.06 Brokers. Neither the Seller nor any of its Affiliates has incurred, nor will any of them incur, directly or indirectly, any Liability for brokers' or finders' fees or agents' commissions or any similar charges in connection with this Agreement or the consummation of the transactions contemplated hereby.

Section 5.07 Litigation.

(a) There is no Legal Proceeding by any Person pending relating to or affecting the Business, Existing Product, the Purchased Assets or the Assumed Liabilities. There is no Legal Proceeding pending or, to the Knowledge of the Seller, threatened that is reasonably likely to prohibit or restrain the ability of the Seller to enter into this Agreement or consummate the transactions contemplated hereby.

(b) There is no written demand or other assertion by any Person pending nor, to the Knowledge of the Seller, threatened in writing, against or by the Seller or its Affiliates (or, to the Knowledge of the Seller, against or by Eisai or any of its Affiliates) relating to or affecting the Business, Existing Product, the Purchased Assets or the Assumed Liabilities (each, a "Business Claim"), which if determined adversely to the Seller would result in a Material Adverse Effect (and, to the Knowledge of the Seller, there is no other Business Claim).

(c) Neither the Seller nor any of its Affiliates is a party or subject to the provisions of any Governmental Order that is unsatisfied or that affects the Business or Purchased Assets.

Section 5.08 Intellectual Property.

(a) To the Knowledge of the Seller, neither the Purchased Intellectual Property nor the Exploitation of the Product (as such Product exists as of the date hereof or, if the Existing Product were being commercialized in the Territory as of the date hereof) infringes any intellectual property rights or misappropriates any trade secrets owned by any Third Party in the Territory. No action, claim, demand, suit or other assertion by any Person is pending, nor to the Knowledge of the Seller, has been threatened in writing as of or prior to the date hereof against the Seller or any of its Affiliates (or, to the Knowledge of Seller, against Eisai or any of its Affiliates) by any Third Party claiming that the (i) Purchased Intellectual Property, or (ii) the Exploitation of any Product (as such Products exist as of the Closing) infringes the intellectual property rights or misappropriates any trade secrets of such Third Party. To the Knowledge of the Seller, no Third Party is infringing any of the Purchased Intellectual Property in the Territory.

(b) Neither the Seller nor any of its Affiliates has granted any Third Party any license, sublicense, option or other rights with respect to any of the Purchased Assets (including, but not limited to, the Purchased Intellectual Property and any rights under any Acquired Contract), nor is the Seller or any of its Affiliates obligated to pay any royalties or licensing fees to any Third Party in connection with any of the Purchased Assets, Products or Compound (except for milestone payments expressly set forth in the Eisai Agreement).

Section 5.09 No Other Assets. Except for the Purchased Assets and the Licensed Know How, neither Seller nor any of its Affiliates owns, licenses or otherwise has any rights with respect to any material asset (including, but not limited to, any Intellectual Property, Contract, Regulatory Approval Application, Regulatory Approval and tangible material (other than materials being assigned and transferred pursuant to the Inventory Letter)) that, as of the Closing Date, is used in, or otherwise necessary for, the Exploitation of any Product (as such Products exist as of the Closing) or the Compound in the Territory.

Section 5.10 No Other Representations and Warranties. Except for the representations and warranties contained in this ARTICLE VI, the Seller has not made any other express or implied representation or warranty, either written or oral, on behalf of the Seller, including any representation or warranty as to the accuracy or completeness of any information regarding the Seller or the Purchased Assets furnished or made available to the Purchaser or its representatives.

ARTICLE VI
REPRESENTATIONS AND WARRANTIES OF PURCHASER

The Purchaser represents and warrants to the Seller that the statements contained in this ARTICLE VI are true and correct as of the date hereof.

Section 6.01 Organization and Authority of the Purchaser. Purchaser is a corporation duly organized, validly existing and in good standing under the Laws of the State of Nevada and has the requisite power and authority to own and operate its business as presently conducted. Purchaser is duly qualified to do business and in good standing in each jurisdiction where the operations of its business requires such qualification, except where the failure to be so qualified or in such good standing will not prevent or delay the ability of Purchaser to consummate the transactions contemplated by this Agreement and the other Transaction Documents.

Section 6.02 Authority; Non-Contravention, Required Filings.

(a) The Purchaser has the requisite corporate power and authority to execute and deliver this Agreement and the other Transaction Documents to which it is a party and to perform its obligations hereunder and thereunder and to consummate the transactions contemplated hereby and thereby. The execution and delivery by the Purchaser of this Agreement and the other Transaction Documents to which the Purchaser is a party, and the performance by the Purchaser of its obligations hereunder and thereunder, and the consummation by the Purchaser of the transactions contemplated hereby and thereby, has been duly authorized by all necessary corporate action on the part of the Purchaser.

(b) This Agreement and the other Transaction Documents to which the Purchaser is a party have been duly executed and delivered by the Purchaser and each constitutes a valid and binding obligation of the Purchaser, enforceable against it in accordance with its terms, in each case subject to: (i) the effects of bankruptcy, insolvency, fraudulent conveyance, reorganization, moratorium and other similar Laws relating to or affecting the enforcement of creditors' rights generally; and (ii) general equitable principles (whether considered in a proceeding in equity or at Law).

(c) The execution and delivery by the Purchaser of this Agreement and the other Transaction Documents to which the Purchaser is a party, the performance by the Purchaser of its obligations hereunder or thereunder, and the consummation by the Purchaser of the transactions contemplated hereby and thereby do not and will not (i) contravene any provision of the Organizational Documents of Purchaser, (ii) constitute a breach, violate the terms, conditions or provisions of, or result in a default under, or give to others any rights of termination, amendment, acceleration or cancellation of any contract or agreement to which the Purchaser is a party or is otherwise bound, or (iii) violate any provision of any Laws to which the Purchaser is subject.

(d) No Permit, Consent, waiting period expiration or termination, approval or authorization of, or designation, declaration or filing with, any Governmental Authority on the part of the Purchaser is required in connection with the execution or delivery by the Purchaser of this Agreement or the consummation of the transactions contemplated hereby.

Section 6.03 Legal Proceedings. There are no Legal Proceedings pending or, to the Knowledge of the Purchaser, threatened against or by Purchaser or any Affiliate of Purchaser, that are reasonably likely to prohibit or restrain the ability of the Purchaser to enter into this Agreement or consummate the transactions contemplated hereby.

Section 6.04 Sufficiency of Funds. The Purchaser has sufficient cash, available lines of credit or other sources of immediately available funds to enable it to timely make payment of the Upfront Payment and consummate the transactions contemplated by this Agreement.

Section 6.05 Brokers. No broker, finder or investment banker is entitled to any brokerage, finder's or other fee or commission in connection with the transactions contemplated by this Agreement based upon arrangements made by or on behalf of the Purchaser.

Section 6.06 Financial Statements. Complete copies of the Purchaser's audited financial statements consisting of the balance sheet of the Purchaser as at September 30, 2020 and as at September 30, 2019 and the related statements of income and retained earnings, stockholders' equity and cash flow for the 12 month periods then ended (the "**Audited Financial Statements**"), and unaudited financial statements consisting of the balance sheet of the Purchaser as at June 30, 2021 and the related statements of income and retained earnings and cash flow for the three-month period then ended (the "**Interim Financial Statements**" and together with the Audited Financial Statements, the "**Financial Statements**") have been filed with the SEC and are publicly available. The Audited Financial Statements have been prepared in accordance with GAAP and the Interim Financial Statements have been prepared in accordance with GAAP, both as applied on a consistent basis throughout the period involved, subject, in the case of the Interim Financial Statements, to normal and recurring year-end adjustments (the effect of which will not be materially adverse) and the absence of notes (that, if presented, would not differ materially from those presented in the Audited Financial Statements). The Financial Statements are based on the books and records of the Purchaser, and fairly present the financial condition of the Purchaser as of the respective dates they were prepared and the results of the operations of the Purchaser for the periods indicated. The Purchaser maintains a standard system of accounting established and administered in accordance with GAAP, as the case may be. The Purchaser acknowledges that, in making their decision to enter into this Agreement and the Transaction Documents and to consummate the transactions contemplated hereby and thereby, the Seller is expressly relying on the Purchasers' representations and warranties in this Section 6.06 and that, without such representations and warranties, the Seller would not have entered into this Agreement and the other Transaction Documents or consented to the transactions contemplated hereby and thereby.

Section 6.07 Solvency. Immediately after the Closing, and after giving effect to the transactions contemplated by this Agreement, the Purchaser will be Solvent.

Section 6.08 Independent Investigation; No Other Warranties. The Purchaser acknowledges that (a) they have conducted their own independent investigation, review and analysis of the materials and information provided by Seller to Purchaser prior to Closing and publicly-available information related to the Purchased Assets and have formed an independent judgment concerning the Purchased Assets, the Assumed Liabilities and the other rights or obligations to be transferred under this Agreement, and (b) they have been provided reasonable access to the personnel, properties, assets, premises, books and records, and other documents and information of the Seller and relating to the Purchased Assets. The Purchaser further acknowledges and agrees that: (i) the only representations, warranties, and covenants made by the Seller are the representations, warranties, and covenants expressly set forth in this Agreement, the other Transaction Documents and the certificates and documents delivered hereunder and thereunder; (ii) in making its decision to enter into this Agreement and to consummate the transactions contemplated hereby, the Purchaser has relied solely upon its own investigation and the express representations and warranties of the Seller set forth in this Agreement and the other Transaction Documents; and (iii) the Purchaser has not relied upon any other representations or other information made or supplied by or on behalf of the Seller (including any information provided by the Seller's advisors or in management presentations) and the Purchaser will not have any right or remedy arising out of any such other representations or information. The Purchaser acknowledges and agrees that, except as expressly provided in ARTICLE V, the sale of the Purchased Assets is "as is" and "where is," and the Purchaser is acquiring the Purchased Assets without any other representation or warranty, written or oral, statutory, express or implied, including any implied warranty of merchantability, fitness of any asset for a particular purpose, title, or non-infringement.

ARTICLE VII
COVENANTS

Section 7.01 Confidentiality. From and after the Closing:

(a) The Confidentiality Agreement will terminate without further action by the Parties thereto.

(b) The Seller shall treat as confidential and shall safeguard any and all Confidential Information of the Purchaser (which shall include information, knowledge, and data regarding the Products, the Purchased Assets, and the Assumed Liabilities and the terms and conditions of this Agreement) by using the same degree of care, but no less than a reasonable standard of care, to prevent the unauthorized use, dissemination, or disclosure of such Confidential Information as the Seller or its Affiliates used with respect thereto prior to the execution of this Agreement. The Seller shall not use the Confidential Information of the Purchaser for any purpose except for the benefit of the Purchaser, unless expressly permitted by this Agreement.

(c) The Purchaser shall treat as confidential and shall safeguard any and all Confidential Information of the Seller relating to the businesses of the Seller, other than any information specifically related to the Products, the Purchased Assets, or the Assumed Liabilities, and except as otherwise agreed to by the Seller in writing; provided, however, that nothing in this Section 7.01(c) shall prevent the disclosure of any such Confidential Information to any directors, officers, employees, or professional advisors of the Purchaser to whom such disclosure is necessary in the conduct of the Purchaser's business if such Persons are informed by the Purchaser of the confidential nature of such information and are directed by the Purchaser to comply with the provisions of this Section 7.01(c).

(d) The Purchaser and the Seller acknowledge that the confidentiality obligations set forth herein shall not extend to information, knowledge and data that is publicly available or becomes publicly available through no act or omission of the Party owing a duty of confidentiality, or becomes available on a non-confidential basis from a source other than the Party owing a duty of confidentiality so long as such source is not known by such Party to be bound by a confidentiality agreement with or other obligations of secrecy to the other Party.

(e) In the event of a breach of the obligations hereunder by the Purchaser or the Seller, the non-breaching Party(ies), in addition to all other available remedies, will be entitled to injunctive relief to enforce the provisions of this Section 7.01 in any court of competent jurisdiction, without the necessity of posting a bond and the burden of proving actual damages.

Section 7.02 Preservation of Books and Records.

(a) The Seller shall have the right to retain copies of all books and records relating to the Purchased Assets relating to periods ending on or prior to the Closing Date, provided that such books and records are kept confidential in accordance with the Seller's normal confidentiality procedures and the provisions of Section 7.01.

(b) Without prejudice to the provisions of Section 3.03, the Purchaser shall preserve and keep, or cause to be preserved and kept, the books and records included in the Purchased Assets in the possession of the Purchaser or its Affiliates for the longer of: (i) any applicable statute of limitations; and (ii) a period of [***] ([***]) years from the Closing.

(c) Without prejudice to the provisions of Section 3.03, during such retention period:

(i) the Seller, its Affiliates and their respective representatives shall, upon reasonable notice and for any reasonable business purpose, have access during normal business hours to examine, inspect and copy such books and records; and

(ii) the Purchaser shall provide, or cause to be provided to, the Seller, its Affiliates and their respective representatives, access to such books and records relating to the Purchased Assets as they shall reasonably request in connection with any Legal Proceeding to which any of them are parties or in connection with the requirements of any Law applicable to them.

(d) No Party shall be obligated to provide the other Party with access to any books or records pursuant to this Section 7.02 where such access would violate any Law.

Section 7.03 Public Announcements. Neither the Seller, the Purchaser nor any of their respective Affiliates shall issue any press release or make any public announcement with respect to this Agreement and the transactions contemplated hereby without obtaining the prior written consent of the other Party, except as may be required by Law, including any federal, state or local securities law (or stock exchange rules and regulations), upon the advice of counsel and only if the disclosing Party (x) provides the non-disclosing Party with an opportunity to first review the release or other public announcement, (y) consults with the non-disclosing Party (whether such Party is named in such publicity, news release or public announcement or not) at a reasonable time prior to its release to allow the non-disclosing Party to comment thereon (provided that the foregoing shall not prevent the disclosing Party from proceeding with such release or other public announcement by any applicable deadline required under applicable Law or stock exchange rules or regulations if the non-disclosing Party fails to timely respond to such requests) and (z) after its release, shall provide the non-disclosing Party with a copy thereof. If a Party, based on the advice of its counsel, determines that this Agreement or exhibits thereto must be filed with the United States Securities and Exchange Commission ("**SEC**") or similar Governmental Authority, then such Party, prior to making any such filing, shall provide the other Party and its counsel with a redacted version of this Agreement which it intends to file and any draft correspondence with the SEC (or similar Governmental Authority) requesting the confidential treatment by the SEC (or similar Governmental Authority) of those redacted sections of the Agreement, and will give due consideration to any comments provided by such other Party or its counsel and use good faith efforts to obtain confidential treatment by the SEC of those sections specified by such other Party or its counsel; provided, however, that the Party filing this Agreement or its exhibits will not be required to seek confidential treatment of any information that it determines it is required to publicly disclose based on advice of counsel. Following the Closing, the Purchaser shall be entitled to make such public announcements as it deems appropriate related to the Compound or Products; provided however that except as otherwise provided above, without the Seller's prior written consent, no such announcement shall contain any reference to the Agreement or the terms set forth therein or the Seller, its Affiliates or actions taken with respect to the Compound or Products prior to the Effective Date other than references consistent with those previously approved by the Seller.

Section 7.04 Further Assurances. Except as otherwise set forth herein, subject to the terms and conditions set forth herein and to applicable legal requirements, each of the Parties hereto shall, and shall cause its respective Affiliates to, cooperate and use their respective commercially reasonable efforts to take, or cause to be taken, all appropriate action, and do, or cause to be done, and assist and cooperate with the other Party in doing, all things necessary, proper or advisable to consummate and make effective, in the most expeditious manner practicable, the transactions contemplated in this Agreement.

Section 7.05 Certain Intellectual Property Matters. Any recovery realized because of litigation of the Purchased Patents or Purchased Intellectual Property (whether by way of settlement or otherwise) shall be first allocated to reimburse Purchaser for their direct and out of pocket costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses). Any remainder after such reimbursement is made shall be retained by Purchaser provided, however, that to the extent that any award or settlement (whether by judgment or otherwise) with respect to Purchased Intellectual Property is attributable to loss of sales or profits with respect to the Product, that has impacted a Milestone Payment based on Net Sales or other Quarterly Earn-Out Payments to Seller, the Parties shall negotiate in good faith an appropriate allocation of such remainder to reflect the economic interests as a whole of the Parties under this Agreement with respect to the Product, including the adjustment of Net Sales.

Section 7.06 License to Licensed Know-How. Effective as of the Closing, Seller (on behalf of itself and its Affiliates) hereby grants to Purchaser a perpetual, irrevocable, paid-up, royalty-free, transferable, sub-licensable, worldwide, exclusive (even as to Seller and its Affiliates) license under the Licensed Know-How solely in order to Exploit the Compound and any Product (including any companion diagnostic related to a Product). For the avoidance of doubt, the Licensed Know-How shall not be used for products of the Purchaser, its Affiliates, Licensees or Transferees, other than Products.

ARTICLE VIII
NON-COMPETE AND NON-SOLICITATION RESTRICTIONS

Section 8.01 Non-Compete. For a period of [***] ([***]) years commencing on the Closing Date (the "**Restricted Period**"), Seller shall not, and shall ensure that its Affiliates do not, directly or indirectly engage in, or assist anyone other than Purchaser in engaging in, the Exploitation in the Territory of any Restricted Product.

Section 8.02 Non-Solicitation. For a period of [**] ([***]) years commencing on the Closing Date, neither Party shall directly or indirectly contact or solicit any person while such person is employed or engaged as an independent contractor by the other Party hereto (or any of its Affiliates) for the purposes of hiring or engaging such person, or encourage any such employee or independent contractor to leave such employment or engagement, without the prior written consent of such other Party. The foregoing restriction shall not apply to employees or independent contractors who respond to general solicitations which are not directed specifically to any such employees or independent contractors.

Section 8.03 Acknowledgements; Remedies. Seller acknowledges that the restrictions contained in Section 8.01 are reasonable and necessary to protect the legitimate interests of Purchaser and constitute a material inducement to Purchaser to enter into this Agreement and consummate the transactions contemplated by this Agreement. Seller further acknowledges that a breach or threatened breach of Section 8.01 may give rise to irreparable harm to Purchaser, for which monetary damages would not be an adequate remedy, and hereby agrees that in the event of a breach or a threatened breach by Seller of any such obligations, Purchaser shall, in addition to any and all other rights and remedies that may be available to it in respect of such breach, be entitled to seek equitable relief, including a temporary restraining order, an injunction, specific performance and any other relief that may be available from a court of competent jurisdiction. In the event that any covenant contained in Section 8.01 should ever be adjudicated to exceed the time, geographic, product or service or other limitations permitted by applicable Law in any jurisdiction, then any court is expressly empowered to reform such covenant, and such covenant shall be deemed reformed, in such jurisdiction to the maximum time, geographic, product or service or other limitations permitted by applicable Law.

ARTICLE IX
INDEMNIFICATION

Section 9.01 Survival. Except for the representations and warranties contained in Section [***] and Section [***] (collectively, the "**Fundamental Representations**") (which shall survive and remain in full force and effect for a period of [***] ([***]) years following the Closing Date), the representations and warranties contained in ARTICLE V and ARTICLE VI of this Agreement shall survive the Closing until the close of business on the [***] ([***]) month anniversary of the Closing Date. All covenants and agreements contained in this Agreement, whether of the Purchaser or the Seller, shall survive the Effective Date until the applicable statute of limitations has expired or until the expiration date for such covenant or agreement specified in this Agreement, if sooner. Any claims for Losses arising out of or caused by or relating to fraud shall survive indefinitely. The representations and warranties of the Seller are bargained for assurances. All claims by any Indemnified Party pursuant to this ARTICLE IX must be made on or before the applicable survival date, it being understood that so long as the Indemnified Party gives written notice of a claim on or prior to the applicable survival date, such representations and warranties and covenants shall continue to survive solely with respect to such claim until such claim is fully and finally resolved in accordance with the terms of this Agreement.

Section 9.02 Indemnification by Seller. Subject to the terms and conditions of this ARTICLE IX, from and after the Closing, the Seller shall indemnify and defend the Purchaser, its Affiliates, and each of their respective employees, directors, officers, stockholders, agents, and representatives (collectively, the "**Purchaser Group**"), against, and shall hold each of them harmless from, any and all Losses incurred or sustained by the Purchaser Group based upon or arising out of:

(a) any inaccuracy in or breach of any of the representations or warranties of the Seller contained in this Agreement, as of the date such representation or warranty was made or as if such representation or warranty was made on and as of the Closing Date (except for representations and warranties that expressly relate to a specified date, the inaccuracy in or breach of which will be determined with reference to such specified date);

(b) any breach or non-fulfillment of any covenant, agreement, or obligation to be performed by the Seller pursuant to this Agreement or any other Transaction Document (which shall not include the Transition Services Agreement); or

(c) any Excluded Asset or Excluded Liability.

The foregoing indemnity obligations will not apply to (i) the extent that such Losses arise out of or result from the fraud, gross negligence, and/or willful misconduct of Purchaser or its Affiliates, and/or any related breach by Purchaser of its representations, warranties, and/or covenants hereunder, or (ii) Losses for which Purchaser has an obligation to indemnify the Seller Group pursuant to Section 9.03, as to which Losses each Party shall indemnify the other to the extent of its respective liability for such Losses.

Section 9.03 Indemnification by Purchaser. Subject to the terms and conditions of this ARTICLE IX, from and after the Closing, the Purchaser shall indemnify and defend the Seller, its Affiliates, and each of their respective employees, directors, officers, stockholders, agents, and representatives (collectively, the "**Seller Group**"), against, and shall hold each of them harmless from, any and all Losses incurred or sustained by the Seller Group based upon or arising out of:

(a) any inaccuracy in or breach of any of the representations or warranties of the Purchaser contained in this Agreement or in any certificate or instrument delivered by or on behalf of the Purchaser pursuant to this Agreement, as of the date such representation or warranty was made or as if such representation or warranty was made on and as of the Closing Date (except for representations and warranties that expressly relate to a specified date, the inaccuracy in or breach of which will be determined with reference to such specified date);

(b) any breach or non-fulfillment of any covenant, agreement, or obligation to be performed by the Purchaser pursuant to this Agreement or any other Transaction Document (which shall not include the Transition Services Agreement);

(c) any Assumed Liability; or

(d) the Exploitation, development, manufacture, supply, marketing or distribution of the Compound or any Product following the Closing.

The foregoing indemnity obligations will not apply to (i) the extent that such Losses arise out of or result from the fraud, gross negligence, and/or willful misconduct of Seller or its Affiliates, and/or any related breach by Seller of its representations, warranties, and/or covenants hereunder, or (ii) Losses for which Seller has an obligation to indemnify the Purchaser Group pursuant to Section 9.02, as to which Losses each Party shall indemnify the other to the extent of its respective liability for such Losses.

Section 9.04 Notice of Direct Claims.

(a) If any of the Persons to be indemnified under this ARTICLE IX (the "**Indemnified Party**") has suffered or incurred any Loss subject to indemnification under this ARTICLE IX that does not involve a Third Party Claim, the Indemnified Party shall so notify the Party responsible for providing indemnification therefor under this Agreement (the "**Indemnifying Party**") promptly in a writing describing such Loss, the basis for indemnification hereunder, the amount or estimated amount of such Loss, if known or reasonably capable of estimation, and the method of computation of such Loss, all with reasonable particularity and containing a reference to the provisions of this Agreement in respect of which such Loss shall have occurred. A failure by the Indemnified Party to give notice in a timely manner pursuant to this Section 9.04(a) (so long as a notice pursuant to this Section 9.04(a) is given before the expiration of the applicable period set forth in Section 9.01) shall not limit the obligation of the Indemnifying Party under this ARTICLE IX, except to the extent such Indemnifying Party is prejudiced by failure to give such notice in a timely manner.

(b) Except when a notice, report or other filing must be filed immediately pursuant to applicable Law, the Purchaser shall provide notice and an opportunity to comment to the Seller before the Purchaser files any report, notification or filing with any Governmental Authority or Third Party in connection with an event that would be reasonably likely to result in a Loss subject to the indemnification provisions of Section 9.02. In the event the Purchaser is required to file such a report, notification or filing immediately, the Purchaser shall provide notice to the Seller promptly after it submits such report, notification or filing to the applicable Governmental Authority.

Section 9.05 Third Party Claims.

(a) If any Legal Proceeding is instituted by or against a Third Party with respect to which the Indemnified Party intends to seek indemnity under this ARTICLE IX (a "**Third Party Claim**"), the Indemnified Party shall promptly notify the Indemnifying Party of such Third Party Claim (such notice describing, to the extent practicable, such matter in reasonable detail and such being accompanied by a copy of any written notice of the Third Party claimant to the Indemnified Party asserting the Third Party Claim) and tender to the Indemnifying Party the conduct or defense of such Third Party Claim. A failure by the Indemnified Party to give notice in a timely manner pursuant to this Section 9.05(a) (so long as a notice pursuant to this Section 9.05(a) that includes any written notice of the Third Party claimant is given before the expiration of the applicable period set forth in Section 9.01) and to tender the conduct or defense of the Third Party Claim in a timely manner pursuant to this Section 9.05(a) shall not limit the obligation of the Indemnifying Party under this ARTICLE IX, except (i) to the extent such Indemnifying Party is materially prejudiced thereby, and (ii) to the extent expenses are incurred during the period in which notice was not provided.

(b) The Indemnifying Party shall have the right to defend the Indemnified Party against such Third Party Claim. If the Indemnifying Party notifies the Indemnified Party that the Indemnifying Party elects to assume the defense of the Third Party Claim (such election to be without prejudice to the right of the Indemnifying Party to dispute whether such claim is an indemnifiable Loss under this ARTICLE IX), then the Indemnifying Party shall have the right to defend such Third Party Claim with counsel selected by the Indemnifying Party, in all appropriate proceedings, to a final conclusion or settlement at the discretion of the Indemnifying Party in accordance with this Section 9.05(b). The Indemnifying Party shall have full control of such defense and proceedings, including any compromise or settlement thereof; provided, however, that the Indemnifying Party shall not enter into any settlement agreement without the written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). Notwithstanding the foregoing, such consent shall not be required if (i) the settlement agreement contains a complete and unconditional general release by the Third Party asserting the Third Party Claim to all Indemnified Parties affected by the claim and (ii) the settlement agreement does not impose any obligation on, or contain any sanction or restriction upon the conduct or operation of any business by, the Indemnified Party or its Affiliates. The Indemnified Party may participate in, but not control, any defense or settlement of any Third Party Claim controlled by the Indemnifying Party pursuant to this Section 9.05(b), and the Indemnified Party shall bear its own costs and expenses with respect to such participation.

(c) If the Indemnifying Party does not notify the Indemnified Party that the Indemnifying Party elects to defend the Indemnified Party pursuant to Section 9.05(b) within thirty (30) days after receipt of any Claim Notice, then the Indemnified Party shall defend, and be reimbursed for its reasonable cost and expense (but only if the Indemnified Party is actually entitled to indemnification hereunder) in regard to the Third Party Claim with counsel selected by the Indemnified Party, in all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnified Party. In such circumstances, the Indemnified Party shall defend any such Third Party Claim in good faith and have full control of such defense and proceedings; provided, however, that the Indemnified Party may not enter into any compromise or settlement of such Third Party Claim if indemnification is to be sought hereunder, without the Indemnifying Party's consent (which consent shall not be unreasonably withheld, conditioned or delayed). The Indemnifying Party may participate in, but not control, any defense or settlement controlled by the Indemnified Party pursuant to this Section 9.05(c), and the Indemnifying Party shall bear its own costs and expenses with respect to such participation; provided, however, if at any time the Indemnifying Party acknowledges in writing that such Third Party Claim is an indemnifiable Loss under this ARTICLE IX, the Indemnifying Party shall be entitled to assume the defense of such Third Party Claim in accordance with Section 9.05(b).

(d) If requested by the Indemnifying Party, the Indemnified Party agrees, at the sole cost and expense of the Indemnifying Party (but only if the Indemnified Party is actually entitled to indemnification hereunder), to cooperate with the Indemnifying Party and its counsel in contesting any Third Party Claim which the Indemnifying Party elects to contest, including providing access to documents, records and information. In addition, the Indemnified Party will make its personnel available to the Indemnifying Party, at the Indemnifying Party's expense, for conferences, discovery, proceedings, hearings, trials or appeals as may be reasonably required by the Indemnifying Party. The Indemnified Party also agrees to cooperate with the Indemnifying Party and its counsel in the making of any related counterclaim against the Person asserting the Third Party Claim or any cross complaint against any Person and executing powers of attorney to the extent necessary.

Section 9.06 Limitations on Indemnification; Limitations on Liability.

(a) Thresholds. Notwithstanding the other provisions of this ARTICLE IX, other than claims for Losses arising out of, or caused by or relating to fraud or for any breach of a Fundamental Representation, the Seller shall not be liable to provide indemnification for any Losses arising from or in connection with matters described under Section 9.02 suffered by any Indemnified Party unless and until the aggregate amount of all such Losses suffered by the Indemnified Parties exceeds, on a cumulative basis, an amount equal to $[***] ([***] Dollars) (the "**Indemnity Threshold**"), and then the Seller shall only be liable to provide indemnification to the extent exceeding the Indemnity Threshold. No Losses shall be included in determining whether the Indemnity Threshold has been reached unless a notice seeking indemnification for such Losses has been given by the Purchaser Group to the Seller in accordance with Section 9.04(a) or Section 9.05(a), as applicable.

(b) Caps. Other than claims for Losses arising out of, or caused by or relating to fraud, in no event shall the Seller be liable to provide indemnification pursuant to ARTICLE IX for Losses arising from or in connection with matters described under Section 9.02(a) in the aggregate in excess of an amount equal to $[***] ([***] Dollars (the "**Cap**"). Notwithstanding anything to the contrary herein, with respect to breaches of Fundamental Representations, the Cap shall be an amount equal to [***].

Section 9.07 Exclusion of Certain Damages. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT TO THE CONTRARY, EXCEPT FOR (I) LIABILITY FOR ANY PARTY'S FRAUD AND (II) THE OBLIGATIONS OF ANY PARTY TO INDEMNIFY AN INDEMNIFIED PARTY UNDER ARTICLE IX FROM AND AGAINST THIRD PARTY CLAIMS PURSUANT TO WHICH A THIRD PARTY HAS BEEN AWARDED SUCH DAMAGES, NO INDEMNIFIED PARTY SHALL BE LIABLE FOR ANY INDIRECT, INCIDENTAL, TREBLE, REMOTE, SPECIAL, EXEMPLARY, OPPORTUNITY COST, CONSEQUENTIAL OR PUNITIVE DAMAGES OR DAMAGES FOR, MEASURED BY OR BASED ON LOST PROFITS, LOSS OF REVENUE OR INCOME, DIMINUTION IN VALUE, MULTIPLE OF EARNINGS, PROFITS OR CASH FLOWS, OR OTHER SIMILAR MEASURES OR FOR ANY LOSS OF BUSINESS REPUTATION OR OPPORTUNITY THAT ARISES OUT OF OR RELATES TO THIS AGREEMENT OR THE PERFORMANCE OR BREACH HEREOF OF ANY LIABILITY RETAINED OR ASSUMED HEREUNDER.

Section 9.08 Purchaser's Opportunity to Review. The Purchaser acknowledges that it and its representatives have received or been afforded the opportunity to review prior to the date of this Agreement all written materials furnished or made available, as the case may be, to the Purchaser on or prior to the date of this Agreement in connection with the transactions contemplated by this Agreement. The Purchaser acknowledges that it and its Affiliates and representatives have been permitted full and complete access to the books and records, and other assets related to the Purchased Assets that it and its representatives have desired or requested to see or review and that it and its representatives have had a full opportunity to meet with the officers and employees of the Seller to discuss the Purchased Assets and the Assumed Liabilities. The Purchaser further acknowledges and agrees that (i) other than the representations and warranties of the Seller specifically contained in ARTICLE V of this Agreement, neither the Seller nor any other Person has made any representation or warranty either expressed or implied (A) with respect to the Purchased Assets, the Assumed Liabilities or the transactions contemplated hereby or (B) as to the accuracy or completeness of any information regarding the Purchased Assets, the Assumed Liabilities or the transactions contemplated hereby or by any other agreements related hereto furnished or made available to the Purchaser and its representatives, (ii) the Purchaser has not relied on any representation or warranty from the Seller or any other Person in determining to enter into this Agreement, except as expressly set forth in ARTICLE V of this Agreement and (iii) no Person who is part of the Purchaser Group shall have any claim or right to indemnification pursuant to this ARTICLE IX and neither the Seller nor any other Person shall have or be subject to any Liability to the Purchaser Group (or any Person who is part of such group) or any other Person with respect to any information, documents or materials furnished by the Seller or any of their representatives or agents to the Purchaser (it being understood that this clause (iii) does not supersede or otherwise affect the representations and warranties of the Seller specifically contained in ARTICLE V of this Agreement). Without limiting the generality of the foregoing, the Purchaser acknowledges and agrees that, except as otherwise expressly set forth in Article 5, (i) the Seller does not make any representations or warranties relating to the maintenance, repair, condition, design, performance or marketability of any Purchased Asset, including merchantability or fitness for a particular purpose, (ii) Purchaser shall obtain rights in the Purchased Asset in their present condition and state of repair, "as is" and "where is".

Section 9.09 Adjustment to Purchase Price. The Seller and the Purchaser agree to treat all payments made either to or for the benefit of the other Party under this Agreement as adjustments to the Purchase Price for tax purposes to the extent permitted under applicable tax Law.

Section 9.10 Reimbursement. If an Indemnified Party recovers an amount from a Third Party in respect of a Loss that is the subject of indemnification hereunder after all or a portion of such Loss has been paid by an Indemnifying Party pursuant to this ARTICLE IX, the Indemnified Party shall promptly remit to the Indemnifying Party the amount received from the Third Party in respect thereof.

Section 9.11 Losses Net of Insurance. In determining the amount of Losses in respect of a claim under this ARTICLE IX, there shall be deducted an amount equal to the amount of any Third Party insurance proceeds actually received (net of direct collection expenses) by an Indemnified Party making such claim with respect to such Losses, provided that the foregoing shall not (i) require an Indemnified Party to proceed or seek action or recovery from any such Third Party as a requirement hereunder or as a condition to seeking or recovering indemnification from any Indemnifying Party hereunder (but the Indemnified Party shall use its good faith efforts to recover under insurance policies or indemnity, contribution or other similar agreements for any Losses and promptly notify in reasonable detail any such recovery to the Indemnifying Party and reimburse it in accordance with the provisions of Section 9.09 hereof, if applicable), or (ii) be construed or interpreted as a guaranty of any level or amount of insurance recovery with the provisions of Section 9.09 hereof, if applicable with respect to any Losses hereunder or as a requirement to maintain any insurance or to make any claim for insurance as a condition to any indemnification hereunder.

Section 9.12 Subrogation. To the extent that the Indemnifying Party makes or is required to make any indemnification payment to the Indemnified Party, the Indemnifying Party shall be entitled to exercise, and shall be subrogated to, any rights and remedies (including rights of indemnity, rights of contribution and other rights of recovery) that the Indemnified Party or any of its Affiliates may have against any other Person with respect to any Losses to which such indemnification payment is directly related.

Section 9.13 Sole Remedy/Waiver. Should the Closing occur, the remedies provided for in this ARTICLE IX shall be the sole and exclusive remedies of any Indemnified Party in respect of this Agreement, the Purchased Assets, the Product, the Excluded Assets, the Assumed Liabilities, the Excluded Liabilities or the transactions contemplated hereby, other than (i) for actions for specific performance or other equitable remedies, (ii) for claims arising out or related to ARTICLE III, or (iii) for claims against a Party directly arising out of the knowing and intentional fraud of such Party in respect of a provision of this Agreement. In furtherance of the foregoing, each Party hereby waives (on behalf of itself and the relevant Indemnified Parties) any provision of applicable Law to the extent that it would limit or restrict the agreement contained in this Section 9.13.

ARTICLE X
MISCELLANEOUS

Section 10.01 Expenses. Except as otherwise provided in this Agreement, the Seller, on the one hand, and the Purchaser, on the other hand, shall bear their own expenses incurred in connection with the negotiation and execution of this Agreement, each other agreement, document and instrument contemplated by this Agreement, and the consummation of the transactions contemplated hereby and thereby.

Section 10.02 Notices. All notices, requests, consents, claims, demands, waivers, and other communications hereunder shall be in writing and shall be deemed to have been given: (i) when delivered, if delivered personally to the intended recipient; (ii) when received by the addressee, if sent by an internationally recognized overnight courier service; (iii) on the date sent by facsimile (with verification of transmission) or email (with confirmation of receipt of the email and any attachments); or (iv) on the fifth (5^{th}) day after the date mailed, by certified or registered mail, return receipt requested, postage prepaid. Such communications must be sent to the respective Parties at the following addresses (or at such other address for a Party as shall be specified in a notice given in accordance with this Section 10.02):

(a) if to the Seller:

Dr. Reddy's Laboratories SA
Elisabethenanlage 11
CH – 4051, Basel
Switzerland
Attention: [***]

With a copy (which shall not constitute notice) to:

Dr. Reddy's Laboratories Limited
8-2-337, Road No. 3
Banjara Hills, Hyderabad – 500 034, Telangana, India
Attention: [***]

And

Dr. Reddy's Laboratories, Inc.
107 College Road East
Princeton, New Jersey 08540
Email: [***]
Fax: [***]
Attention: Legal Affairs

(b) if to the Purchaser:

Citius Pharmaceuticals, Inc.
11 Commerce Drive, First Floor
Cranford, New Jersey 07016
Facsimile: (908) 967-6683
Email: [***]
Attention: Chief Financial Officer

With a copy (which shall not constitute notice) to:

Lowenstein Sandler LLP
One Lowenstein Drive
Roseland, New Jersey 07068
Attn: Michael J. Lerner, Esq.

Section 10.03 Severability. If any term or provision of this Agreement is invalid, illegal, or unenforceable in any jurisdiction, such invalidity, illegality, or unenforceability shall not affect any other term or provision of this Agreement in such jurisdiction or invalidate or render unenforceable such term or provision in any other jurisdiction.

Section 10.04 Entire Agreement. This Agreement, together with the Exhibits, Annexes and Schedules hereto, the Seller Disclosure Schedule, the other Transaction Documents, Transition Services Agreement, constitute the entire agreement, and supersedes all prior agreements and understandings (both written and oral), among the Parties regarding the subject matter hereof.

Section 10.05 Successors and Assigns. This Agreement shall be binding upon and shall inure to the benefit of the Parties hereto and their respective successors and permitted assigns. Seller may assign their rights or obligations hereunder without the prior written consent of the Purchaser. Purchaser may not assign any of its rights or obligations hereunder without the prior written consent of the Seller (such consent not to be unreasonably withheld, denied or conditioned); provided, that following the payment in full of the Milestone Payment for the US CTCL Approval Milestone, the Purchaser may make an assignment or transfer of any of its rights or obligations hereunder without Seller's consent to its Affiliates or to a Third Party successor that acquires all or substantially all of the assets of the business of Purchaser to which this Agreement relates or rights with respect to any Product. As a condition to any assignment hereunder, (i) the assignee hereunder shall agree in writing to assume all applicable obligations (as defined in Section 3.03(d), in the case of an assignment by Purchaser) of the assignor under this Agreement, the Transition Services Agreement (as applicable) and other Transaction Documents as a condition to such assignment and (ii) the assignor shall provide notice to remaining party containing the name and contact information of the assignee. Further, as a condition to any assignment by the Purchaser hereunder, Purchaser shall pay any amounts owed to Seller as of the date of such assignment. No assignment hereunder will relieve any Party of responsibility for the performance of any accrued obligation of such Party prior to the date of such assignment under this Agreement. Any assignment in breach of the provisions of this Section 10.05 shall be *null and void ab initio*. Notwithstanding the foregoing, Seller hereby acknowledges and agrees that for so long as New Subsidiary (defined below) remains a wholly owned subsidiary of the Purchaser, Purchaser shall have the right to assign its rights and obligations in whole or in part under this Agreement to Citius Acquisition Corp., a wholly owned subsidiary of Purchaser ("New Subsidiary"), without any requirement to obtain Seller's prior consent; provided, that (a) Purchaser hereby guarantees and remains jointly and severally liable for all of such subsidiary's obligations under this Agreement and (b) for the purposes of the definition of Commercially Reasonable Efforts: (i) [***] and (ii) with respect to the Purchaser, all references to a "Party" shall refer to Purchaser, Citius Pharmaceuticals, Inc. and New Subsidiary, taken as a whole. Further, upon assignment to New Subsidiary, until [***], Purchaser shall not permit a Subsidiary Change of Control to occur without the prior written consent of the Seller (such consent not to be unreasonably withheld, denied or conditioned). As a condition to its assignment of its rights and obligations hereunder to New Subsidiary, Purchaser shall deliver to the Seller written confirmation that New Subsidiary has assumed, in writing, all obligations of the Purchaser under this Agreement. "Subsidiary Change of Control" means, with respect to New Subsidiary, (i) the sale, transfer or other disposition of (in one transaction or a series of related transactions) all or substantially all of the assets of such Person, (ii) any event, transaction or upon any occurrence under which Citius Pharmaceuticals, Inc. ceases to own greater than [***]% of the capital stock or voting power of New Subsidiary.

Section 10.06 No Third Party Beneficiaries. This Agreement is for the sole benefit of the Parties hereto and their respective successors and permitted assigns. Nothing in this Agreement, express or implied, is intended to or shall confer on any other Person any legal or equitable right, benefit, or remedy of any nature whatsoever.

Section 10.07 Amendment and Waiver. This Agreement may only be amended, modified or supplemented by an agreement in writing signed by each Party hereto. No waiver by any Party of any of the provisions hereof shall be effective unless explicitly set forth in writing and signed by the Party so waiving. No waiver by any Party shall operate or be construed as a waiver in respect of any failure, breach or default not expressly identified by such written waiver, whether of a similar or different character, and whether occurring before or after that waiver. No failure to exercise, or delay in exercising, any right, remedy, power or privilege arising from this Agreement shall operate or be construed as a waiver thereof; nor shall any single or partial exercise of any right, remedy, power or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power or privilege.

Section 10.08 Governing Law; Jurisdiction.

(a) This Agreement and its negotiation, execution, performance or non-performance, interpretation, termination, construction and all claims or causes of action (whether in contract, in tort, at Law or otherwise) that may be based upon, arise out of, or relate to this Agreement, or the transactions contemplated hereby (including any claim or cause of action based upon, arising out of or related to any representation or warranty made in connection with this Agreement or as an inducement to enter this Agreement), shall be exclusively governed by, and construed in accordance with, the Laws of the State of Delaware regardless of Laws that might otherwise govern under any applicable conflict of laws principles.

(b) Any Legal Proceeding based upon, arising out of, or related to this Agreement and its negotiation, execution, performance, non-performance, interpretation, termination, construction or the transactions contemplated hereby shall be heard and determined in the Court of Chancery in the City of Wilmington, New Castle County, Delaware or, in the event such court lacks subject matter jurisdiction, the United States District Court sitting in Wilmington, Delaware or, in the event such federal district court lacks subject matter jurisdiction, then in the Superior Court in the City of Wilmington, New Castle County, Delaware. The Parties hereto hereby irrevocably submit to the exclusive jurisdiction and venue of such courts in any such Legal Proceeding and irrevocably and unconditionally waive the defense of an inconvenient forum, or lack of jurisdiction to the maintenance of any such Legal Proceeding. The consents to jurisdiction and venue set forth herein shall not constitute general consents to service of process in the State of Delaware and shall have no effect for any purpose except as provided in this Section 10.08 and shall not be deemed to confer rights on any Person other than the Parties hereto. Each Party hereto agrees that the service of process upon such Party in any Legal Proceeding arising out of or relating to this Agreement shall be effective if notice is given by overnight courier at the address set forth in Section 10.02. Each of the Parties also agrees that any final, non-appealable judgment against a Party in connection with any Legal Proceeding arising out of or relating to this Agreement shall be conclusive and binding on such Party and that such award or judgment may be enforced in any court of competent jurisdiction, either within or outside of the United States. A certified or exemplified copy of such award or judgment shall be conclusive evidence of the fact and amount of such award or judgment.

Section 10.09 WAIVER OF JURY TRIAL. TO THE FULLEST EXTENT PERMITTED BY LAW, THE PARTIES HERETO HEREBY WAIVE THEIR RESPECTIVE RIGHTS TO A JURY TRIAL OF ANY LEGAL PROCEEDING (WHETHER IN CONTRACT, IN TORT, AT LAW OR OTHERWISE) BASED UPON, ARISING OUT OF, OR RELATED TO THIS AGREEMENT OR ANY OF THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL-ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT AND THAT RELATE TO THE SUBJECT MATTER OF THIS AGREEMENT, INCLUDING WITHOUT LIMITATION, CONTRACT CLAIMS, TORT CLAIMS, BREACH OF DUTY CLAIMS AND ALL OTHER COMMON LAW AND STATUTORY CLAIMS. THE PARTIES HERETO ACKNOWLEDGE THAT THIS WAIVER IS A MATERIAL INDUCEMENT TO ENTER INTO A BUSINESS RELATIONSHIP, THAT EACH HAS ALREADY RELIED ON THE WAIVER IN ENTERING INTO THIS AGREEMENT AND THAT EACH WILL CONTINUE TO RELY ON THE WAIVER IN THEIR RELATED FUTURE DEALINGS. THE PARTIES HERETO FURTHER WARRANT AND REPRESENT THAT EACH HAS REVIEWED THIS WAIVER WITH ITS LEGAL COUNSEL, AND THAT EACH KNOWINGLY AND VOLUNTARILY WAIVES ITS JURY TRIAL RIGHTS FOLLOWING CONSULTATION WITH LEGAL COUNSEL. THIS WAIVER IS IRREVOCABLE, MEANING THAT IT MAY NOT BE MODIFIED EITHER ORALLY OR IN WRITING, AND THIS WAIVER SHALL APPLY TO ANY SUBSEQUENT AMENDMENTS, RENEWALS, SUPPLEMENTS OR MODIFICATIONS TO THIS AGREEMENT OR TO ANY OTHER DOCUMENTS OR AGREEMENTS RELATING TO THE TRANSACTIONS CONTEMPLATED HEREBY. IN THE EVENT OF LITIGATION, THIS AGREEMENT MAY BE FILED AS A WRITTEN CONSENT TO A TRIAL BY THE COURT.

Section 10.10 Specific Performance. The Seller, on the one hand, and the Purchaser, on the other hand, acknowledge and agree that the breach of this Agreement or other failure to perform any provision of this Agreement would cause irreparable damage to the other and such other Party will not have an adequate remedy at law. Therefore, the Parties shall be entitled to specific performance of the terms of this Agreement in addition to any other remedy to which they are entitled at law or in equity.

Section 10.11 No Other Duties. The only duties and obligations of the Parties under this Agreement are as specifically set forth in this Agreement, and no other duties or obligations shall be implied in fact, Law or equity, or under any principle of fiduciary obligation.

Section 10.12 Reliance on Counsel and Other Advisors. Each Party has consulted such legal, financial, technical or other expert as it deems necessary or desirable before entering into this Agreement. Each Party represents and warrants that it has read, knows, understands and agrees with the terms and conditions of this Agreement.

Section 10.13 Bulk Transfer Laws. The Purchaser hereby waives compliance by the Seller and its Affiliates with any applicable provisions of any so-called "bulk transfer law" of any jurisdiction in connection with the transactions contemplated under this Agreement.

Section 10.14 Setoff Rights. Neither Party shall have any right of setoff of any amounts due and payable, or any Liabilities arising, under against any amounts due and payable under this Agreement against any other amounts due and payable under this Agreement or any amounts due and payable, or any Liabilities arising, under the Transition Services Agreement or any other Transaction Document.

Section 10.15 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall be deemed to be one and the same agreement. A signed copy of this Agreement delivered by facsimile, email, or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

[*SIGNATURE PAGE FOLLOWS*]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the date first written above by their respective duly authorized officers.

Seller:

DR. REDDY'S LABORATORIES S.A.

By: /s/ Patrick Aghanian
Name: Patrick Aghanian
Title Head of PPG

By: /s/ Sameer Natu
Name: Sameer Natu
Title Finance Head

Purchaser

CITIUS PHARMACEUTICALS, INC.

By: /s/ Myron Holubiak
Name: Myron Holubiak
Title CEO and President

[Signature Page of Asset Purchase Agreement]

SCHEDULE 1.01

DEFINITIONS

"**Acquired Contracts**" shall mean those Contracts listed on Exhibit A.

"**Affiliate**" of a Person or Party shall mean any other Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such Person or Party. The term "**control**" (including the terms "**controlled by**" and "**under common control with**") shall mean the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person or Party, whether through the ownership of voting securities, by contract or otherwise.

"**Agreement**" shall have the meaning set forth in the Preamble.

"**Approval Efforts**" shall have the meaning set forth in Section 3.04(b).

"**Applicable Healthcare Industry Laws**" means any international, federal, state, local municipal, foreign or other statute, law, ordinance, order, ruling, judgment, rule, regulation or other requirement issued by a Governmental Authority, including, but not limited to: (i) the Federal Food, Drug, and Cosmetic Act, the False Claims Act, the Anti-Kickback Statute, and HIPAA/HITECH, and any equivalent or similar Law enacted in any state in the United States, (ii) the EU Drug Directives, and related national legislation of individual EU Member States implementing the provisions of the EU Drug Directives into their national laws, the relevant guidelines published by the European Commission, the EU Member States and the NBOG, and national laws of individual EU Member States governing bribery and corruption, related industry codes and physicians' codes of professional conduct and (iii) all equivalent or similar Laws relating to the development, regulatory approval, provision, administration, management or payment for health care or healthcare-related products, services or professionals.

"**Approval Milestones**" shall have the meaning set forth in Section 3.04(b).

"**Assignment of Patents**" shall mean the certain Assignment of Patents Agreement to be entered into on the Closing Date by and between the Purchaser and the Seller in the form attached hereto as Exhibit C.

"**Assumed Liabilities**" shall mean the following Liabilities, but in each case solely to the extent such Liability arises after the Closing (and subject to the last sentence of Section 2.01(d)):

a) Liabilities arising under or relating to the Regulatory Approvals, Regulatory Approval Applications, Regulatory Documentation, including any and all costs and expenses relating thereto;

b) Liabilities arising under or relating to the Proof of Concept Plan including any and all costs and expenses relating thereto;

c) all Liabilities arising out of or relating to the ownership or operation of the Business and the Purchased Assets after the Closing, including the development of the Compound and Products;

d) all Liabilities arising out of or relating to any product liability, breach of warranty or similar claim for injury or other harm to person or property, which result from the use or misuse of a Product or otherwise related to a Product (including all Legal Proceedings relating to any such liabilities) sold by or on behalf of the Purchaser and its Affiliates after the Closing;

e) all Liabilities, obligations and commitments arising out of or relating to any Product recall in the Territory;

f) any Liabilities, obligations or commitments arising out of or relating to any Acquired Contract to the extent incurred after the Closing;

g) all Liabilities, obligations and commitments arising out of or relating to the return of, or warranty claims relating to any Product sold after the Closing;

h) any liability or amount payable to Eisai, after the Closing;

i) any Liabilities, obligations or commitments arising out of or relating to any Legal Proceeding relating to the Purchased Assets or the Compound for which the cause of action arises after the Closing;

j) all other Liabilities, obligations and commitments of whatever kind and nature, primary or secondary, direct or indirect, absolute or contingent, known or unknown, whether or not accrued, arising out of or relating to, directly or indirectly, the Compound, a Product, the Purchased Assets, the Business or the ownership, sale or lease of any of the Purchased Assets in the Territory to the extent arising after the Closing.

"**Bill of Sale & Assignment and Assumption Agreement**" shall mean the certain Bill of Sale and Assignment and Assumption Agreement, to be entered into on the Closing Date by and between the Purchaser and the Seller in the form attached hereto as Exhibit B.

"**Biosimilar Entry**" means with respect to a Product in a country within the Territory, the first Business Day following the occurrence of both of the following: (i) the date that the first sale of a Biosimilar of the Product is sold in such country within the Territory, and (ii) the reduction in Net Sales of the Product in such country [***] from the average Net Sales of such Product in such country in [***] immediately prior to the first commercial sale of a Biosimilar in such country.

"**Biosimilar**" means, with respect to a particular Product in a particular country in the Territory, any pharmaceutical product that: (a) is claimed to be biosimilar to or interchangeable with such Product or otherwise references or relies on such Product to support a Drug Approval Application or an application submitted under Section 351(k) of the PHSA or any corresponding foreign application in the Territory, including, with respect to the European Union, a Marketing Authorization Application filed with the EMA or with respect to the United Kingdom, a Marketing Authorization Application filed with MHRA pursuant to the centralized approval procedure; (b) is approved for sale for at least one (1) Indication that is the same as an Indication for which such Product is approved for sale in such country; and (c) is sold in such country by a Third Party that (i) is not a direct or indirect Licensee or Transferee of the Purchaser or its Affiliates, (ii) did not purchase such product in a chain of distribution that included any of the Purchaser or its Affiliates, Licensees or Transferees, as applicable, and/or (iii) did not otherwise acquire any rights from the Purchaser or its Affiliates, Licensees or Transferees, as applicable, including any Purchased Patents, Eisai Patents (as defined in the Eisai Agreement) Purchased Know-how or Eisai Know-how (as defined in the Eisai Agreement), directly or indirectly, from the Purchaser or its Affiliates, Licensees or Transferees, as applicable.

"**BLA**" means a Biologics License Application submitted to the FDA under subsection (a) of Section 351 of the PHSA.

"**Business Day**" shall mean any day other than a Saturday, Sunday, or other day on which commercial banks located in New York, New York or Mumbai, India are authorized or required by Law to be closed for business.

"**Business**" shall mean the development of the Compound.

"**Calendar Year**" shall mean each respective period of twelve (12) consecutive months ending on December 31.

"**Cash Consideration**" shall mean the Upfront Payment, plus the Purchaser's Prorated Portion.

"**Commercially Reasonable Efforts**" means with respect to any objective hereunder, including, relating to the development or commercialization of a Product or the Compound by a Party, the application by such Party, consistent with the exercise of its prudent scientific and business judgment, of diligent efforts and resources to fulfill the obligation in issue, consistent with the level of efforts as [***] would devote to a product at a similar stage in its product life and having similar profit potential and strategic value, taking into account, without limitation, commercial, legal and regulatory factors, target product profiles, product labeling, past performance, the regulatory environment and competitive market conditions in the therapeutic area, safety and efficacy and such other factors as such Party may reasonably consider, all based on conditions then prevailing.

"**Compound**" means the recombinant DNA-derived cytotoxic protein as described on Annex B.

"**Confidential Information**" shall mean, with respect to a Party, all Information, data, documents, agreements, files, and other materials, whether disclosed orally or disclosed or stored in written, electronic, or other form or media, which is obtained from or disclosed by a Party or its representatives, whether obtained before or on or after the date hereof, relating to such Party, its business, any of its Affiliates or any of their respective businesses, or the Purchased Assets, together with the terms and conditions or other facts relating to the transactions contemplated hereby, including, without limitation, all notes, analyses, compilations, reports, forecasts, studies, samples, and other documents prepared by or for the other Party which contain or otherwise reflect or are derived or based in whole or in part on such information, data, documents, agreements, files, or other materials. The terms and conditions of this Agreement shall be deemed the Confidential Information of both Parties. The term Confidential Information as used herein does not include information that: (a) at the time of disclosure or thereafter is generally available to and known by the public, other than as a result of disclosure by the receiving Party or any of its representatives in violation of this Agreement; or (b) is or becomes available to the receiving Party on a non-confidential basis from a source other than the disclosing Party provided that such source, to the receiving Party's knowledge after reasonable inquiry, is not and was not bound by a confidentiality agreement with respect to such information or otherwise prohibited from transmitting such information by a contractual, legal, or fiduciary obligation; or (c) has been independently acquired or developed by the receiving Party without reference to the Confidential Information.

"**Confidentiality Agreement**" shall mean the confidentiality agreement between the Parties dated as of March 23, 2021.

"**Consent**" shall mean any and all notices to, consents, approvals, clearances, ratifications, permissions, authorizations or waivers from Third Parties, including from any Governmental Authority.

"**Contract**" shall mean all contracts, leases, deeds, mortgages, licenses, purchase orders, statements of work, instruments, notes, commitments, undertakings, indentures, joint ventures and all other agreements, commitments and legally binding arrangements, whether written or oral.

"**Cover**" means, as used in relation to a Patent and a product or invention, and in connection with a duty, obligation or performance of a Party, that such Patent would be infringed by the manufacture, use, offer for sale, sale or import of, or other Exploitation of, such product or invention by such Party, but for this Agreement, including infringement of patent claims claiming compositions of matter as well as methods of manufacture or use.

"**CTCL Indication**" means Cutaneous T-Cell Lymphoma.

"**CTCL Milestones**" means Milestones No. 1, 2 and 3 set forth in Table 3.01(b).

"**Cure Period**" shall have the meaning set forth in Section 3.04(c).

"**Discontinued Product**" means all dosage forms, formulations, strengths, package sizes and types of pharmaceutical products containing the Compound, previously sold in the United States under the Trademark ONTAK® and described in BLA #103767.

"**Earn-Out Term**" shall have the meaning set forth in Section 3.01(c)(iii).

"**Eisai Agreement**" means, collectively, that Amended and Restated License, Development and Commercialization Agreement made and entered into as of February 26, 2018 by and between Eisai and the Seller, as amended by that (i) Amendment to Amended and Restated License, Development and Commercialization Agreement made as of August 9, 2018 by and between Eisai and the Seller, (ii) the Inventory Letter and (iii) that Amendment No. 2 to Amended and Restated License, Development and Commercialization Agreement made as of August 31, 2021 by and between Eisai and the Seller.

"**Eisai Assignment and Assumption Agreement**" means that certain Consent to Assignment and Assumption Agreement with Novation by and among the Seller, Eisai and the Purchaser, dated as of August 31, 2021.

"**Eisai Territory**" means Japan, China, Korea, Taiwan, Hong Kong, Macau, Indonesia, Thailand, Malaysia, Brunei, Singapore, India, Pakistan, Sri Lanka, Philippines, Vietnam, Myanmar, Cambodia, Laos, Afghanistan, Bangladesh, Bhutan, Nepal, Mongolia and Papua New Guinea.

"**Eisai**" means EISAI Co. Ltd.

"**EMA**" means the European Medicines Agency and any successor agency thereto.

"**Encumbrances**" shall mean any charge, claim, community property interest, pledge, condition, equitable interest, lien (statutory or other), option, security interest, mortgage, easement, encroachment, right of way, right of first refusal, or restriction of any kind, including any restriction on use, voting, transfer, receipt of income or exercise of any other attribute of ownership.

"**Europe**" means all of countries in continental Europe, including the European Union, the United Kingdom, Ireland, Switzerland, Turkey and Eastern Europe, including the Czech Republic, Serbia, Russia and Central Independent States of the former USSR.

"**European Approval**" means Regulatory Approval of a Product in any country in Europe, including any approval from the EMA or MHRA.

"European Union" means, at any particular time, all countries that are then officially recognized as member states of the European Union or members of the European Economic Area. For clarity, any event that first occurs in a county of the European Union that later ceases to be a member of the European Union will still be treated as an event that occurred in the European Union.

"**Excluded Assets**" shall have the meaning set forth in Section 2.01(b).

"**Excluded Liabilities**" shall have the meaning set forth in Section 2.01(d).

"**Existing Product**" means the pharmaceutical product known as E7777, containing the Compound as an active ingredient and described in IND #110489. For the avoidance of doubt, the definition of "Existing Product" does not include the Discontinued Product.

"**Exploit**" means to make, have made, import, use, sell, or offer for sale, including to research, develop, commercialize, register, modify, enhance, improve, manufacture, have manufactured, hold or keep (whether for disposal or otherwise), formulate, optimize, have used, export, transport, distribute, promote, market, have sold or otherwise dispose of, and otherwise exploit.

"**FDA**" shall mean the United States Food and Drug Administration and any successor agency thereto.

"**First Commercial Sale**" means the first sale of a Product by Purchaser or its Affiliate, Licensee or Transferee, as applicable, for monetary value to a Third Party in the Territory. For clarity, sales prior to receipt of Regulatory Approval for a Product, if any, such as so-called "treatment IND sales," "named patient sales," and "compassionate use sales," shall not be construed as a First Commercial Sale with respect to a Product.

"**GAAP**" shall mean generally accepted accounting principles in the United States, consistently applied.

"**Governmental Authority**" shall mean any federal, state, local or foreign government, or political subdivision thereof, any regulatory or administrative authority, any agency or instrumentality of any such government or political subdivision, or any self-regulated organization or other non-governmental regulatory authority or quasi-governmental authority (to the extent that the rules, regulations or orders of such organization or authority have the force of Law), or any arbitrator, court or tribunal of competent jurisdiction.

"**Governmental Order**" shall mean any order, writ, judgment, injunction, decree, stipulation, determination, or award entered by or with any Governmental Authority.

"**Health Canada**" means the Canadian federal Department of Health and any successor thereof.

"**I/O Indication**" means the targeting of a cell, cell surface or the like, whose engagement has the effect of modulating, inducing, enhancing, or suppressing an immune response for the purpose of preventing or treating any cancer. Solely for the purposes of determining whether the I/O Milestone is achieved, and therefore payable, the I/O Indication shall not include any CTCL Indication or any PTCL Indication.

"**I/O Milestone**" means Milestone No. 7 set forth in Table 3.01(b).

"**IND**" means: (a) an investigational new drug application filed with the FDA for authorization to commence clinical studies and its equivalent in other countries or regulatory jurisdictions; and (b) all supplements and amendments that may be filed with respect to the foregoing.

"**Indemnified Party**" shall have the meaning set forth in Section 9.04(a).

"**Indemnifying Party**" shall have the meaning set forth in Section 9.04(a).

"**Indemnity Threshold**" shall have the meaning set forth in Section 9.06(a).

"Indication" means a disorder or medical condition for which a product is approved by a Regulatory Authority to diagnose, treat, prevent, cure, and/or mitigate in the indication section of the product labeling for such product.

"**Information**" means any technical, scientific and other data, in written, electronic or other form, including results, approvals, technology, trade secrets, practices, techniques, methods, processes, inventions, ideas, drawings, study designs, protocols, assays and biological methodology, developments, specifications, formulations, formulae, materials or compositions of matter of any type or kind (whether or not patentable), software, algorithms, marketing reports, expertise, technology, test data (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical, analytical test data and data resulting from pre-clinical and clinical studies), manufacturing and quality control data, and safety data.

"**Intellectual Property**" shall mean any and all intellectual property and proprietary rights of any kind or nature, whether protected, created or arising under any Law, including all: (i) Patents, (ii) Know-How, (iii) trademarks, (iv) domain names and URLs, (v) copyrights, mask works, and works of authorship, (vi) registered designs, (vii) rights in databases, compilations of data and data, including all personally identifiable information and clinical trial data, and all aggregated data, (viii) moral rights, rights of publicity and other rights to use or exploit the name, image and likeness of any individual, (ix) rights under applicable Laws in customer lists, supplier lists, pricing and cost information, and business and marketing plans, in any form whether or not specifically listed herein, all rights to limit the use or disclosure of any of the foregoing, and all embodiments of, and all documentation relating to, any of the foregoing, (x) rights under applicable Laws in software (including both object codes and source codes) and application programming interfaces, (xi) rights under applicable Laws to bring an action for infringement, dilution, misappropriation or other impairment or violation of rights and to receive damages, proceeds or any other legal or equitable protections and remedies with respect to any of the foregoing, and (xii) similar or equivalent rights to any of the foregoing recognized by any Governmental Authority anywhere in the world.

"**Inventory Letter**" shall mean that certain Letter dated 12 August 2021 from Eisai to the Seller entitled "Available Inventory of E7777 Injection Vials" which is attached hereto as Exhibit I.

"**Know-How**" shall mean all technical, scientific and other know-how and information, trade secrets, knowledge, technology, methods, processes, formulae, designs, drawings, assembly procedures, specifications, data, results and other material, including: biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, assays and biological methodology, in each case (whether or not confidential, proprietary, patented or patentable) in written or electronic form.

"**Knowledge of the Purchaser**" shall mean the actual knowledge after due inquiry of any of the individuals listed on Exhibit D (Knowledge of the Purchaser).

"**Knowledge of the Seller**" shall mean the actual knowledge after due inquiry of any of the individuals listed on Exhibit E (Knowledge of the Seller).

"**Law**" shall mean any statute, law, ordinance, regulation, rule, code, Order, constitution, treaty, common law, judgment, decree, other requirement or rule of law of any Governmental Authority.

"**Legal Proceeding**" shall mean any judicial, administrative or arbitral action, suit, proceeding (public or private), litigation, investigation, hearing, or any other claim or proceeding by or before a Governmental Authority.

"**Liability**" shall mean, with respect to any Person, any indebtedness, liabilities, obligation, commitment, expense, claim, complaint, deficiency, guaranty or endorsement of or by such Person of any type, whether or not accrued, absolute, contingent, matured, unmatured, liquidated, unliquidated, determined or determinable, known or unknown.

"**Licensed Know-How**" means all Know-How owned by the Seller or any of its Affiliates (other than Purchased Know-How) within the Territory that (a) is related to a Product or the Compound and (b) has been developed or is used by Seller or its Affiliates or Eisai or its Affiliates in the Territory prior to or as of the Closing in connection with the Exploitation of any Product or Compound. Without limiting the foregoing, Licensed Know-How includes any such Know-How (as of the Closing) relating to (i) any companion diagnostics relating to any Product or (ii) the manufacture of any Product or Compound.

"**Licensee Consideration**" means any consideration (other than Licensee Sales-Based Royalties) received by the Purchaser and/or its Affiliates from a Licensee in consideration of a license to exploit a Product, the Compound or any Purchased Asset, including, but not limited to, lump-sum payments, up-front payments, milestones (of all kind) and other deferred payments. For clarity, Licensee Consideration does not include any bona fide payments from Third Parties for (a) research, development, manufacturing or other services, (b) supply of Compounds or Products or other items to customers, (c) amounts received for the acquisition of equity interests (including stock, options or preferred shares) in Purchaser or any of its Affiliates or (d) amounts received in the form of a loan (but, with respect to (c) and (d), that is not in consideration of the grant of a license to exploit a Product, the Compound or any Purchased Asset).

"**Licensee Net Sales**" means Net Sales of Product(s) by or on behalf of a Licensee (other than any licensee or sublicensee that is an Affiliate of Purchaser).

"**Licensee Sales-Based Royalties**" means any amounts (whether characterized as royalties, earn-out payments, revenue payments, revenue share payments, license fees, profit share payments, or otherwise) that are received by Purchaser or its Affiliates from any Licensee (or a sublicensee of a Licensee (as applicable), in each case only to the extent the calculation of such amounts payable to Purchaser or its Affiliates is based on sales of Product(s) by or on behalf of a Licensee. Notwithstanding the foregoing, any milestone payments or other comparable one-time lump sum payments received by the Purchaser and/or its Affiliates from a Licensee that are based on achievement of an aggregate level of sales are Licensee Consideration and are not Licensee Sales-Based Royalties.

"Licensee" means any Person (other than an Affiliate of Purchaser) to which a license or sublicense is granted by the Purchaser or its Affiliates with respect to the Purchased Assets, Product(s) or Compounds enabling such Person to promote, market, offer for sale, sell, distribute or otherwise commercialize a Product or Compound. For clarity, Purchaser and its Affiliates' customers (which shall include distributors, wholesalers, and/or resellers of a Product) shall not be considered Licensees, provided that the sale of Products to such Persons are considered Net Sales by the Purchaser or its Affiliates.

"**Loss**" or "**Losses**" shall mean actual out-of-pocket losses, damages, liabilities, costs or expenses, including reasonable attorneys' fees.

"**Material Adverse Effect**" means any event, occurrence, fact, condition, change or effect that is materially adverse (individually or in the aggregate) to the Purchased Assets, Exploitation of the Compound or the Product, the Business, the results of operations of the Seller or the financial condition of the Seller; provided, however, that none of the following shall be deemed, either alone or in combination, to constitute a Material Adverse Effect, or be taken into account in determining whether there has or will be a Material Adverse Effect: (a) changes or effects that are generally applicable in the economies (including changes in interest or exchange rates) of any country in which Purchased Assets are located or in which any of the Parties to this Agreement operate, or in the securities, syndicated loan, credit or financial markets of any such country; (b) changes in general legal, tax, regulatory, political or economic conditions affecting the exploitation of the Compound or the Product in general or within the relevant jurisdiction; (c) changes in GAAP; (d) changes or effects that arise out of or are attributable to (i) the acts or omissions of, or circumstances affecting, the Purchaser and/or its Affiliates, or (ii) the transactions contemplated by this Agreement or changes or effects that arise out of or are attributable to the negotiation, execution, public announcement or performance of this Agreement; (e) changes or effects that generally affect the markets in which the Compound or the Product are exploited; (f) changes or effects that arise out of or are attributable to the commencement, occurrence, continuation or intensification or reduction or cessation of any war (whether or not declared), sabotage, armed hostilities or acts of terrorism, (g) changes or effects that arise out of or are attributable to earthquakes, hurricanes or other natural disasters, epidemics or other outbreaks of disease; (h) any matter disclosed in the Seller Disclosure Schedules to this Agreement, including in each case, any adverse effect that occurs after the date of this Agreement but that arises out of or results from any such matter or (i) any existing event or occurrence or circumstance of which the Purchaser has Knowledge as of the date hereof.

"**MHRA**" means the Medicines and Healthcare Products Regulatory Agency, and any successor thereof.

"**Milestone and Earn-Out Information**" shall have the meaning set forth in Section 3.03(a).

"**Milestone Event**" shall have the meaning set forth in Section 3.01(b).

"**Milestone Payment**" shall have the meaning set forth in Section 3.01(b).

"**Net Sales**" shall mean the aggregate gross amounts invoiced or otherwise received for all of the Purchaser's, its Affiliates', Licensees' or Transferees (as applicable) sales or other commercial distribution of a Product (including any Biosimilar version of a Product), for any Indication, during the applicable period in the considered territory less the sum of the following, to the extent related to the sale or commercial distribution of a Product and otherwise included in such gross amounts: (1) trade, quantity and cash discounts in amounts reasonable or customary in the trade and to extent accrued or actually taken; (2) credits, refunds, allowances, chargebacks, volumes rebates, direct and indirect rebates, distribution fees, reimbursements, or similar payments granted or given to wholesalers and other distributors, managed care and pharmacy benefit management companies, but only to the extent not previously deducted from gross sales; (3) rejected goods, damaged goods, product recall and sales returns; (4) patient co-pay assistance benefits, rebates and coupon or voucher redemptions provided specifically to the concerned Product; (5) reasonable rebates paid or other price reductions provided in connection with sale of the concerned Product to any government or regulatory authority in respect of any state or federal Medicare, Medicaid, or similar programs available under or required by applicable Law; (6) freight, postage, shipping and insurance charges, (7) taxes, duties or other governmental charges levied on, absorbed or otherwise imposed on sale of such Product, including value-added taxes, or other governmental charges otherwise measured by the billing amount (including a reasonable allocation of any fees paid pursuant to Section 9008 of the Patient Protection and Affordable Care Act), and (8) any other deductions taken by Purchaser or any of its Affiliates, licensees or sub-licensees in calculating net sales in the ordinary course of its business, consistent with GAAP (or the applicable accounting standard of such Purchaser or any of its Affiliates, licensees or sub-licensees if the sale occurs in a jurisdiction outside of the United States). In the event the Purchaser (and/or any its Affiliates, licensees or sublicensees) sells the concerned Product as part of a bundle or group sale with other products, (i) the Net Sales shall be adjusted to be proportional to the ratio of the individual selling price of the concerned Product to the aggregate of the individual selling prices of each other product included as part of such bundle or group sale, and (ii) to the extent the Purchaser (and/or any its Affiliates, licensees or sublicensees) provides discounts, allowance or rebate to the purchaser of the concerned Product based on the invoiced price for the products sold as a bundle or group sale, such discount must be allocated pro rata based on the selling prices of such products sold individually before taking into account the discount, allowance or rebate on product provided as part of such bundle. The foregoing deductions from gross sales shall be deducted only once and only to the extent not otherwise deducted from the gross sales. "**Net Sales"** cannot be negative. For clarity, Net Sales does not include any Licensee Consideration or Licensee Sales-Based Royalties.

"**Orders**" shall mean all judgments, orders, writs, injunctions, decisions, rulings, decrees and awards of any Governmental Authority.

"**Organizational Documents**" shall mean with respect to a Person (other than an individual), the documents by which such Person was organized (such as a certificate of incorporation, certificate of limited partnership or articles of organization, and including, without limitation, any certificates of designation for preferred stock or other forms of preferred equity) and which relate to the internal governance of such Person (such as bylaws, a partnership agreement or an operating, limited liability or members agreement), all, as amended.

"**Party**" or "**Parties**" shall have the meaning set forth in the introductory paragraph hereto.

"**Patents**" means any and all (a) patent applications and issued patents, including, all national, regional, and international patents and patent applications; provisionals; continuations; divisionals; continuations-in-part; continued prosecution applications; reissues, renewals, substitutions, reexaminations, and revivals thereof; (b) patents that have issued or in the future issue from the foregoing patent applications, including utility models, petty patents and design patents and certificates of invention; and (c) extensions (including pediatric exclusivity, patent term extension and supplementary patent certificate) or restorations of the patents described above by existing or future extension or restoration mechanisms.

"**Permits**" shall mean all certifications (including those of standards-setting organizations), licenses, permits, franchises, approvals, authorizations, exemptions, notices to, consents or orders of, or filings with, any trade association, any standards-setting organization, or any Governmental Authority.

"**Permitted Encumbrances**" shall mean: (a) liens for Taxes not yet due and payable or being contested in good faith by appropriate procedures; (b) mechanics', carriers', workmen's, repairmen's or other like liens arising or incurred in the ordinary course of business; (c) liens arising under original purchase price conditional sales contracts and equipment leases with Third Parties entered into in the ordinary course of business; and (d) other immaterial imperfections of title or immaterial Encumbrances, if any.

"**Person**" shall mean an individual, a limited liability company, joint venture, a corporation, a partnership, an association, a trust, a division or operating group of any of the foregoing or any other entity or organization.

"**PHSA**" means the Public Health Service Act as set forth at 42 U.S.C. Chapter 6A, as may be amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

"**Product**" means any product that is comprised of or contains the Compound as an active ingredient, including: (a) any combination product which contains the Compound as an active ingredient; (b) the Existing Product; and (c) all formulations, dosages and forms of release for any of the foregoing products.

"**Proof of Concept Efforts**" has the meaning set forth in Section 3.04(c).

"**Proof of Concept Plan**" means the Proof of Concept Plan which is set forth in Annex A hereto. The Proof of Concept Plan includes the Proof of Concept Studies.

"**Proof of Concept Studies**" has the meaning set forth in Annex A hereto.

"**Proration Schedule**" shall have the meaning set forth in Section 2.01(g).

"**PTCL Indication**" means Peripheral T-Cell Lymphoma.

"**PTCL Milestones**" means Milestones No. 4 and 5 set forth in Table 3.01(b).

"**Purchase Price**" shall have the meaning set forth in Section 3.01(a).

"**Purchased Assets**" shall mean each of the following: (a) the Purchased Intellectual Property, (b) the Regulatory Documentation, (c) the Acquired Contracts (including all rights and claims of Seller and its Affiliates to any amounts prepaid under any Acquired Contracts), and (d) a copy of all books, records, files and papers of the Seller and/or its Affiliates to the extent exclusively relating to the Business and/or the Compound.

"**Purchased Intellectual Property**" shall mean collectively all Purchased Patents, Purchased Trademarks and Purchased Know-How.

"**Purchased Know-How**" means all Know-How owned by the Seller or any of its Affiliates that (a) is exclusively related to any Product, and (b) has been used in connection with the Exploitation of, or is otherwise necessary or useful to Exploit, any Product.

"**Purchased Patent(s)**" means the Patents set forth in Exhibit F.

"**Purchased Trademarks**" shall mean, as owned by the Seller or its Affiliates, and to the extent exclusively related to the Product, the trademarks, service marks, logos, slogans and trade names (whether or not registered), including all variations, derivations, combinations, registrations applications for registration or renewals of the foregoing and all goodwill associated therewith, listed on Exhibit G.

"**Purchaser Group**" shall have the meaning set forth Section 9.02.

"**Purchaser's Prorated Portion"** means the amount equal to the Purchaser's portion of the prorated expenses and other items, which the Purchaser shall pay to the Seller at Closing and is set forth on the Proration Schedule.

"**Purchaser**" shall have the meaning set forth in the preamble.

"**Quarter**" shall mean each respective period of three (3) consecutive months ending on March 31, June 30, September 30, and December 31.

"**Quarterly Earn-Out Payments**" shall have the meaning set forth in Section 3.01(c)(i).

"**Quarterly Earn-Out Rate**" has the meaning set forth in Section 3.01(c)(i).

"Regulatory Approval Application" means an application to the applicable Regulatory Authority for approval to commercialize a product in a particular country or other jurisdiction.

"**Regulatory Approval**" means any and all approvals (including supplements, amendments, pre- and post-approvals), licenses, registrations or authorizations of any Regulatory Authority, national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, that are necessary for the manufacture, distribution, use or sale of a product in a regulatory jurisdiction.

"**Regulatory Authority(ies)**" means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the exploitation of any Product in the Territory, including the FDA, EMA, MHRA and Health Canada.

"**Regulatory Documentation**" shall mean the following, to the extent owned by the Seller or any of its Affiliates and related to the Compound or any Product: (a) any applications (including all investigational new drug (INDs) and Regulatory Approvals), registrations, licenses, authorizations and approvals; (b) correspondence and reports submitted to or received from Regulatory Authorities and all supporting documents with respect thereto, including all adverse event files and complaint files; (c) chemistry, manufacturing and controls data and documentation (including, but not limited to, batch records, master batch production records, standard operating procedures that specifically pertain to any Product, testing logs, sample logs, laboratory logs, and stability logs), preclinical and clinical studies and tests, (d) records maintained under record keeping or reporting requirements of the FDA or any Governmental Authority; and (e) clinical and other data contained or relied upon in any of the foregoing.

"**Restricted Products**" shall mean any product that contains (a) [***] or (b) [***]; in each case whether formulated alone or in combination with any other compound or product.

"**Sales Reports**" shall have the meaning set forth in Section 3.03(b).

"**SEC**" shall have the meaning set forth in Section 7.03.

"**Seller Disclosure Schedules**" shall have the meaning set forth in the introductory sentence to ARTICLE V.

"**Seller**" shall have the meaning set forth in the preamble.

"**Solvent**" shall mean used with respect to any Person, shall mean that, as of any date of determination, (a) the amount of the "fair saleable value" of the assets of such Person on a going concern basis will, as of such date, exceed (i) the value of all "liabilities of such Person, including contingent and other liabilities" as of such date, as such quoted terms are generally determined in accordance with applicable United States federal Laws governing determinations of the insolvency of debtors and (ii) the amount that will be required to pay the probable liabilities of such Person on its existing debts (including contingent liabilities) as such debts become absolute and matured, (b) such Person will not have, as of such date, an unreasonably small amount of capital for the operation of the businesses in which it is engaged or proposed to be engaged following such date and (c) such Person will be able to pay its liabilities, including contingent and other liabilities, as they mature. For purposes of this definition, each of the phrases "not have an unreasonably small amount of capital for the operation of the businesses in which it is engaged or proposed to be engaged" and "able to pay its liabilities, including contingent and other liabilities, as they mature" means that such Person will be able to generate enough cash from operations, asset dispositions or refinancing, or a combination thereof, to meet its obligations as they become due.

"**Successful Proof of Concept**" has the meaning set forth in Annex A hereto.

"**Taxes**" shall mean all federal, state, local, foreign and other income, gross receipts, sales, use, production, ad valorem, transfer, franchise, registration, profits, license, lease, service, service use, withholding, payroll, employment, unemployment, estimated, excise, severance, environmental, stamp, occupation, premium, property (real or personal), real property gains, windfall profits, customs, duties or other taxes, fees, assessments or charges of any kind whatsoever, together with any interest, additions or penalties with respect thereto and any interest in respect of such additions or penalties.

"**Territory**" means all countries in the world, excluding those countries in the Eisai Territory.

"**Third Party Claim**" shall have the meaning set forth in Section 9.05(a).

"**Third Party**" shall mean any Person other than the Parties.

"**Transaction Documents**" shall mean this Agreement, the Bill of Sale & Assignment and Assumption Agreement, the Eisai Assignment and Assumption Agreement and the Assignment of Patents.

"**Transfer Taxes**" shall have the meaning set forth in Section 3.02(c).

"**Transferee**" means any Third Party (other than an Affiliate of Purchaser or an Affiliate of Seller) to which any rights in or to the Compound, a Product or the Purchased Assets that are granted or transferred to Purchaser under this Agreement are subsequently assigned or transferred in turn by Purchaser following the Closing.

"**Transition Services Agreement**" shall have the meaning set forth in Section 4.02(c).

"**United States**" shall mean the United States of America and its territories and possessions.

"**Upfront Payment**" shall have the meaning set forth in Section 3.01(a)(i).

"**US CTCL Approval Milestone**" means Milestone No. 1 set forth in Table 3.01(b).

"**Valid Claim**" shall mean (i) any claim of a Patent or any other patent covering the considered Product (including if filed after the date hereof and including all reissues, reexaminations, divisionals, continuations, continuations-in-part, provisional and continued examinations, extensions, restorations or renewals of such patents to the extent they relate to the Product) that has been granted by a patent granting authority, that is in force, and that has not been surrendered, abandoned, revoked or held invalid or unenforceable by a decision taken by an administrative or civil court in a jurisdiction, or (ii) a pending claim in an application for a Patent or any other patent set forth under (i).

Exhibit 10.31

*Information in this exhibit marked [***] has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such information is not material and is the type of information that the registrant treats as private or confidential.

AMENDED AND RESTATED LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

between

EISAI CO., LTD.

and

DR. REDDY'S LABORATORIES S.A.
Dated as of February 26, 2018

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Schedules

AMENDED AND RESTATED LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This Amended and Restated License, Development and Commercialization Agreement (this "**Agreement**") is made and entered into as of February 26, 2018 (the "**Execution Date**") by and between Eisai Co., Ltd., a Japanese corporation ("**Eisai**") and Dr. Reddy's Laboratories S.A., a Swiss company (the "**Licensee**"). Each of Eisai and the Licensee are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Eisai owns or controls certain intellectual property rights with respect to the Licensed Compound (as defined herein) and Licensed Products (as defined herein);

WHEREAS, Eisai wishes to grant to the Licensee, and the Licensee wishes to receive, a license (or sublicense) under such intellectual property rights to develop and commercialize Licensed Products in the Field (as defined herein) in the Licensee Territory (as defined herein), in each case in accordance with the terms and conditions set forth below;

WHEREAS, the Parties previously executed a License, Development and Commercialization Agreement on March 30, 2016 (the "**Original Agreement**") and a binding term sheet (the "**Binding Term Sheet**") dated as of the September 29, 2017 (the "**Effective Date**"); and

WHEREAS, the Parties desire to incorporate the terms of the Binding Term Sheet into this agreement and to amend and restate the Binding Term Sheet on the terms and subject to the conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions set forth herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

ARTICLE 1
DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

1.1. "**'302 Development Activities**" means the activities necessary to generate the deliverables set forth in the '302 Development Plan.

1.2. "**'302 Development Costs**" means the FTE Costs incurred and the direct out-of-pocket costs recorded as an expense, in accordance with GAAP, by or on behalf of Eisai or any of its Affiliates related to the '302 Development Activities.

1.3. "**'302 Development Plan**" means the development plan, including a detailed budget, setting forth the deliverables (including the Final '302 Development Report) to be provided by Eisai with respect to a pivotal Phase 2 clinical trial for the Existing Licensed Product for the CTCL Indication, attached hereto as Schedule 1.3, as the same may be amended from time to time by the Parties in accordance with Section 3.1.2(a).

1.4. "**Affiliate**" means, with respect to a Person, any Person that, directly or indirectly, through one (1) or more intermediaries, controls, is controlled by or is under common control with such first Person at any time for so long as such Person controls, is controlled by or is under common control with such first Person. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" mean: (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance or otherwise; or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interests of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity).

1.5. "**Agreement**" has the meaning set forth in the preamble hereto.

1.6. "[***] **Agreement**" means that certain Distributorship Agreement, dated December 24, 1999, as amended, between [***] and [***], collectively (as predecessor in interest to Eisai) and [***] (as predecessor in interest to [***]) with respect to Italy, the Vatican State and the Republic of San Marino.

1.7. "**Alliance Manager**" has the meaning set forth in Section 4.7.

1.8. "**Anti-Corruption Laws**" means, as applicable, the U.S. Foreign Corrupt Practices Act, as amended, the UK Bribery Act 2010, as amended, sanctions administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury or any sanctions or measures imposed by the United Nations Security Council, the European Union or Her Majesty's Treasury, and any other applicable anti-corruption laws and laws for the prevention of bribery, fraud, racketeering, money laundering or terrorism.

1.9. "**Applicable Law**" means applicable laws, rules and regulations, including any rules, regulations, guidelines or other requirements of the Regulatory Authorities, that may be in effect from time to time, including the FFDCA, the PHSA and the Anti-Corruption Laws.

1.10. "**Arbitral Tribunal**" has the meaning set forth in Section 11.5.2(a).

1.11. "**Arbitration Rules**" has the meaning set forth in Section 11.5.2(a).

1.12. "**Auditor**" has the meaning set forth in Section 5.9.

1.13. "Binding Term Sheet" has the meaning set forth in the recitals hereto.

1.14. "**Biosimilar Product**" means, with respect to a particular Licensed Product in a particular country in the Eisai Territory or Licensee Territory, any pharmaceutical product that: (a) is claimed to be biosimilar to or interchangeable with such Licensed Product or otherwise references or relies on such Licensed Product to support a Drug Approval Application or an application submitted under Section 351(k) of the PHSA or any corresponding foreign application in the Eisai Territory or Licensee Territory, including, with respect to the European Union, a Marketing Authorization Application filed with the EMA pursuant to the centralized approval procedure; (b) is approved for sale for at least one (1) Indication that is the same as an Indication for which such Licensed Product is approved for sale in such country; and (c) is sold in such country by a Third Party that is not a direct or indirect sublicensee of the Licensee or its Affiliates, did not purchase such product in a chain of distribution that included any of the Licensee or its Affiliates or sublicensees, and did not otherwise acquire any Eisai Patents or Eisai Know-how, directly or indirectly, from the Licensee.

1.15. "**BLA**" has the meaning set forth in the definition of Drug Approval Application.

1.16. "**BPCI Act**" means the Biologics Price Competition and Innovation Act of 2009, as set forth at 42 U.S.C. §262 and as may be amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

1.17. "**Breaching Party**" has the meaning set forth in Section 10.2.1.

1.18. "**Business Day**" means a day other than a Saturday or Sunday or a day on which banking institutions in New York, New York, Tokyo, Japan or Basel, Switzerland are permitted or required to be closed.

1.19. "**Calendar Quarter**" means each successive period of three (3) calendar months commencing on April 1, July 1, October 1 and January 1, except that the first Calendar Quarter of the Term shall commence on the Original Effective Date and end on the day immediately prior to the first to occur of April 1, July 1, October 1 or January 1 after the Original Effective Date and the last Calendar Quarter shall end on the last day of the Term.

1.20. "**Challenge**" means, with respect to any Eisai Patents or Licensee Patents, to contest the validity or enforceability of any such Patents, in whole or in part, in any court, arbitration proceeding or other tribunal, including the United States Patent and Trademark Office and the United States International Trade Commission. As used in this Section 1.20, the term "contest" includes (a) filing an action under 28 U.S.C. §§ 2201-2202 seeking a declaration of invalidity or unenforceability of any such Patents; (b) filing, or joining in, a petition under 35 U.S.C. § 311 to institute inter partes review of any such Patents or any portion thereof; (c) filing, or joining in, a petition under 35 U.S.C. § 321 to institute post-grant review of any such Patents or any portion thereof; (d) any foreign equivalent of clauses (a), (b) or (c) in any country outside of the United States; or (e) filing or commencing any opposition, nullity or similar proceedings challenging the validity of any such Patents in any country outside the United States; but excludes (i) becoming a party to a Third Party interference for the purpose of defending the validity of any such Patents, (ii) filing a request under 35 U.S.C. § 302 for re-examination of any such Patents, (iii) filing a request under 35 U.S.C. § 251 for a reissue of any such Patents or (iv) any foreign equivalents of clause (i) to (iii) applicable outside of the United States.

1.21. "**Change of Control**" means, with respect to a Party: (a) a merger, reorganization or consolidation involving such Party, or any parent company of such Party and a Third Party in which the voting securities of such Party or its parent company, as applicable, outstanding immediately prior thereto cease to represent fifty percent (50%) or more of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation or (b) a Person, or group of Persons (acting in concert), directly or indirectly, become the beneficial owner (as defined in Rule 13d-3 under the U.S. Securities Exchange Act of 1934, as amended) of fifty percent (50%) or more of the voting equity securities or management control of such Party or any parent company of such Party.

1.22. "**Clinical Quality Agreement**" has the meaning set forth in Section 3.5.3.

1.23. "**Clinical Supply Agreement**" has the meaning set forth in Section 3.5.3.

1.24. "**CMC Development Activities**" means the activities necessary to generate the deliverables set forth in the CMC Development Plan.

1.25. "**CMC Development Plan**" means the development plan, including a detailed budget, setting forth the deliverables (including the Final CMC Development Report) to be provided by Eisai with respect to chemistry, manufacturing and controls for the Existing Licensed Product, attached hereto as Schedule 1.25, as will be finalized by the Parties in accordance with Section 3.1.3(a), and as may be amended from time to time by the Parties in accordance with Section 3.1.3(b).

1.26. "**Commercialization**" means, in respect of a biologic product, any and all activities directed to the preparation for sale of, offering for sale of or sale of such product, including activities related to using, holding or keeping (whether for disposal or otherwise), marketing, promoting, co-promoting, distributing, transporting, exporting, importing and disposing of such product and interacting with Regulatory Authorities regarding any of the foregoing. When used as a verb, "to Commercialize" or "Commercializing" means to engage in Commercialization and "Commercialized" has a corresponding meaning.

1.27. "**Commercially Reasonable Efforts**" means, with respect to the performance of any particular Exploitation activities with respect to the Licensed Compound or a Licensed Product by a Party, the carrying out of such activities in a sustained and diligent manner and using efforts and resources comparable to the efforts and resources commonly used in the [***] for compounds or products of similar market potential at a similar stage in development or product life. "Commercially Reasonable Efforts" shall be determined on a country-by-country (or region-by-region, where applicable) and Indication-by-Indication basis.

1.28. "**Committee**" has the meaning set forth in Section 4.3.1.

1.29. "**Confidential Information**" has the meaning set forth in Section 7.1.

1.30. "**Contract Year**" means each successive period of twelve (12) calendar months commencing on April 1 and ending on March 31, except that the first Contract Year of the Term shall commence on the Original Effective Date and end on the first March 31 to occur after the Original Effective Date and the last Contract Year of the Term shall commence on April 1 of the year in which the Term ends and end on the last day of the Term.

1.31. "**Control**" means, with respect to any Intellectual Property Rights or Regulatory Documentation, and subject to Section 11.3.2, possession of the right, whether directly or indirectly and whether by ownership, license or otherwise (other than by operation of the license and other grants in Section 2.1 or Section 2.2), to grant a license, sublicense or other right (including the right to reference Regulatory Documentation or a covenant not to sue, as applicable) to or under such Intellectual Property Rights or Regulatory Documentation as provided for herein without violating the terms of any agreement with any Third Party.

1.32. "**Controlling Party**" has the meaning set forth in Section 6.5.

1.33. "**Copyrights**" means any works of authorship, copyrights (including copyright in software), database rights, rights in designs and mask work rights, in each case whether registered or unregistered and including applications for registration of any of the foregoing.

1.34. "**Corporate Names**" means: (a) with respect to Eisai, the Trademarks, names and logos identified in Schedule 1.34(a) and such other Trademarks, names and logos as Eisai may designate in writing from time to time; and (b) with respect to the Licensee, the name Dr. Reddy's, Dr. Reddy's Laboratories or any similar name and such other Trademarks, names and logos as Licensee may designate in writing from time to time.

1.35. "**Corruption**" has the meaning set forth in Section 8.4.1.

1.36. "**Cost of Goods**" means, with respect to any Licensed Product, the Licensee's cost of goods for such Licensed Product, excluding corporate, general and administrative overheads and overheads not attributable to any facility or activities relating to the Manufacture of such Licensed Product, determined in accordance with the Licensee's cost accounting policies that are in accordance with GAAP and consistently applied across the Licensee's manufacturing network to other products that the Licensee or any of its Affiliates manufactures and shall not include inter-company profits among the Licensee and its Affiliates.

1.37. "**CTCL Indication**" means cutaneous T-cell lymphoma.

1.38. "**Defending Party**" has the meaning set forth in Section 6.4.2.

1.39. "**Development**" means, in respect of a biologic product, all activities related to research, pre-clinical and other non-clinical testing, clinical testing and clinical test method development, including the performance of trials relating to the safety, dosing and efficacy, stability testing, toxicology, formulation, process development, manufacturing scale-up, qualification and validation, quality assurance/quality control, including Manufacturing in support thereof, statistical analysis and report writing and, to the extent necessary to conduct any of the foregoing, the preparation and submission of Drug Approval Applications, regulatory affairs and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval for any of the foregoing activities. When used as a verb, "Develop" means to engage in Development.

1.40. "Development Plans" means the CMC Development Plan and the '302 Development Plan.

1.41. "**Discontinued Licensed Product**" means all dosage forms, formulations, strengths, package sizes and types of pharmaceutical products containing the Licensed Compound, previously sold in the United States under the Trademark ONTAK® and described in BLA #103767.

1.42. "**Dispute**" has the meaning set forth in Section 11.5.1.

1.43. "**Distribution Agreements**" means the [***] Agreement and the [***] Agreements.

1.44. "**Distribution Products**" means, with respect to a Distribution Agreement, Products that contain denileukin diftitox, as defined in such Distribution Agreement.

1.45. "**Dollars**" or "**$**" means United States Dollars.

1.46. "**Drug Approval Application**" means (a) a Biologics License Application submitted to the FDA under subsection (a) of Section 351 of the PHSA ("**BLA**") or any corresponding foreign application, including, with respect to the European Union, a Marketing Authorization Application filed with the EMA pursuant to the centralized approval procedure, and (b) all supplements and amendments that may be filed with respect to the foregoing.

1.47. "**Effective Date**" has the meaning set forth in the recitals hereto.

1.48. "**Eisai**" has the meaning set forth in the preamble hereto.

1.49. "**Eisai Covenant Patent**" means any Patent that (a) Eisai or any of its Affiliates Controls that is not part of the Eisai Technology and (b) would be infringed by the exercise by the Licensee of any of the rights granted to the Licensee under Section 2.1.1.

1.50. "**Eisai Developed Know-how**" means all rights in Know-how comprised within the Eisai Developed Technology.

1.51. "**Eisai Developed Technology**" means all Intellectual Property Rights (including any Intellectual Property Rights subsisting in any Improvements) owned by Eisai pursuant to Section 6.1.2.

1.52. "**Eisai Existing Know-how**" means all rights in Know-how Controlled by Eisai or any of its Affiliates as of the Original Effective Date that is necessary or reasonably useful for the Exploitation of the Licensed Compound or the Existing Licensed Product.

1.53. "**Eisai Existing Regulatory Documentation**" means all Regulatory Documentation, Controlled by Eisai or any of its Affiliates as of the Original Effective Date which relates to the Licensed Compound, Existing Licensed Product or Discontinued Licensed Product.

1.54. "**Eisai Indemnitees**" has the meaning set forth in Section 9.1.

1.55. "**Eisai Know-how**" means: (a) the Eisai Existing Know-how and (b) the Eisai Developed Know-how, but excluding in each of clauses (a) and (b) above any rights in Know-how to the extent covered or claimed by any published Eisai Patents.

1.56. "**Eisai Patents**" means all Patents owned by Eisai or any of its Affiliates that are filed after the Original Effective Date and that contain, disclose or claim any Eisai Developed Know-how.

1.57. "**Eisai Proprietary Product**" means any pharmaceutical product that is owned, licensed or otherwise controlled by Eisai or any of its Affiliates.

1.58. "**Eisai Regulatory Documentation**" means the Eisai Existing Regulatory Documentation and all Regulatory Documentation Controlled by Eisai or any of its Affiliates created after the Original Effective Date which relates to the Licensed Compound or Licensed Products.

1.59. "**Eisai Technology**" means: (a) all Intellectual Property Rights Controlled by Eisai or any of its Affiliates as of the Original Effective Date that are necessary or reasonably useful for the Exploitation of the Licensed Compound or a Licensed Product; and (b) all Eisai Developed Technology.

1.60. "**Eisai Territory**" means (a) the following countries: Japan, China, Korea, Taiwan, Hong Kong, Macau, Indonesia, Thailand, Malaysia, Brunei, Singapore, India, Pakistan, Sri Lanka, Philippines, Vietnam, Myanmar, Cambodia, Laos, Afghanistan, Bangladesh, Bhutan, Nepal, Mongolia and Papua New Guinea, *provided* that following any exercise of the India Option by the Licensee in accordance with Section 2.7 the "Eisai Territory" shall exclude India and (b) any Terminated Territory.

1.61. "**Eisai Territory Commercial Quality Agreement**" has the meaning set forth in Section 3.5.4.

1.62. "**Eisai Territory Commercial Supply Agreement**" has the meaning set forth in Section 3.5.4.

1.63. "**Eisai Territory Commercialization Plan**" has the meaning set forth in Section 3.3.3(b).

1.64. "**Eisai Territory Development Plan**" has the meaning set forth in Section 3.1.5.

1.65. "**Eisai Territory Product Trademarks**" means any Trademark other than an Eisai Trademark or any Corporate Name used by or on behalf of Eisai or any of its Affiliates on or in connection with the Exploitation of any Licensed Product in the Eisai Territory, but excluding, for clarity, any trade dress.

1.66. "**Eisai Trade Secrets**" means the information described on Schedule 1.66.

1.67. "**Eisai Trademarks**" means (a) the Trademarks set forth on Schedule 1.67 and (b) any variation or derivation thereof used by or on behalf of the Licensee or any of its Affiliates on or in connection with the Exploitation of any Licensed Product in the Licensee Territory.

1.68. "**EMA**" means the European Medicines Agency and any successor agency thereto.

1.69. "**Enforcing Party**" has the meaning set forth in Section 6.3.2.

1.70. "**European Union**" means the economic, scientific and political organization of member states as it may be constituted from time to time, which as of the Original Effective Date consists of Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom of Great Britain and Northern Ireland and that certain portion of Cyprus included in such organization.

1.71. "**Exclusion Lists**" has the meaning set forth in Section 8.1.5.

1.72. "**Execution Date**" has the meaning set forth in the preamble hereto.

1.73. "**Existing Licensed Product**" means the pharmaceutical product known as E7777, containing the Licensed Compound as an active ingredient and described in IND #110489.

1.74. "**Expedited Matters**" has the meaning set forth in Section 3.2.2(d).

1.75. "**Expedited Procedures**" has the meaning set forth in Section 3.2.2(d).

1.76. "**Expert**" has the meaning set forth in Section 10.6.5.

1.77. "**Expert List**" has the meaning set forth in Section 10.6.6.

1.78. "**Exploit**" means, in respect of a biologic product, to Develop, obtain or maintain Regulatory Approvals for, Manufacture, have Manufactured or Commercialize such product, including to make, have made, import, use, sell or offer for sale such product. "Exploitation" means the act of Exploiting a product.

1.79. "**Extension Term**" has the meaning set forth in Section 10.1.

1.80. "**FDA**" means the United States Food and Drug Administration and any successor agency thereto.

1.81. "[***] **Agreements**]" means that certain Distributorship Agreement, dated March 26, 1999, as amended, between [***] and [***], collectively (as predecessor in interest to Eisai) and [***] with respect to Spain, Portugal and Greece, and that certain Distributorship Agreement, dated March 26, 1999, as amended, between [***] and [***], collectively (as predecessor in interest to Eisai) and [***] with respect to Argentina, Chile, Uruguay, Paraguay, Bolivia, Brazil, Peru, Ecuador, Colombia, Venezuela, Guyana, Surinam, French Guyana, Panama, Costa Rica, Nicaragua, Honduras, El Salvador, Guatemala, Belize and Dominican Republic.

1.82. "**FFDCA**" means the United States Food, Drug, and Cosmetic Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

1.83. "**Field**" means the diagnostic, prophylactic or therapeutic use of a product in humans or animals.

1.84. "**Final '302 Development Report**" means a clinical study report in a format that is in accordance with Eisai's standard operating procedures and customary practices with respect to its other proprietary oncology products that (a) has been signed by the applicable investigator and applicable Eisai personnel, (b) except for publication (which will occur in connection with the filing of the BLA for the Existing Licensed Product for the CTCL Indication in the United States), is in a format that is ready for submission to FDA, and (c) has been fully reviewed by all appropriate quality control personnel at Eisai.

1.85. "**Final '302 Development Report Dispute**" has the meaning set forth in Section 3.1.2(b).

1.86. "**Final CMC Development Report**" means a written report in a format that is in accordance with Eisai's standard operating procedures and customary practices with respect to its other proprietary oncology products that (a) has been signed by the applicable Eisai personnel, (b) except for publication (which will occur in connection with the filing of the BLA for the Existing Licensed Product for the CTCL Indication in the United States), is in a format that is ready for submission to FDA, and (c) has been fully reviewed by all appropriate quality control personnel at Eisai.

1.87. "**Final CMC Development Report Dispute**" has the meaning set forth in Section 3.1.3(b).

1.88. "**FTE**" means the equivalent of the work of one (1) employee full time for one (1) Contract Year (consisting of at least a total of [***] ([***]) hours per Contract Year) of work directly related to the applicable FTE Activities. No additional payment shall be made with respect to any employee who works more than [***] ([***]) hours per Contract Year related to the applicable FTE Activities, and any employee who devotes less than [***] ([***]) hours per Contract Year to the applicable FTE Activities shall be treated as an FTE on a pro rata basis based upon the actual number of hours worked divided by [***] ([***]).

1.89. "**FTE Activity**" means any activity for which Eisai is reimbursed for its FTEs Costs and direct out-of-pocket costs with respect to such activity.

1.90. "**FTE Costs**" means, with respect to any activity for any period, the applicable FTE Rate multiplied by the applicable number of FTEs of the applicable Party or any of its Affiliates performing such activity during such period, including on a pro rata basis.

1.91. "**FTE Rate**" means, as of the Original Effective Date, [***] Dollars ($[***]). The FTE Rate shall be adjusted annually, with each annual adjustment effective as of April 1 of each Contract Year, with the first such annual adjustment to be made as of April 1, 2017, to correspond with the total percentage change in the Consumer Price Index for All Urban Consumers (CPI-U) for the U.S. City Average, 1982-84 = 100, calculated by the Bureau of Labor Statistics over the twelve (12)-month period preceding each such April 1.

1.92. "**GAAP**" means, with respect to a Party or its Affiliates or, with respect to the Licensee, its or their Sublicensees, United States generally accepted accounting principles, International Financial Reporting Standards or such other similar national standards as such Party, Affiliates or, with respect to the Licensee, its or their Sublicensee adopts, in each case, consistently applied.

1.93. "**Governmental Authority**" means any federal, state, national, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

1.94. "**ICC**" has the meaning set forth in Section 11.5.2(a).

1.95. "**Improvements**" means any invention, discovery, development or modification with respect to the Licensed Compound or a Licensed Product or relating to the Exploitation thereof, whether or not patented or patentable, including any enhancement in the efficiency, operation, Manufacture, ingredients, preparation, presentation, formulation, means of delivery or dosage of such Licensed Compound or Licensed Product, any discovery or development of any new or expanded Indications for such Licensed Compound or Licensed Product, any diagnostic devices relating to such Licensed Compound or Licensed Product, or any discovery or development that improves the stability, safety or efficacy of such Licensed Compound or Licensed Product, in each case, arising directly from any Development activities under or in connection with this Agreement.

1.96. "**IND**" means: (a) an investigational new drug application filed with the FDA for authorization to commence clinical studies and its equivalent in other countries or regulatory jurisdictions; and (b) all supplements and amendments that may be filed with respect to the foregoing.

1.97. "**Indemnification Claim Notice**" has the meaning set forth in Section 9.3.1.

1.98. "**Indemnified Party**" has the meaning set forth in Section 9.3.1.

1.99. "**India Option**" has the meaning set forth in Section 2.7.

1.100. "**India Option Period**" has the meaning set forth in Section 2.7.

1.101. "**Indication**" means any human and animal diagnostic, prophylactic and therapeutic indications.

1.102. "**Infringement**" has the meaning set forth in Section 6.3.1.

1.103. "**Initial Term**" has the meaning set forth in Section 10.1.

1.104. "**Intellectual Property Rights**" means all: (a) rights in Patents; (b) rights in Know-how; (c) rights in Copyrights; and (d) rights or forms of protection, anywhere in the world, having equivalent or similar effect to the rights referred to in paragraphs (a) to (c) above, in each case, whether registered or unregistered and including applications for registration of any of the foregoing, but excluding Trademarks and internet domain names.

1.105. "**IP Strategy**" has the meaning set forth in Section 4.2.4.

1.106. "**Joint Commercialization Committee**" or "**JCC**" has the meaning set forth in Section 4.2.

1.107. "**Joint Development Committee**" or "**JDC**" has the meaning set forth in Section 4.2.

1.108. "**Joint IP Committee**" or "**JIPC**" has the meaning set forth in Section 4.2.4.

1.109. "**Joint Manufacturing Committee**" or "**JMC**" has the meaning set forth in Section 4.2.

1.110. "**Joint Steering Committee**" or "**JSC**" has the meaning set forth in Section 4.1.

1.111. "**Joint Subcommittees**" has the meaning set forth in Section 4.2.

1.112. "**Know-how**" means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, apparatuses, specifications, data, results and other material, including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, assays and biological methodology, in each case (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed.

1.113. "**Knowledge**" means the actual knowledge after reasonable internal inquiry of, (a) with respect to Eisai, Associate Director, Global Business Development Unit, Asia and Executive Director, Program & Alliance Management, Oncology PCU of Eisai and (b) with respect to the Licensee, Head of Corporate Ethics & Compliance in North America and Senior Director of Finance of the Licensee.

1.114. "**Licensed Compound**" means the recombinant DNA-derived cytotoxic protein as described on Schedule 1.114.

1.115. "**Licensed Product**" means any product that is comprised of or contains the Licensed Compound as an active ingredient, including: (a) any combination product which contains the Licensed Compound as an active ingredient; (b) the Existing Licensed Product; and (c) all formulations, dosages and forms of release for any of the foregoing products.

1.116. "**Licensed Product Agreement**" means, with respect to a Licensed Product, any agreement entered into by and between a Party or any of its Affiliates, on the one hand, and one (1) or more Third Parties, on the other hand, that is necessary or reasonably useful for the Exploitation of such Licensed Product in the Field, including: (a) supply agreements pursuant to which a Party or its Affiliates obtain or will obtain quantities of such Licensed Product; (b) clinical trial agreements; (c) contract research organization agreements; and (d) service agreements.

1.117. "**Licensee**" has the meaning set forth in the preamble hereto.

1.118. "**Licensee Covenant Patent**" means any Patent that (a) the Licensee or any of its Affiliates Controls that is not part of the Licensee Technology and (b) would be infringed by the exercise by Eisai of any of the rights granted to Eisai under Section 2.2.

1.119. "**Licensee Developed Technology**" means all Intellectual Property Rights owned by Licensee pursuant to Section 6.1.2.

1.120. "**Licensee Funded Technology**" has the meaning set forth in Section 6.1.3.

1.121. "**Licensee Indemnitees**" has the meaning set forth in Section 9.2.

1.122. "**Licensee Know-how**" means all rights in Know-how comprised within the Licensee Technology.

1.123. "**Licensee Patents**" means all Patents owned by the Licensee or any of its Affiliates that are filed after the Original Effective Date and that contain, disclose or claim any Licensee Know-how.

1.124. "**Licensee Proprietary Product**" means any pharmaceutical product that is owned, licensed or otherwise controlled by Licensee or any of its Affiliates.

1.125. "**Licensee Regulatory Documentation**" means (a) all Regulatory Documentation transferred to the Licensee under this Agreement, including Eisai Existing Regulatory Documentation for the Licensee Territory and (b) all Regulatory Documentation Controlled by the Licensee or any of its Affiliates created after the Original Effective Date which relates to the Licensed Compound or Licensed Products.

1.126. "**Licensee Technology**" means the Licensee Developed Technology and the Licensee Funded Technology.

1.127. "**Licensee Territory**" means all countries in the world, excluding those countries in the Eisai Territory; *provided* that following any exercise of the India Option by the Licensee in accordance with Section 2.7 the "Licensee Territory" shall include India.

1.128. "**Licensee Territory Commercialization Plan**" has the meaning set forth in Section 3.3.3(a).

1.129. "**Licensee Territory Development Plan**" has the meaning set forth in Section 3.1.6.

1.130. "**Licensee Trademarks**" means any Trademark other than an Eisai Trademark or any Corporate Name used by or on behalf of the Licensee or any of its Affiliates on or in connection with the Exploitation of any Licensed Product in the Licensee Territory in accordance with Section 6.7.1(b), but excluding, for clarity, any trade dress.

1.131. "**Losses**" has the meaning set forth in Section 9.1.

1.132. "**Manufacture**" and "**Manufacturing**" mean, in respect of a biologic product, all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, shipping and holding of such product or any intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, stability testing, quality assurance and quality control.

1.133. "**Manufacturing Process**" has the meaning set forth in Section 3.5.2.

1.134. "**Manufacturing Transfer Services**" has the meaning set forth in Section 3.5.2.

1.135. "**Material Anti-Corruption Law Violation**" means a violation of an Anti-Corruption Law relating to the subject matter of this Agreement that would, if it were publicly known, be reasonably likely to have a material adverse effect on a Party or on the reputation of the Party because of its relationship with the other Party.

1.136. "**Net Sales**" means, with respect to a Licensed Product in a particular country in the Licensee Territory and a particular period of time, the gross sales recorded by the Licensee or any of its Affiliates or Sublicensees for such Licensed Product sold to Third Parties, less the following deductions specifically related to such Licensed Product and actually taken or applied, in the case of both gross sales and deductions as determined in accordance with GAAP:

1.136.1. normal trade and cash discounts;

1.136.2. amounts repaid or credited by reasons of defects, rejections, recalls or returns;

1.136.3. fees, rebates and chargebacks to customers and Third Parties (including Medicare, Medicaid, Managed Healthcare, including managed care or pharmacy benefit management companies, and similar types of rebates), and distribution fees paid to wholesalers and any other Third Party administrative fees;

1.136.4. amounts provided or credited to customers through coupons and other discount programs;

1.136.5. delayed ship order credits, discounts or payments related to the impact of price increases between purchase and shipping dates and retroactive price reductions;

1.136.6. costs of outbound freight, insurance, and other transportation charges directly related to the distribution of such Licensed Product to the purchaser;

1.136.7. compensation paid to non-Affiliate distributors and wholesalers for maintaining agreed inventory level and providing information; and

1.136.8. other reductions or specifically identifiable amounts deducted for reasons similar to those listed above in accordance with GAAP.

Such deductions shall be booked on an accrual basis by the Licensee and its Affiliates and Sublicensees under GAAP to calculate the recorded net sale from gross sales. In no event shall any particular amount of deduction identified above be deducted more than once in calculating Net Sales (i.e., no "double counting" of reductions). With respect to the calculation of Net Sales: (a) Net Sales only include the value charged or invoiced on an arm's length sale to a Third Party and sales between or among the Licensee and its Affiliates and Sublicensees will be disregarded for the purposes of calculating Net Sales unless such Affiliate or Sublicensee is the end-user of such Licensed Product; and (b) if the Licensed Product is delivered to the Third Party before being invoiced (or is not invoiced), Net Sales will be calculated at the time all the revenue recognition criteria under GAAP are met, or when payment is received, whichever is earlier.

1.137. "**Non-Breaching Party**" has the meaning set forth in Section 10.2.1.

1.138. "**Notice Period**" has the meaning set forth in Section 10.2.1.

1.139. "**Original Agreement**" has the meaning set forth in the recitals hereto.

1.140. "**Original Effective Date**" means March 30, 2016.

1.141. "**Party**" and "**Parties**" have the meaning set forth in the preamble hereto.

1.142. "**Patents**" means: (a) all national, regional and international patents and patent applications, including provisional patent applications; (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications; (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents, innovation patents and design patents and certificates of invention; (d) any and all associated exclusivities, extensions or restorations by existing or future exclusivity, extension or restoration mechanisms, including post-grant proceedings, revalidations, re-issues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b) and (c)); and (e) any similar rights subsisting anywhere in the world, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents ((a), (b), (c) and (d)).

1.143. "**Payment**" has the meaning set forth in Section 5.5.1.

1.144. "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.145. "**PHSA**" means the Public Health Service Act as set forth at 42 U.S.C. Chapter 6A, as may be amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

1.146. "**President Arbitrator**" has the meaning set forth in Section 11.5.2(b).

1.147. "**Prosecuting Party**" has the meaning set forth in Section 6.2.1.

1.148. "**Qualifications**" has the meaning set forth in Section 11.5.2(b).

1.149. "**Quality Agreement**" means the Clinical Quality Agreement or Eisai Territory Commercial Quality Agreement, as applicable.

1.150. "**Regulatory Approval**" means, with respect to a particular Licensed Product and a particular country, any and all approvals (including approvals of Drug Approval Applications), licenses, registrations or authorizations of any Regulatory Authority necessary to commercially distribute, sell or market a Licensed Product in such country, including, where applicable: (a) pricing or reimbursement approval in such country; (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto); and (c) labeling approval.

1.151. "**Regulatory Authority**" means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Exploitation of the Licensed Compound or Licensed Products, including the FDA in the United States and the EMA in the European Union.

1.152. "**Regulatory Documentation**" means all: (a) applications (including all INDs and Drug Approval Applications), registrations, licenses, authorizations and approvals (including Regulatory Approvals) and (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all adverse event files and complaint files; in each case relating to the Licensed Compound or a Licensed Product.

1.153. "**Representatives**" has the meaning set forth in Section 8.4.

1.154. "**Senior Officer**" means, with respect to Eisai, the chief executive officer or a designee who directly reports to him or her, and with respect to the Licensee, the chief executive officer or a designee who directly reports to him or her.

1.155. "**Sublicensee**" means a Person, other than an Affiliate, to which the Licensee grants a sublicense under the grants in Section 2.1 as provided in Section 2.3.

1.156. "**Supply Agreement**" means the Clinical Supply Agreement or the Eisai Territory Commercial Supply Agreement, as applicable.

1.157. "**Term**" means the Initial Term, plus any Extension Term.

1.158. "**Termination Notice**" has the meaning set forth in Section 10.2.1.

1.159. "**Territory**" means: (a) in relation to Eisai, the Eisai Territory; and (b) in relation to the Licensee, the Licensee Territory.

1.160. "**Third Party**" means any Person other than Eisai, the Licensee and their respective Affiliates.

1.161. "**Third Party Claims**" has the meaning set forth in Section 9.1.

1.162. "**Third Party Infringement Claim**" has the meaning set forth in Section 6.4.1.

1.163. "**Third Party Patent Right**" has the meaning set forth in Section 6.6.

1.164. "**Trademark**" means any word, name, logo, tagline, slogan, symbol, device, design, color, shape, designation or any combination thereof, including any trademark, service mark, trade name, brand name, sub-brand name, trade dress, product configuration rights, program name, delivery form name, certification mark or collective mark, that functions as an identifier of source, origin or quality, in each case, whether or not registered, and all statutory and common law rights therein and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing.

1.165. "**United States**" or "**U.S.**" means the United States of America and its territories and possessions (including the District of Columbia and Puerto Rico).

1.166. "**United States CTCL Regulatory Costs**" means the FTE Costs incurred and the direct out-of-pocket costs recorded as an expense, in accordance with GAAP, by or on behalf of Eisai or any of its Affiliates with respect to obtaining Regulatory Approval of the Existing Licensed Product in the United States for the CTCL Indication that are incurred or recorded after the pre-BLA meeting with the FDA with respect to the Existing Licensed Product in the United States for the CTCL Indication.

1.167. "**US CTCL Regulatory Matters**" has the meaning set forth in Section 4.2.1(b).

1.168. "**Unresolved Joint Subcommittee Matter**" has the meaning set forth in Section 4.4.1.

1.169. "**Unresolved JSC Matter**" has the meaning set forth in Section 4.4.2.

1.170. "**VAT**" has the meaning set forth in Section 5.5.2.

1.171. "**Working Team**" has the meaning set forth in Section 4.6.

ARTICLE 2
GRANT OF RIGHTS

2.1. Grants to Licensee.

2.1.1. Eisai Technology and Eisai Regulatory Documentation. Subject to Section 2.4.1, as of the Original Effective Date, Eisai hereby grants, and shall procure that each of its relevant Affiliates shall grant, to the Licensee an exclusive (including with regard to Eisai and its Affiliates) license (or sublicense) under the Eisai Technology, and an exclusive (including with regard to Eisai and its Affiliates) license and right of reference under the Eisai Regulatory Documentation, in each case with the right to grant sublicenses and further rights of reference in accordance with Section 2.3 to: (a) Exploit (other than to Develop, Manufacture, have Manufactured, make or have made) the Licensed Compound and Licensed Products in the Field in the Licensee Territory; (b) Develop the Licensed Compound and Licensed Products in the Field anywhere in the world solely for the purposes of obtaining or maintaining Regulatory Approvals for (i) the Licensed Compound and Licensed Products in the Field in the Licensee Territory or (ii) any Licensee Proprietary Product for use in concomitant or sequential administration with a Licensed Product anywhere in the world; (c) Manufacture, have Manufactured, make and have made the Licensed Compound and Licensed Products anywhere in the world solely for the purposes of Developing, obtaining or maintaining Regulatory Approvals for, or Commercializing the Licensed Compound and Licensed Products in the Field in the Licensee Territory; (d) Commercialize any Licensee Proprietary Product for use in concomitant or sequential administration with a Licensed Product anywhere in the world; and (e) perform its obligations under this Agreement, including any agreements entered into pursuant to this Agreement. For purposes of the use of Regulatory Approval in connection with clause (b)(ii) above, the term "Licensed Product" in the definition of Regulatory Approval shall be deemed to be a reference to "Licensee Proprietary Product".

2.1.2. Eisai Trademarks. Subject to Section 2.4.1, as of the Original Effective Date, Eisai hereby grants, and shall procure that each of its relevant Affiliates shall grant, to the Licensee an exclusive (including with regard to Eisai and its Affiliates) license (or sublicense) under the Eisai Trademarks, with the right to grant sublicenses in accordance with Section 2.3, to exercise the rights grants to the Licensee under Section 2.1.1.

2.1.3. Eisai Territory Licensed Product Trademarks. Subject to Section 2.4.1, as of the Original Effective Date, Eisai hereby grants, and shall procure that each of its relevant Affiliates shall grant, to the Licensee a non-exclusive license (or sublicense) under the Eisai Territory Product Trademarks, with the right to grant sublicenses solely to any licensee or sublicensee of the Licensee's rights with respect to the applicable Licensee Proprietary Product, to Commercialize any Licensee Proprietary Product for use in concomitant or sequential administration with a Licensed Product in the Eisai Territory.

2.2. Grants to Eisai.

2.2.1. Licensee Technology and Licensee Regulatory Documentation. Subject to Section 2.4.2, as of the Original Effective Date, the Licensee hereby grants, and shall procure that each of its relevant Affiliates shall grant, to Eisai an exclusive (including with regard to the Licensee and its Affiliates) license under the Licensee Technology, and an exclusive (including with regard to the Licensee and its Affiliates) license and right of reference under the Licensee Regulatory Documentation, in each case with the right to grant sublicenses and further rights of reference in accordance with Section 2.3, to: (a) Exploit (other than to Develop, Manufacture, have Manufactured, make or have made) the Licensed Compound and Licensed Products in the Field in the Eisai Territory; (b) Develop the Licensed Compound and Licensed Products in the Field anywhere in the world solely for the purposes of obtaining or maintaining Regulatory Approvals for (i) the Licensed Compound and Licensed Products in the Field in the Eisai Territory or (ii) any Eisai Proprietary Product for use in concomitant or sequential administration with a Licensed Product anywhere in the world; (c) Manufacture, have Manufactured, make and have made the Licensed Compound and Licensed Products anywhere in the world solely for the purposes of Developing, obtaining or maintaining Regulatory Approvals for, or Commercializing the Licensed Compound and Licensed Products in the Field in the Eisai Territory; (d) Commercialize any Eisai Proprietary Product for use in concomitant or sequential administration with a Licensed Product anywhere in the world; and (e) perform its obligations under this Agreement, including any agreements entered into pursuant to this Agreement. For purposes of the use of Regulatory Approval in connection with clause (b)(ii) above, the term "Licensed Product" in the definition of Regulatory Approval shall be deemed to be a reference to "Eisai Proprietary Product".

2.2.2. Licensee Trademarks. Subject to Section 2.4.2, as of the Original Effective Date, the Licensee hereby grants, and shall procure that each of its relevant Affiliates shall grant, to Eisai a non-exclusive license (or sublicense) under the Licensee Trademarks, with the right to grant sublicenses solely to any licensee or sublicensee of Eisai's rights with respect to the applicable Eisai Proprietary Product, to Commercialize any Eisai Proprietary Product for use in concomitant or sequential administration with a Licensed Product in the Licensee Territory.

2.2.3. Eisai Technology, Eisai Trademarks and Eisai Regulatory Documentation. Subject to Section 2.4.2, as of the Original Effective Date until full assignment of Eisai's rights and delegation of Eisai's obligations under the Distribution Agreements with respect to the Distribution Products to Licensee, the Licensee hereby grants, and shall procure that each of its relevant Affiliates shall grant, to Eisai a non-exclusive license (or sublicense) under the Eisai Technology and Eisai Trademarks, and a non-exclusive license and right of reference under the Eisai Regulatory Documentation, in each case, with the right to grant sublicenses and further rights of reference as necessary to maintain Eisai's compliance with the Distribution Agreements, solely to the extent necessary under the Distribution Agreements.

2.3. Sublicenses.

2.3.1. Right to Sublicense. Subject to Section 2.3.2, each Party shall have the right to grant sublicenses (or further rights of reference), through multiple tiers of sublicensees, under the licenses and rights of reference granted in Section 2.1 and Section 2.2 (as applicable) to:

(a) its Affiliates;

(b) with respect to Eisai, any other Persons; and

(c) with respect to the Licensee, any other Persons; *provided* that any sublicenses to such other Persons shall be subject to the prior written consent of Eisai, such consent not to be unreasonably withheld, conditioned or delayed; *provided, further*, that with respect to any sublicense to a contract manufacturer or supplier for a Licensed Product that would not involve the disclosure of any Eisai Trade Secret, Eisai shall provide its response to any request for such consent within [***] ([***]) Business Days after the Licensee's request with respect thereto; *provided, further*, that any sublicense to such other Persons that would involve the disclosure of any Eisai Trade Secret shall be subject to the prior written consent of Eisai, which may be withheld, conditioned or delayed in its sole discretion.

2.3.2. Sublicense Terms. Any sublicenses granted pursuant to Section 2.3.1 shall be consistent with, and subject to, the terms and conditions of this Agreement. Each Party shall cause each of its sublicensees to comply with the applicable terms and conditions of this Agreement, as if such sublicensee were a Party to this Agreement, and shall be responsible to the other Party for the actions and inactions of its sublicensees. Each Party hereby waives any requirement that the other Party exhaust any right, power or remedy, or proceed against any sublicensee of the first Party for any obligation or performance under this Agreement prior to proceeding directly against the sublicensing Party. Any sublicense granted pursuant to Section 2.3.1 shall terminate immediately if the relevant sublicensee commits or omits to do any act which would, if committed or omitted by a Party, be a material breach of this Agreement, or would give rise to a right of termination pursuant to Section 10.2.

2.4. Reservation of Rights.

2.4.1. No Other Rights Granted by Eisai. Notwithstanding anything to the contrary in this Agreement but subject to Section 2.6.2, Eisai retains, on behalf of itself and its Affiliates, rights in and to the Eisai Technology, the Eisai Regulatory Documentation and the Eisai Trademarks to: (a) Develop, Manufacture, have Manufactured, make and have made the Licensed Compound and Licensed Products anywhere in the world solely for the purposes of (i) obtaining or maintaining Regulatory Approvals for, or Commercializing, the Licensed Compound and Licensed Products in the Field in the Eisai Territory or (ii) obtaining or maintaining Regulatory Approvals for any Eisai Proprietary Product for use in concomitant or sequential administration with a Licensed Product anywhere in the world; (b) Commercialize any Eisai Proprietary Product for use in concomitant or sequential administration with a Licensed Product anywhere in the world; and (c) perform its obligations under this Agreement, including any agreements entered into pursuant to this Agreement. Except as expressly provided herein, Eisai grants no other right or license, including any rights or licenses to the Eisai Technology, the Eisai Regulatory Documentation, the Eisai Trademarks, the Eisai Territory Product Trademarks or other Intellectual Property Rights. In no event shall the Licensee or any of its Affiliates obtain any right or license to any Intellectual Property Rights with respect to any Eisai Proprietary Product under this Agreement. For purposes of the use of Regulatory Approval in connection with clause (a)(ii) above, the term "Licensed Product" in the definition of Regulatory Approval shall be deemed to be a reference to "Eisai Proprietary Product".

2.4.2. No Other Rights Granted by the Licensee. Notwithstanding anything to the contrary in this Agreement but subject to Section 2.6.1, the Licensee retains, on behalf of itself and its Affiliates, rights in and to the Licensee Technology and the Licensee Regulatory Documentation to: (a) Develop, Manufacture, have Manufactured, make and have made the Licensed Compound and Licensed Products anywhere in the world solely for the purposes of (i) obtaining or maintaining Regulatory Approvals for, or Commercializing, the Licensed Compound and Licensed Products in the Field in the Licensee Territory or (ii) obtaining or maintaining Regulatory Approvals for any Licensee Proprietary Product for use in concomitant or sequential administration with a Licensed Product anywhere in the world; (b) Commercialize any Licensee Proprietary Product for use in concomitant or sequential administration with a Licensed Product anywhere in the world; and (c) perform its obligations under this Agreement, including any agreements entered into pursuant to this Agreement. Except as expressly provided herein, the Licensee grants no other right or license, including any rights or licenses to the Licensee Technology, the Licensee Regulatory Documentation, the Licensee Trademarks or any other Intellectual Property Rights. In no event shall Eisai or any of its Affiliates obtain any right or license to any Intellectual Property Rights with respect to any Licensee Proprietary Product under this Agreement. For purposes of the use of Regulatory Approval in connection with clause (a)(ii) above, the term "Licensed Product" in the definition of Regulatory Approval shall be deemed to be a reference to "Licensee Proprietary Product".

2.5. Covenant Not to Sue.

2.5.1. Covenant Not to Sue the Licensee. Eisai hereby covenants not to assert or cause to be asserted, and will cause its Affiliates not to assert or cause to be asserted, against the Licensee or any of the Licensee's Affiliates or Sublicensees, any claim of infringement under any Eisai Covenant Patent solely with respect to the exercise of the rights granted to the Licensee under Section 2.1.1. If Eisai or any of its Affiliates licenses, assigns or otherwise transfers any Eisai Covenant Patent to a Third Party, then Eisai or its Affiliate, as applicable, will require such licensee, assignee or transferee to be bound by a covenant substantially identical to the covenant made by Eisai in this Section 2.5.1.

2.5.2. Covenant Not to Sue Eisai. The Licensee hereby covenants not to assert or cause to be asserted, and will cause its Affiliates not to assert or cause to be asserted, against Eisai or any of Eisai's Affiliates or Sublicensees, any claim of infringement under any Licensee Covenant Patent solely with respect to the exercise of the rights granted to Eisai under Section 2.2. If the Licensee or any of its Affiliates licenses, assigns or otherwise transfers any Licensee Covenant Patent to a Third Party, then the Licensee or its Affiliate, as applicable, will require such licensee, assignee or transferee to be bound by a covenant substantially identical to the covenant made by the Licensee in this Section 2.5.2.

2.6. Exclusivity and Territorial Restrictions.

2.6.1. Licensee. The Licensee shall not, and shall not permit any of its Affiliates or any of its and their licensees, Sublicensees, or distributors to, distribute, market, promote, offer for sale, or sell the Licensed Products, directly or indirectly, to any Person for use outside the Field outside the Licensee Territory. If the Licensee or any of its Affiliates receives or becomes aware of the receipt by a licensee, Sublicensee or distributor of any orders for any Licensed Products for commercial use outside the Field outside the Licensee Territory, the Licensee shall notify Eisai thereof and shall cause such recipient to refer such orders to Eisai.

2.6.2. Eisai. Eisai shall not, and shall not permit any of its Affiliates or any of its and their licensees or distributors to, distribute, market, promote, offer for sale or sell the Licensed Products, directly or indirectly, to any Person for use in the Field in the Licensee Territory. If Eisai or any of its Affiliates receives or becomes aware of the receipt by a (sub)licensee or distributor of any orders for any Licensed Product for commercial use in the Field in the Licensee Territory, Eisai shall notify the Licensee thereof and shall cause such recipient to refer such orders to the Licensee.

2.7. India Option. At any time prior to the filing of a Drug Approval Application for the Exploitation of the Existing Licensed Product in the United States (the "**India Option Period**"), the Licensee may, upon [***] ([***]) Business Days' written notice to Eisai elect to add India to the Licensee Territory (the "**India Option**"). If the Licensee timely elects the India Option during the India Option Period, then thereafter for the purposes of this Agreement, the term "Licensee Territory" shall include India and the term "Eisai Territory" shall not include India.

2.8. India Restriction. Prior to the filing of a Drug Approval Application for the Exploitation of the Existing Licensed Product in the United States, Eisai must not Commercialize the Licensed Compound or Licensed Products in India without the prior written consent of the Licensee.

2.9. Technical Document and Know-How Transfer. Eisai shall, and shall procure that each of its relevant Affiliates shall, provide to the Licensee the Know-how, Regulatory Documentation (including Eisai Existing Regulatory Documentation for the Licensee Territory) and other documents relating to the Existing Licensed Product and the Discontinued Product set forth on Schedule 2.9 in the form, and by the delivery date, set forth on Schedule 2.9. In addition, Eisai will use Commercially Reasonable Efforts to provide the Licensee any other documentation reasonably requested by the Licensee that embodies any Eisai Technology or Eisai Regulatory Documentation relating to the Licensee Territory. The Licensee shall reimburse Eisai for the direct out-of-pocket costs recorded as an expense, in accordance with GAAP, by or on behalf of Eisai or any of its Affiliates related to the provision of any Know-how, Regulatory Documentation or other documents pursuant to this Section 2.9 within [***] ([***]) days after receipt of an invoice with respect thereto. For clarity, this Section 2.9 contains Eisai's obligation to deliver the documents and information set forth on Schedule 2.9 and Eisai's obligations to provide knowledge transfer and support are set forth in Section 3.2.2 and Section 3.5.2.

2.10. Distribution Agreements.

(a) Eisai shall use good faith efforts to obtain (or, if requested in writing by Licensee, assist Licensee in obtaining) (i) a written acknowledgement from [***] of Eisai's right to partially assign Eisai's rights and delegate Eisai's obligations, under the [***] Agreements with respect to the Distribution Products to Licensee and (ii) written consent from [***] to partially assign Eisai's rights and delegate Eisai's obligations under the [***] Agreement with respect to the Distribution Products to Licensee. If any such acknowledgement or consent is not obtained within [***] ([***]) days after the Original Effective Date, Eisai shall continue to use its good faith efforts to obtain such acknowledgement or consent, and Eisai shall cooperate with Licensee in any lawful and economically feasible arrangement (including subcontracting) to provide that Licensee shall receive the interest of Eisai in any such Distribution Agreement with respect to the Distribution Products; *provided* that Licensee shall fulfill any obligations for which Licensee would have been responsible if such acknowledgement or consent had been obtained, subject to the indemnification obligations of Eisai in Section 9.2. Eisai shall hold in trust for and pay to Licensee, promptly upon receipt thereof, all income, proceeds and other monies received by Eisai or any of its Affiliates in connection with the distribution of the Distribution Products under the Distribution Agreements.

(b) Effective upon obtaining such written acknowledgement or consent as described in Section 2.10(a) with respect to the [***] Agreements or the [***] Agreement, as applicable, Eisai hereby assigns to Licensee all of Eisai's rights and delegates to Licensee all of Eisai's obligations, in each case, under the [***] Agreements or the [***] Agreement, as applicable, with respect to the Distribution Products and Licensee hereby accepts such assignment and assumes such obligations.

ARTICLE 3
DEVELOPMENT, REGULATORY AND COMMERCIALIZATION ACTIVITIES

3.1. Development.

3.1.1. In General. Except as provided in Section 3.1.2, Section 3.1.3, and Section 3.2, as between the Parties, (a) subject to clause (c) and (d), Licensee shall have the sole right and responsibility, at its sole expense, for all aspects of the Development of the Licensed Compound and Licensed Products for Commercialization in the Field in the Licensee Territory, (b) Eisai shall have the sole right and responsibility, at its sole expense, for all aspects of the Development of the Licensed Compound and Licensed Products for Commercialization in the Field in the Eisai Territory, (c) Licensee shall have the sole right and responsibility, at its sole expense, for all aspects of the Development of any Licensee Proprietary Product for use in concomitant or sequential administration with a Licensed Product anywhere in the world and (d) Eisai shall have the sole right and responsibility, at its sole expense, for all aspects of the Development of any Eisai Proprietary Product for use in concomitant or sequential administration with a Licensed Product anywhere in the world. Neither Party shall perform any Development activities, other than pre-clinical research activities, with respect to the Licensed Compound nor the Licensed Products except as set forth in the '302 Development Plan, CMC Development Plan, Eisai Territory Development Plan or Licensee Territory Development Plan, as applicable.

3.1.2. '302 Development Activities.

(a) Eisai shall use Commercially Reasonable Efforts to perform the '302 Development Activities in compliance with the '302 Development Plan. Either Party, through its representatives on the JSC, may propose amendments to the '302 Development Plan from time to time. Any and all such amendments to the '302 Development Plan shall be subject to approval by the JSC as set forth in Section 4.1.1. No amendment to the '302 Development Plan will be effective unless approved by the JSC in accordance with Section 4.1.1, including the dispute resolution procedures set forth in Section 4.4. All amendments to the '302 Development Plan must be in writing.

(b) After completing the clinical trial described in the '302 Development Plan, after internal Eisai review of the first draft of the Final '302 Development Report, Eisai shall provide the Licensee with a copy of each additional draft of the Final '302 Development Report that Eisai distributes within Eisai for review and comment. Eisai shall consider in good faith any comments provided by the Licensee within the comment period provided for the internal Eisai reviewers; *provided* that any dispute regarding whether or not to implement any of the Licensee's comments with respect to any draft of the Final '302 Development Report (each, a "**Final '302 Development Report Dispute**") shall be submitted to the JSC for resolution. Eisai shall implement any of the Licensee's comments with respect to any draft of the Final '302 Development Report that has been approved by the JSC (including, if applicable, in accordance with Section 4.4.2(g)).

3.1.3. CMC Development Activities.

(a) Within [***] ([***]) days after the Original Effective Date, the Parties shall finalize the CMC Development Plan.

(b) Eisai shall use Commercially Reasonable Efforts to perform the CMC Development Activities in compliance with the CMC Development Plan. Either Party, through its representatives on the JSC, may propose amendments to the CMC Development Plan from time to time. Any and all such amendments to the CMC Development Plan shall be subject to approval by the JSC as set forth in Section 4.1.1. No amendment to the CMC Development Plan will be effective unless approved by the JSC in accordance with Section 4.1.1, including the dispute resolution procedures set forth in Section 4.4. All amendments to the CMC Development Plan must be in writing.

(c) After completing the activities necessary to generate the data and information necessary for the deliverables described in the CMC Development Plan, after internal Eisai review of the first draft of the Final CMC Development Report, Eisai shall provide the Licensee with a copy of each additional draft of the Final CMC Development Report that Eisai distributes within Eisai for review and comment. Eisai shall consider in good faith any comments provided by the Licensee within the comment period provided for the internal Eisai reviewers; provided that any dispute regarding whether or not to implement any of the Licensee's comments with respect to any draft of the Final CMC Development Report (each, a "**Final CMC Development Report Dispute**") shall be submitted to the JSC for resolution. Eisai shall implement any of the Licensee's comments with respect to any draft of the Final CMC Development Report that has been approved by the JSC (including, if applicable, in accordance with Section 4.4.2(g)).

3.1.4. '302 Development Costs. Subject to this Section 3.1.4, Licensee shall reimburse Eisai for its '302 Development Costs.

(a) Eisai shall report to Licensee, within [***] ([***]) days after the end of each Calendar Quarter, the '302 Development Costs incurred by Eisai or any of its Affiliates during such Calendar Quarter. Each such report shall (i) specify in reasonable detail all amounts included in '302 Development Costs during such Calendar Quarter (broken down by activity) and the corresponding budgeted expenses for such Calendar Quarter and (ii) include an invoice for the '302 Development Costs incurred by Eisai or any of its Affiliates during such Calendar Quarter and copies of any invoices or other supporting documentation for any payments to a Third Party that individually exceed [***] Dollars ($[***]) (or such other amount approved by the JSC). Eisai agrees to provide upon request copies of invoices and details to Licensee on any invoices not otherwise submitted to Licensee to enable Licensee to comply with its tax, auditing and other obligations. The Parties shall seek to resolve any questions related to such reports and invoice details within [***] ([***]) days following the Licensee's receipt of Eisai's report hereunder. Subject to clause (b) below, within [***] ([***]) days after the later of (i) the receipt of any report and (ii) the resolution of any questions with respect to any report, Licensee shall reimburse Eisai for the '302 Development Costs set forth in such report; it being understood and agreed that all undisputed amounts shall be payable within [***] ([***]) days after the receipt of the applicable report referred to in clause (i) above.

(b) Unless otherwise agreed by the Parties in writing, in no event shall the Licensee be obligated to reimburse Eisai for more than (i) [***] Dollars ($[***]) in '302 Development Costs , with respect to the '302 Development Plan, as it exists as of the Original Effective Date or as the '302 Development Plan may be amended to enable Eisai to provide the Licensee the deliverables set forth in '302 Development Plan as of the Original Effective Date in accordance with the timeframe set forth therein, or if FDA requires changes to the '302 Development Plan due to changes in the manufacturing site. For clarity, unless otherwise agreed by the Parties in writing, Licensee shall reimburse Eisai for its '302 Development Costs resulting from any other amendment to the '302 Development Plan.

3.1.5. Eisai Territory Development Plan. As soon as reasonably practicable after the Original Effective Date, and in any event within [***] ([***]) days after the Original Effective Date, Eisai shall provide the JSC with a copy of its plan for the Development of the Licensed Compound and Licensed Products for Commercialization in the Eisai Territory or any Eisai Proprietary Product for use in concomitant or sequential administration with a Licensed Product anywhere in the world, other than the '302 Development Activities and the CMC Development Activities (the "**Eisai Territory Development Plan**"), which Eisai Territory Development Plan shall be subject to approval by the JSC as set forth in Section 4.1.3. Eisai, through its representatives on the JSC, may propose amendments to the Eisai Territory Development Plan from time to time. Any and all such amendments to the Eisai Territory Development Plan shall be subject to approval by the JSC as set forth in Section 4.1.3. Neither the initial Eisai Territory Development Plan nor any amendment to the Eisai Territory Development Plan will be effective unless approved by the JSC in accordance with Section 4.1.3, including the dispute resolution procedures set forth in Section 4.4. All amendments to the Eisai Territory Development Plan must be in writing.

3.1.6. Licensee Territory Development Plan. As soon as reasonably practicable after the Original Effective Date, and in any event within [***] ([***]) days after the Original Effective Date, the Licensee shall provide the JSC with a copy of its plan for the Development of the Licensed Compound and Licensed Products for Commercialization in the Licensee Territory or any Licensee Proprietary Product for use in concomitant or sequential administration with a Licensed Product anywhere in the world, other than the '302 Development Activities and the CMC Development Activities (the "**Licensee Territory Development Plan**"), which Licensee Territory Development Plan shall be subject to approval by the JSC as set forth in Section 4.1.3. Licensee, through its representatives on the JSC, may propose amendments to the Licensee Territory Development Plan from time to time. Any and all such amendments to the Licensee Territory Development Plan shall be subject to approval by the JSC as set forth in Section 4.1.3. Neither the initial Licensee Territory Development Plan nor any amendment to the Licensee Territory Development Plan will be effective unless approved by the JSC in accordance with Section 4.1.3, including the dispute resolution procedures set forth in Section 4.4. All amendments to the Licensee Development Plan must be in writing.

3.1.7. Licensee Development Diligence. Subject to Eisai's performance of the '302 Development Activities and the CMC Development Activities, Licensee shall use Commercially Reasonable Efforts to Develop a Licensed Product for the United States for the CTCL Indication.

3.1.8. Development Records. Each Party shall, and shall cause its Affiliates to, maintain, in good scientific manner, complete and accurate books and records pertaining to its Development of the Licensed Compound and the Licensed Products, in sufficient detail to verify compliance with its obligations under this Agreement. Such books and records shall: (a) be appropriate for patent and regulatory purposes; (b) be in compliance with Applicable Law; (c) properly reflect all work done and results achieved in the performance of its Development activities hereunder, including all data and other information obtained in the performance of such activities; and (d) record only such activities and not include or be commingled with records of activities outside the scope of this Agreement. Eisai shall provide the Licensee electronic access to such books and records in Eisai or any of its Affiliate's possession that relate to the CMC Development Activities and the '302 Development Activities via a secure file transfer protocol site or other similar site, which site Eisai shall update at least once a Calendar Quarter. Except to the extent prohibited by Applicable Law, promptly after Eisai files the BLA for the Existing Licensed Product for the CTCL Indication in the United States, Eisai shall transfer to the Licensee or its designated Affiliate the original version (or, where the transfer of the original version is prohibited by Applicable Law, a copy) of all such books and records that relate to the CMC Development Activities and the '302 Development Activities (except that Eisai may retain a copy of the same). Each Party shall retain a copy of all such books and records for at least [***] ([***]) years after the expiration or termination of this Agreement or for such longer period as may be required by Applicable Law. Each Party shall have the right, during normal business hours and upon reasonable notice, to inspect all records of the other Party maintained pursuant to this Section 3.1.8.

3.1.9. FTE Reports. In addition, Eisai shall record and account for (on a monthly and position-by-position basis) its FTE effort with respect to its FTE Activities performed under this Agreement, in each case, consistent with past practice and in the same manner as used for other products developed by Eisai, unless otherwise agreed by the Parties in writing.

3.1.10. Development Reports. Without limiting Section 3.1.8, within [***] ([***]) days of the end of the first and third Calendar Quarter of each Contract Year during which a Party is performing, or causing to be performed, Development activities in relation to the Licensed Compound or Licensed Product, such Party shall provide the JSC with a reasonably detailed written report of the Development activities it has performed, or caused to be performed, in respect of the Licensed Compound or Licensed Product since the preceding report (or, with respect to the first such report, since the Original Effective Date), and the future Development activities it expects to initiate in respect of the Licensed Compound or Licensed Product during the following twelve (12)-month period. In the case of any report submitted by Eisai to Licensee, each such report shall contain sufficient detail to enable the Licensee to assess Eisai's compliance with the obligations set forth in Section 3.1.2 and Section 3.1.3.

3.1.11. Compliance with Applicable Law. Each Party shall, and shall cause its Affiliates to, comply with all Applicable Law with respect to the Development of the Licensed Compound and Licensed Products.

3.2. Regulatory Activities.

3.2.1. In General.

(a) Except as otherwise set forth in this Section 3.2, the Licensee shall have the exclusive right, at its own cost, to prepare, submit to Regulatory Authorities in the Licensee Territory, obtain, and maintain Drug Approval Applications based on the regulatory strategy therefor approved by the JSC and other submissions (including INDs) for the Licensed Products in the Field in the Licensee Territory, and to conduct communications with the Regulatory Authorities with respect thereto and all Regulatory Documentation for the Licensed Products in the Licensee Territory shall be owned by, and shall be the sole property and held in the name of, Licensee or its designated Affiliate. For clarity, any Eisai Know-how included or referenced in any such Regulatory Documentation shall remain the exclusive property of Eisai or its applicable Affiliate.

(b) Except as otherwise set forth in this Section 3.2, Eisai shall have the exclusive right, at its own cost, to prepare, submit to Regulatory Authorities in the Eisai Territory, obtain, and maintain Drug Approval Applications based on the regulatory strategy therefor approved by the JSC, and other submissions (including INDs) for the Licensed Products in the Field in the Eisai Territory, and to conduct communications with the Regulatory Authorities with respect thereto and all Regulatory Documentation for the Licensed Products in the Eisai Territory shall be owned by, and shall be the sole property and held in the name of, Eisai or its designated Affiliate. For clarity, any Licensee Know-how included or referenced in any such Regulatory Documentation shall remain the exclusive property of the Licensee or its applicable Affiliate.

(c) Except as otherwise set forth in this Section 3.2, the Licensee shall have the exclusive right to prepare, submit to Regulatory Authorities, obtain, and maintain all INDs necessary to conduct any Development activities set forth in the Licensee Territory Development Plan, and to conduct communications with the Regulatory Authorities with respect thereto and all such INDs shall be owned by, and shall be the sole property and held in the name of, the Licensee or its designated Affiliate.

(d) Eisai shall (i) prepare, submit to Regulatory Authorities, obtain, and maintain all INDs necessary to conduct the ‘302 Development Activities and the CMC Development Activities, and (ii) have the exclusive right to prepare, submit to Regulatory Authorities, obtain, and maintain all INDs necessary to conduct any Development activities set forth in the Eisai Territory Development Plan, and in each case ((i) and (ii)), subject to Section 3.2.2, to conduct communications with the Regulatory Authorities with respect thereto and, subject to Section 3.2.3, all such INDs shall be owned by, and shall be the sole property and held in the name of, Eisai or its designated Affiliate.

3.2.2. Initial Regulatory Approval in the United States for CTCL Indication.

(a) Eisai shall use Commercially Reasonable Efforts to obtain Regulatory Approval of the Existing Licensed Product in the United States for the CTCL Indication. For clarity, if any additional non-clinical studies or clinical trials other than the ‘302 Development Activities, the CMC Development Activities and the non-clinical studies or clinical trials that have been completed by or on behalf of Eisai prior to the Original Effective Date are required by the FDA to grant Regulatory Approval of the Existing Licensed Product in the United States for the CTCL Indication, Eisai shall have no obligation to file the BLA for the Existing Licensed Product in the United States for the CTCL Indication, or engage in communications with the FDA with respect thereto, unless and until such additional non-clinical or clinical trials have been completed by or on behalf of Licensee.

(b) Subject to Section 3.2.2(d), Eisai shall provide the JDC with copies of the BLA for, and other material or substantive submissions or communications to the FDA relating to, the Existing Licensed Product for the CTCL Indication in the United States a reasonable amount of time prior to the anticipated date for the submission or communication to allow the JDC to review and approve such BLA or other submission or communication. Eisai shall not submit the BLA for, or any other material or substantive submission or communication to the FDA relating to, the Existing Licensed Product for the CTCL Indication in the United States that has not been approved by the JDC (including, if applicable, in accordance with Section 4.4.2(g)) or the Expedited Procedures, if applicable; *provided*, that if Eisai has complied with the approval procedures set forth in Section 4.4 or the Expedited Procedures, as applicable, and, due to the Licensee's failure to comply with the procedures under Section 4.4 of the Expedited Procedures, as applicable, such approval is not provided prior to the applicable required response date and Eisai is not able to obtain, through reasonable effort, an extension of such response date, Eisai may submit such BLA or other material or substantive submission or communication to the FDA without such approval.

(c) Subject to Section 3.2.2(d), Eisai shall notify the JDC reasonably in advance of the date of any anticipated meeting with the FDA relating to the Existing Licensed Product for the CTCL Indication in the United States. The JDC shall agree in advance on the objectives to be accomplished at, the agenda for, and, if appropriate, the script for, each such meeting. Upon the Licensee's reasonable request, Eisai shall, to the extent permitted by the FDA, permit the Licensee to attend meetings between Eisai and the FDA relating to the Existing Licensed Product for the CTCL Indication in the United States and shall, if requested by Licensee, request that the FDA allow at least one (1) representative of the Licensee to attend, and, to the extent provided in the applicable agreed agenda or script, participate in such meetings. Eisai shall use good faith efforts to provide the Licensee with an opportunity to be present at, as an observer, to the extent practical, any unscheduled or ad-hoc meetings with the FDA relating to the Existing Licensed Product for the CTCL Indication in the United States, *provided* that if an applicable agenda or script is agreed to by both Parties prior to any unscheduled or ad hoc meetings, Licensee may participate in such meetings to the extent provided therein.

(d) Within [***] ([***]) after the Original Effective Date, senior regulatory representatives from each Party shall agree in good faith on written expedited procedures for the approval of material or substantive submissions or communications to the FDA relating to the Existing Licensed Product for the CTCL Indication in the United States or, with respect to any meeting with the FDA relating to the Existing Licensed Product for the CTCL Indication in the United States, the objectives to be accomplished at, and the agenda for, and, if appropriate, the script for, each such meeting, to the extent that an expedited review is necessary to enable Eisai to comply with Applicable Law or requirements of the FDA (such matters "**Expedited Matters**" and such procedures, "**Expedited Procedures**"). The allocation of final-decision making authority between the Parties with respect to the Expedited Matters shall be the same as the allocation set forth in Section 4.4.2(g) with respect to US CTCL Regulatory Matters. Each Party shall comply with the applicable Expedited Procedures with respect to each Expedited Matter.

(e) Licensee shall reimburse Eisai for its United States CTCL Regulatory Costs. Eisai shall report to Licensee, within [***] ([***]) days after the end of each Calendar Quarter, the United States CTCL Regulatory Costs incurred by Eisai or any of its Affiliates during such Calendar Quarter. Each such report shall (i) specify in reasonable detail all amounts included in such United States CTCL Regulatory Costs during such Calendar Quarter (broken down by activity) and the corresponding budgeted expenses for such Calendar Quarter and (ii) include an invoice for United States CTCL Regulatory Costs incurred by Eisai or any of its Affiliates during such Calendar Quarter and copies of any invoices or other supporting documentation for any payments to a Third Party (including filings fees) that individually exceed [***] Dollars ($[***]) (or such other amount approved by the JSC). Eisai agrees to provide upon request copies of invoices and details to Licensee on any invoices not otherwise submitted to Licensee to enable Licensee to comply with its tax, auditing and other obligations. The Parties shall seek to resolve any questions related to such reports within [***] ([***]) days following the Licensee's receipt of Eisai's report hereunder. Within [***] ([***]) days after the later of (A) the receipt of any report and (B) the resolution of any questions with respect to any report, Licensee shall reimburse Eisai for the United States CTCL Regulatory Costs set forth in such report; it being understood and agreed that all undisputed amounts shall be payable within [***] ([***]) days after the receipt of the applicable report referred to in clause (A) above.

3.2.3. Transfer of BLA and INDs. Promptly after the earlier of (a) Regulatory Approval of the Existing Licensed Product in the United States for the CTCL Indication and (b) Eisai's receipt of a complete response letter from the FDA with respect to the BLA filed by Eisai with the FDA for the Existing Licensed Product for the CTCL Indication, Eisai shall assign, and shall cause its Affiliates to assign, to the Licensee all of Eisai's and its Affiliates' right, title and interest in and to such BLA and any INDs with respect to the Existing Licensed Product in the Licensee Territory and all related Regulatory Documentation with respect thereto; *provided*, that with respect to a complete response letter that only identifies minor deficiencies with respect to the BLA for the Existing Licensed Product in the United States for the CTCL Indication, then, at the Licensee's option, Eisai shall either (x) assign, and shall cause its Affiliates to assign, to the Licensee all of Eisai's and its Affiliates' right, title and interest in and to such BLA and any INDs with respect to the Existing Licensed Product in the Licensee Territory and all related Regulatory Documentation with respect thereto or (y) retain such BLA and any INDs and use Commercially Reasonable Efforts to resubmit such BLA to correct such deficiency. Where Licensee elects to have Eisai retain such BLA and INDs and use Commercially Reasonable Efforts to resubmit such BLA to correct minor deficiencies, the first sentence of this Section 3.2.3 shall apply with respect to additional FDA action. During the [***] ([***]) months after any such assignment, at the Licensee's reasonable request, Eisai shall provide the Licensee reasonable knowledge transfer and support as necessary for the Licensee to Develop Licensed Products in the Field in the Licensee Territory or prepare, obtain and maintain any Regulatory Approvals for the Licensed Products in the Field in the Licensee Territory; *provided*, that in no event shall Eisai be required to provide the Licensee more than [***] ([***]) hours of such knowledge transfer and support. For clarity, Eisai's support obligations with respect to the transfer of the Manufacturing Process shall be as set forth in Section 3.5.2. The Licensee shall reimburse Eisai for the FTE Costs incurred and the direct out-of-pocket costs recorded as an expense, in accordance with GAAP, by or on behalf of Eisai or any of its Affiliates pursuant to this Section 3.2.3 within [***] ([***]) days after receipt of an invoice with respect thereto. Save as otherwise agreed by the Parties, the JSC shall be responsible for discussing, planning and coordinating any technical transfer services pursuant to this Section 3.2.3 and any responses to a complete response letter from the FDA with respect to the BLA filed by Eisai.

3.2.4. Access to Regulatory Documentation. Except to the extent prohibited by Applicable Law, and without limiting Section 3.1.10, each Party shall, promptly following receipt of a request from the other Party, deliver to the other Party a copy of all Regulatory Documentation Controlled by the first Party or any of its Affiliates which relates to the Licensed Compound or Licensed Products in the Field in the other Party's Territory and which the requesting Party requires to, or which are necessary or reasonably useful for the requesting Party to, exercise the rights granted to it under Section 2.1.1 or Section 2.2, as applicable.

3.2.5. [***Intentionally left blank***.]

3.2.6. Communications and Filings with Regulatory Authorities. The provisions of this Section 3.2.6 shall not apply with respect to Eisai's activities under Section 3.2.2(a), which shall be governed by Section 3.2.2(b), Section 3.2.2(c) or Section 3.2.2(d), as applicable. Each Party shall, subject to Applicable Law and except to the extent a need for exigent action prevents it from doing so, provide the other Party with copies of each Drug Approval Application or other submission or communication to a Regulatory Authority relating to the Licensed Compound or a Licensed Product in its own Territory a reasonable amount of time prior to the anticipated date for the submission or communication to allow the other Party to review and comment on such Drug Approval Application, submission or communication, and the first Party shall consider all reasonable comments and proposed revisions from the other Party in good faith in connection with effecting such submission or communication. The first Party shall consult with the other Party regarding, and keep the other Party reasonably informed of, the status of the preparation of all Drug Approval Applications it submits relating to a Licensed Product, Regulatory Authority review of any such Drug Approval Application, and all approvals of Drug Approval Applications or other Regulatory Approvals and other submissions (including INDs) that it obtains with respect to a Licensed Product in its Territory. Upon the other Party's reasonable request, and subject to Applicable Law, the first Party shall provide to the other Party full, complete and correct copies of all final Drug Approval Applications it submits in its Territory. The first Party shall consult with the other Party reasonably in advance of the date of any anticipated meeting with a Regulatory Authority relating to the Licensed Compound or a Licensed Product and shall consider any timely and reasonable recommendations made by the other Party in preparation for such meeting. Upon the other Party's reasonable request, the first Party shall, to the extent permitted by the relevant Regulatory Authority, permit the other Party to attend particular meetings between the first Party and any Regulatory Authority in the first Party's Territory relating to the Licensed Compound or a Licensed Product if such meeting is anticipated to address a matter that does, or may be reasonably expected to, impact the Exploitation of the Licensed Compound or a Licensed Product in the other Party's Territory and shall, where necessary, request that the applicable Regulatory Authority allow at least one (1) representative of the other Party to attend, solely as an observer, such meetings; provided that the foregoing shall not apply to informal meetings or unscheduled teleconferences or meetings or teleconferences otherwise intended by the Regulatory Authority to be between it and the first Party's representatives only. The other Party shall strictly follow the first Party's instructions with respect to any such meeting that it attends pursuant to this Section 3.2.6 and shall not discuss the contents of any such meeting with any Regulatory Authority in the first Party's Territory except as required by Applicable Law or authorized by the first Party in writing.

3.2.7. Recalls, Suspensions or Withdrawals. Each Party shall notify the other Party promptly following its determination that any event, incident or circumstance has occurred that may result in the need for a recall, market suspension, or market withdrawal of a Licensed Product in the Field in the first Party's Territory and shall include in such notice the reasoning behind such determination and any supporting facts. As between the Parties, the first Party shall have the right to make the final determination whether to voluntarily implement any such recall, market suspension, or market withdrawal in the Field in its Territory; *provided* that prior to any implementation of such a recall, market suspension, or market withdrawal, the first Party shall consult with the other Party and shall consider the other Party's reasonable comments in good faith. If a recall, market suspension, or market withdrawal of a Licensed Product in the Field in a Party's Territory is mandated by a Regulatory Authority in such Territory, then, as between the Parties, such Party shall initiate such a recall, market suspension, or market withdrawal in compliance with Applicable Law. For all recalls, market suspensions, or market withdrawals undertaken pursuant to this Section 3.2.7, each Party shall, as between the Parties, be solely responsible for the execution and costs thereof in its own Territory.

3.2.8. Pharmacovigilance Agreement; Global Safety Database. No later than the earlier of (a) the date that is [***] ([***]) months before the date Licensee files an IND for a clinical study with respect to any Licensed Product and (b) the date that Eisai files the BLA for the Existing Licensed Product for the CTCL Indication in the United States, the Parties shall enter into a separate written pharmacovigilance agreement providing details related to managing and reporting adverse events in respect of the Licensed Compound or any Licensed Product that occur during clinical studies and other safety and reporting practices and procedures in compliance with all Applicable Laws. Each Party shall, at its sole cost, establish, hold and maintain the safety database for Licensed Products in its respective Territory. Each Party shall provide the other Party with information in the possession and Control of the first Party as necessary for the other Party to comply with its pharmacovigilance responsibilities in respect of the Licensed Compound and the Licensed Products in its Territory, including, as applicable, any adverse drug experiences (including those events or experiences that are required to be reported to the FDA under 21 C.F.R. section 312.32 or 600.80 or to foreign Regulatory Authorities under corresponding Applicable Law outside the United States) from pre-clinical or clinical laboratory, animal toxicology and pharmacology studies, clinical studies, and commercial experiences with a Licensed Product, in each case, in the form reasonably requested by the other Party.

3.3. Commercialization.

3.3.1. Responsibility. The Licensee shall, as between the Parties, be solely responsible for the Commercialization of the Licensed Products in the Field throughout the Licensee Territory at the Licensee's own cost and Eisai shall, as between the Parties, be solely responsible for the Commercialization of the Licensed Products throughout the Eisai Territory at Eisai's own cost. The Licensee shall use Commercially Reasonable Efforts to Commercialize a Licensed Product in the United States for the CTCL Indication.

3.3.2. Booking of Sales; Distribution. Each Party shall be responsible for invoicing and booking sales, establishing all terms of sale (including pricing and discounts), and warehousing and distributing the Licensed Products (including Licensed Products that are used in concomitant or sequential administration with a Licensee Proprietary Product or an Eisai Proprietary Product, as the case may be) in the Field in its Territory and performing or causing to be performed all related services. Subject to Section 3.2.7, each Party shall handle all returns, recalls or withdrawals, order processing, invoicing, collection, distribution, and inventory management with respect to the Licensed Products in the Field in its Territory.

3.3.3. Commercialization Plans.

(a) At least [***] ([***]) days prior to the anticipated first commercial sale of a Licensed Product in the Licensee Territory, the Licensee shall provide the JCC with a copy of its plan for the Commercialization of the Licensed Products in the Licensee Territory (the "**Licensee Territory Commercialization Plan**"). At least once each Contract Year, the Licensee shall provide the JCC with an updated Licensee Territory Commercialization Plan that reflects all amendments and updates to the previously provided Licensee Territory Commercialization Plan.

(b) At least [***] ([***]) days prior to the anticipated first commercial sale of a Licensed Product in the Eisai Territory, Eisai shall provide the JCC with a copy of its plan for the Commercialization of the Licensed Products in the Eisai Territory (the "**Eisai Territory Commercialization Plan**"). At least once each Contract Year, Eisai shall provide the JCC with an updated Eisai Territory Commercialization Plan that reflects all amendments and updates to the previously provided Eisai Territory Commercialization Plan.

3.3.4. Commercialization Reports. Within [***] ([***]) days of the end of the first and third Calendar Quarter of each Contract Year during which the Licensee is conducting Commercialization activities hereunder, the Licensee shall provide the JSC with reasonably detailed written reports of the Commercialization activities it has performed, or caused to be performed, in respect of the Licensed Product since the preceding report (or, with respect to the first such report, since the Original Effective Date), and the future Commercialization activities it expects to initiate in respect of the Licensed Product during the following twelve (12)-month period.

3.4. Compliance with Applicable Law. Each Party shall, and shall cause its Affiliates to, comply with all Applicable Law with respect to the Exploitation of Licensed Products.

3.5. Supply of Licensed Compound and Licensed Products.

3.5.1. In General. As between the Parties, each Party shall, at its own cost, be solely responsible for the Manufacture and supply of the Licensed Compound and Licensed Products for all of its Development and Commercialization activities under this Agreement. Subject to Section 3.5.3 and Section 3.5.4, neither Party shall have any obligation to supply the other Party with any quantities of Licensed Compound or Licensed Product. Promptly after the Original Effective Date, the Parties shall discuss in good faith the Manufacture and supply plan for the Licensed Compound and the Existing Licensed Product for Commercialization in the Licensee Territory, which shall take into account the Manufacturing Process transfer as set forth in Section 3.5.2 and as well as timing of approval of additional permitted Manufacturing sites that Licensee may designate.

3.5.2. Manufacturing Process Transfer. Eisai shall, when and as reasonably requested by the Licensee in writing, transfer, at the Licensee's sole expense, to the Licensee or its permitted designee (which designee may be an Affiliate, Sublicensee or a permitted Third Party manufacturer) the Know-how related to the then-current process for the Manufacture of the Licensed Compound and the Existing Licensed Product (the "**Manufacturing Process**") and, subject to Section 3.1.8, Regulatory Documentation. In addition, Eisai shall, as reasonably requested by the Licensee and subject to this Section 3.5.2, provide such support, at the Licensee's sole expense, as may be necessary or reasonably useful to the Licensee or its designee to use and practice the Manufacturing Process (the "**Manufacturing Transfer Services**"). The Licensee shall reimburse Eisai for the FTE Costs incurred and the direct out-of-pocket costs recorded as an expense, in accordance with GAAP, by or on behalf of Eisai or any of its Affiliates related to the transfer of the Manufacturing Process or provision of Manufacturing Transfer Services within [***] ([***]) days after receipt of an invoice with respect thereto. Save as otherwise agreed by the Parties, the JMC shall be responsible for discussing, planning and coordinating any technical transfer services pursuant to this Section 3.5.2.

3.5.3. Clinical Supply Agreement. Eisai shall have the right at any time upon written notice to the Licensee to elect to have the Licensee supply Eisai with some or all of its requirements of Licensed Products for its Development activities under this Agreement. If Eisai provides such notice to the Licensee, then the Parties shall, through the JMC, use diligent efforts to negotiate and execute a manufacturing and supply agreement pursuant to which the Licensee, or its designated subcontractor, Sublicensee or Affiliate, would supply Licensed Products to Eisai for its Development activities under this Agreement (the "**Clinical Supply Agreement**"), and a related quality agreement (the "**Clinical Quality Agreement**") within [***] ([***]) days after Eisai provides such notice. The Clinical Supply Agreement and Clinical Quality Agreement shall contain terms and conditions that are usual and customary for a clinical supply agreement or related quality agreement, as applicable, between companies in the pharmaceutical/biological industry of comparable size and expertise to the respective Parties; *provided*, that purchase price payable by Eisai to the Licensee for Licensed Products under the Clinical Supply Agreement shall be equal to the Licensee's Cost of Goods for such Licensed Products.

3.5.4. Eisai Territory Commercial Supply Agreement. Eisai shall have the right at any time upon written notice to the Licensee to elect to have the Licensee supply Eisai with some or all of its requirements of Licensed Compound or Licensed Products for Commercialization in the Eisai Territory. If Eisai provides such notice to the Licensee, then the Parties shall, through the JMC, use diligent efforts to negotiate and execute a manufacturing and supply agreement pursuant to which the Licensee, or its designated subcontractor, Sublicensee or Affiliate, would supply Licensed Compound or Licensed Products to Eisai for Commercialization in the Eisai Territory (the "**Eisai Territory Commercial Supply Agreement**"), and a related quality agreement (the "**Eisai Territory Commercial Quality Agreement**") within [***] ([***]) days after Eisai provides such notice. The Eisai Territory Commercial Supply Agreement and Eisai Territory Commercial Quality Agreement shall contain terms and conditions that are usual and customary for a commercial supply agreement or related quality agreement, as applicable, between companies in the pharmaceutical/biological industry of comparable size as expertise to the respective Parties.

3.5.5. Failure to Agree on Supply Agreement or Quality Agreement. If a Supply Agreement (or related Quality Agreement) has not been agreed and executed within the applicable period set forth in Section 3.5.3 or Section 3.5.4, as applicable, then the determination of the final terms and conditions of such Supply Agreement (or related Quality Agreement) shall be subject to the applicable dispute resolution procedures in Section 4.4.2(g).

3.6. Subcontracting. Eisai may subcontract with a Third Party to perform any or all of its rights or obligations hereunder. The Licensee may subcontract with a Third Party to perform any or all of its rights or obligations hereunder (including by appointing one (1) or more distributors); *provided* that any subcontracting by the Licensee that would involve the disclosure of any Eisai Trade Secret shall be subject to the prior written consent of Eisai, which may be withheld, conditioned or delayed in its sole discretion.

3.7. Assumption of Activities upon a Change of Control of Eisai. If Eisai undergoes a Change of Control prior to the completion of the '302 Development Activities or the CMC Development Activities or the assignment of the BLA and INDs to the Licensee pursuant to Section 3.2.3, then not later than [***] ([***]) Business Days following the public announcement of such Change of Control of Eisai, Eisai shall provide written notice to the Licensee of such transaction. In the event of any such Change of Control, the Licensee shall have the right, in its sole discretion, to (a) assume control of (i) the '302 Development Activities and the CMC Development Activities and (ii) obtaining Regulatory Approval of the Existing Licensed Products in the United States for the CTCL Indication and (b) have the BLA and INDs assigned to the Licensee, by notifying Eisai of such election within [***] ([***]) days after receipt of such notice. If the Licensee makes such election, then:

(a) Eisai shall use Commercially Reasonable Efforts to effect a smooth and orderly transition of the '302 Development Activities and the CMC Development Activities to the Licensee and the Licensee shall thereafter use Commercially Reasonable Efforts to perform such activities;

(b) the Licensee shall use Commercially Reasonable Efforts to obtain Regulatory Approval of the Existing Licensed Product in the United States for the CTCL Indication, and the provision of Section 3.2.2 shall apply *mutatis mutandis*;

(c) the Parties shall enter into good faith negotiations with regard to compensating the Licensee for any expenses the Licensee may incur due to the Licensee's assumption of the control of the '302 Development Activities or the CMC Development Activities;

(d) Eisai shall no longer have any obligations under Section 3.1.2, Section 3.1.3 or Section 3.2.2;

(e) Eisai shall assign the BLA (or any in-process draft BLA, if applicable) and INDs to the Licensee pursuant to Section 3.2.3;

(f) notwithstanding Section 4.4.2(a), the Licensee shall have the right to make the final decision with respect to the Development Plans, unless such amendment would decrease the scope of the activities to be performed under the Development Plans, in which case the proposed amendment shall be deemed rejected; and

(g) notwithstanding Section 4.4.2(g), the Licensee shall have the right to make the final decision on any US CTCL Regulatory Matter.

ARTICLE 4
GOVERNANCE

4.1. Joint Steering Committee. Within [***] ([***]) days after the Original Effective Date, the Parties shall establish a joint committee (the "**Joint Steering Committee**" or "**JSC**"), which shall consist of at least two (2) executive-level representatives from each of the Parties, each with the requisite experience and seniority to enable such person to make decisions on behalf of the Party it represents with respect to the issues falling within the jurisdiction of the JSC; *provided*, that no Senior Officer may be a representative to the JSC. Simultaneously with establishing the JSC, the Parties shall identify their initial representatives. From time to time, each Party may substitute one (1) or more of its representatives to the JSC with a suitably qualified substitute on written notice to the other Party. The JSC shall have the responsibilities and authority allocated to it in this Section 4.1 and shall operate by the procedures set forth in Section 4.3. Neither the JSC nor any Joint Subcommittee shall have any decision-making authority other than as explicitly set forth in this Section 4.1 or Section 4.2, as applicable, and all such decision-making authority shall be subject to the dispute resolution procedures in Section 4.4. The JSC shall:

4.1.1. review and approve any and all amendments to the '302 Development Plan or the CMC Development Plan(for the avoidance of doubt, the JSC will not be responsible for managing or controlling '302 Development Activities or CMC Development Activities);

4.1.2. review and approve the regulatory strategy for Licensed Products in the Licensee Territory;

4.1.3. review and approve the initial Licensee Territory Development Plan, the initial Eisai Territory Development Plan and any and all updates or amendments to either of the foregoing;

4.1.4. discuss whether any proposed Development activities under the Licensee Territory Development Plan or the Eisai Territory Development Plan should be jointly funded by the Parties;

4.1.5. review and approve the regulatory strategy for Licensed Products in the Eisai Territory;

4.1.6. review and discuss the proposed labeling of each Licensed Product in each country in either Territory;

4.1.7. monitor the performance of the Development of the Licensed Compound and Licensed Products in the Field in the Licensee Territory and Eisai Territory, including by reviewing the conduct of the Development activities and reviewing Development reports as provided in Section 3.1.10;

4.1.8. monitor the performance of the Commercialization of Licensed Products in the Field in the Licensee Territory and Eisai Territory, including by reviewing the conduct of the Commercialization activities and reviewing Commercialization reports as provided in Section 3.3.3;

4.1.9. serve as a forum for discussing matters, and attempting to resolve disputes, disagreements or other issues arising under this Agreement and referred by the Parties that the Joint Subcommittees or Alliance Managers are unable to resolve;

4.1.10. coordinate the Parties' activities under this Agreement;

4.1.11. discuss, plan and coordinate any technical transfer services pursuant to Section 3.2.3 or Section 3.5.2 not otherwise planned or coordinated by the JDC or JMC;

4.1.12. if Licensee elects the India Option pursuant to Section 2.7, discuss feasibility of Eisai or its Affiliates co-promoting or co-marketing the Licensed Products in India;

4.1.13. resolving Final '302 Development Report Disputes and Final CMC Development Report Disputes; and

4.1.14. perform such other functions as are set forth herein or as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.

4.2. Joint Subcommittees. Within fifteen (15) days after the Original Effective Date, the Parties shall establish (a) a joint development committee ("**Joint Development Committee**" or "**JDC**"), (b) a joint manufacturing committee ("**Joint Manufacturing Committee**" or "**JMC**"), and (c) a joint intellectual property committee ("**Joint IP Committee**" or "**JIPC**"). The JSC may, at its option establish a joint commercialization committee ("**Joint Commercialization Committee**" or "**JCC**," and together with the JDC, JMC and JIPC, the "Joint Subcommittees"). Each Joint Subcommittee shall consist of (i) with respect to the JDC and JMC, at least two (2) representatives from each of the Parties, and (ii) with respect to the JIPC and JCC, at least one (1) representative from each of the Parties, in each case ((i) and (ii)), each with the requisite experience to enable such person to make decisions on behalf of the Parties with respect to the issues falling within the jurisdiction of the relevant Joint Subcommittee; *provided*, that no Senior Officer may be a representative to a Joint Subcommittee. Simultaneously with establishing each such Joint Subcommittee, the Parties shall identify their initial representatives to such Joint Subcommittee. Each Subcommittee shall have the responsibilities and authority allocated to it in this Section 4.2 and shall operate by the procedures set forth in Section 4.3. If any Joint Subcommittee is not established, then the JSC shall have the responsibilities allocated to such Joint Subcommittee and any reference to such Joint Subcommittee in this Agreement shall be deemed to be a reference to the JSC. No Joint Subcommittee shall have authority that exceeds the authority granted to the JSC.

4.2.1. Joint Development Committee. The JDC shall have the following responsibilities:

(a) develop the overall strategic objectives and plans, including objectives and plans with respect to Regulatory Approval(s), for the Development of the Licensed Products in the Field in the Licensee Territory and Eisai Territory and submit the same to the JSC for review and approval, if applicable;

(b) except with respect to Expedited Matters, which shall be reviewed and approved in accordance with the applicable Expedited Procedures, review and approve (i) the BLA for, and any other material or substantive submissions or communications to the FDA relating to the Existing Licensed Product for the CTCL Indication in the United States and (ii) with respect to any meeting with the FDA relating to, the Existing Licensed Product for the CTCL Indication in the United States, the objectives to be accomplished at, the agenda for, and, if appropriate, the script for, each such meeting (such review and approval responsibilities, "**US CTCL Regulatory Matters**");

(c) oversee and coordinate the transfer of Know-how, Regulatory Documentation and other documents pursuant to Section 2.9 that are not related to the Manufacturing Process;

(d) review and approve clinical protocols for any clinical trial to be conducted by or on behalf of either Party under this Agreement;

(e) review Eisai Territory Development Plan with respect to activities that may impact the Licensee Territory;

(f) review Licensee Territory Development Plan with respect to activities that may impact the Eisai Territory; and

(g) after the execution of the pharmacovigilance agreement pursuant to Section 3.2.8, oversee global safety data exchange and pharmacovigilance-related matters for the Licensed Products in accordance with such agreement.

4.2.2. Joint Manufacturing Committee. The JMC shall have the following responsibilities (for the avoidance of doubt, the JMC will not be responsible for managing or controlling CMC Development Activities):

(a) oversee any manufacturing technical transfer services pursuant to Section 3.5.2;

(b) oversee and coordinate the transfer of Know-how, Regulatory Documentation and other documents pursuant to Section 2.9 that are related to the Manufacturing Process;

(c) manage the supply chain for the Licensed Compound and Licensed Products;

(d) negotiate and determine the final terms and conditions of any Supply Agreement (or related Quality Agreement) elected by Eisai in accordance with Section 3.5.3 or Section 3.5.4, as applicable; and

(e) serve as a forum for discussing any quality-related issues with respect to the Licensed Compound or Licensed Products.

4.2.3. Joint Commercialization Committee. The JCC shall have the following responsibilities:

(a) discuss and review the Licensee Territory Commercialization Plan and the Eisai Territory Commercialization Plan;

(b) discuss any new Trademark (other than an Eisai Trademark or any Corporate Name) that the Licensee wishes to use on or in connection with the Exploitation of any Licensed Product in the Licensee Territory; and

(c) discuss any new Trademark (other than a Licensee Trademark, Eisai Trademark or any Corporate Name) that Eisai wishes to use on or in connection with the Exploitation of any Licensed Product anywhere in the world.

4.2.4. Joint Intellectual Property Committee. The JIPC shall have the following responsibilities:

(a) determine the worldwide strategy for the prosecution and maintenance of the Eisai Patents and the Licensee Patents to maximize the commercial potential of the Licensed Products (the "**IP Strategy**"); and

(b) discuss and agree with respect to ownership of any inventions that are conceived, discovered, developed or otherwise made jointly by or on behalf of Eisai or its Affiliates or its or their (sub)licensees, as applicable, on the one hand, and Licensee, or its Affiliates or its or their (sub)licensees, as applicable, in each case, under or in connection with this Agreement and the responsibility for the prosecution, maintenance, enforcement and defense of any Patents with respect thereto.

4.3. General Provisions Applicable to Committees.

4.3.1. Meetings and Minutes. The JSC and any Joint Subcommittee (each, a "**Committee**") shall meet (a) with respect to the JSC, not less than once every [***] ([***]) months and (b) with respect to any Joint Subcommittee, at least once each Calendar Quarter, in each case of ((a) and (b)), unless otherwise agreed by the Parties. The location of such meetings shall alternate between locations designated by the Licensee and locations designated by Eisai. The chairman of the JSC for the Contract Year of the Original Effective Date and the chairman of each Joint Subcommittee for the Contract Year in which such Joint Subcommittee was created shall be appointed by Eisai, and thereafter the power to appoint the chairman shall alternate each Contract Year between the Licensee and Eisai. The chairperson of each Committee shall be responsible for calling meetings on no less than [***] ([***]) Business Days' notice unless exigent circumstances require shorter notice. The chairman of a Committee shall call a meeting of such Committee promptly upon the reasonable request of the other Party. Each Party shall make all proposals for agenda items at least [***] ([***]) Business Days in advance of the applicable meeting and shall provide all appropriate information with respect to such proposed items at least [***] ([***]) Business Days in advance of the applicable meeting; *provided* that under exigent circumstances requiring input by a Committee a Party may provide its agenda items to the other Party within a shorter period of time in advance of the meeting (or at the meeting) or may propose that there not be a specific agenda for a particular meeting, so long as the other Party consents to such later addition of such agenda items or the absence of a specific agenda for such meeting (which consent shall not be unreasonably withheld, conditioned or delayed). The chairperson of each Committee shall arrange for the preparation and circulation for review and approval of the Parties minutes of each meeting within [***] ([***]) days of the meeting. The Parties shall agree on the minutes of each meeting promptly, but in any event prior to the next meeting of such Committee.

4.3.2. Procedural Rules. Each Committee shall have the right to adopt such standing rules as shall be necessary for its work, to the extent that such rules are not inconsistent with this Agreement. A quorum of a Committee shall exist whenever there is present at a meeting at least one (1) representative appointed by each Party. Representatives of the Parties on each Committee may attend a meeting either in person or by telephone, video conference or similar means in which each participant can hear what is said by, and be heard by, the other participants. Representation by proxy shall be allowed. Subject to Section 4.4.3 and, with respect to the JSC, Section 4.4.1, each Committee shall take action by unanimous consensus of the representatives present at a meeting at which a quorum exists. Alliance Managers or other employees or consultants of a Party who are not representatives of the Parties on a Committee may attend meetings of such Committee, as applicable; *provided, however*, that such attendees: (a) shall not vote or otherwise participate in the decision-making process of such Committee; and (b) are bound by obligations of confidentiality and non-disclosure at least as protective of the other Party as those set forth in Article 7.

4.4. JSC and Joint Subcommittee Dispute Resolution.

4.4.1. Unresolved Joint Subcommittee Matters. If any Joint Subcommittee is unable to reach a consensus with respect to any matter under the jurisdiction of such Joint Subcommittee within [***] ([***]) Business Days of initially considering such matter (each an "Unresolved Joint Subcommittee Matter"), then the Unresolved Joint Subcommittee Matter shall be referred to the JSC.

4.4.2. Unresolved JSC Matters. Except as provided otherwise in Section 3.5.5, if the JSC is unable to reach a consensus with respect to any matter under the jurisdiction of the JSC within [***] ([***]) Business Days of initially considering such matter (each an "**Unresolved JSC Matter**"), then

(a) subject to Section 3.7(e), if the Unresolved JSC Matter relates to the approval of any amendment to the Development Plans, or the approval of any clinical protocol for any clinical trial set forth therein, such Unresolved JSC Matter shall be referred to the Senior Officers for attempted resolution by good faith negotiations during a period of [***] ([***]) Business Days from the date of such referral, or such longer period as the Senior Officers may agree in writing. Any final decision mutually agreed to in writing by the Senior Officers shall be conclusive and binding on the Parties. If such Senior Officers are unable to reach a decision regarding such Unresolved JSC Matter within such [***] ([***])-Business Day period (or such longer period as the Senior Officers may agree in writing), then the Licensee shall have the right to make the final decision on such Unresolved JSC Matter unless: (i) such amendment would decrease the scope of the activities to be performed under the Development Plans, or (ii) with respect to any amendment that is not required by the FDA in order to obtain or maintain an approved BLA for the Existing Licensed Product for the CTCL Indication in the United States, (A) Eisai would need to hire additional personnel to implement such amendment without impacting any other programs of Eisai or any of its Affiliates, (B) such amendment would require that Eisai or any of its Affiliates purchase or acquire access to any additional equipment or Intellectual Property Rights, or (C) such amendment would reasonably be expected to adversely impact patient safety as demonstrated by written scientific evidence, in which case ((i) or (ii)), the proposed amendment shall be deemed rejected;

(b) subject to Section 4.4.2(d) and Section 4.4.2(g), if the Unresolved JSC Matter relates to (i) the regulatory strategy for the Licensee Territory or (ii) the approval of the initial Licensee Territory Development Plan or any amendment thereto, or the approval of any clinical protocol for any clinical trial set forth therein, in either case ((i) or (ii)),the Licensee shall have the right to make the final decision on such Unresolved JSC Matter;

(c) subject to Section 4.4.2(e), if the Unresolved JSC Matter relates to (i) the regulatory strategy for the Eisai Territory or (ii) the approval of the initial Eisai Territory Development Plan or any amendment thereto, or the approval of any clinical protocol for any clinical trial set forth therein, in either case ((i) or (ii)), Eisai shall have the right to make the final decision on such Unresolved JSC Matter;

(d) if the Unresolved JSC Matter relates to the initiation or continuation of any Development activities under the Licensee Territory Development Plan that Eisai reasonably believes may result in unreasonable safety risks for patients or subjects, then such activity shall, as applicable, either not be initiated by or on behalf of the Licensee or shall be terminated by the Licensee as promptly as possible in accordance with Applicable Law and with due regard to patient safety;

(e) if the Unresolved JSC Matter relates to the initiation or continuation of any Development activities under the Eisai Territory Development Plan that Licensee reasonably believes may result in unreasonable safety risks for patients or subjects, then such activity shall, as applicable, either not be initiated by or on behalf of the Eisai or shall be terminated by the Eisai as promptly as possible in accordance with Applicable Law and with due regard to patient safety;

(f) if the Unresolved JSC Matter relates to the IP Strategy for a Patent, then the Prosecuting Party with respect to such Patent shall have the right to make a final decision regarding the strategy for the prosecution and maintenance of such Patent;

(g) subject to Section 3.7(f), if the Unresolved JSC Matter relates to any US CTCL Regulatory Matter, any Final '302 Development Report Dispute or any Final CMC Development Report Dispute, such Unresolved JSC Matter shall be referred to the Senior Officers for attempted resolution by good faith negotiations during a period of [***] ([***]) Business Days from the date of such referral, or such longer period as the Senior Officers may agree in writing. Any final decision mutually agreed to in writing by the Senior Officers shall be conclusive and binding on the Parties. If such Senior Officers are unable to reach a decision regarding such Unresolved JSC Matter within such [***] ([***])-Business Day period (or such longer period as the Senior Officers may agree in writing), then the Licensee shall have the right to make the final decision on such Unresolved JSC Matter unless Eisai provides written, quantitative evidence that the Licensee's approach would reasonably be expected to (i) adversely impact patient safety as demonstrated by written scientific evidence; *provided*, that this clause (i) shall not apply with respect to disputes regarding the proposed labeling for the Existing Licensed Product for the CTCL Indication in the United States, (ii) result in the FDA not approving the BLA for the Existing Licensed Product for the CTCL Indication in the United States or a substantial delay in such approval or (iii) materially adversely impact the reputation of Eisai or any of its Affiliates, in which case ((i), (ii) or (iii)), Eisai shall have the right to make the final decision on such Unresolved JSC Matter; provided that if Eisai undergoes a Change of Control, the exception to the Licensee's final decision-making authority set forth in the foregoing clause (ii) shall no longer apply;

(h) if the Unresolved JSC Matter relates to a Supply Agreement or Quality Agreement, such Unresolved JSC Matter shall be referred to the Senior Officers for attempted resolution by good faith negotiations during a period of [***] ([***]) Business Days from the date of such referral, or such longer period as the Senior Officers may agree in writing. Any final decision mutually agreed to in writing by the Senior Officers shall be conclusive and binding on the Parties. If such Senior Officers are unable to reach a decision regarding such Unresolved JSC Matter within such [***] ([***])-Business Day period (or such longer period as the Senior Officers may agree in writing), then no action shall be taken on such Unresolved JSC Matter; and

(i) if the Unresolved JSC Matter involves any other matter, such Unresolved JSC Matter shall be referred to the Senior Officers for attempted resolution by good faith negotiations during a period of [***] ([***]) Business Days from the date of such referral, or such longer period as the Senior Officers may agree in writing. Any final decision mutually agreed to in writing by the Senior Officers shall be conclusive and binding on the Parties. If such Senior Officers are unable to reach a decision regarding an Unresolved JSC Matter within such [***] ([***])-Business Day period (or such longer period as the Senior Officers may agree in writing), then the Unresolved JSC Matter shall be resolved through binding arbitration in accordance with Section 11.5.2.

4.4.3. Limitations on Authority. Without limitation to the foregoing, the Parties hereby agree that matters explicitly reserved to the consent, approval or other decision-making authority of one (1) or both Parties, as expressly provided in this Agreement, are outside the jurisdiction and authority of each Committee, including: (a) amendment, modification or waiver of compliance with this Agreement (which may only be amended or modified as provided in Section 11.8 or compliance with which may only be waived as provided in Section 11.12); and (b) such other matters as are reserved to the consent, approval, agreement or other decision-making authority of either or both Parties in this Agreement that are not required by this Agreement to be considered by a Committee prior to the exercise of such consent, approval or other decision-making authority. The JSC's and each Joint Subcommittee's role as a forum for reviewing, monitoring or discussing items set out in Section 4.1 or Section 4.2, as applicable, shall not include any authority to make binding decisions regarding such items.

4.5. Discontinuation; Disbandment; Annual Reports. Each Committee shall continue to exist until the Parties mutually agree to disband such Committee. Upon the occurrence of the foregoing: (a) such Committee shall disband, have no further responsibilities or authority under this Agreement and will be considered dissolved by the Parties; and (b) any requirement of a Party to provide Know-how or other materials to such Committee shall be deemed a requirement to provide such Know-how or other materials to the other Party and the Party with final decision-making authority pursuant to Section 4.4.2 shall, after consultation with the other Party and taking the other Party's comments, if any, into consideration in good faith, have the right to decide all matters that were subject to the review or approval by such Committee.

4.6. Working Teams. From time to time, each Committee may establish and delegate duties to other subcommittees or working teams (each, a "**Working Team**") as it deems necessary to achieve the objectives of this Agreement; *provided* that: (a) each such Working Team shall have equal representation from each Party; (b) the activities of such Working Team shall be subject to the oversight, review and approval of, and shall report to, the Committee that established such Working Team; and (c) in no event shall the authority of any such Working Team exceed that specified for the Committee that established such Working Team under this Agreement.

4.7. Alliance Managers. Each Party shall appoint an individual (each an "**Alliance Manager**") who shall oversee contact between the Parties for all matters between meetings of the JSC and shall have such other responsibilities as the Parties may agree in writing after the Original Effective Date. A Party may replace the individual serving as its Alliance Manager at any time by notice in writing to the other Party. The Alliance Managers shall work together to manage and facilitate communication between the Parties under this Agreement, including the resolution (in accordance with the terms of this Agreement) of issues between the Parties that arise in connection with this Agreement. The Alliance Managers shall not have final decision-making authority with respect to any matter under this Agreement.

ARTICLE 5

PAYMENTS AND RECORDS

5.1. Upfront Payment. Licensee shall pay to Eisai the following consideration as an upfront payment, which shall be nonrefundable:

5.1.1. US$[***] million shall be due and payable within [***] ([***]) days after September 29, 2017; and

5.1.2. US$[***] million shall be due and payable within [***] ([***]) days after Eisai's written notice to Licensee of Eisai's submission of the application for the Type C meeting with FDA related to CMC.

5.2. Milestones.

5.2.1. Development and Regulatory Milestones. In consideration of the rights granted by Eisai to the Licensee hereunder, the Licensee shall pay to Eisai the following payments within [***] ([***]) days after the achievement of each of the following milestone events, which shall be non-refundable, non-creditable and fully earned upon the achievement of the applicable milestone event:

Milestone Event	**Milestone Payment**
First approval by the FDA of a Biologics License Application (submitted under subsection (a) of Section 351 of the PHSA) for a Licensed Product for the CTCL Indication.	US$6 million, save that the payment shall be increased by US$1 million (to US$7 million in total) if, prior to approval by the FDA of the BLA for a Licensed Product, the Licensee exercises the India Option pursuant to Section 2.7.
Achieving US$[***] in cumulative Net Sales of Licensed Products in the Licensee Territory.	US$[***] million.
Achieving US$[***] in cumulative Net Sales of Licensed Products in the Licensee Territory.	US$[***] million.
Achieving US$[***] in cumulative Net Sales of Licensed Products in the Licensee Territory.	US$[***] million.
Achieving US$[***] in cumulative Net Sales of Licensed Products in the Licensee Territory; *provided*, that such milestone shall only be due and payable if occurring during the Extension Term.	US$[***] million.

The milestone payments set out above shall each be payable only once in total, irrespective of the number of Licensed Products which are the subject of a BLA (and the number of Indications for any single Licensed Product). The Parties acknowledge and agree that the [***] dollar ($[***]) exclusivity fee paid to Eisai by the Licensee pursuant to that certain letter agreement between the Parties dated November 20, 2015, as amended and extended, shall be set-off against the first milestone payment made hereunder.

5.2.2. Determination That Milestones Have Occurred. The Licensee shall notify Eisai promptly of the achievement of each of the events identified as a milestone event in Section 5.2.1 and Eisai shall invoice the Licensee for the corresponding milestone payment within [***] ([***]) days after receipt of such notice. In the event that, notwithstanding the fact that the Licensee has not provided Eisai such a notice, Eisai believes that any such milestone has been achieved, it shall so notify the Licensee in writing and the Parties shall promptly meet and discuss in good faith whether such milestone has been achieved. Any dispute under this Section 5.2.2 regarding whether or not such a milestone has been achieved shall be subject to resolution in accordance with Section 11.5.

5.3. Reports and Reconciliation. Following the first commercial sale of a Licensed Product in the Licensee Territory pursuant to this Agreement until the payment of all milestone payments pursuant to Section 5.2.1, the Licensee shall, within [***] ([***]) days of the end of each Contract Year, report to Eisai the Net Sales with respect to all Licensed Products in the Licensee Territory during such Contract Year. Such report shall specify in reasonable detail all deductions in the calculation of Net Sales.

5.4. Mode of Payment; Offsets. All payments to Eisai under this Agreement shall be made by deposit of Dollars in the requisite amount to such bank account as Eisai may from time to time designate by notice to the Licensee. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales), the Licensee shall convert any amount expressed in a foreign currency into Dollar equivalents using its or its Affiliate's, as applicable, standard conversion methodology consistent with GAAP. The Licensee shall have no right to offset, set off or deduct any amounts from or against the amounts due to Eisai hereunder.

5.5. Taxes.

5.5.1. General. The milestone payments and other amounts payable by the Licensee to Eisai pursuant to this Agreement (each a "**Payment**") shall be paid free and clear of any and all taxes (which, for clarity, shall be the responsibility of the Licensee), except for any withholding taxes required by Applicable Law. Except as provided in this Section 5.4, Eisai shall be solely responsible for paying any and all taxes (other than withholding taxes required by Applicable Law to be deducted from the Payments and remitted by the Licensee) levied on account of, or measured in whole or in part by reference to, any Payments it receives. The Licensee shall deduct or withhold from the Payments any taxes that it is required by Applicable Law to deduct or withhold. Notwithstanding the foregoing, if Eisai is entitled under any applicable tax treaty to a reimbursement of, reduction of rate of, or the elimination of, applicable withholding tax, it may deliver to the Licensee or the appropriate Governmental Authority (with the assistance of the Licensee to the extent that this is reasonably required and is requested in writing) the prescribed forms necessary to reimburse the withholding, reduce the applicable rate of withholding or relieve the Licensee of its obligation to withhold such tax and the Licensee shall seek or issue such reimbursement, as applicable, apply the reduced rate of withholding or dispense with withholding, as the case may be; *provided* that, in the case of any reduction of rate of, or elimination of, applicable withholding tax, the Licensee has received evidence of Eisai's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least [***] ([***]) days prior to the time that the applicable Payment is due. If, in accordance with the foregoing, the Licensee withholds any amount, it shall pay to Eisai the balance when due, make timely payment to the proper taxing authority of the withheld amount and send to Eisai proof of such payment within [***] ([***]) days of such payment.

5.5.2. Value Added Tax. Notwithstanding anything contained in Section 5.5.1, this Section 5.5.2 shall apply with respect to value added tax ("**VAT**"). All Payments are exclusive of VAT. If any VAT is chargeable in respect of any Payments, the Licensee shall pay VAT at the applicable rate in respect of any such Payments following the receipt of a VAT invoice in the appropriate form issued by Eisai in respect of those Payments, such VAT to be payable on the later of the due date of the payment of the Payments to which such VAT relates and [***] ([***]) days after the receipt by the Licensee of the applicable invoice relating to that VAT payment.

5.6. Interest on Late Payments. If any payment due under this Agreement is not paid when due, then the Licensee shall pay interest thereon (before and after any judgment) at a rate (but with interest accruing on a daily basis) of [***] percent ([***]%) per annum or the maximum rate allowable by Applicable Law, whichever is lower, such interest to run from the date on which payment of such sum became due until payment thereof in full together with such interest.

5.7. Financial Records. The Licensee shall, and shall cause its Affiliates and its and their Sublicensees to, keep complete and accurate financial books and records pertaining to the Commercialization of Licensed Products hereunder, including books and records of Net Sales, in sufficient detail to calculate and verify all amounts payable hereunder. The Licensee shall, and shall cause its Affiliates and its and their Sublicensees to, retain such books and records of Net Sales until the latest of: (a) the end of the Term; (b) [***] ([***]) years after the end of the period to which such books and records pertain; (c) the expiration of the applicable tax statute of limitations (or any extensions thereof); and (d) such longer period as may be required by Applicable Law. The Licensee shall, and shall cause its Affiliates and its and their Sublicensees to, retain such books and records (except books and records of Net Sales) until the latest of: (x) [***] ([***]) years after the end of the period to which such books and records pertain; (y) the expiration of the applicable tax statute of limitations (or any extensions thereof); and (z) such longer period as may be required by Applicable Law.

5.8. Audit. At the request of Eisai, the Licensee shall, and shall cause its Affiliates and its and their Sublicensees to, permit Eisai or an independent auditor designated by Eisai and reasonably acceptable to the Licensee, at reasonable times and upon reasonable notice, to audit the books and records maintained pursuant to Section 5.6 to ensure the accuracy of all reports and payments made hereunder, *provided* that this may occur no more than one (1) time per Contract Year unless an audit reveals, with respect to a period, a variance of more than [***] percent ([***]%) from the reported amounts for such period, in which case Eisai or an independent auditor designated by Eisai may conduct an additional audit during such Contract Year. Upon its completion, Eisai shall provide a copy of the final audit report to the Licensee. Except as provided below, the cost of the audit shall be borne by Eisai, unless the audit reveals, with respect to a period, a variance of more than [***] percent ([***]%) from the reported amounts for such period, in which case the Licensee shall bear the cost of the audit. For clarity, any second audit during a Contract Year shall be at Eisai's expense unless such audit reveals a variance of more than [***] percent ([***]%) from the reported amounts for such period, in which case the Licensee shall bear the cost of the audit. Unless disputed pursuant to Section 5.9, if such audit concludes that: (a) additional amounts were owed by the Licensee, the Licensee shall pay the additional amounts, with interest from the date originally due as provided in Section 5.6; or (b) excess payments were made by the Licensee, Eisai shall reimburse such excess payments, in either case ((a) or (b)), within [***] ([***]) days of the date on which such audit is completed by Eisai.

5.9. Audit Dispute. In the event of a dispute with respect to any audit under Section 5.8, Eisai and the Licensee shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within [***] ([***]) days, the dispute shall be submitted for resolution to a certified public accounting firm jointly selected by each Party's certified public accountants or to such other Person as the Parties shall mutually agree (the "**Auditor**"). The decision of the Auditor shall be final and the costs of such proceeding as well as the initial audit shall be borne between the Parties in such manner as the Auditor shall determine. Not later than [***] ([***]) days after such decision and in accordance with such decision, the Licensee shall pay the additional amounts, with interest from the date originally due as provided in Section 5.6 or Eisai shall reimburse the excess payments, as applicable.

ARTICLE 6
INTELLECTUAL PROPERTY

6.1. Ownership of Intellectual Property.

6.1.1. Ownership of Background Technology. Save as otherwise expressly set out in this Agreement, the Parties acknowledge and agree that nothing in this Agreement shall transfer or license, or shall operate as an agreement to transfer or license, any right, title, or interest in or to any Intellectual Property Rights owned by a Party or any of its Affiliates as of the Original Effective Date or otherwise licensed to a Party, and all such Intellectual Property Rights shall remain the exclusive property of the Party or its applicable Affiliate owning them (or, where applicable, the Third Party from whom its right to use the Intellectual Property Rights has derived).

6.1.2. Ownership of Developed Technology. Subject to Section 6.1.3, as between the Parties, each Party shall own all right, title and interest in and to any and all Intellectual Property Rights (including any Intellectual Property Rights subsisting in any Improvements) that are conceived, discovered, developed or otherwise made solely by or on behalf of such Party or its Affiliates or its or their (sub)licensees, as applicable, under or in connection with this Agreement.

6.1.3. Ownership of Licensee Funded Developed Technology. As between the Parties, the Licensee shall own all right, title and interest in and to any and all Intellectual Property Rights (including any Intellectual Property Rights subsisting in any Improvements) conceived, discovered, developed or otherwise made by or on behalf of a Party or its Affiliates or its or their (sub)licensees, as applicable, arising out of the '302 Development Activities or the CMC Development Activities during the performance of the '302 Development Activities or the CMC Development Activities, as applicable ("**Licensee Funded Technology**").

6.1.4. United States Law. The determination of whether Intellectual Property Rights were conceived, discovered, developed or otherwise made by a Party for the purpose of allocating proprietary rights therein shall, for purposes of this Agreement, be made in accordance with Applicable Law in the United States as such law exists as of the Effective Date irrespective of where or when such conception, discovery, development or making occurs.

6.1.5. Assignment. Each Party shall, and shall cause its Affiliates and its and their (sub)licensees to, assign, to the other Party, without additional compensation, such right, title and interest in and to any Intellectual Property Rights (including Intellectual Property Rights subsisting in Improvements) as is necessary to fully effect the sole ownership provided for in Section 6.1.2 or Section 6.1.3, as applicable.

6.1.6. Assignment Obligation. Each Party shall cause all Persons who perform Development activities, Manufacturing activities, or regulatory activities for such Party or its Affiliates under this Agreement, or who conceive, discover, develop or otherwise make any Intellectual Property Rights on behalf of such Party or its Affiliates or its or their (sub)licensees under or in connection with this Agreement, to be under an obligation to assign (or, if such Party is unable to cause such Person to agree to such assignment obligation despite such Party's using commercially reasonable efforts to negotiate such assignment obligation, then to grant an exclusive license under (with a scope no less broad than the scope of the license of Intellectual Property Rights granted by such Party under this Agreement) such Intellectual Property Rights resulting therefrom to such Party).

6.1.7. Ownership of Corporate Names. As between the Parties, each Party shall retain all right, title and interest in and to its Corporate Names.

6.1.8. Joint Inventions. The Parties shall, through the JIPC, discuss and agree with respect to ownership of any inventions that are conceived, discovered, developed or otherwise made jointly by or on behalf of Eisai or its Affiliates or its or their (sub)licensees, as applicable, on the one hand, and Licensee, or its Affiliates or its or their (sub)licensees, as applicable, in each case, under or in connection with this Agreement and the responsibility for the prosecution, maintenance, enforcement and defense of any Patents with respect thereto; provided that, notwithstanding the foregoing, any inventions made pursuant to Section 6.1.3 shall be solely owned by Licensee.

6.2. Maintenance and Prosecution of Patents.

6.2.1. In General. Subject to Sections 6.2.2 and 6.2.3, as between the Parties:

(a) Eisai shall have the sole right through counsel of its choice, at its own cost to prepare, file, prosecute and maintain the Eisai Patents, in accordance with the IP Strategy, including directing any related interference, re-issuance, re-examination and opposition proceedings with respect thereto; and

(b) the Licensee shall have the sole right through counsel of its choice, at its own cost to prepare, file, prosecute and maintain the Licensee Patents, in accordance with the IP Strategy, including directing any related interference, re-issuance, re-examination and opposition proceedings with respect thereto, worldwide, in each case ((a) and (b)), at its sole cost and expense and through counsel of its choice, and for the purposes of this Section 6.2, the Party prosecuting, maintaining or undertaking other related activities pursuant to the foregoing sentence with respect to a Patent shall be the "**Prosecuting Party**". In no event shall the Licensee disclose any Eisai Trade Secrets in connection with the preparation, filing, prosecution or maintenance of any Licensee Patent.

6.2.2. Notice. The Prosecuting Party shall give the non-Prosecuting Party and JSC [***] ([***]) Business Days' written notice prior to filing any Eisai Patents (in the case of Eisai) or Licensee Patents (in the case of the Licensee), and, following the provision of such notice shall, consult with the non-Prosecuting Party in good faith regarding the countries in respect of which such Patents will be filed, and give the non-Prosecuting Party an opportunity to nominate countries in its Territory in respect of which to file the Patents. The Prosecuting Party shall, at the non-Prosecuting Party's cost, use Commercially Reasonable Efforts to prepare, file, prosecute and maintain such Patents, including by directing any related interference, re-issuance, re-examination and opposition proceedings with respect thereto, in any countries within the Territory of the non-Prosecuting Party nominated by the non-Prosecuting Party.

6.2.3. Abandonment. If the Prosecuting Party decides to abandon the prosecution of any of the Eisai Patents (in the case of Eisai) or the Licensee Patents (in the case of the Licensee) or any claims thereof, in each case which relate to the Territory of the other Party, or to discontinue the payment of any maintenance or renewal fees with respect to any such Patents, it shall first offer to assign such Patents to the other Party by written notice a reasonable amount of time prior to such abandonment such that the other Party has sufficient time to determine whether to take over the prosecution and maintenance of such Patents. If the other Party elects in writing to take over the prosecution and maintenance of such Patents, the Prosecuting Party shall assign such Patents to the other Party, and such Patents shall constitute Licensee Patents (where they have been assigned by Eisai to the Licensee) or Eisai Patents (where they have been assigned by the Licensee to Eisai). If the other Party does not elect to take over the prosecution and maintenance of the relevant Patents within [***] ([***]) Business Days of receiving notice of the abandoning Party's intention to abandon the prosecution of, or discontinue the payment of any maintenance or renewal fees for, the relevant Patents, the Prosecuting Party may, in its sole discretion, abandon the prosecution of, or discontinue the payment of any maintenance or renewal fees for, the relevant Patents.

6.2.4. Cooperation. The non-Prosecuting Party shall, and shall cause its Affiliates to, assist and cooperate with the Prosecuting Party, as the Prosecuting Party may reasonably request from time to time, in the preparation, filing, prosecution and maintenance of the Eisai Patents or Licensee Patents (as applicable). The Prosecuting Party shall keep the non-Prosecuting Party informed of all steps to be taken in the preparation and prosecution of all applications for Patents filed by it pursuant to Section 6.2.1 and shall furnish the non-Prosecuting Party with copies of such applications, amendments thereto and other related correspondence to and from patent offices, and, to the extent reasonably practicable, permit the non-Prosecuting Party an opportunity to offer its comments thereon before making a submission to a patent office and the Prosecuting Party shall consider in good faith the non-Prosecuting Party's comments. Without limiting the foregoing, the non-Prosecuting Party shall, and shall ensure that its Affiliates shall: (a) offer its comments, if any, promptly; and (b) provide access to relevant documents and other evidence and make its employees available at reasonable business hours; *provided, however*, that neither Party shall be required to provide legally privileged information unless and until procedures reasonably acceptable to such Party are in place to protect such privilege; and, *provided, further*, that the Prosecuting Party shall, subject to Section 6.2.2, reimburse the non-Prosecuting Party for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith.

6.2.5. Patent Term Extension and Supplementary Protection Certificate. Subject to Section 6.2.6, as between the Parties, (a) Eisai shall, at its own cost, have the sole right to make decisions regarding, and to apply for, patent term extensions, including in the United States with respect to extensions pursuant to 35 U.S.C. §156 et. seq. and in other jurisdictions pursuant to supplementary protection certificates, and in all jurisdictions with respect to any other extensions that are now or become available in the future, wherever applicable, for the Eisai Patents; and (b) Licensee shall, at its own cost, have the sole right to make decisions regarding, and to apply for, patent term extensions, including in the United States with respect to extensions pursuant to 35 U.S.C. §156 et. seq. and in other jurisdictions pursuant to supplementary protection certificates, and in all jurisdictions with respect to any other extensions that are now or become available in the future, wherever applicable, for the Licensee Patents. Each Party shall provide prompt and reasonable assistance, as requested by and at the cost of (subject to Section 6.2.6) the Party filing the patent term extension, including by taking such reasonable action as is required of the Regulatory Approval holder under any Applicable Law to obtain such extension or supplementary protection certificate.

6.2.6. Notice – Patent Term Extension and Supplementary Protection Certificate. Prior to applying for any patent term extension in respect of the Eisai Patents (in the case of Eisai) or the Licensee Patents (in the case of the Licensee), the relevant Party shall give the other Party and the JSC [***] ([***]) Business Days' written notice, and, following the provision of such notice, shall consult with the other Party in good faith to determine a course of action with respect to such filings, and give the other Party an opportunity to nominate countries in its Territory in respect of which to file the patent term extensions. The Party applying for any such patent term extensions in respect of such Patents shall, at the other Party's cost, use Commercially Reasonable Efforts to prepare, file, prosecute and maintain such patent term extensions in any countries within the other Party's Territory nominated by the other Party.

6.2.7. Common Ownership Under Joint Research Agreements. Notwithstanding anything to the contrary in this Article 6, neither Party shall have the right to make an election under 35 U.S.C. 102(c) when exercising its rights under this Article 6 without the prior written consent of the other Party. With respect to any such permitted election, the Parties shall coordinate their activities with respect to any submissions, filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in 35 U.S.C. 100(h).

6.3. Enforcement of Patents.

6.3.1. Notice. Each Party shall promptly notify the other Party in writing of: (a) any alleged or threatened infringement of the Eisai Patents or the Licensee Patents in any jurisdiction; or (b) any certification filed under the BPCI Act claiming that any of the Eisai Patents or Licensee Patents are invalid or unenforceable or claiming that any Eisai Patents or the Licensee Patents would not be infringed by the making, having made, use, offer for sale, sale or import of a product for which an application under the BPCI Act is filed or any equivalent or similar certification or notice in any other jurisdiction, in each case ((a) and (b)), of which such Party becomes aware (an "**Infringement**").

6.3.2. Enforcement of Patents. Subject to Section 6.3.3, as between the Parties:

(a) Eisai shall have the first right through counsel of its choice, at its cost, to take whatever action it deems appropriate, for the enforcement of the Eisai Patents and Licensee Patents against any Infringement, including as a defense or counterclaim in connection with any Third Party Infringement Claim, that arises in the Eisai Territory. If Eisai fails to take any action in relation to the enforcement of the Licensee Patents against any Infringement, including as a defense or counterclaim in connection with any Third Party Infringement Claim, that arises in the Eisai Territory within [***] ([***]) Business Days of being notified of such Infringement, or notifies the Licensee that it does not wish to take any such action, the Licensee shall have the right through counsel of its choice, at its cost, to take whatever action it deems appropriate in its sole discretion, for the enforcement of the Licensee Patents against such Infringement in the Eisai Territory; and

(b) The Licensee shall have the first right through counsel of its choice, at its cost, to take whatever action it deems appropriate, for the enforcement of the Eisai Patents and Licensee Patents against any Infringement, including as a defense or counterclaim in connection with any Third Party Infringement Claim, that arises in the Licensee Territory. If the Licensee fails to take any action in relation to the enforcement of the Eisai Patents against any Infringement, including as a defense or counterclaim in connection with any Third Party Infringement Claim, that arises in the Licensee Territory within [***] ([***]) Business Days of being notified of such Infringement, or notifies Eisai that it does not wish to take any such action, Eisai shall have the right through counsel of its choice, at its cost, to take whatever action it deems appropriate in its sole discretion, for the enforcement of the Eisai Patents against such Infringement in the Licensee Territory.

For the purposes of this Section 6.3, the Party prosecuting any Infringement pursuant to this Section 6.3.2 with respect to a Patent shall be the "**Enforcing Party**".

6.3.3. Cooperation. The Parties shall cooperate fully in any Infringement action pursuant to this Section 6.3, including by making the inventors, applicable records, and documents (including laboratory notebooks) with respect to the relevant Patents available to the Enforcing Party on the Enforcing Party's request. With respect to an action controlled by the applicable Enforcing Party, the other Party shall, and shall cause its Affiliates to, assist and cooperate with the Enforcing Party, as the Enforcing Party may reasonably request from time to time, in connection with its activities set forth in this Section 6.3, including, where necessary, furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access to relevant documents and other evidence, and making its employees available at reasonable business hours; *provided* that the Enforcing Party shall reimburse such other Party for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith. Unless otherwise set forth herein, the Enforcing Party shall have the right to settle such claim; provided that neither Party shall have the right to settle any Infringement action under this Section 6.3 in a manner that has a material adverse effect on the rights or interest of the other Party or in a manner that imposes any costs or liability on, or involves any admission by, the other Party, without the express written consent of such other Party (which consent shall not be unreasonably withheld, conditioned or delayed). In connection with any activities with respect to an Infringement action prosecuted by the applicable Enforcing Party pursuant to this Section 6.3 involving Patents owned by the other Party or its Affiliates, the Enforcing Party shall: (a) consult with the other Party as to the strategy for the prosecution of such claim, suit or proceeding; (b) consider in good faith any comments from the other Party with respect thereto and (c) keep the other Party reasonably informed of any material steps taken, and provide copies of all material documents filed, in connection with such action.

6.3.4. Counterclaims. If any Third Party alleges that any of the Patents the subject of an Infringement action brought by a Party pursuant to Section 6.3.2 is invalid or unenforceable as a defense to such Infringement action, the Party that owns such Patents shall have a right to join such action to defend against such allegation of invalidity or unenforceability in accordance with Section 6.5.

6.3.5. Recovery. Except as otherwise agreed by the Parties in connection with a cost-sharing arrangement, any recovery realized as a result of such litigation described above in this Section 6.3 (whether by way of settlement or otherwise) shall be first allocated to reimburse the Parties for their costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses). Any remainder after such reimbursement is made shall be retained by the Enforcing Party; *provided, however*, that to the extent that any award or settlement (whether by judgment or otherwise) with respect to an Eisai Patent or Licensee Patent is attributable to loss of sales or profits with respect to a Licensed Product in the Licensee Territory, the Parties shall negotiate in good faith an appropriate allocation of such remainder to reflect the economic interests of the Parties under this Agreement with respect to such Licensed Product.

6.3.6. Biosimilar Applicants. Notwithstanding the other provisions of Section 6.3, if either Party receives a copy of an application for a Biosimilar Product referencing a Licensed Product, or otherwise becomes aware that such an application has been submitted to a Regulatory Authority for Regulatory Approval (such as in an instance described in Section 351(l)(9)(C) of the PHSA), then such Party shall promptly notify the other Party, and the Parties shall discuss in good faith a strategy for responding to such application for a Biosimilar Product.

6.4. Infringement Claims by Third Parties.

6.4.1. If the Exploitation of a Licensed Product results in, or is reasonably expected to result in, any claim, suit or proceeding by a Third Party alleging infringement of such Third Party's Intellectual Property Rights (a "**Third Party Infringement Claim**"), including as part of any defense or counterclaim in connection with an Infringement action initiated pursuant to Section 6.3.2, the Party first becoming aware of such Third Party Infringement Claim shall promptly notify the other Party thereof in writing.

6.4.2. As between the Parties, the Licensee shall have the sole right at its discretion to defend against any Third Party Infringement Claim initiated against the Licensee or any of its Affiliates at its sole cost and expense (subject to the last sentence of this Section 6.4.2), using counsel of the Licensee's choice, and Eisai shall have the sole right at its discretion to defend against any Third Party Infringement Claim initiated against Eisai, at its sole cost and expense, using counsel of Eisai's choice (in each case, the "**Defending Party**"). The non-Defending Party shall, and shall cause its Affiliates to, assist and cooperate with the Defending Party, as the Defending Party may reasonably request from time to time, in connection with its activities set forth in this Section 6.4, including, where necessary, furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access to relevant documents and other evidence, and making its employees available at reasonable business hours; provided that the Defending Party shall reimburse the non-Defending Party for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith. The Defending Party shall keep the non-Defending Party reasonably informed of all material developments in connection with any such claim, suit or proceeding. The Defending Party agrees to provide the non-Defending Party with copies of all material pleadings filed in such action and to allow the non-Defending Party reasonable opportunity to participate in the defense of the claims. The Parties shall negotiate in good faith an appropriate allocation of the Licensee's out-of-pocket expenses, damages, or awards, including royalties incurred or awarded in connection with any Third Party Infringement Claim defended under this Section 6.4.2, to reflect the economic interests of the Parties under this Agreement with respect to the Licensed Products.

6.5. Invalidity or Unenforceability Defenses or Actions. Each Party shall promptly notify the other Party in writing of any alleged or threatened assertion of invalidity or unenforceability of any of the Eisai Patents or the Licensee Patents by a Third Party of which such Party becomes aware. As between the Parties: (a) Eisai shall have the sole right through counsel of its choice, at its own cost to defend and control the defense of the validity and enforceability of the Eisai Patents; and (b) the Licensee shall have the sole right through counsel of its choice, at its own cost to defend and control the defense of the validity and enforceability of the Licensee Patents, including, in each case ((a) and (b)), when such invalidity or unenforceability is raised as a defense or counterclaim in connection with an Infringement action initiated pursuant to Section 6.3. For the purposes of this Section 6.5, the Party defending and controlling the defense of the invalidity or unenforceability action pursuant to the foregoing sentence with respect to a Patent shall be the "Controlling Party". In connection with any activities with respect to a defense, claim or counterclaim relating to the Eisai Patents or the Licensee Patents pursuant to this Section 6.5, the Controlling Party shall: (i) consult with the non-Controlling Party as to the strategy for such activities; (ii) consider in good faith any comments from the non-Controlling Party; and (iii) keep the non-Controlling Party reasonably informed of any material steps taken, and provide copies of all material documents filed, in connection with such defense, claim or counterclaim.

6.6. Third Party Patent Rights. If, in the reasonable opinion of the Licensee, the Exploitation of the Licensed Compound or the Licensed Products in the Field in the Licensee Territory by the Licensee, any of its Affiliates or any of its or their Sublicensees or distributors or customers infringes or is reasonably expected to infringe any Patent of a Third Party in any country in the Licensee Territory (such right, a "**Third Party Patent Right**"), then, as between the Parties, the Licensee shall have the first right to negotiate and obtain a license from such Third Party to such Third Party Patent Right as necessary or desirable for the Licensee or its Affiliates or its or their Sublicensees to Exploit the Licensed Compound and the Licensed Products in the Field in such country; provided that, as between the Parties, the Licensee shall bear all expenses incurred in connection therewith, including any royalties, milestones or other payments incurred under any such license.

6.7. Eisai Trademarks.

6.7.1. Use of Eisai Trademarks.

(a) The Licensee hereby acknowledges Eisai's exclusive right, title and interest in and to the Eisai Trademarks, together with all goodwill associated therewith and all registrations and registration applications therefor, on a worldwide basis and acknowledges that nothing herein shall be construed to accord to the Licensee any rights in the Eisai Trademarks except for the license right expressly granted to the Licensee under Section 2.1.2. The Licensee shall not, and shall cause its Affiliates, Sublicensees and distributors not to, use in their respective businesses, any Trademark that is confusingly similar to or a colorable imitation of, misleading or deceptive with respect to or that dilutes any (or any part) of the Eisai Trademarks.

(b) The Licensee shall be free to Commercialize the Licensed Products in the Licensee Territory using the Eisai Trademarks or the Licensee Trademarks.

(c) The Licensee shall, and shall cause its Affiliates, Sublicensees and distributors to, (i) comply with all Trademark usage guidelines, quality standards, business practices, methodology, policies and procedures and technical and operational specifications as may be reasonably specified by Eisai in writing from time to time or as may be imposed by Applicable Law with respect to the nature and quality of the Licensed Products and the manner of use of the Eisai Trademarks and (ii) promptly make any changes to any Licensed Product labeling, Licensed Product packaging, Licensed Product inserts or any advertising, marketing, promotional or other materials bearing any of the Eisai Trademarks as Eisai may reasonably request to achieve compliance with clause (i), and (iii) use Commercially Reasonable Efforts not to do any act that endangers, destroys or similarly affects, in any material respect, the Eisai Trademarks or the value of the goodwill associated with the Eisai Trademarks.

(d) Without limiting the Licensee's obligations under Section 6.7.1(c), the Licensee shall submit to Eisai for review and comment any new, or any revisions to any existing, Licensed Product label, Licensed Product packaging, Licensed Product insert or advertising, marketing, promotional or other materials, in each case, bearing an Eisai Trademark that the Licensee wishes to use on or in connection with the Exploitation of a Licensed Product in the Licensee Territory and shall take any comments from Eisai in good faith that are provided by Eisai to Licensee within [***] ([***]) days of Licensee's submission to Eisai.

(e) The Licensee shall not, and shall cause its Affiliates, Sublicensees and distributors not to, (i) directly or indirectly, at any time challenge Eisai's or any of its Affiliates' rights, title or interest in and to the Eisai Trademarks or in any registration or registration application therefor in any jurisdiction, (ii) do or cause to be done or omit to do anything, the doing, causing or omitting of which would contest or in any way materially impair the rights of Eisai or any of its Affiliates in and to the Eisai Trademarks or in any registrations or registration applications therefor in any jurisdiction, (iii) represent to any Third Party that it has, in any jurisdiction, any ownership rights in or to the Eisai Trademarks or in any registration or registration application therefor or any other rights in the Eisai Trademarks other than the specific license rights conferred by this Agreement, or (iv) register or attempt to register the Eisai Trademarks or any confusingly similar Trademark (including any translation or transliteration of any of the Product Trademarks or any colorable imitation thereof) as a Trademark with any Governmental Authority in its own name or in the name of any of its Affiliate or any Third Party in any jurisdiction.

(f) The Licensee acknowledges and agrees that no ownership rights are vested or created in the Eisai Trademarks anywhere in the world by the licenses and other rights granted in this Agreement (including, for clarity, Section 2.1.2) and that all use of the Eisai Trademarks by the Licensee, its Affiliates, Sublicensees, and distributors and all goodwill generated in connection therewith, shall inure solely for and to the benefit of Eisai and its Affiliates.

6.7.2. New Eisai Trademarks. During the Term, the Licensee shall submit to Eisai for review any variation or derivative of an existing Eisai Trademark, that the Licensee wishes to use on or in connection with the Exploitation of any Licensed Product in the Licensee Territory. The Licensee shall consider in good faith any comments from Eisai with respect to any proposed Trademarks. With respect to any proposed Trademark that is a variation or derivation of an existing Eisai Trademark, upon written approval by Eisai in its sole discretion, such proposed Trademark shall be deemed an Eisai Trademark under this Agreement and subject to the terms hereof.

6.7.3. Clearance, Registration, Prosecution and Maintenance of Eisai Trademarks. All registrations and applications therefor with respect to the Eisai Trademarks shall be filed, prosecuted, registered and maintained in the name, and for the benefit, of Eisai or its Affiliates. The Licensee shall have the first right, through counsel reasonably acceptable to Eisai and at Licensee's cost, to clear, register, prosecute and maintain the Eisai Trademarks in the Licensee Territory. The Licensee shall (a) provide Eisai from time to time, as reasonably requested by Eisai, a detailed, written report identifying the current status of all applications and registrations for the Eisai Trademarks in the Licensee Territory; (b) notify Eisai promptly of, and consult with Eisai with respect to, any material, substantive issue or any opposition, cancellation, invalidity or other proceeding that may be raised or asserted against any application or registration for any Eisai Trademark within the Licensee Territory prior to taking any action in response thereto; and (c) from time to time, upon Eisai's reasonable request, provide Eisai with copies of any Trademark clearance search reports, registration certificates, renewal applications and certificates, registration applications, pleadings, or other documentation or information relating to any application or registration for an Eisai Trademark; *provided, however,* that the Licensee shall not be required to provide legally privileged information unless and until procedures reasonably acceptable to the Licensee are in place to protect such privilege. Eisai shall execute such documents as may be required in the reasonable opinion of the Licensee for the Licensee to be entered as a "registered user" or recorded licensee of the Eisai Trademarks or to be removed as registered user or licensee thereof. If the Licensee decides to abandon or withdraw any application for any Eisai Trademark, or permit any registration for any Eisai Trademark to lapse, expire or be cancelled, in either case, in the Licensee Territory, it shall first notify Eisai. If Eisai elects to continue to register, prosecute and maintain such Eisai Trademark, it shall have the right to do so using counsel of its choice at is sole expense and such Eisai Trademark shall cease to be an Eisai Trademark under this Agreement.

6.7.4. Notice. Each Party shall provide to the other Party prompt written notice of any actual or threatened infringement of the Eisai Trademarks in the Licensee Territory and of any actual or threatened claim that the use of the Eisai Trademarks in the Licensee Territory violates the rights of any Third Party, in each case, of which such Party becomes aware.

6.7.5. Enforcement of Eisai Trademarks. The Licensee shall have the first right to take such action as the Licensee, after consultation with Eisai, deems necessary against a Third Party based on any alleged, threatened or actual infringement, dilution, misappropriation, or other violation of, or unfair trade practices or any other like offense relating to, the Eisai Trademarks by a Third Party in the Licensee Territory at its sole cost and expense and using counsel of its own choice; *provided* that Eisai shall have the right to provide input on the overall strategy for such action and the Licensee shall consider such input in good faith. The Licensee shall retain any damages or other amounts collected in connection therewith; *provided, however*, that to the extent that any award or settlement (whether by judgment or otherwise) with respect to an Eisai Trademark is attributable to loss of sales or profits with respect to a Licensed Product, the Parties shall negotiate in good faith an appropriate allocation of such remainder to reflect the economic interests of the Parties under this Agreement with respect to such Licensed Product. If the Licensee fails to take any action in relation to the enforcement of the Eisai Trademarks against any infringement of the Eisai Trademarks in the Licensee Territory within [***] ([***]) Business Days of being notified of such Infringement, or notifies Eisai that it does not wish to take any such action, Eisai shall have the right through counsel of its choice, at its cost, to take whatever action it deems appropriate in its sole discretion, for the enforcement of the Eisai Trademarks against such infringement in the Licensee Territory and Eisai shall retain any damages or other amounts collected in connection therewith.

6.7.6. Third Party Claims. Eisai shall have the first right to defend against and settle any alleged, threatened or actual claim by a Third Party that the use or registration of the Eisai Trademarks in the Licensee Territory infringes, dilutes, misappropriates or otherwise violates any Trademark or other right of that Third Party or constitutes unfair trade practices or any other like offense or any other claims as may be brought by a Third Party against the Licensee in connection with the use of the Eisai Trademarks with respect to a Licensed Product in the Licensee Territory, at its sole cost and expense and using counsel of its choice; *provided* that the Licensee shall have the right to provide input on the overall strategy for such defense and settlement and Eisai shall consider such input in good faith. If Eisai fails to take any action in relation to any such claim within [***] ([***]) Business Days of being notified of such claim, or notifies the Licensee that it does not wish to take any such action, the Licensee shall have the right through counsel of its choice, at its cost, to take whatever action it deems appropriate in its sole discretion, for the defense of such claim. Any damages or awards, including royalties incurred or awarded in connection with any such claim defended under this Section 6.7.6, shall be for the account of the Party defending such claim.

6.7.7. Cooperation. Each Party shall, and shall cause its Affiliates to, assist and cooperate with the other Party, as the other Party may reasonably request from time to time, in connection with its activities set forth in this Section 6.7, including, where necessary and applicable, furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access to relevant documents and other evidence, and making its employees available at reasonable business hours; *provided* that the requesting Party shall reimburse the other Party for its and its Affiliates' reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith.

6.8. Eisai Territory Product Trademarks.

6.8.1. The Licensee hereby acknowledges Eisai's exclusive right, title and interest in and to the Eisai Territory Product Trademarks, together with all goodwill associated therewith and all registrations and registration applications therefor, with respect to the Eisai Territory and acknowledges that nothing herein shall be construed to accord to the Licensee any rights in the Eisai Territory Product Trademarks except for the license right expressly granted to the Licensee under Section 2.1.3. The Licensee shall not, and shall cause its Affiliates and sublicensees with respect to the Eisai Territory Product Trademarks not to, use in their respective businesses, any Trademark that is confusingly similar to or a colorable imitation of, misleading or deceptive with respect to or that dilutes any (or any part) of the Eisai Territory Product Trademarks.

6.8.2. The Licensee shall, and shall cause its Affiliates and sublicensees with respect to the Eisai Territory Product Trademarks to, (a) comply with all Trademark usage guidelines, quality standards, business practices, methodology, policies and procedures and technical and operational specifications as may be reasonably specified by Eisai in writing from time to time or as may be imposed by Applicable Law with respect to the manner of use of the Eisai Territory Product Trademarks and (b) promptly make any changes to any advertising, marketing, promotional or other materials bearing any of the Eisai Territory Product Trademarks as Eisai may reasonably request to achieve compliance with clause (i), and (iii) use Commercially Reasonable Efforts not to do any act that endangers, destroys or similarly affects, in any material respect, the Eisai Territory Product Trademarks or the value of the goodwill associated with the Eisai Territory Product Trademarks.

6.8.3. Without limiting the Licensee's obligations under Section 6.8.2, the Licensee shall submit to Eisai for review and comment any new, or any revisions to any existing, advertising, marketing, promotional or other materials, in each case, bearing an Eisai Territory Product Trademark that the Licensee wishes to use in connection with Commercializing any Licensee Proprietary Product for use in concomitant or sequential administration with a Licensed Product in the Eisai Territory, and shall take any comments from Eisai in good faith that are provided by Eisai to the Licensee within [***] ([***]) days of Licensee's submission to Eisai.

6.8.4. As between the Parties, Eisai shall have the sole right, at its sole cost and expense, to (a) clear, register, prosecute and maintain the Eisai Territory Product Trademarks in the Eisai Territory, (b) take such action as Eisai deems necessary against a Third Party based on any alleged, threatened or actual infringement, dilution, misappropriate or other violation of, or unfair trade practices or any other like offense relating to, the Eisai Territory Product Trademarks, by a Third Party in the Eisai Territory and retain any damages or other amounts collected in connection therewith and (c) defend against and settle any alleged, threatened or actual claim by a Third Party that the use or registration of the Eisai Territory Product Trademarks in the Eisai Territory infringes, dilutes, constitutes, unfair trade practices or any other like offense or any other claims as may be brought by a Third Party in connection with the use of the Eisai Territory Product Trademarks with respect to a Licensed Product in the Eisai Territory.

6.9. Licensee Trademarks.

6.9.1. Eisai hereby acknowledges the Licensee's exclusive right, title and interest in and to the Licensee Trademarks, together with all goodwill associated therewith and all registrations and registration applications therefor, with respect to the Licensee Territory and acknowledges that nothing herein shall be construed to accord to Eisai any rights in the Licensee Trademarks except for the license right expressly granted to Eisai under Section 2.2.2. Eisai shall not, and shall cause its Affiliates and sublicensees with respect to the Licensee Trademarks not to, use in their respective businesses, any Trademark that is confusingly similar to or a colorable imitation of, misleading or deceptive with respect to or that dilutes any (or any part) of the Licensee Trademarks in the Licensee Territory.

6.9.2. Eisai shall, and shall cause its Affiliates and sublicensees with respect to the Licensee Trademarks to, (a) comply with all Trademark usage guidelines, quality standards, business practices, methodology, policies and procedures and technical and operational specifications as may be reasonably specified by the Licensee in writing from time to time or as may be imposed by Applicable Law with respect to the manner of use of the Licensee Trademarks and (b) promptly make any changes to any advertising, marketing, promotional or other materials bearing any of the Licensee Trademarks as the Licensee may reasonably request to achieve compliance with clause (i), and (iii) use Commercially Reasonable Efforts not to do any act that endangers, destroys or similarly affects, in any material respect, the Licensee Trademarks or the value of the goodwill associated with the Licensee Trademarks.

6.9.3. Without limiting Eisai's obligations under Section 6.9.2, Eisai shall submit to the Licensee for review and comment any new, or any revisions to any existing, advertising, marketing, promotional or other materials, in each case, bearing a Licensee Trademark that Eisai wishes to use in connection with Commercializing any Eisai Proprietary Product for use in concomitant or sequential administration with a Licensed Product in the Licensee Territory, and shall take any comments from the Licensee in good faith that are provided by the Licensee to Eisai within [***] ([***]) days of Eisai's submission to the Licensee.

6.9.4. As between the Parties, the Licensee shall have the sole right, at its sole cost and expense, to (a) clear, register, prosecute and maintain the Licensee Trademarks in the Licensee Territory, (b) take such action as the Licensee deems necessary against a Third Party based on any alleged, threatened or actual infringement, dilution, misappropriate or other violation of, or unfair trade practices or any other like offense relating to, the Licensee Trademarks, by a Third Party in the Licensee Territory and retain any damages or other amounts collected in connection therewith and (c) defend against and settle any alleged, threatened or actual claim by a Third Party that the use or registration of the Licensee Trademarks in the Licensee Territory infringes, dilutes, constitutes, unfair trade practices or any other like offense or any other claims as may be brought by a Third Party in connection with the use of the License Trademarks with respect to a Licensed Product in the Licensee Territory.

6.10. Corporate Names. Each Party shall not, and shall procure that each of its Affiliates shall not: (a) use, in their respective businesses, any Trademark that is confusingly similar to, misleading or deceptive with respect to or that dilutes any (or any part) of the Corporate Names of the other Party; (b) do any act that endangers, destroys or similarly affects, in any material respect, the value of the goodwill pertaining to the Corporate Names or the other Party; or (c) attack, dispute or contest the validity of or ownership of the Corporate Names of the other Party or any registrations issued or issuing with respect thereto or any pending registration thereof. Each Party shall, and shall procure that each of its Affiliates shall: (i) conform to the customary industry standards for the protection of corporate names and to such trademark usage guidelines as the other Party may furnish from time to time with respect to the use of its Corporate Names; and (ii) adhere to and maintain the highest quality standards of the other Party with respect to goods sold and services provided under the Corporate Names of the other Party.

ARTICLE 7
CONFIDENTIALITY AND NON-DISCLOSURE

7.1. Confidentiality Obligations. At all times during the Term and for a period of [***] ([***]) years following termination or expiration hereof (or, with respect to the Eisai Trade Secrets, for a period of unlimited duration), each Party shall, and shall cause its officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose to a Third Party and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement. "**Confidential Information**" means any technical, business or other information provided by or on behalf of one Party to the other Party in connection with this Agreement, whether prior to, on or after the Effective Date, including information relating to the terms of this Agreement (subject to Section 7.4), information relating to the Licensed Compound or any Licensed Product (including the Regulatory Documentation), any Exploitation of the Licensed Compound or any Licensed Product, any Know-how with respect thereto developed by or on behalf of the disclosing Party or its Affiliates (including the Licensee Know-how and Eisai Know-how, as applicable) or the scientific, regulatory or business affairs or other activities of either Party and shall include the Eisai Trade Secrets. Notwithstanding the foregoing, the terms of this Agreement shall be deemed to be the Confidential Information of both Parties and both Parties shall be deemed to be the receiving Party and the disclosing Party with respect thereto. Notwithstanding the foregoing, the confidentiality and non-use obligations under this Section 7.1 with respect to any Confidential Information shall not include any information that:

7.1.1. is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no breach of this Agreement by the receiving Party;

7.1.2. can be demonstrated by documentation or other competent proof to have been in the receiving Party's possession prior to disclosure by the disclosing Party without any obligation of confidentiality with respect to such information;

7.1.3. is subsequently received by the receiving Party from a Third Party who is not bound by any obligation of confidentiality with respect to such information;

7.1.4. has been published by a Third Party or otherwise enters the public domain through no fault of the receiving Party in breach of this Agreement; or

7.1.5. can be demonstrated by documentation or other competent evidence to have been independently developed by or for the receiving Party without reference to the disclosing Party's Confidential Information.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the receiving Party, unless the combination and its principles are in the public domain or in the possession of the receiving Party.

7.2. Permitted Disclosures. Each Party may disclose Confidential Information to the extent that such disclosure is:

7.2.1. to Third Parties and Affiliates as necessary, as reasonably determined by the receiving Party, for the performance of the receiving Party's obligations under this Agreement; *provided, however*, that any such Third Party or Affiliate must be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use of the receiving Party pursuant to this Article 7;

7.2.2. to the professional advisers (including accountants, counsel, consultants, employees and agents) of a Party; *provided, however,* that those advisers must be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use of the receiving Party pursuant to this Article 7;

7.2.3. made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial and local governmental or regulatory body of competent jurisdiction or, if in the reasonable opinion of the receiving Party's legal counsel, such disclosure is otherwise required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed (or to which an application for listing has been submitted); *provided, however*, that the receiving Party shall first have given notice to the disclosing Party and given the disclosing Party a reasonable opportunity to quash such order or to obtain a protective order or confidential treatment requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and *provided, further*, that the Confidential Information disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order;

7.2.4. made by or on behalf of the receiving Party to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; *provided, however*, that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with Applicable Law;

7.2.5. made by or on behalf of the receiving Party to a patent authority as may be reasonably necessary or useful for purposes of obtaining or enforcing a Patent; *provided, however*, that reasonable measures shall be taken to assure confidential treatment of such information, to the extent such protection is available;

7.2.6. made by or on behalf of the receiving Party to potential or actual investors or acquirers as may be necessary in connection with their evaluation of such potential or actual investment or acquisition; *provided, however,* that such persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use of the receiving Party pursuant to this Article 7 (which confidentiality and non-use obligations shall subsist for a period that is either: (a) consistent with the period for which the receiving Party's confidentiality and non-use obligations subsist under this Article 7; or (b) a minimum of [***] ([***]) months from the date of disclosure; *provided, further*, that the disclosure of such Confidential Information to a potential or actual investor or acquirer is subject to a customary return or destroy provision, which the receiving Party agrees to enforce to protect any disclosed Confidential Information); or

7.2.7. made with the other Party's prior written approval.

Notwithstanding the foregoing, the Licensee shall not, and shall cause its Affiliates not to, disclose any Eisai Trade Secrets to any Third Party without the prior written consent of Eisai, such consent not to be unreasonably withheld, conditioned or delayed.

7.3. Use of Name. Except as expressly provided herein, neither Party shall mention or otherwise use the name, logo or Trademark of the other Party or any of its Affiliates or any of its or their (sub)licensees (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material or other form of publicity without the prior written approval of such other Party. The restrictions imposed by this Section 7.3 shall not prohibit: (a) either Party from making any disclosure identifying the other Party to the extent required in connection with its exercise of its rights or obligations under this Agreement; and (b) either Party from making any disclosure identifying the other Party that is required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed (or to which an application for listing has been submitted).

7.4. Public Announcements. The Parties have agreed upon the content of one (1) or more press releases which shall be issued substantially in the form(s) attached hereto as Schedule 7.4, the release of which the Parties shall coordinate in order to accomplish such release promptly upon execution of this Agreement. Neither Party shall issue any other public announcement, press release or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed, except for any such disclosure that is, in the opinion of the disclosing Party's counsel, required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed (or to which an application for listing has been submitted). In the event a Party is, in the opinion of its counsel, required by Applicable Law or the rules of a stock exchange on which its securities are listed (or to which an application for listing has been submitted) to make such a public disclosure, such Party shall, to the extent permitted by Applicable Law, submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable (and in no event less than [***] ([***]) Business Days prior to the anticipated date of disclosure) so as to provide a reasonable opportunity to comment thereon. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement or any amendment hereto that has already been publicly disclosed by such Party or by the other Party, in accordance with this Section 7.4; provided that such information remains accurate as of such time and *provided, further*, that the frequency and form of such disclosure are reasonable.

7.5. Publications. The Parties recognize the desirability of publishing and publicly disclosing the results of, and information regarding, activities under this Agreement. Accordingly, each Party shall be free to publicly disclose the results of, and information regarding, activities under this Agreement, subject to prior review by the other Party of any disclosure of that Party's Confidential Information for issues of patentability and protection of such Confidential Information, in a manner consistent with Applicable Law and industry practices, as provided in this Section 7.5. Accordingly, prior to publishing any Confidential Information of the other Party, the publishing Party shall provide such other Party with drafts of proposed abstracts, manuscripts or summaries of presentations that cover such Confidential Information. The non-publishing Party shall respond promptly through its designated representative and in any event no later than [***] ([***]) days after receipt of such proposed publication or presentation. The publishing Party agrees to allow a reasonable period (not to exceed [***] ([***]) days) to permit filings for patent protection and to otherwise address issues of Confidential Information or related competitive harm to the reasonable satisfaction of the non-publishing Party and, in any event, the publishing Party shall not publish or publicly disclose any Confidential Information of the other Party over such other Party's objection. In addition, the publishing Party shall give due regard to comments furnished by the non-publishing Party and such comments shall not be unreasonably rejected.

7.6. Return of Confidential Information. Upon the effective date of the expiration or termination of this Agreement for any reason, either Party may request in writing and the non-requesting Party shall either, with respect to Confidential Information of the requesting Party to which such non-requesting Party does not retain rights under the surviving provisions of this Agreement, at the requesting Party's election: (a) promptly destroy all copies of such Confidential Information in the possession or control of the non-requesting Party and confirm such destruction in writing to the requesting Party; or (b) promptly deliver to the requesting Party, at the non-requesting Party's sole cost and expense, all copies of such Confidential Information in the possession or control of the non-requesting Party. Notwithstanding the foregoing, the non-requesting Party shall be permitted to retain such Confidential Information: (i) to the extent necessary or useful for purposes of performing any continuing obligations or exercising any ongoing rights hereunder and, in any event, a single copy of such Confidential Information for archival purposes; and (ii) any computer records or files containing such Confidential Information that have been created solely by such non-requesting Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such non-requesting Party's standard archiving and back-up procedures, but not for any other uses or purposes. All Confidential Information shall continue to be subject to the terms of this Agreement for the period set forth in Section 7.1.

7.7. Privileged Communications. In furtherance of this Agreement, it is expected that the Parties may, from time to time, disclose to one another privileged communications with counsel, including opinions, memoranda, letters and other written, electronic and verbal communications. Such disclosures are made with the understanding that they shall remain confidential in accordance with this Article 7, that they will not be deemed to waive any applicable attorney-client or attorney work product or other privilege and that they are made in connection with the shared community of legal interests existing between Eisai and the Licensee, including the community of legal interests in avoiding infringement of any valid, enforceable patents of Third Parties and maintaining the validity of the Eisai Patents and the Licensee Patents. In the event of any litigation (or potential litigation) with a Third Party related to this Agreement or the subject matter hereof, the Parties shall, upon either Party's request, enter into a reasonable and customary joint defense agreement. In any event, each Party shall consult in a timely manner with the other Party before engaging in any conduct (*e.g.*, producing information or documents) in connection with litigation or other proceedings that could conceivably implicate privileges maintained by the other Party. Notwithstanding anything contained in this Section 7.7, nothing in this Agreement shall prejudice a Party's ability to take discovery of the other Party in disputes between them relating to the Agreement and no information otherwise admissible or discoverable by a Party shall become inadmissible or immune from discovery solely by this Section 7.7.

7.8. Obligations of the Licensee with Respect to Eisai Trade Secrets. In addition to its obligations in Section 7.1, the Licensee shall (a) treat the Eisai Trade Secrets as it does its own trade secrets, and (b) implement controls to protect the Eisai Trade Secrets that are standard in the innovative biopharmaceuticals industry, including using diligent efforts to (i) restrict access to the Eisai Trade Secrets to individuals with a reasonable need to access such information and restrict use to the Licensed Products, (ii) maintain a list of such individuals and (iii) inform each such individual regarding the Licensee's obligations with respect to the Eisai Trade Secrets under this Agreement and instruct such individuals not to disclose the Eisai Trade Secrets to any individuals that are not on the list described in the foregoing clause (ii).

ARTICLE 8
REPRESENTATIONS AND WARRANTIES

8.1. Mutual Representations and Warranties. Each of Eisai and the Licensee represents and warrants to the other, as of the Original Effective Date and as of the Execution Date, and covenants, that:

8.1.1. it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform this Agreement;

8.1.2. the execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action and do not violate: (a) such Party's charter documents, bylaws or other organizational documents; (b) in any material respect, any agreement, instrument or contractual obligation to which such Party is bound; (c) any requirement of any Applicable Law; or (d) any order, writ, judgment, injunction, decree, determination or award of any court or governmental agency presently in effect applicable to such Party;

8.1.3. this Agreement is a legal, valid and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity);

8.1.4. except, with respect to Eisai, under the Distribution Agreements, it is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder; and

8.1.5. neither it nor any of its Affiliates has been debarred or is subject to debarment and neither it nor any of its Affiliates will use, in any capacity, in connection with the services to be performed under this Agreement, any Person who has been debarred pursuant to Section 306 of the FFDCA or who is the subject of a conviction described in such section. It will inform the other Party in writing promptly if it or any such Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306 or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of its or its Affiliates' Knowledge, is threatened, relating to the debarment or conviction of it or any such Person performing services hereunder. Upon request by either Party (which may be made no more than [***] per Contract Year), the such Party shall (a) screen against the Exclusion Lists all of its directors, officers, and employees, whose responsibilities, to such Party's Knowledge, involve the Development or Commercialization of the Licensed Products as authorized by this Agreement, and (b) certify the results of such screening to the other Party. For purposes of this Agreement, "**Exclusion Lists**" shall mean: (i) the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.oig.hhs.gov) or any successor list; and (ii) the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.epls.gov) or any successor list.

8.2. Additional Representations and Warranties of Eisai. Eisai further represents and warrants to the Licensee, as of the Original Effective Date, that:

8.2.1. neither Eisai nor any of its Affiliates Controls any Patents that are necessary or desirable for the Exploitation of the Licensed Compound or a Licensed Product in the Licensee Territory as contemplated herein;

8.2.2. Eisai Controls the Eisai Existing Know-how and Eisai Existing Regulatory Documentation as of the Original Effective Date and has the right to grant the licenses, rights of reference, sublicenses and further rights of reference specified herein, and, except as set forth in the Distribution Agreements, has not granted to any Third Parties any conflicting licenses, rights of reference, sublicenses and further rights of reference;

8.2.3. Eisai owns all right, title and interest in and to the Eisai Trademarks, free and clear of liens, security interests and other encumbrances. All post-registration requirements with the United States Patent and Trademark Office with respect to the Eisai Trademarks have been satisfied;

8.2.4. To Eisai's Knowledge, no Person has infringed, violated or misappropriated, or is infringing, violating or misappropriating, any of the Eisai Trademarks;

8.2.5. Eisai has not received any written claim or demand alleging that the Exploitation of the Licensed Products as contemplated herein infringes any Intellectual Property Rights owned by any Third Party;

8.2.6. to Eisai's Knowledge, the Exploitation of the Licensed Products as contemplated herein does not infringe any Intellectual Property Rights owned by any Third Party;

8.2.7. to Eisai's Knowledge, no Person is infringing or threatening to infringe the Eisai Technology and Eisai has not made any such claim against any Person, nor, to its Knowledge, is there any basis for such a claim;

8.2.8. the Eisai Existing Know-how and the Eisai Existing Regulatory Documentation constitute all of the Intellectual Property Rights that are owned, licensed or otherwise controlled by Eisai or any of its Affiliates that are necessary or reasonably useful for the Exploitation of the Licensed Compound and the Licensed Products in the Licensee Territory, as such activities are contemplated on the Original Effective Date;

8.2.9. all of the Eisai Technology is owned by either Eisai or one of its Affiliates;

8.2.10. except for those serious adverse events with respect to the Existing Licensed Product that have been reported to the FDA and disclosed in writing to the Licensee set forth in the email with the subject "E7777 Reportable Adverse Event Disclosure - Rep 8.2.10" from Eisai to Licensee dated March 25, 2016, neither Eisai nor any of its Affiliates nor, to Eisai's Knowledge, any Third Parties involved with Eisai in the Development of the Existing Licensed Product, has any Knowledge of any adverse event, arising prior to the Original Effective Date, reportable to a Regulatory Authority under Applicable Law with respect to the safety or efficacy of the Existing Licensed Product;

8.2.11. Eisai or one of its Affiliates is the registered holder of each Regulatory Approval and IND required under Applicable Law for the Development of the Existing Licensed Product, such Regulatory Approvals and INDs are in full force and effect, no material deficiencies have been asserted by any applicable Governmental Authority with respect to such Regulatory Approvals and INDs and, to Eisai's Knowledge, no facts or circumstances exist that would be likely to lead to such assertions being made;

8.2.12. the Existing Licensed Product has been and is being Developed in all material respects in accordance with applicable Regulatory Approvals and INDs and in accordance with Applicable Laws. Neither Eisai nor any of its Affiliates nor, to Eisai's Knowledge, any Third Parties involved with Eisai in the Development of the Existing Licensed Product, has received any written notices or other correspondence from any Governmental Authority requiring the termination, suspension or material modification of any studies or tests relating to the Development of the Existing Licensed Product; and

8.2.13. the information set forth on Schedule 8.2.13 is true, complete and correct.

8.3. DISCLAIMER OF WARRANTIES. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES. WITHOUT LIMITING THE FOREGOING, EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, THE EISAI TRADEMARKS ARE LICENSED "AS IS," "WITH ALL FAULTS," AND "WITH ALL DEFECTS," AND THE LICENSEE EXPRESSLY WAIVES ALL RIGHTS TO MAKE ANY CLAIM WHATSOEVER AGAINST EISAI FOR MISREPRESENTATION OR FOR BREACH OF PROMISE, GUARANTEE OR WARRANTY OF ANY KIND RELATING TO ANY EISAI TRADEMARK.

8.4. Anti-Bribery and Anti-Corruption Compliance. Each of the Licensee and Eisai agrees, on behalf of itself, its officers, directors and employees and on behalf of its Affiliates, agents, representatives, consultants and subcontractors hired in connection with the subject matter of this Agreement ("**Representatives**"), that for the performance of its obligations hereunder:

8.4.1. Compliance. Such Party and its Representatives shall comply with the Anti-Corruption Laws and shall not take any action that would, or would reasonably be expected to, cause the other Party or its Affiliates to be in violation of any such laws or policies. In the course of the business, each of the Licensee and Eisai and the respective Representatives (a) shall not, directly or indirectly, make payment or offer or promise to make payment of any bribe ("**Corruption**") to a governmental official (including a foreign official, a person deemed to be a governmental official under the law, and a healthcare professional), a person related to a political party, or a candidate for public post, (b) shall not engage in Corruption even in terms of private citizens other than government officials through providing entertainments or gifts deemed inappropriate under business customs, and (c) shall establish and maintain an appropriate compliance procedure to prevent its management or employees from engaging in Corruption.

8.4.2. Notice. Such Party shall promptly provide the other Party with written notice of the following events: (a) upon becoming aware of any breach or violation by such Party or its Representative of any representation, warranty or undertaking set forth in Section 8.4.1; or (b) upon receiving a formal notification that it is the target of a formal investigation by a Governmental Authority for a Material Anti-Corruption Law Violation or upon receipt of information from any of its Representatives connected with this Agreement that any of them is the target of a formal investigation by a Governmental Authority for a Material Anti-Corruption Law Violation.

ARTICLE 9
INDEMNITY

9.1. Indemnification of Eisai. The Licensee shall indemnify Eisai, its Affiliates and its and their respective directors, officers, employees and agents (collectively, "**Eisai Indemnitees**"), and defend and hold each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively "**Losses**") incurred by such Persons in connection with any and all suits, investigations, claims or demands of Third Parties (collectively "**Third Party Claims**") arising from or occurring as a result of: (a) the breach by the Licensee of this Agreement, including the enforcement of Eisai's rights under this Section 9.1; (b) the gross negligence or willful misconduct on the part of any Licensee Indemnitee in connection with this Agreement or (c) the Exploitation of any Licensed Product by or on behalf of Licensee, its Sublicensees or any of its or their respective Affiliates (excluding any Third Party Claims alleging death, personal injury or other product liability to the extent arising out of or related to the use of any Licensed Compound or Licensed Product sold by or behalf of Eisai in the Eisai Territory), *provided* that, in each case ((a), (b) and (c)), with respect to any Third Party Claim for which the Licensee has an obligation to any Eisai Indemnitee pursuant to this Section 9.1 and Eisai has an obligation to any Licensee Indemnitee pursuant to Section 9.2, each Party shall indemnify each of the Eisai Indemnitees or the Licensee Indemnitees, as applicable, for its Losses to the extent of its responsibility, relative to the other Party.

9.2. Indemnification of the Licensee. Eisai shall indemnify the Licensee, its Affiliates and its and their respective directors, officers, employees and agents (collectively, "**Licensee Indemnitees**") and defend and hold each of them harmless, from and against any and all Losses incurred by such Persons in connection with any and all Third Party Claims arising from or occurring as a result of: (a) the breach by Eisai of this Agreement, including the enforcement of the Licensee's rights under this Section 9.2; (b) the gross negligence or willful misconduct on the part of any Eisai Indemnitee in connection with this Agreement; (c) the Exploitation of the Discontinued Licensed Product by Eisai, its sublicensees or any of its or their respective Affiliates prior to the Original Effective Date; (d) the Exploitation of any Licensed Product by or on behalf of Eisai, its Sublicensees or any of its or their respective Affiliates (excluding any Third Party Claims alleging death, personal injury or other product liability to the extent arising out of or related to the use of any Licensed Compound or Licensed Product sold by or behalf of the Licensee in the Licensee Territory) or (e) the partial assignment and delegation with respect to the Distribution Agreements pursuant to Section 2.10(a) or Eisai's breach of any of its obligations under the Distribution Agreements, except to the extent Licensee is obligated to fulfill such obligation pursuant to Section 2.10 (a) or such breach arises out of any act or omission by Licensee, *provided* that, in each case ((a) (b), (c), (d) and (e)), with respect to any Third Party Claim for which Eisai has an obligation to any Licensee Indemnitee pursuant to this Section 9.2 and the Licensee has an obligation to any Eisai Indemnitee pursuant to Section 9.1, each Party shall indemnify each of the Eisai Indemnitees or the Licensee Indemnitees, as applicable, for its Losses to the extent of its responsibility, relative to the other Party.

9.3. Indemnification Procedures.

9.3.1. Notice of Claim. All indemnification claims in respect of an Eisai Indemnitee or a Licensee Indemnitee, as applicable, shall be made solely by such Party to this Agreement (the "**Indemnified Party**"). The Indemnified Party shall give the indemnifying Party prompt written notice (an "**Indemnification Claim Notice**") of any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under this Article 9, but in no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice to the extent materially prejudiced thereby. Each Indemnification Claim Notice must contain a reasonably detailed description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party Claims.

9.3.2. Control of Defense. The indemnifying Party shall have the right to assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within [***] ([***]) days of the indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgment that the indemnifying Party is liable to indemnify any Eisai Indemnitee or Licensee Indemnitee, as applicable, in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against an Eisai Indemnitee's or a Licensee Indemnitee's, as applicable, claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party. In the event the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall promptly deliver to the indemnifying Party all original notices and documents (including court papers) received by any Eisai Indemnitee or Licensee Indemnitee, as applicable, in connection with the Third Party Claim. Should the indemnifying Party assume the defense of a Third Party Claim, except as provided in Section 9.3.3, the indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party or any Eisai Indemnitee or Licensee Indemnitee, as applicable, in connection with the analysis, defense or settlement of the Third Party Claim, unless the incurrence of such legal expenses by the Indemnified Party or Eisai Indemnitee or Licensee Indemnitee, as applicable, is specifically requested in writing by the indemnifying Party; *provided* that the indemnifying Party is diligently pursuing the defense or settlement of such Third Party Claim. In the event that it is ultimately determined that the Indemnifying Party is not obligated to indemnify, defend or hold harmless an Eisai Indemnitee or Licensee Indemnitee, as applicable, from and against a Third Party Claim, the Indemnified Party shall reimburse the indemnifying Party for any and all costs and expenses (including attorneys' fees and costs of suit) incurred by the indemnifying Party in its defense of such Third Party Claim.

9.3.3. Right to Participate in Defense. Without limiting Section 9.3.2, any Indemnified Party shall be entitled to participate in the defense of a Third Party Claim and to employ counsel of its choice for such purpose; *provided, however*, that such employment shall be at the Indemnified Party's sole cost and expense, unless: (a) the employment thereof has been specifically authorized by the indemnifying Party in writing (in which case, the defense shall be controlled as provided in Section 9.3.2); (b) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 9.3.2 or otherwise is not diligently pursuing the defense and settlement of such claim (in which case the Indemnified Party shall control the defense at the indemnifying Party's sole expense); or (c) the interests of any Eisai Indemnitee or Licensee Indemnitee, as applicable, on the one hand, and the indemnifying Party, on the other hand, with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of all such Persons under Applicable Law, ethical rules or equitable principles (in which case, the Indemnified Party shall control its defense at the indemnifying Party's sole expense).

9.3.4. Settlement. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that shall not result in any Eisai Indemnitee or Licensee Indemnitee, as applicable, becoming subject to injunctive or other relief or otherwise adversely affecting the business of any Eisai Indemnitee or Licensee Indemnitee, as applicable, in any manner hereunder, and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify such Eisai Indemnitee or Licensee Indemnitee, as applicable, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate so long as the terms of any such settlement contain a complete and unconditional release of such Eisai Indemnitees or Licensee Indemnitees, as applicable, with respect to such Third Party Claim. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 9.3.2, the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss; *provided* that it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed, and a consent shall not be considered unreasonably withheld, conditioned or delayed if the terms of such settlement do not contain a complete and unconditional release of such Eisai Indemnitees or Licensee Indemnitees, as applicable, with respect to such Third Party Claim). If the indemnifying Party does not assume and conduct the defense of a Third Party Claim as provided above, the Indemnified Party may defend against such Third Party Claim at the indemnifying Party's sole cost and expense; *provided* that the Indemnified Party shall not settle any Third Party Claim without the prior written consent of the indemnifying Party (which consent shall not be unreasonably withheld, conditioned or delayed).

9.3.5. Cooperation. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall, and shall cause each Eisai Indemnitee or Licensee Indemnitee, as applicable, to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals and access to records and information and other employees and agents, as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the indemnifying Party to, and reasonable retention by the Indemnified Party and any Eisai Indemnitee or Licensee Indemnitee, as applicable, of, records and information that are reasonably relevant to such Third Party Claim, and making all Eisai Indemnitees or Licensee Indemnitees, as applicable, and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder; provided that neither Party shall be required to disclose legally privileged information unless and until procedures reasonably acceptable to such Party are in place to protect such privilege. The indemnifying Party shall reimburse the Indemnified Party for all reasonable and verifiable out-of-pocket expenses of any Eisai Indemnitee or Licensee Indemnitee, as applicable, in connection therewith.

9.3.6. Expenses. Except as provided above, the costs and expenses, including fees and disbursements of counsel, incurred by any Eisai Indemnitee or Licensee Indemnitee, as applicable, in connection with any Third Party Claim shall be reimbursed on a Calendar Quarter basis by the indemnifying Party, without prejudice to the indemnifying Party's right to contest such Eisai Indemnitee's or Licensee Indemnitee's, as applicable, right to indemnification and subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the Eisai Indemnitee or Licensee Indemnitee, as applicable.

9.4. Special, Indirect and Other Losses. EXCEPT (a) IN THE EVENT OF WILLFUL MISCONDUCT OR FRAUD OF A PARTY OR OF A PARTY'S BREACH OF ITS OBLIGATIONS UNDER Article 7 OR SECTION 2.6 OR (b) TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS Article 9, NEITHER PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE FOR ANY INDIRECT, CONSEQUENTIAL, EXEMPLARY, SPECIAL OR PUNITIVE DAMAGES OR FOR LOSS OF PROFITS SUFFERED BY THE OTHER PARTY.

ARTICLE 10
TERM AND TERMINATION

10.1. Term and Expiration. This Agreement shall commence on the Effective Date and, unless earlier terminated in accordance herewith, shall continue in full force and effect until (a) if there has not been a first commercial sale of a Licensed Product in the Licensee Territory before the tenth (10th) anniversary of the Original Effective Date, the tenth (10th) anniversary of the Original Effective Date, or (b) if there has been a first commercial sale of a Licensed Product in the Licensee Territory before the tenth (10th) anniversary of the Original Effective Date, the tenth (10th) anniversary of the first commercial sale of a Licensed Product in the Licensee Territory (such period, the "**Initial Term**"); *provided*, that if the Licensee does not extend the Initial Term pursuant to the following sentence, then with respect to each country in the Territory in which there has been a first commercial sale of a Licensed Product prior to the tenth (10^{th}) anniversary of the Original Effective Date, then the Initial Term shall continue in each such country until the tenth (10^{th}) anniversary of the first commercial sale of a Licensed Product in such country. The Licensee may extend the Term for additional ten (10)-year periods (each, an "**Extension Term**") for all countries in the Licensee Territory by notifying Eisai in writing of such extension and paying Eisai an extension fee equal to $10 Million at least [***] ([***]) days prior to the expiration of the then current Term.

10.2. Termination.

10.2.1. Material Breach. In the event that either Party (the "**Breaching Party**") shall be in material breach of any of its obligations under this Agreement, in addition to any other right and remedy the other Party (the "**Non-Breaching Party**") may have, the Non-Breaching Party may terminate this Agreement in its entirety by providing [***] ([***]) days' (or, with respect to payment breaches, [***] ([***]) days') (the "**Notice Period**") prior written notice (the "**Termination Notice**") to the Breaching Party specifying the breach and its claim of right to terminate; *provided* that:

(a) prior to issuing the Termination Notice, the Non-Breaching Party shall refer the issue to the Senior Officers for attempted resolution by good faith negotiations during a period of [***] ([***]) Business Days from the date of such referral, or such longer period as the Senior Officers may agree in writing;

(b) if any alleged material breach hereunder is disputed in accordance with Section 11.5, the Notice Period shall be suspended for the duration of, and until resolution of, such dispute resolution process; and

(c) the termination shall not become effective at the end of the Notice Period if the Breaching Party cures the breach specified in the Termination Notice during the Notice Period (or, if such default cannot be cured within the Notice Period, if the Breaching Party commences actions to cure such breach within the Notice Period and thereafter diligently continues such actions, provided, that such breach is cured within [***] ([***]) [***] after the receipt of the Termination Notice).

10.2.2. Termination for Anti-Bribery and Anti-Corruption Breach. Notwithstanding Section 10.2.1, in the event that either Party materially breaches of any of its obligations under Section 8.4 in a way that constitutes a Material Anti-Corruption Law Violation, in addition to any other right and remedy the other Party may have, such other Party may terminate this Agreement in its entirety immediately upon written notice to such first Party; provided that if any such alleged breach is disputed in accordance with Section 11.5, the termination shall not become effective for the duration of such dispute resolution process, and unless and until such dispute is resolved in favor of the terminating Party.

10.2.3. Termination for Eisai Trade Secret Breach. Notwithstanding Section 10.2.1, in the event that the Licensee breaches any of its obligations under the last sentence of Section 7.2, in addition to any other right and remedy Eisai may have, Eisai may terminate this Agreement in its entirety immediately upon written notice to the Licensee; provided that if any such alleged breach is disputed in accordance with Section 11.5, the termination shall not become effective for the duration of such dispute resolution process, and unless and until such dispute is resolved in favor of Eisai.

10.2.4. Termination for Insolvency. In the event that either Party (a) files for protection under bankruptcy or insolvency laws, (b) makes an assignment for the benefit of creditors, (c) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within [***] ([***]) days of such filing, (d) proposes a written agreement of composition or extension of its debts, (e) proposes or is a voluntary party to any dissolution or liquidation, (f) files a petition under any bankruptcy or insolvency act or (g) admits in writing its inability generally to meet its obligations as they fall due in the general course, then the other Party shall have the right to terminate this Agreement in its entirety, immediately upon written notice to such Party.

10.2.5. Termination for Challenge.

(a) If the Licensee or any of its Affiliates (i) Challenges an Eisai Patent in any country or (ii) challenges the validity of any Eisai Trade Secret in any country, then, in either case ((i) or (ii)), Eisai may terminate this Agreement immediately upon written notice of termination to the Licensee.

(b) If Eisai or any of its Affiliates Challenges a Licensee Patent in any country, then Licensee may terminate this Agreement immediately upon written notice of termination to Eisai.

10.2.6. Termination for Change of Control.

(a) Not later than [***] ([***])) days following the effective date of a Change of Control of the Licensee, the Licensee shall provide written notice to Eisai of such transaction and Eisai shall have the right to request a determination of the fair market value pursuant to Section 10.6.5 on written notice to the Licensee given at any time during the period commencing on the date described above and ending [***] ([***]) days after receipt of such notice.

(b) Eisai shall have the right to terminate this Agreement immediately on written notice to the Licensee given at any time during the period commencing on the date the Licensee notifies Eisai of the Change of Control of the Licensee and ending [***] ([***]) days after the determination of the fair market value pursuant to Section 10.6.5.

(c) If at any time during the period beginning upon the Change of Control of the Licensee and ending upon the expiration of the [***] ([***])-day period in Section 10.2.6(b), the Licensee is in material breach of any of its obligations under this Agreement, the time periods set forth in this Section 10.2.6 and Section 10.6.5 shall be suspended for the duration of, and until resolution of, any dispute regarding such material breach (including pursuant to Section 10.2.1(a)), and if it is determined that the Licensee is in material breach of any of its obligations under this Agreement, then Eisai shall have the right to terminate this Agreement pursuant to Section 10.2.1 and the provisions of Section 10.6 shall not apply.

10.2.7. Termination for Withdrawal. If Regulatory Authorities cause the withdrawal on a permanent basis of any Licensed Product from any national or supra-national market in the Licensee Territory, Eisai may terminate this Agreement with respect to such market (each such market, on a country-by-country basis, a "**Terminated Territory**") immediately upon notice to the Licensee, except that such right of termination shall apply only to withdrawal of the entire marketing authorization for such Licensed Product and shall not apply in circumstances where such withdrawal is limited to particular Manufacturing batches or lots as a result of a correctable Manufacturing defect.

10.3. Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by the Licensee or Eisai are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, the Party that is not a Party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under clause (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

10.4. Consequences of Termination of this Agreement in its Entirety. In the event of a termination of this Agreement in its entirety:

10.4.1. all rights and licenses granted by either Party under Section 2.1 or Section 2.2, as applicable, and any sublicenses granted by either Party pursuant to Section 2.3 shall immediately terminate;

10.4.2. the Licensee hereby grants, and shall cause its Affiliates to grant, Eisai and its Affiliates an exclusive, perpetual, royalty-free license, with the right to grant multiple tiers of sublicenses, in and to the Licensee Technology owned or Controlled by the Licensee or any of its Affiliates as of the effective date of the applicable termination of this Agreement to Exploit the Licensed Products in the Field anywhere in the world;

10.4.3. to the extent requested in writing by Eisai:

(a) the Licensee shall, and shall cause its Affiliates to, assign to Eisai all of its right, title and interest in and to all Licensee Regulatory Documentation then owned or Controlled by the Licensee or any of its Affiliates and notify the applicable Regulatory Authorities of, and take any other action reasonably necessary to effect, such assignment; *provided* that, if any such Regulatory Documentation is not immediately transferable in a country, the Licensee shall provide Eisai with all benefit of such Regulatory Documentation, and such assistance and cooperation as necessary or reasonably requested by Eisai to timely transfer such Regulatory Documentation to Eisai or its designee or, at Eisai's option, to enable Eisai to obtain a substitute for such Regulatory Documentation;

(b) the Licensee shall, and shall cause its Affiliates to, grant Eisai an exclusive, perpetual, royalty-free right of reference, with the right to grant multiple tiers of further rights of reference, in and to all Licensee Regulatory Documentation then owned or Controlled by the Licensee or any of its Affiliates that is not assigned to Eisai pursuant to clause (a) above to the extent necessary to Exploit the Licensed Products in the Field anywhere in the world, as such Regulatory Documentation exists as of the effective date of such termination of this Agreement and the Licensee shall continue to maintain such Regulatory Documentation (including any Regulatory Approvals) at Eisai's sole cost and expense unless and until Eisai notifies the Licensee in writing that such maintenance is no longer required;

(c) unless expressly prohibited by any Regulatory Authority, the Licensee shall, and shall cause its Affiliates to, transfer control to Eisai or its designee of all clinical studies of each Licensed Product being conducted by or on behalf of the Licensee as of the effective date of termination and continue to conduct such clinical studies, at Eisai's sole cost and expense, for up to [***] ([***]) months to enable such transfer to be completed without interruption of any such clinical study; provided that (i) Eisai shall not have any obligation to continue any clinical study unless required by Applicable Law and (ii) with respect to each clinical study (A) for which such transfer is expressly prohibited by the applicable Regulatory Authority or (B) that is required for Regulatory Approval that Eisai does not request that the Licensee transfer control of such clinical study to Eisai, if any, the Licensee shall continue to conduct such clinical study to completion, at Eisai's sole cost and expense;

(d) the Licensee shall, and shall cause its Affiliates to, assign to Eisai or its designee all Licensed Product Agreements relating to the Exploitation of the Licensed Products in the Field in the Licensee Territory, unless, with respect to any such Licensed Product Agreement, such Licensed Product Agreement: (i) expressly prohibits such assignment (in which case, the Licensee or its Affiliate, as applicable, shall cooperate with Eisai in all reasonable respects to secure the consent of the applicable Third Party to such assignment); and (ii) does not relate solely to the Exploitation of the Licensed Products in the Field in the Licensee Territory (in which case, at Eisai's request, the Licensee or its Affiliate, as applicable, shall cooperate with Eisai in all reasonable respects to secure the written agreement of the applicable Third Party to a partial assignment of the applicable part of the Licensed Product Agreement that relates to the Exploitation of the Licensed Products in the Eisai Territory) and if the Licensee is unable to secure such consent to assign or partially assign any such Licensed Product Agreement, then the Licensee shall use Commercially Reasonable Efforts to obtain for Eisai substantially all of the practical benefit and burden under such Licensed Product Agreement, including by (A) entering into appropriate and reasonable alternative arrangements on terms mutually agreeable to Eisai and the Licensee and (B) subject to the consent and control of Eisai, enforcing, at Eisai's sole cost and expense and for the account of Eisai, any and all rights of the Licensee against the other party thereto arising out of the breach or cancellation thereof by such other party or otherwise;

(e) the Licensee shall, and shall cause its Affiliates to, provide Eisai with copies of all reports and data generated or obtained by the Licensee or any of its Affiliates that relate to any Licensed Product that have not previously been provided to Eisai; and

(f) the Licensee shall, and shall cause its Affiliates to, assign to Eisai all of Licensee's and its Affiliates' right, title and interest in and to the Licensee Trademarks and any trade dress with respect to the Licensed Products;

10.4.4. all Confidential Information of the Licensee relating to the Exploitation of the Licensed Products in the Field in the Licensee Territory shall become the Confidential Information of Eisai; and

10.4.5. without limiting Eisai's rights under other provisions of this Article 10, the Licensee shall, at the request and sole expense of Eisai, provide Eisai with such assistance as is reasonably necessary to effectuate a smooth and orderly transition of any Development, Manufacture and Commercialization activities to Eisai or its designee so as to minimize any disruption of such activities.

10.5. Consequences of Termination of this Agreement for a Terminated Territory. In the event of a termination of this Agreement with respect to a Terminated Territory:

10.5.1. to the extent requested in writing by Eisai:

(a) the Licensee shall, and shall cause its Affiliates to, assign to Eisai all of its right, title and interest in and to all Licensee Regulatory Documentation in the Terminated Territory then owned or Controlled by the Licensee or any of its Affiliates and notify the applicable Regulatory Authorities in the Terminated Territory of, and take any other action reasonably necessary to effect, such assignment; *provided* that, if any such Regulatory Documentation is not immediately transferable in the Terminated Territory or also relates to countries that are not in the Terminated Territory, the Licensee shall provide Eisai with all benefit of such Regulatory Documentation, and such assistance and cooperation as reasonably necessary or reasonably requested by Eisai to timely transfer such Regulatory Documentation to Eisai or its designee or, at Eisai's option, to enable Eisai to obtain a substitute for such Regulatory Documentation;

(b) the Licensee shall, and shall cause its Affiliates to, assign to Eisai or its designee all Licensed Product Agreements relating to the Exploitation of the Licensed Products in the Field in the Terminated Territory, unless, with respect to any such Licensed Product Agreement, such Licensed Product Agreement: (i) expressly prohibits such assignment (in which case, the Licensee or its Affiliate, as applicable, shall cooperate with Eisai in all reasonable respects to secure the consent of the applicable Third Party to such assignment); and (ii) does not relate solely to the Exploitation of the Licensed Products in the Field in the Terminated Territory (in which case, at Eisai's request, the Licensee or its Affiliate, as applicable, shall cooperate with Eisai in all reasonable respects to secure the written agreement of the applicable Third Party to a partial assignment of the applicable part of the Licensed Product Agreement that relates to Exploitation of the Licensed Products in the Terminated Territory) and if the Licensee is unable to secure such consent to assign or partially assign any such Licensed Product Agreement, then the Licensee shall use Commercially Reasonable Efforts to obtain for Eisai substantially all of the practical benefit and burden under such Licensed Product Agreement, including by (A) entering into appropriate and reasonable alternative arrangements on terms mutually agreeable to Eisai and the Licensee and (B) subject to the consent and control of Eisai, enforcing, at Eisai's sole cost and expense and for the account of Eisai, any and all rights of the Licensee against the other party thereto arising out of the breach or cancellation thereof by such other party or otherwise;

(c) the Licensee shall, and shall cause its Affiliates to, assign to Eisai all of the Licensee's and its Affiliates' right, title and interest in and to the Licensee Trademarks and any trade dress with respect to the Licensed Products, in the Terminated Territory;

(d) the Licensee shall, and shall cause its Affiliates to, provide Eisai with copies of all reports and data generated or obtained by the Licensee or any of its Affiliates that relate to any Licensed Product in the Terminated Territory that have not previously been provided to Eisai; and

(e) all Confidential Information of the Licensee relating solely to the Exploitation of the Licensed Products in the Field in the Terminated Territory shall become the Confidential Information of Eisai.

10.6. Additional Consequences for Change of Control Termination. If Eisai exercises its termination right pursuant to Section 10.2.6, then:

10.6.1. if Eisai exercises such termination right on or prior to the date the FDA approves the BLA for the Existing Licensed Product for the CTCL Indication in the United States, Eisai shall pay the Licensee an amount equal to the sum of (a) the '302 Development Costs for which Licensee had paid Eisai hereunder, plus (b) the FTE Costs incurred and the direct out-of-pocket costs recorded as an expense (including pre-marketing expenses and research and development costs), in accordance with GAAP, by or on behalf of Licensee or any of its Affiliates in connection with the Development of a Licensed Product prior to the effective date of such termination, which amount shall be payable within [***] ([***]) days after the end of Calendar Quarter in which the later of the following occurs (x) Eisai's receipt of a report with respect to the costs described in the foregoing clause (b) and (y) the effective date of such termination. Section 3.1.4(a) and Section 3.1.8 shall apply *mutatis mutandis* for purposes of this Section 10.6.1; and

10.6.2. if Eisai exercises such termination right within [***] ([***]) years from the first commercial sale of the Existing Licensed Product for the CTCL Indication in the United States ("**US First Commercial Sale**"), Eisai shall pay the Licensee an amount equal to [***] percent ([***]%) of the fair market value of the Licensee Technology and Licensee Trademarks owned or Controlled by Licensee or any of its Affiliates as of the effective date of such termination;

10.6.3. if Eisai exercises such termination right at any time after [***] ([***]) years from US First Commercial Sale up to and including seven (7) years from US First Commercial Sale, Eisai shall pay the Licensee an amount equal to [***] percent ([***]%) of the fair market value of the Licensee Technology and Licensee Trademarks owned or Controlled by Licensee or any of its Affiliates as of the effective date of such termination; and

10.6.4. if Eisai exercises such termination right at any time after [***] ([***]) years from US First Commercial Sale, Eisai shall pay Licensee an amount equal to [***] percent ([***]%) of the fair market value of the Licensee Technology and Licensee Trademarks owned or Controlled by Licensee or any of its Affiliates as of the effective date of such termination.

10.6.5. For purposes of this Section 10.6, "fair market value" shall mean, as of any date of determination, the current fair market value of the fully paid-up license to the Licensee Technology and assignment of the Licensee Trademarks, taking into account the prior investment in the Exploitation of the Licensed Products, any milestone payments, future royalties, lifecycle extensions, and additional Indications which may not have been approved, determined as follows:

(a) Within [***] ([***]) days following Eisai's exercise of its right under Section 10.2.6(a) to request a determination of the fair market value, the Parties shall appoint a valuation expert from the Expert List (the "**Expert**").

(b) Within [***] ([***]) days after the appointment of the Expert, each Party shall submit to the Expert a written statement of its position regarding the fair market value, which may include any scientific, financial, technical or other relevant information in support of such fair market value. No later than [***] ([***]) days after the earlier of (i) receipt of such written statement from each of the Parties and (ii) the [***] ([***]) day after appointment of the Expert, the Expert shall make a determination of the fair market value, which determination shall not be less than the lower of the fair market values submitted by the Parties or greater than the higher of the fair market values submitted by the Parties. Eisai shall bear the fees and costs of the Expert.

10.6.6. Within [***] ([***]) days after the BLA transfer pursuant to Section 3.2.3 and thereafter at least once per Contract Year, the Senior Officers will mutually agree in writing on a list of at least three (3) valuation experts with relevant expertise with respect to the valuation of Intellectual Property Rights and Trademarks in the biopharmaceutical industry (the "**Expert List**"). In connection with each such agreement on the Expert List, each Party must disclose any prior business relationship it that it has had with any proposed valuation experts within the past [***] ([***]) months.

10.7. Remedies. Except as otherwise expressly provided herein, termination of this Agreement in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

10.8. Accrued Rights; Surviving Obligations. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement. Without limiting the foregoing, Section [***] and [***] of this Agreement shall survive the termination or expiration of this Agreement for any reason.

ARTICLE 11
MISCELLANEOUS

11.1. Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement (other than an obligation to make payments) when such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), changes in laws, regulations, orders and embargoes, acts of God or acts, omissions or delays in acting by any Governmental Authority (except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement). The non-performing Party shall notify the other Party of such force majeure within [***] ([***]) days of such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary, and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform. Without limitation to the foregoing, in the event that the suspension of performance continues for [***] ([***]) days after the date of the occurrence and such suspension of performance would constitute a material breach of this Agreement in the absence of this Section 11.1, the other Party shall have the right to terminate this Agreement in its entirety, in its sole discretion, upon written notice to the non-performing Party.

11.2. Export Control. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that, at the time of export, requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity in accordance with Applicable Law.

11.3. Assignment.

11.3.1. Assignment. Neither Party may assign its rights or, except as provided in Section 3.6, delegate its obligations under this Agreement, whether by operation of law or otherwise, in whole or in part, without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed, except that (a) Eisai may, without such consent, (i) prior to the transfer of the BLA and INDs pursuant to Section 3.2.3, assign this Agreement and its rights and obligations hereunder to its successor entity or acquirer in the event of a merger, consolidation or Change of Control of Eisai; *provided* that such successor has at least substantially similar pharmaceutical research and development capabilities to those of Eisai at the time of such merger, consolidation or Change of Control and (ii) after the transfer of the BLA and INDs pursuant to Section 3.2.3, assign this Agreement and its rights and obligations hereunder to the purchaser of the Eisai Technology or to its successor entity or acquirer in the event of a merger, consolidation or Change of Control of Eisai; (b) the Licensee may, without such consent, assign this Agreement and its rights and obligations hereunder to its successor entity or acquirer in the event of a merger, consolidation or Change of Control of the Licensee and (c) either Party may, without such consent, assign any or all of its rights and delegate any or all of its obligations hereunder to any of its Affiliates. Any permitted successor of a Party or any permitted assignee of all of a Party's rights under this Agreement that has also assumed all of such Party's obligations hereunder in writing shall, upon any such succession or assignment and assumption, be deemed to be a party to this Agreement as though named herein in substitution for the assigning Party, whereupon the assigning Party shall cease to be a party to this Agreement and shall cease to have any rights or obligations under this Agreement. All validly assigned rights of a Party shall inure to the benefit of and be enforceable by, and all validly delegated obligations of such Party shall be binding on and be enforceable against, the permitted successors and assigns of such Party. Any attempted assignment or delegation in violation of this Section 11.3.1 shall be void and of no effect.

11.3.2. Treatment of Assignee's Intellectual Property Rights. The Intellectual Property Rights: (a) owned, licensed or otherwise controlled by a Third Party permitted assignee of a Party that were owned, licensed or otherwise controlled by such Third Party permitted assignee (and not such Party) immediately prior to such assignment (other than as a result of a license or other grant of rights, covenant or assignment by such Party or its Affiliates to, or for the benefit of, such Third Party permitted assignee); or (b) owned, licensed or otherwise controlled by an Affiliate of a Party that becomes an Affiliate through any Change of Control of such Party that were owned, licensed or otherwise controlled by such Affiliate (and not such Party) immediately prior to such Change of Control (other than as a result of a license or other grant of rights, covenant or assignment by such Party or its other Affiliates to, or for the benefit of, such Affiliate), in each case ((a) and (b)), shall be automatically excluded from the rights licensed or granted to the other Party under this Agreement.

11.4. Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable for any reason, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby: (a) such provision shall be fully severable; (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof; (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom; and (d) such provision shall be deemed modified to the minimum degree necessary to make such provision valid and enforceable under Applicable Law and reasonably acceptable to the Parties, and such modified provision shall thereafter be enforced to the fullest extent possible. To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid or unenforceable in any respect.

11.5. Dispute Resolution.

11.5.1. Referral to Senior Officers. Except as provided in Section 4.4, Section 5.9 or Section 11.9, if a dispute arises between the Parties in connection with or relating to this Agreement, including a dispute as to the interpretation, validity or performance of this Agreement or this Section 11.5.1, or any document or instrument delivered in connection herewith, or any payment dispute, excluding any Unresolved JSC Matter, excluding any dispute regarding Eisai withholding its consent under the third proviso in Section 2.3.1 or the proviso in Section 3.6 (a "**Dispute**"), then either Party shall have the right to refer such Dispute to the Senior Officers for attempted resolution by good faith negotiations during a period of [***] ([***]) Business Days. Any final decision mutually agreed to by the Senior Officers in writing shall be conclusive and binding on the Parties.

11.5.2. Arbitration.

(a) If such Senior Officers are unable to resolve any such Dispute within such [***] ([***])-Business Day period, either Party shall be free to submit such Dispute to the International Chamber of Commerce (the "**ICC**") for resolution by arbitration before three (3) arbitrators (such arbitrators, collectively, the "**Arbitral Tribunal**") under the Arbitration Rules of the ICC (the "**Arbitration Rules**"), as modified by this Section 11.5.2. Except as expressly limited by Section 11.5.2(h), the Arbitral Tribunal shall have the authority to grant any equitable relief or any other remedies that would be available in any judicial proceeding instituted to resolve a disputed matter under the substantive laws of New York.

(b) The number of arbitrators shall be three (3), who shall be selected as follows: each of Eisai, on the one hand, and the Licensee on the other hand, shall nominate one (1) arbitrator. The initiating Party shall nominate its arbitrator in the Request for Arbitration (as described in the Arbitration Rules), and the other Party shall nominate its arbitrator in its Answer (as described in the Arbitration Rules) to the Request for Arbitration (provided, that if the other Party receives an extension of time to submit its Answer, it shall nonetheless nominate its arbitrator on the date its Answer otherwise would have been due under Article 5(1) of the Arbitration Rules), and those Party-nominated arbitrators shall unanimously nominate the third arbitrator, who will act as president of the Arbitral Tribunal (the "**President Arbitrator**"), within [***] ([***]) days of the appointment of the last Party-nominated arbitrator. Each of the three arbitrators shall be an attorney in good standing licensed to practice for at least [***] ([***]) years and with substantial experience representing pharmaceutical companies in disputes or contract negotiations (the "**Qualifications**"); provided that if the Party-nominated arbitrators do not jointly nominate such a President Arbitrator within the [***] ([***])-day period, then the ICC Court (as described in the Arbitration Rules) shall within [***] ([***]) days after the expiration of that [***] ([***])-day period prepare and submit to each of the Party-nominated arbitrators (with copies sent to the Parties) a list of fifteen (15) candidates for nomination as President Arbitrator, each of which candidates shall have the Qualifications. The list shall be accompanied by copies of the candidates' curriculum vitae. Each Party-nominated arbitrator may object to any unacceptable candidates on the list, and shall rank each acceptable candidate in numerical order, with the candidate ranked number 1 being that Party-nominated arbitrator's most preferred candidate, and with any other acceptable candidates listed with ascending numerical ranking thereafter through the last acceptable candidate remaining on the list. The Party-nominated arbitrators may discuss the candidates on the list. Each Party-nominated arbitrator shall return the list to the ICC Court within [***] ([***]) days after receiving it, reflecting the objected-to candidates and the numerical ranking of the acceptable candidates. The Party-nominated arbitrators shall not exchange their returned lists with each other. The candidate ranked as acceptable on both returned lists with the lowest combined numerical ranking shall be deemed by the ICC Court to be nominated as the President Arbitrator by both Party-nominated arbitrators.

(c) If the two lists returned to the ICC Court by the Party-nominated arbitrators do not contain any candidates ranked as acceptable by both Party-nominated arbitrators, then the ICC Court shall within [***] ([***]) days thereafter submit to each of the Party-nominated arbitrators (with copies sent to the Parties) a second list of fifteen (15) candidates for nomination as President Arbitrator, each of which candidates shall have the Qualifications. The list shall be accompanied by copies of the candidates' curriculum vitae. Each Party-nominated arbitrator may object to any unacceptable candidates on the list, but not to all candidates on the list, and shall rank each acceptable candidate in numerical order, with the candidate ranked number 1 being that Party-nominated arbitrator's most preferred candidate, and with any other acceptable candidates listed in ascending numerical ranking thereafter through the last acceptable candidate remaining on the list. The Party-nominated arbitrators may discuss the candidates on the list. Each Party-nominated arbitrator shall return the list to the ICC Court within [***] ([***]) days after receiving it, reflecting the objected-to candidates and the numerical ranking of the acceptable candidates. The Party-nominated arbitrators shall not exchange their returned lists with each other. The candidate ranked as acceptable on both returned lists with the lowest combined numerical ranking shall be deemed by the ICC Court to be nominated as the President Arbitrator by both Party-nominated arbitrators.

(d) If the two lists returned to the ICC Court by the Party-nominated arbitrators again do not contain any candidates ranked as acceptable by both Party-nominated arbitrators, then the ICC Court shall within [***] ([***]) days thereafter so advise both Party-nominated arbitrators and the Parties, and shall give the Party-nominated arbitrators a final period of [***] ([***]) days within which to determine if they can agree upon a nominee for President Arbitrator, whether from either list submitted to them by the ICC Court, or otherwise. The two Party-nominated arbitrators will, at or before the expiration of that [***]-day period, jointly advise the ICC Court either of the name of an agreed-upon nominee for President Arbitrator, or that they have been unable to agree. If they are unable to agree, then the ICC Court shall appoint the President Arbitrator pursuant to the Arbitration Rules, provided that the appointee must have the Qualifications.

(e) The place of arbitration shall be New York, New York. All proceedings involving attendance by the Parties shall be conducted in New York, New York (unless another location is otherwise agreed to by the parties on one or more occasions), at a suitable venue to be agreed by the Parties and arbitrators. The proceedings shall be conducted in the English language.

(f) The decision and award of the Arbitral Tribunal shall be made by majority decision and shall be conclusive and binding on the Parties and their successors and assigns. The arbitral award shall be accompanied by a reasoned opinion.

(g) The arbitral award may include both pre-and post-award interest, at the rate of [***] percent ([***]%) per annum or the maximum rate allowable by Applicable Law, whichever is lower.

(h) Without limiting the authority of the Arbitral Tribunal with respect to non-monetary relief, the Arbitral Tribunal shall only have the power to award monetary relief consistent with Section 9.4.

(i) The Arbitral Tribunal's final award shall be rendered within the [***] ([***])-month period specified in Article 30(1) of the Arbitration Rules, and any extension thereof pursuant to Article 30(2) of the Arbitration Rules. Notwithstanding any provision of the Arbitration Rules: (i) each Party shall be permitted to (A) serve up to ten (10), interrogatories on the other Party, (B) take up to five (5), depositions, (C) obtain production of documents from the other Party pursuant to Article 3 of the International Bar Association Rules on the Taking of Evidence in International Arbitration as current on the Effective Date, (D) appoint one (1) or more experts to testify at the hearing, each of whom the appointing Party shall identify to the other Party (by name, address and employer/professional affiliation) and for whom the appointing Party shall provide to the other Party a general statement of the subject matter and opinions to which such expert is expected to testify, and each of whom shall provide a written, dated and signed report, setting forth a complete statement of all opinions the expert will express and the bases and reasons for them, the facts or data considered by the expert in forming the opinions, and including any exhibits that will be used to summarize or support the opinions and a copy of such expert's then-current curriculum vitae, which report shall constitute the direct testimony of such expert at the hearing (it being agreed by the Parties that any such expert shall be made available for examination at the hearing by the other Party and the Arbitral Tribunal), and (E) exchange exhibits and information as provided for in the Arbitration Rules, all of the foregoing on dates and locations to be mutually agreed upon (or, failing such agreement, as the President Arbitrator shall select after hearing from the Parties); and (ii) neither Party shall be required to provide legally privileged information. The Parties shall make their respective employees available for depositions (subject to the above limitations) and hearing testimony as reasonably requested by the other Party. Judgment on any arbitral award issued by the Arbitral Tribunal may be entered in any court having competent jurisdiction.

(j) Except as required by Applicable Law or the rules of a stock exchange on which its securities are listed (or to which an application for listing has been submitted), or as necessary for recognition and enforcement of the arbitral decision and award, neither a Party nor an arbitrator may disclose the existence, content or results of any arbitration hereunder without the prior written consent of the Parties. Any documents submitted to or issued by the Arbitral Tribunal shall be kept confidential and shall not be disclosed, except that any such documents may be disclosed (i) as reasonably necessary in connection with any action to enforce or collect the award or (ii) to the extent discoverable or admissible in any action arising out of or in connection with this Agreement.

(k) The (i) fees of the Arbitral Tribunal and (ii) costs and expenses of the arbitration will be shared equally by the Parties. The Parties will otherwise bear their respective expenses (including their respective legal, expert and other fees, expenses and costs) of the arbitration.

11.6. Governing Law, Jurisdiction and Service.

11.6.1. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York excluding any conflicts or choice of law, rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

11.6.2. Jurisdiction. Subject to Section 11.5 and Section 11.9, the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the federal and state courts of the state of New York for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts, not to assert, as a defense in any action, suit or proceeding for the interpretation or enforcement hereof, that it is not subject thereto or that such action, suit or proceeding may not be brought or is not maintainable in said courts or that this Agreement may not be enforced in or by said courts. The Parties hereby consent to and grant any such court jurisdiction over the person of such Parties and over the subject matter of any such dispute.

11.6.3. Waiver of Jury Trial. EACH PARTY ACKNOWLEDGES AND AGREES THAT ANY CONTROVERSY THAT MAY ARISE UNDER THIS AGREEMENT IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES, AND THEREFORE EACH SUCH PARTY HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT SUCH PARTY MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LITIGATION DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT. EACH PARTY CERTIFIES AND ACKNOWLEDGES THAT: (A) NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER; (B) EACH SUCH PARTY UNDERSTANDS AND HAS CONSIDERED THE IMPLICATIONS OF THIS WAIVER; (C) EACH SUCH PARTY MAKES THIS WAIVER VOLUNTARILY; AND (D) EACH SUCH PARTY HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 11.6.3.

11.6.4. Venue. The Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the federal and state courts of the state of New York and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

11.6.5. Service. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 11.7.2 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

11.7. Notices.

11.7.1. Notice Requirements. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or sent by facsimile transmission (with transmission confirmed) or by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 11.7.2 or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 11.7.1. Such notice shall be deemed to have been given as of the date delivered by hand or transmitted by facsimile (with transmission confirmed) or on the second Business Day (at the place of delivery) after deposit with an internationally recognized overnight delivery service. Any notice delivered by facsimile shall be confirmed by a hard copy delivered as soon as practicable thereafter. This Section 11.7.1 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

11.7.2. Address for Notice.

If to the Licensee, to:

Dr. Reddy's Laboratories S.A.
Elisabethenanlage 11
4051 Basel, Switzerland
Attention: Executive Vice President, Proprietary Products
Facsimile: [***]

with a copy (which shall not constitute notice) to:

Dr. Reddy's Laboratories, S.A.
Attention: Legal Affairs
Facsimile: [***]

If to Eisai:

Eisai Co., Ltd.
Koishikawa 4-6-10
Bunkyo-Ku
Tokyo 112-8088
Japan
Attention: President, Oncology Business Group
Facsimile: [***]

with copies to:

Eisai Co., Ltd.
Koishikawa 4-6-10
Bunkyo-Ku
Tokyo 112-8088
Japan
Attention: General Counsel
Facsimile: [***]

and

Eisai Inc.
100 Tice Blvd.
Woodcliff Lake, NJ 07677
Attention: President
General Counsel
Facsimile: [***]

11.8. Entire Agreement; Amendments; Termination of Binding Term Sheet.

11.8.1. This Agreement, together with the Schedules attached hereto, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof, and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto are superseded hereby (including the Binding Term Sheet). Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement. No amendment, modification, release or discharge shall be binding on the Parties unless in writing and duly executed by authorized representatives of both Parties. In the event of any inconsistencies between this Agreement and any schedules or other attachments hereto, the terms of this Agreement shall control. For the avoidance of doubt, the all performances and activities (including payments) under the Original Agreement and the Binding Term Sheet until the Effective Date shall be valid.

11.8.2. The Parties mutually agree that the Binding Term Sheet is hereby terminated as of the Execution Date.

11.9. English Language. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof and, in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

11.10. Equitable Relief. Each Party acknowledges and agrees that the restrictions and obligations set forth in Section 2.6 and Article 6 and Article 7 are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such restrictions and that any breach or threatened breach of any provision of such Section or Articles may result in irreparable injury to such other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of such Section or Articles, the non-breaching Party shall be authorized and entitled to obtain from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance and an equitable accounting of all earnings, profits and other benefits arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which such non-breaching Party may be entitled in law or equity. Both Parties agree to waive any requirement that the other (a) post a bond or other security as a condition for obtaining any such relief and (b) show irreparable harm, balancing of harms, consideration of the public interest or inadequacy of monetary damages as a remedy. Nothing in this Section 11.10 is intended or should be construed, to limit either Party's right to equitable relief or any other remedy for a breach of any other provision of this Agreement.

11.11. Change of Control. In the event of a Change of Control of the Licensee, if Eisai elects not to terminate pursuant to Section 10.2.6, Eisai shall have the right, in its sole discretion, by written notice delivered to the Licensee (or its successor), to provide that the Licensee no longer has the right to make the final decision on Unresolved JSC Matters that relate to the approval of any amendment to the '302 Development Plan that is not required by the FDA in order to obtain or maintain an approved BLA for the Existing Licensed Product for the CTCL Indication in the United States, in which case any such proposed amendment to the '302 Development Plan would be deemed rejected if the Senior Officers are unable to reach a decision regarding such amendment within the applicable time period set forth in Section 4.4.1.

11.12. Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

11.13. No Benefit to Third Parties. Except as provided in Article 9, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other Persons.

11.14. Further Assurance. Each Party shall duly execute and deliver or cause to be duly executed and delivered, such further instruments, and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

11.15. Relationship of the Parties. It is expressly agreed that Eisai, on the one hand, and the Licensee, on the other hand, shall be independent contractors and that the relationship between the two (2) Parties shall not constitute a partnership, joint venture or agency. Neither Eisai, on the one hand, nor the Licensee, on the other hand, shall have the authority to make any statements, representations or commitments of any kind or to take any action that will be binding on the other Party without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such first Party.

11.16. References. Unless otherwise specified: (a) references in this Agreement to any Article, Section or Schedule shall mean references to such Article, Section or Schedule of this Agreement; (b) references in any Section to any clause are references to such clause of such Section; and (c) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently amended, replaced or supplemented from time to time, as so amended, replaced or supplemented and in effect at the relevant time of reference thereto.

11.17. Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word “or” is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The terms “including”, “include”, or “includes” as used herein shall mean including without limiting the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party.

11.18. Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile, PDF format via email, or other electronically transmitted signatures, and such signatures shall be deemed to bind each Party as if they were original signatures.

[SIGNATURE PAGE FOLLOWS.]

THIS AGREEMENT IS EXECUTED by the authorized representatives of the Parties as of the date first written above.

Eisai Co, Ltd.

By: /s/ [***]
Name: [***]
Title Corporate Officer, Chief Planning

Date: March 9, 2018

Dr. Reddy's Laboratories S.A.

By: /s/ Sameeer Natu
Name: Sameer Natu
Title Sr. Director
Date: 20/3/18

By: /s/ Mukundan Baprothan
Name: Mukundan Baprothan
Title Director
Date:

Exhibit 10.32

*Information in this exhibit marked [***] has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such information is not material and is the type of information that the registrant treats as private or confidential

EXECUTION VERSION

AMENDMENT TO AMENDED AND RESTATED LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This Amendment (the "**Amendment**") is made as of August 9, 2018, by between Eisai Co., Ltd., a Japanese corporation ("**Eisai**"), and Dr. Reddy's Laboratories S.A., a Swiss company ("**Licensee**", and together with Eisai, the "**Parties**", and each, a "**Party**").

WHEREAS, the Parties have entered into that certain Amended and Restated License, Development and Commercialization Agreement, dated as of February 26, 2018 (the "**Existing Agreement**"); and

WHEREAS, the Parties hereto desire to amend the Existing Agreement on the terms and subject to the conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Definitions. Capitalized terms used and not defined in this Amendment have the respective meanings assigned to them in the Existing Agreement.

2. Amendments to the Existing Agreement. As of the Effective Date (defined below), the Existing Agreement is hereby amended or modified as follows:

(a) A new definition is hereby added in alphabetical order as a new Section 1.88 of the Existing Agreement (and the subsequent Sections of Article 1 shall be renumbered accordingly), as follows:

"1.88. "**Final Comparability Study Report**" means a written report prepared by Eisai's personnel that establishes analytical comparability of the Licensed Product manufactured at Eisai's Raleigh facility in the U.S. with the Licensed Product manufactured at [***]'s facility in Italy, that has been reviewed and accepted by both parties at a JMC meeting conducted for the purpose within [***] ([***]) calendar days of Eisai sharing the report with the Licensee. "

(b) Section 5.1.2 of the Existing Agreement is hereby deleted in its entirety and replaced with the following:

"US$[***] million shall be due and payable within [***] ([**]) days after review and acceptance by the JMC of the Final Comparability Study Report."

3. Date of Effectiveness; Limited Effect. This Amendment will be deemed effective as of the date first written above (the "**Effective Date**"). Except as expressly provided in this Amendment, all of the terms and provisions of the Existing Agreement are and will remain in full force and effect and are hereby ratified and confirmed by the Parties. Without limiting the generality of the foregoing, the amendments contained herein will not be construed as an amendment to or waiver of any other provision of the Existing Agreement or as a waiver of or consent to any further or future action on the part of either Party that would require the waiver or consent of the other Party. On and after the Effective Date, each reference in the Existing Agreement to "this Agreement," "the Agreement," "hereunder," "hereof," "herein," or words of like import, will mean and be a reference to the Existing Agreement as amended by this Amendment.

4. Miscellaneous.

(a) This Amendment is governed by and construed in accordance with, the laws of the State of New York, without regard to the conflict of laws provisions of such State. The Parties agree to exclude the application of this Amendment to United Nations Convention on Contracts for the International Sale of Goods.

(b) This Amendment shall inure to the benefit of and be binding upon each of the Parties and each of their respective permitted successors and permitted assigns.

(c) The headings in this Amendment are for reference only and do not affect the interpretation of this Amendment.

(d) This Amendment may be executed in counterparts, each of which is deemed an original, but all of which constitute one and the same agreement. Delivery of an executed counterpart of this Amendment electronically or by facsimile shall be effective as delivery of an original executed counterpart of this Amendment.

(e) This Amendment constitutes the sole and entire agreement between the Parties with respect to the subject matter contained herein, and supersedes all prior and contemporaneous understandings, agreements, representations, and warranties, both written and oral, with respect to such subject matter.

(f) Each Party shall pay its own costs and expenses in connection with this Amendment (including the fees and expenses of its advisors, accountants, and legal counsel).

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the Parties have executed this Amendment as of the Effective Date.

EISAI CO., LTD.

By /s/ [***]
Name: [***]
Title: [***]

DR. REDDY'S LABORATORIES S.A.

By /s/ Sameer Natu
Name: Sameer Natu
Title: Sr. Director, Finance

By /s/ B. Mukundan
Name: B. Mukundan
Title: Regional General Counsel

* Information in this exhibit marked [***] has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such information is not material and is the type of information that the registrant treats as private or confidential.

AMENDMENT NO. 2 TO AMENDED AND RESTATED LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This AMENDMENT NO. 2 TO AMENDED AND RESTATED LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT (this "Amendment") is dated as of August 31, 2021 (the "Amendment Effective Date"), by and between Eisai Co., Ltd., a Japanese corporation ("Eisai"), and Dr. Reddy's Laboratories S.A., a Swiss company ("Licensee", and together with Eisai, collectively, the "Parties", and individually, a "Party").

RECITALS

WHEREAS, the Parties entered into that Amended and Restated License, Development and Commercialization Agreement made and entered into as of February 26, 2018 by and between Eisai and the Licensee, as amended by that Amendment to Amended and Restated License, Development and Commercialization Agreement made as of August 9, 2018 by and between Eisai and the Licensee (each of the foregoing, together with all other exhibits, attachments, amendments and modifications thereto, collectively, the "Agreement"); and

WHEREAS, the Parties further desire to amend the Agreement on the terms and subject to the conditions herein; and

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, and intending to be legally bound hereby, the Parties hereto agree as follows:

1. Definitions. Capitalized terms used and not defined in this Amendment have the respective meanings assigned to them in the Agreement.

2. Amendments to the Agreement. As of the Amendment Effective Date, the Existing Agreement is hereby amended or modified as follows:

(a) Each of Section 10.2.6, Section 10.6 and Section 11.11 are hereby deleted in their entirety and replaced with "[reserved]". All references or cross references to such sections existing elsewhere in the Agreement shall also be deemed to be deleted.

(i) Section 2.3.1 of the Agreement is hereby amended by adding the words "and subject to Section 2.3.1(d)" immediately following the phrase "Subject to Section 2.3.2,"

(b) Section 2.3.1 of the Agreement is hereby amended by adding the following new Section 2.3.1(d)

"(d) Notwithstanding anything to the contrary provided herein, or elsewhere, following the payment by Licensee to Eisai of the first milestone payment set forth in the table in Section 5.2.1 (First approval by the FDA of a Biologics License Application (submitted under subsection (a) of Section 351 of the PHSA) for a Licensed Product for the CTCL Indication) (the "Approval Milestone Payment"), Licensee shall not be required to obtain the prior written consent of Eisai in order to enter into any sublicense, and upon the Approval Milestone Payment, Section 2.3.1(c) shall be amended to and replaced in its entirety with "with respect to the Licensee, any other Persons."

(c) Section 2.3.2 of the Agreement is hereby amended by deleting the last sentence in such section its entirety, and replacing it in its entirety with the following:

"In the event any such sublicensee commits or omits to do any act which would, if committed or omitted by a Party, be a material breach of this Agreement, the Party granting such sublicense pursuant to Section 2.3.1 shall either (a) cure such breach in accordance with Section 10.2.1 of this Agreement or (b) enforce its rights by terminating such sublicense agreement in accordance with the terms thereof."

(d) Section 3.1.1. of the Agreement is hereby amended by adding the following sentence after the last sentence:

"Notwithstanding the foregoing, prior to the receipt of a Regulatory Approval of the Existing Licensed Product in the United States for the CTCL Indication, either Party may conduct clinical studies at its own expense if approved by the JSC, provided such research does not have any impact on the '302 Development Plan, BLA submission activities or the ability to obtain Regulatory Approval of the Existing Licensed Product in the United States for the CTCL Indication."

(e) Section 3.1.4 (b) of the Agreement shall amended by deleting the phrase: within (i):

"(i) [***] Dollars ($[***]) in '302 Development Costs, with respect to the '302 Development Plan, as it exists as of the Original Effective Date or as the '302 Development Plan may be amended to enable Eisai to provide the Licensee the deliverables set forth in '302 Development Plan as of the Original Effective Date in accordance with the timeframe set forth therein, or if FDA requires changes to the '302 Development Plan due to changes in the manufacturing site."

and replacing such phrase with:

"(i) [***] U.S. Dollars (US$[***]) in '302 Development Costs, with respect to the '302 Development Plan, as amended."

The Parties hereby acknowledge and agree that (i) [***] U.S. Dollars $[***] of the '302 Development Costs have been paid by Dr. Reddy's Laboratories SA to Eisai (or billed to Dr. Reddy's Laboratories SA, which billed amount is the obligation of Dr. Reddy's Laboratories SA and will be paid to Eisai in accordance with the terms thereof); (ii) Dr. Reddy's Laboratories SA shall be responsible for the '302 Development Costs with respect to the month of August 2021 (currently anticipated to be approximately $[***]) ((i) and (ii), in the aggregate the "DRL Portion" and which DRL Portion is, as of the Amendment Effective Date, approximately [***] U.S. Dollars ($[***]); and (iii) Licensee shall have no obligation to pay any '302 Development Costs on or after the Amendment Effective Date that in the aggregate exceeds an amount equal to [***] U.S. Dollars ($[***]), less the DRL Portion (such remaining amount is, approximately, as of the Amendment Effective Date, estimated to be Two Million Six Hundred Fifty Thousand U.S. Dollars ($2,650,000).

(f) Section 3.1.8 of the Agreement is hereby amended by adding the following language after the sentence beginning with "Eisai shall provide…"

"For purposes of clarity, upon the transfer to Licensee from Eisai of all Development records as described in this Section 3.1.8 (including without limitation any Regulatory Documentation), Licensee shall be solely responsible for further transferring such records to any subsequent successor in interest including but not limited to an assignee of this Agreement, provided, however, that nothing herein shall prejudice any other obligation of Eisai under any clause or Section in this Agreement, including the obligation for Eisai to maintain books and records (including without limitation any Regulatory Documentation) and transferring any BLA or IND and any Regulatory Documentation relating thereto directly to Licensee or its successor in interest, as applicable. In the event that any Regulatory Authority or similar governmental authority makes a request with respect to any Development records, Eisai shall in good faith fulfill any request to provide such Development records (including without limitation any Regulatory Documentation) as so requested by Licensee or any successor in interest of Licensee, provided that Eisai shall be reimbursed for its costs at the FTE Rate. The foregoing payment obligation shall not apply to any records (including without limitation any Regulatory Documentation) that are or will be transferred to Licensee or a successor in interest of Licensee in connection with the transfer of any BLA or IND."

(g) Section 3.2.2 (a) of the Agreement is hereby amended by deleting the last phrase of the paragraph beginning with "unless and until…" and ending the sentence immediately prior to such phrase. Immediately following such sentence, Section 3.2.2(a) of the Agreement is hereby amended by adding the following new sentence:

"Additionally, for purposes of clarity, Licensee shall be solely responsible for developing the Companion Diagnostic ("CDx") and the Pediatric Study Plan ("PSP")."

(h) Section 3.2.2 (c) of the Agreement is hereby deleted in its entirety and replaced with the following:

"Subject to Section 3.2.2(d), either Licensee or Eisai (as applicable) shall notify the JDC reasonably in advance of the date of any anticipated meeting with the FDA relating to the Existing Licensed Product for the CTCL Indication in the United States. The JDC shall agree in advance on the objectives to be accomplished at, the agenda for, and, if appropriate, the script for, each such meeting. Upon Licensee's request, Eisai shall, to the extent permitted by the FDA, attend meetings between Licensee and the FDA relating to the Existing Licensed Product for the CTCL Indication in the United States and, if requested by Licensee, Eisai shall make available all necessary representatives of Eisai to attend, and, to the extent provided in the applicable agreed agenda or script, participate in such meetings. Licensee shall use good faith efforts to provide Eisai with an opportunity to be present at, to the extent practical, any unscheduled or ad-hoc meetings with the FDA relating to the Existing Licensed Product for the CTCL Indication in the United States (and Eisai shall attend such meetings that the Licensee requests Eisai to attend), *provided* that if an applicable agenda or script is agreed to by both Parties prior to any unscheduled or ad hoc meetings, Eisai shall participate in such meetings to the extent provided therein."

(i) Section 3.2.3 of the Agreement is hereby deleted in its entirety and replaced with the following:

"3.2.3 Transfer of BLA and INDs.

"(a) INDs. Promptly following the BLA filing, Eisai shall assign and shall cause its Affiliates to assign, to the Licensee all of Eisai' s and its Affiliates' rights, title and interest in and to any INDs with respect to the Existing Licensed Product in the Licensee Territory and all related Regulatory Documentation with respect thereto. During the [***] ([***]) months after any such assignment, at the Licensee's reasonable request, Eisai shall provide the Licensee reasonable knowledge transfer and support as necessary for the Licensee to Develop Licensed Products in the Field in the Licensee Territory or prepare, obtain and maintain any Regulatory Approvals for the Licensed Products in the Field in the Licensee Territory; *provided, however,* that in no event shall Eisai be required to provide the Licensee more than [***] ([***]) hours of such "knowledge transfer and support. The Licensee shall reimburse Eisai for the FTE Costs incurred and the direct out of pocket costs recorded as an expense, in accordance with GAAP, by or on behalf of Eisai or any of its Affiliates pursuant to this section 3.2.3 within forty five (45) days of receipt of an invoice with respect thereto. Except as otherwise agreed by the Parties, the JSC shall be responsible for discussing, planning and coordinating any technical transfer services.

"(b) BLA. During the [***] ([***]) months leading up to the BLA filing, at the Licensee's reasonable request, Eisai shall provide the Licensee reasonable knowledge transfer and support as necessary for the Licensee to Develop Licensed Products in the Field in the Licensee Territory or prepare, obtain and maintain any Regulatory Approvals for the Licensed Products in the Field in the Licensee Territory; *provided,* that in no event shall Eisai be required to provide the Licensee more than seventy five (75) hours of such "knowledge transfer and support". For the avoidance of doubt, Eisai shall (i) prepare a full copy of the BLA for the Existing Licensed Product for the CTCL Indication, (ii) upon Licensee's request, Eisai shall become the US agent of Licensee for BLA submission and manage all correspondence with the FDA, (iii) coordinate with Licensee to prepare responses to the FDA, (iv) provide Commercially Reasonable Effort to support Licensee in obtaining BLA approval, and (v) in the event that FDA issues a complete response identifying minor deficiencies with respect to the BLA filed by Licensee with the FDA for the Existing Licensed Product for the CTCL Indication, then at the Licensee's option, Eisai shall use Commercially Reasonable Efforts to support Licensee to resubmit such BLA to correct minor deficiencies (such support obligation of Eisai shall apply with respect to additional FDA action). For clarity, Eisai's support obligations with respect to the transfer of the Manufacturing Process shall be as set forth in Section 3.5.2.

(c) Within [***] ([***]) days following the Amendment Effective Date of Amendment No. 2 to this Agreement, Eisai will submit to the EMA the transfer of the Orphan Drug Designation to Licensee or its designee. In the event such submission of transfer does not occur within the specified time frame Eisai shall have the right to withdraw the ODD.

(d) The Licensee shall reimburse Eisai for the FTE Costs incurred and the direct out-of-pocket costs recorded as an expense, in accordance with GAAP, by or on behalf of Eisai or any of its Affiliates pursuant to this Section 3.2.3 within [***] ([***]) days after receipt of an invoice with respect thereto. Save as otherwise agreed by the Parties, the JSC shall be responsible for discussing, planning and coordinating any technical transfer services."

(j) The Agreement is hereby amended by adding the following new Section 3.2.9:

Eisai shall use Commercially Reasonable Efforts to complete the activities set forth in Schedule 3.2.9. The Licensee shall reimburse Eisai for the FTE Costs incurred and the direct out-of-pocket costs recorded as an expense, in accordance with GAAP, by or on behalf of Eisai or any of its Affiliates pursuant to this Section 3.2.9 within [***] ([***]) days after receipt of an invoice with respect thereto.

(k) Schedule 1.3 of the Agreement shall hereby be deleted in its entirety and replaced with a revised Schedule 1.3 attached hereto as Exhibit A.

(l) Section 4.4.2 (a) of the Agreement is hereby deleted in its entirety by replacing the language "(A) Eisai would need to hire additional personnel to implement such amendment without impacting any other programs of Eisai or any of its Affiliates" and replacing such language with the following "(A) Eisai would need to incur additional costs to implement such amendment without impacting any other programs of Eisai or any of its Affiliates".

(m) The Agreement is hereby amended by adding the new Schedule 3.2.9 which is attached hereto as Exhibit B.

(n) Sections 3.5.3, 3.5.4 and 3.5.5 of the Agreement are hereby deleted in their entirety. Section 3.5.1 is hereby deleted in its entirety and replaced with the following: "Notwithstanding anything otherwise to the contrary in this Agreement, Eisai and Licensee shall negotiate in good faith with the intention of entering into a definitive supply agreement (the "Supply Agreement") in accordance with (and no less favorable to Licensee than) the Key Supply Terms attached hereto as Exhibit C, which Supply Agreement shall include an associated quality agreement (the "Quality Agreement"), pursuant to which Supply Agreement Eisai shall (subject to execution of the FDB Agreement) supply Licensee with Licensee's requirements of finished Licensed Product for both clinical and commercial uses during the term of the Supply Agreement. For the avoidance of doubt, in the event that Eisai is unable to finalize and execute the FDB Agreement (as defined in Exhibit C), Eisai shall have no obligation to enter into the Supply Agreement; *provided*, that Eisai shall use Commercially Reasonable Efforts to negotiate and enter into such FDB Agreement. If Eisai is unable to contract with FDB for such supplies of Licensed Product (notwithstanding Eisai's use of Commercially Reasonable Efforts), then Eisai shall waive any restrictions that would otherwise prohibit or restrict FDB from contracting directly with Licensee for such supplies of Licensed Product."

3. Upon the Amendment Effective Date, that Letter Agreement dated September 30, 2020 by and between Eisai and the Licensee is hereby terminated in its entirety, and is of no further force and effect.

4. Date of Effectiveness; Limited Effect. This Amendment will be deemed effective as of 12:00:01 AM Eastern Time on the Amendment Effective Date. Except as expressly provided in this Amendment, all of the terms and provisions of the Agreement are and will remain in full force and effect and are hereby ratified and confirmed by the Parties. Without limiting the generality of the foregoing, the amendments contained herein will not be construed as an amendment to or waiver of any other provision of the Agreement or as a waiver of or consent to any further or future action on the part of either Party that would require the waiver or consent of the other Party, except as expressly set forth herein. On and after the Amendment Effective Date, each reference in the Existing Agreement to "this Agreement," "the Agreement," "hereunder," "hereof," "herein," or words of like import, will mean and be a reference to the Existing Agreement as amended by this Amendment.

5. Miscellaneous**.**

(a) This Amendment is governed by and construed in accordance with, the laws of the State of New York, without regard to the conflict of laws provisions of such State. The Parties agree to exclude the application of this Amendment to United Nations Convention on Contracts for the International Sale of Goods.

(b) This Amendment shall inure to the benefit of and be binding upon each of the Parties and each of their respective permitted successors and permitted assigns.

(c) The headings in this Amendment are for reference only and do not affect the interpretation of this Amendment.

(d) This Amendment may be executed in counterparts, each of which is deemed an original, but all of which constitute one and the same agreement. Delivery of an executed counterpart of this Amendment electronically or by facsimile shall be effective as delivery of an original executed counterpart of this Amendment.

(e) This Amendment constitutes the sole and entire agreement between the Parties with respect to the subject matter contained herein, and supersedes all prior and contemporaneous understandings, agreements, representations, and warranties, both written and oral, with respect to such subject matter.

(f) Each Party shall pay its own costs and expenses in connection with this Amendment (including the fees and expenses of its advisors, accountants, and legal counsel).

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, the Parties have executed this Amendment as of the Amendment Effective Date.

EISAI CO., LTD.

By: /s/ [***]
Name: [***]
Title [***], Eisai

DR. REDDY'S LABORATORIES S.A.

By: /s/ Sameer Natu
Name: Sameer Natu
Title Finance Head

By: /s/ Patrick Aghanian
Name: Patrick Aghanian
Title Head of PPG

EXHIBIT A

Schedule 1.3

Amended '302 Development Plan as of August 31, 2021

Exhibit B

Schedule 3.2.9

Eisai BLA Related Matters

Exhibit C

Key Supply Terms

Exhibit 21

Listing of Subsidiaries

Name of Subsidiary	Jurisdiction of Incorporation
Citius Pharmaceuticals, LLC	Massachusetts
Leonard-Meron Biosciences, Inc.	Delaware
NoveCite, Inc.	Delaware
Citius Acquisition Corp.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-1 (No.'s 333-224386, 333-226395, 333-230919, 333-233759, 333-237638 and 333-238975) and on Form S-3 (No's. 333-252561, 333-253179, 333-255005 and 333-256063) of Citius Pharmaceuticals, Inc. of our report dated December 15, 2021, relating to the consolidated financial statements of Citius Pharmaceuticals, Inc., appearing in the Annual Report on Form 10-K for the year ended September 30, 2021.

/s/ Wolf & Company, P.C.

Wolf & Company, P.C.
Boston, Massachusetts
December 15, 2021

Exhibit 31.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE
SARBANES-OXLEY ACT OF 2002

I, Myron Holubiak, certify that:

1. I have reviewed this Annual Report on Form 10-K of Citius Pharmaceuticals, 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.

December 15, 2021

By: /s/ Myron Holubiak
Myron Holubiak
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE
SARBANES-OXLEY ACT OF 2002

I, Jaime Bartushak, certify that:

1. I have reviewed this Annual Report on Form 10-K of Citius Pharmaceuticals, 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.

December 15, 2021

By: /s/ Jaime Bartushak
Jaime Bartushak
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER AND THE PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Citius Pharmaceuticals, 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"), Myron Holubiak, President and Chief Executive Officer of the Company, and Jaime Bartushak, Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

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

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

Date: December 15, 2021

By: /s/ Myron Holubiak
Myron Holubiak
President and Chief Executive Officer
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

By: /s/ Jaime Bartushak
Jaime Bartushak
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)