IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

CYTODYN, INC.	)	
	)	
Plaintiff,	)	Civil Action No. 21-2533
	)	
v.	)	
	)	
	)	**Complaint for Declaratory**
AMAREX CLINICAL RESEARCH, LLC, and NSF INTERNATIONAL, INC.	)	**and Injunctive Relief**
	)	
	)	
Defendant.	)	

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff CytoDyn, Inc. ("CytoDyn") brings this Complaint against Defendant Amarex Clinical Research, LLC and NSF International, Inc. (referred to together herein as "Amarex"). CytoDyn alleges as follows:

INTRODUCTION

1. CytoDyn brings this Complaint to protect 67 patients with treatment-resistant HIV and 25 patients with non-alcoholic steatohepatitis (a kind of liver disease) that are currently receiving CytoDyn's drug in clinical trials. The safety of these patients is being threatened by Amarex, the clinical research organization managing the trials under contracts with CytoDyn. Amarex is threatening to end these trials and cease all safety monitoring for them, while simultaneously cutting off CytoDyn from accessing the clinical trial databases necessary for it to take over management of the trials. CytoDyn is seeking a preliminary injunction to compel Amarex to provide full access to the data—which CytoDyn owns—to protect the integrity of these critical studies and to protect the patients receiving CytoDyn's drug in them.

PARTIES

2. CytoDyn is a Delaware corporation and maintains its principal place of business in Vancouver, Washington.

3. Amarex Clinical Research LLC is a limited liability corporation with its principal place of business in Germantown, Maryland. Upon information and belief, no member of Amarex Clinical Research LLC is a citizen of, is incorporated in, or has its principal place of business in either Delaware or Washington.

4. NSF International, Inc. is a Michigan corporation with its principal place of business in Ann Arbor, Michigan. NSF International owns and controls Amarex. A Global Vice President for NSF has taken over discussions regarding the CytoDyn clinical trials being run by Amarex.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332. The amount in controversy exceeds $75,000 because unless the Court issues the requested injunction, CytoDyn will suffer monetary damages of far more than $75,000, and the clinical data that is the subject of the parties' dispute is worth far more than $75,000. Upon information and belief, there is complete diversity of citizenship between the parties.

6. This Court is a proper venue for this action pursuant to 28 U.S.C § 1391(b) because Amarex resides in this judicial district, and because a substantial part of the events or omissions giving rise to the claims occurred in this district.

GENERAL ALLEGATIONS

Background on CytoDyn and Leronlimab

7. CytoDyn is a biotech company focused on the clinical development of leronlimab, an investigational drug being studied as a treatment for HIV, cancer, COVID-19, and other serious diseases. In order to obtain FDA approval for leronlimab, CytoDyn has sponsored 22 clinical trials to test the drug for safety and efficacy. There are currently four main trials in which patients are receiving leronlimab: three studies of HIV, and one study of non-alcoholic steatohepatitis (also known as NASH, a kind of liver disease).

8. CytoDyn engaged Amarex as its contract research organization (CRO) to manage the clinical trials of leronlimab. CROs are clinical research specialists with extensive experience conducting clinical trials.

9. CytoDyn and Amarex formed a Master Services Agreement (MSA) in May 2014. **Exhibit A.** The Master Services Agreement set up a framework for Amarex to run clinical studies that CytoDyn would sponsor and Amarex would agree to conduct. The work on individual studies would be documented in specific project work orders. The Master Services Agreement stated that it "constitutes the entire agreement between the parties to be described and defined in future Project Work Orders." **MSA § 15.1**. Both Amarex and CytoDyn "intend[ed] [the Master Services Agreement] to be a complete statement of the terms of their agreement." **MSA § 15.1**.

10. The MSA defines the relationship between CytoDyn and Amarex. Under the agreement, Amarex committed to provide clinical trial management services for clinical trials of leronlimab. **MSA at 1.** Amarex in turn invoices CytoDyn for services rendered. **MSA § 3.2.**

11. The Master Services Agreement also provides CytoDyn with the right to audit Amarex's records at any time to ensure its compliance with the contract. **MSA § 2.4.** Specifically,

the agreement provides: "Amarex will maintain accurate, complete, and current records relating to all Services. Amarex will furnish to CytoDyn all data, information, and records maintained in connection with the Services as well as written reports of the process of the Services at reasonable times upon CytoDyn's request. CytoDyn shall be entitled, with at least 24 hours' prior notice, to audit and inspect records, facilities used, and the conduct of the Services relating to a Project Work Order under this Agreement. CytoDyn will not be responsible for payment to Amarex for time spent on audits." **MSA § 2.4.**

12. The Master Services Agreement included an arbitration clause. Specifically, that clause states: "All claims arising under or relating to this Agreement, including any claims created by statutory law, will be decided by final and binding arbitration. . . . This provision will provide the exclusive means for dispute resolution, provided, however, that neither party will be prohibited from proceeding in a court to seek injunctive relief or other equitable remedies pending arbitration." **MSA § 15.4.**

13. The arbitration clause does not bar this action because it provides that "neither party will be prohibited from proceeding in a court to seek injunctive relief or other equitable remedies pending arbitration." **MSA § 15.4.**

14. Although neither Amarex nor CytoDyn signed the MSA, both parties understood the MSA to be a complete embodiment of their agreement and both parties acted accordingly. Since 2014, both Amarex and CytoDyn have treated the MSA as a binding agreement governing their relationship. Amarex and CytoDyn have each signed over 70 project work orders obligating Amarex to conduct clinical trial management on all but two of CytoDyn's studies. Those fully executed project work orders expressly incorporate the MSA. Amarex has also sent hundreds of

invoices to CytoDyn for work performed under the MSA and work orders. CytoDyn has paid Amarex more than $80 million pursuant to the MSA and those work orders.

15. Under these work orders, Amarex had complete responsibility for the clinical trials. Specifically, Amarex was required to, among other things:

a. "Communicate with Sponsor"—*i.e.*, CytoDyn

b. "Management of drug shipments"

c. "Develop Data Management Plan"

d. "Standard Data Cleaning (Run edit checks, generate, process, and track data queries)"

e. "Code Adverse Events and Medications"

f. "Receive, Load, and Reconcile Clean SAS Data from Labs/Vendors"

g. "Perform Data Transfer to Sponsor"

h. "EDC [Electronic Data Capture] Maintenance"

i. "Conduct QC [quality control] of EDC Database"

j. "Perform Site Identification"

k. "Negotiate Site Contracts and Budgets"

l. "Set Up Trial Master File"

m. "Set Up, File, and Track Investigator/Site Regulatory Files"

n. "Conduct Ongoing Regulatory Document Collection, Review, Tracking, and Maintenance of Trial Master File"

o. "Prepare Monitoring Guidelines"

p. "Perform Site Management"

q. "Prepare for Site Visit"

r. "Prepare Documents for Site Initiation"

s. Conduct Remote Site Qualification Visits"

t. "Write and Review Standard Monitoring Report"

u. "Prepare Safety Management Plan"

v. "Set Up EDC Safety Management Module"

w. "Medical Monitoring (24/7)

x. "Submit Safety Reports to Regulatory Authorities"

y. "Prepare and Submit Full Annual Report for IND"

16. Amarex has been the contractually assigned CRO for all but two of CytoDyn's leronlimab clinical studies. The chart below provides information on each study.

Study ID	Conditions	Title	Status
CDI-NASH-01	Nonalcoholic Steatohepatitis (NASH)	Leronlimab (PRO 140) in Patients With Nonalcoholic Steatohepatitis(NASH)	Active
PRO 140 _CD02 Extension	Hiv|Human Immunodeficiency Virus	An Extension Protocol for Subjects Who Successfully Completed PRO140_CD02 Study	Active
PRO 140_CD 01-Extension	HIV|Human Immunodeficiency Virus	An Extension of Protocol PRO 140_CD01 TS Study	Active
PRO 140_CD03	HIV	Study of PRO 140 SC as Single Agent Maintenance Therapy in Virally Suppressed Subjects With CCR5-tropic HIV-1 Infection	Active
ARO_21_018_002	COVID-19 Pneumonia	Leronlimab in Patients With Coronavirus Disease 2019 (COVID-19) With Need for Mechanical Ventilation or Extracorporeal Membrane Oxygenation	Completed
CD09_Basket	Solid Tumor, Adult	Basket Study of Leronlimab (PRO 140) in Patients With CCR5+ Locally Advanced or Metastatic Solid Tumors	Completed
ARO_21_018_001	COVID-19 Pneumonia	Leronlimab in Moderately Ill Patients With COVID-19	Completed

		Pneumonia	
CD07_TNBC	Triple Negative Breast Neoplasms	Leronlimab (PRO 140) Combined With Carboplatin in Patients With CCR5+ mTNBC	Completed
CD12_COVID-19	Coronavirus Disease 2019	Study to Evaluate the Efficacy and Safety of Leronlimab for Patients With Severe or Critical Coronavirus Disease 2019 (COVID-19)	Completed
CD10_COVID-19	Coronavirus Disease 2019	Study to Evaluate the Efficacy and Safety of Leronlimab for Mild to Moderate COVID-19	Completed
CD07_TNBC_CompassionateUse	Metastatic Triple-Negative Breast Carcinoma	A Compassionate Use Study of Leronlimab in Breast Cancer	Completed
PRO 140_CD 02	HIV	A Randomized, Double-blind, Placebo-controlled Trial, Followed by Single-arm Treatment of PRO 140 in Combination w/ Optimized Background Therapy in Treatment-Experienced HIV Subjects	Completed
CD15_COVID-19	Coronavirus Disease 2019	COVID-19 Long-Haulers Study	Completed
PRO 140_CD 01	HIV|Human Immunodeficiency Virus	Treatment Substitution With PRO 140 Monotherapy in Adult Subjects With HIV-1 Infection	Completed
2009-P-0023471	HIV Infections	Observational Study of Blood Treated With Cytolin	Completed
PRO 140 2101	HIV -1 Infection|HIV Infections	Study of PRO 140 by Subcutaneous Administration in Adult Subjects With HIV -1 Infection	Completed
PRO 140 2301|1U19AI066329	HIV Infections	PRO 140 by IV Administration in Adults With HIV-1 Infection	Completed
5R44AI046871-04|PRO140-1101	HIV Infections	Safety and Tolerability of PRO 140 in HIV Uninfected Male Volunteers	Completed
PRO 140_CD02_OpenLabel	HIV-1-infection	PRO 140 in Treatment-Experienced HIV-1 Subjects	Completed
PRO 140_CD 03_GVHD	Graft Vs Host Disease	Study of PRO 140 for Prophylaxis of Acute GVHD in Patients Undergoing RIC Allogenic Stem-Cell Transplantaton	Completed
PRO140 CD02_EA	HIV	An Expanded Access Protocol for a Single Subject Who Has Completed 24-Weeks of Treatment in PR0140_CD02	Completed

		Study	
PRO 140 2102	HIV	A Trial of Observed Long-acting, Anti-HIV Treatment With a Monoclonal CCR5 Antibody (PRO 140) as an Adjunct to a New, Optimized, Oral Antiretroviral Regimen in HIV-infected Injection Drug Users With Viral Rebound and Documented Poor Adherence	Completed

17. In addition to the Project Work Orders, the parties also signed a Monitoring Plan for each study. The Monitoring Plan expressly required Amarex to conduct safety and other monitoring of all clinical trials. For example, the monitoring plan for the still-active CD02 study, for HIV patients, acknowledged that "CytoDyn . . . has contracted with Amarex . . . to perform pre-study visits (PSV), site initiation visits (SIV), interim monitoring visits (IMG), and close-out visits (COV) in the United States (US) for this protocol," and that "[a]ll Amarex and independent contractors designated to fulfill those functions involved in monitoring activities, are responsible for complying with this plan. The managers of these individuals are responsible for ensuring compliance with this plan." **Exhibit B** (monitoring plan), at 8.

18. The plan expressly noted that "Compliance with this guidance . . . ensures that the trial is conducted in accordance with the principles of Good Clinical Practice" and with federal regulations of clinical trials. *Id.* The monitoring plans specified what Amarex was required to do at each trial site, *id.* at 14-20 (describing documentation, product accountability, site supply, and randomization procedures), as well as Amarex's obligation to communicate with CytoDyn regarding the progress of the trials and Amarex's performance of its monitoring duties, *id.* at 11-12. The requirements for monitoring visits are also defined in detail. *Id.* at 21-42.

19. One of the main things Amarex did for each clinical trial was maintain CytoDyn's data. The dynamic data used and collected in a clinical trial is maintained, by a process of collection and ongoing quality control, in a dynamic database known as the "electronic data capture" or the "EDC." This EDC database is purpose-built for each study according to the study protocol, and includes all data collected on patients enrolled in the studies. In the HIV studies for example, the data includes patient demographics, medical history, vital signs, electrocardiogram data, biochemistry, coagulation tests, urinalysis, adverse events, concomitant medications, treatment data, survival follow-up, and death information.

20. The EDC database for each study has significant patient safety implications. It is used to track adverse events and ensure proper adverse event reporting to the FDA. It is also the means by which the sponsor—CytoDyn—can verify that the study is being conducted in accordance with the study protocol, including that study participants are included or excluded properly, and that data entry is being performed correctly at the trial sites.

21. Pursuant to work orders under the MSA, Amarex programmed and maintained, at CytoDyn's expense, the EDC for each study. *See* **Exhibit C** (Work Order 37, including "EDC Programming," "EDC Maintenance," and "Conduct QC of EDC Database" among Amarex's responsibilities).

22. CytoDyn owns the EDCs, which are an indispensable component of the clinical trial data. Without the EDCs, the raw information contained in the database is effectively useless: the EDC defines the meaning of the information in each database field, and maintains an audit trail of each time a record is updated, which is necessary to ensure data integrity for FDA purposes. The MSA explains that all such study data is the property of CytoDyn, which owns "all right, title and interest" to clinical data collected from its trials. **MSA § 5.2**. Specifically, "CytoDyn owns all

right, title and interest . . . in and to all information, materials, documents and raw data (i) supplied to Amarex, including without limitation clinical data, in connection with this Agreement; (ii) developed by Amarex as a result of performing the Services, including without limitation any Deliverables; and (iii) CytoDyn's Confidential Information (all such information and materials, 'Client Materials')." **MSA § 5.2**.

23. Upon CytoDyn's request, the MSA requires that Amarex return the data from any clinical study immediately. Section 4.1 provides that "[a]ll Client Materials. . . shall be deemed the 'Confidential Information' of CytoDyn," and shall be "*return[ed] or destroy[ed] . . . at the request and cost of the Disclosing Party*[.]"[1] **MSA § 4.1.**

24. CytoDyn paid Amarex more the $80,000,000 for services rendered pursuant to the MSA.

The Relationship Between CytoDyn and Amarex Broke Down

25. Unfortunately, after years of what CytoDyn thought was a productive partnership, the relationship between CytoDyn and Amarex began to break down. CytoDyn has discovered that Amarex has failed to perform some of its responsibilities under the MSA, work orders, and monitoring plans. Specifically, Amarex did not perform the monitoring that was required under

[1] The MSA describes this obligation in terms of a "Disclosing Party" and a "Receiving Party," but it applies to more than just information sent from CytoDyn to Amarex or vice-versa, as the context makes clear: "'Confidential Information' means all information provided by or on behalf of one party (the 'Disclosing Party') to the other party in connection with this Agreement and the Services including without limitation, all . . . information acquired or developed in or as a result of the performance of this Agreement, whether in oral, written, graphic or electronic form. Without limiting the generality of the foregoing, all Client Materials (as defined in Section 5.2) shall be deemed the 'Confidential Information' of CytoDyn." MSA § 4.1. As discussed above, the "client materials" include "information . . . developed by Amarex as a result of performing the Services[.]" MSA § 5.2. Together, these clauses make clear that the "Disclosing Party" referred to in the MSA is better understood as the party that owns the information, regardless of how the "Receiving Party" came to possess the information

the MSA, work orders, and Monitoring Plans. For the limited monitoring that Amarex has done, it has back-dated certain letters regarding this monitoring (in violation of FDA regulations).

26. Amarex has also failed to properly maintain the clinical data as required by the MSA, the work orders, and the Data Management Plans that accompanied each study. *See* **Exhibit D** (data management plan). The Data Management Plan provides for "queries" to be auto-generated by the EDC for quality control purposes. *See id.* § 5 ("Once the data is entered, queries will automatically be fired by the validation component of the program if discrepant and/or erroneous (e.g. out of protocol specified visit windows, out of range values, etc) data is being entered."). Queries are supposed to be addressed "[d]aily, upon generation of queries." However, Amarex has failed to resolve some queries for months or even years, raising questions about the integrity of the study data maintained by Amarex.

27. Amarex has also failed to close out study data as required by the study protocols.

28. Amarex has covered up its failures by making false statements to CytoDyn about the work it performed. CytoDyn repeatedly requested monitoring documentation required by the Monitoring Plans, and access to the EDC to oversee Amarex's compliance with the Data Management Plans. This is information that would routinely be provided to a sponsor by any other CRO.

29. After each request, Amarex refused to provide the requested information or simply ignored the request.

30. One of the ways CytoDyn has confirmed that Amarex is not performing under the MSA and the Work Orders is by downloading a snapshot of the clinical data for certain clinical trials managed by Amarex. 21.22. This snapshot is incomplete: it does not include the definitions of the EDC fields (*i.e.*, the database's "column headings"), the audit trails showing each

time the data has been modified, the auto-generated "data queries" that are essential to cleaning and maintaining the clinical data, or many other of the essential components of the clinical data that can only be ob-tained through full access to the EDC.It is impossible for CytoDyn to monitor the ongoing trials or to submit applications to the FDA based on the data contained in the snapshots. Moreover, the snapshot was not provided by Amarex, but obtained through CytoDyn's limited access to the EDCs for certain clinical trials. Even this limited access has now been cut off by Amarex, making it impossible for CytoDyn to obtain additional snapshots.

31. However, these limited snapshots are enough for CytoDyn to confirm that the clinical data for multiple studies is in disarray, and has not been maintained by Amarex as the parties' agreements require.

32. Finally, CytoDyn was left with no choice and on August 2, 2021, CytoDyn demanded that Amarex make its facilities available (for a virtual or in person) audit under the MSA. CytoDyn believed this audit was necessary to determine what else Amarex was failing to do and to protect the integrity of its clinical trial programs.

33. On August 9, 2021, Amarex refused to consent to the audit.

34. Amarex has continued to submit invoices for work that CytoDyn does not believe Amarex performed and for work that it did not perform in compliance with the MSA and relevant standards.

35. CytoDyn has therefore refused to pay Amarex for a number of invoices. Amarex still demanded payment and has refused to do any more work on the studies until CytoDyn pays. In order to resolve that monetary dispute, pursuant to the MSA, CytoDyn has filed an arbitration demand against Amarex with the American Arbitration Association. In that arbitration, CytoDyn alleges that it has overpaid Amarex for work that was not properly performed and it is seeking

damages from Amarex for harm to its clinical trial program and business reputation. The arbitration will resolve the dispute between CytoDyn and Amarex over the payment of fees.

36. This lawsuit is brought for the separate and necessary reason of obtaining an injunction while the arbitration is pending.

37. In light of the dispute about Amarex's compliance with the contracts and Amarex's refusal to continue its monitoring of the ongoing studies, CytoDyn told Amarex that it intends to replace it as the CRO for the ongoing studies. CytoDyn accordingly requested that Amarex provide a transition plan. Amarex repeatedly stated that it would provide a transition plan so that CytoDyn can take over the studies and patient safety can be assured.

38. However, on September 23, 2021, rather than provide an actual transition plan, Amarex informed CytoDyn that it is suspending all activities including safety monitoring for the ongoing clinical trials and that CytoDyn must take over all safety monitoring and other clinical trial management activities.

39. CytoDyn stands ready to take on this vital responsibility. In order to manage the ongoing clinical trials, CytoDyn needs access to the data from the clinical trials (the EDCs). CytoDyn has repeatedly requested that Amarex give it access to its own study data and EDCs. But Amarex has refused.

If CytoDyn Does Not Obtain Its EDCs and Data, Patients and CytoDyn Will Suffer Irreparable Harm

40. Without full access to the EDCs and clinical study data, CytoDyn cannot adequately monitor or manage the ongoing clinical trials. With no monitoring, patients and CytoDyn will suffer significant irreparable harm.

41. Without full access to its EDCs and data, CytoDyn cannot ensure that trial sites are able to timely communicate any significant adverse safety event for proper reporting to the FDA. The delays and lack of audit trail associated with implementing a new system for adverse event reporting will put patients at risk and interfere with CytoDyn's ability to comply with FDA regulations.

42. Under FDA regulations, "significant adverse events"—*i.e.*, serious symptoms that may be side effects of the trial drug—must be reported to the trial monitor within 24 hours. Trial sites put the information about adverse events into the EDC database. The CRO or Sponsor then reviews that information to determine if a report to the FDA is necessary. But without access to the EDC database, CytoDyn will be limited in its ability to see or identify any adverse event information that is reported by doctors, and reporting will have to be moved to unfamiliar channels, such as email or fax, that will introduce additional risk of errors. It is crucial that Amarex provide CytoDyn with the EDC database so that it can properly monitor the studies.

43. If adverse events are not tracked in an EDC, CytoDyn will also lose the capability to readily identify trends and correlations in the adverse event data, which could suggest safety issues with the drug.

44. The EDC database is necessary for CytoDyn to ensure that the study protocols are being followed. A study sponsor—either itself or through a CRO—must monitor the clinical trial for compliance. The EDC is used to monitor compliance: for example, if a patient begins taking a concomitant medication that may interfere with the trial, that patient may need to be excluded from the study. Without access to the EDC, the study cannot continue.

45. In an emergency situation, it may be necessary to "unblind" a study participant to determine whether the participant has received the drug or placebo. This can be critically important

because doctors may treat a medical emergency differently depending on whether it could be caused by the investigational drug. But without access to the EDC and a related system called WebView, CytoDyn cannot unblind study participants and cannot track their progress through the study, which may be necessary to see whether the participant reported symptoms or had vital sign variations that may assist doctors in responding to the medical emergency.

46. It is not an option for CytoDyn to simply shut down the studies. Patients discontinuing use of leronlimab need to be titrated off the drug, and monitored afterward to ensure no side effects occur as a result of discontinuance. Moreover, the patients in CytoDyn's studies are seriously ill and, in the case of the 24 of the HIV patients receiving leronlimab, have developed a resistance to other HIV treatments. If leronlimab is helping these patients, therefore, discontinuance may actually shorten their lives.

47. It is also not an option for CytoDyn to allow the studies to continue unmonitored, which would violate the study protocols, harm the integrity of studies, and put patients at risk. Monitoring is the way that a study sponsor ensures that trial sites are conforming to the study protocol; in the absence of effective monitoring, there is no guarantee that the protocol has been followed, and the reliability of the study data is uncertain.

48. Amarex's abrupt termination of safety monitoring will also make it impossible for CytoDyn to comply with FDA regulations governing the safety of clinical trials.

49. Questions about the reliability of data from even temporarily unmonitored studies may also prevent CytoDyn from using the data to get FDA approval, dealing a major setback to CytoDyn's only drug prospect. This could irreparably harm CytoDyn's reputation in front of the FDA

50. Further, a delay in bringing leronlimab to market will also harm CytoDyn in its business reputation. When the FDA rejected one of CytoDyn's filings (because of Amarex's failures), CytoDyn lost more than $1 billion in market cap. By causing CytoDyn to fail to meet its clinical targets, Amarex would cause irreparable harm to CytoDyn's business.

51. Delays in bringing leronlimab to market will also harm patients who might benefit from the drug, if it proves to be safe and effective.

52. CytoDyn's reputation will also be severely damaged if it is forced to completely re-create multiple clinical trials as a result of Amarex's failures as CRO. In addition to reputational damage from the delay in bringing leronlimab to market, doctors, patients, potentially business partners, and the FDA may all come to associate CytoDyn with the data integrity and accountability issues arising from Amarex's failures.

53. The parties' dispute over payment will be resolved through arbitration, but by then it might be too late for some patients. The 67 patients in CytoDyn's HIV studies are treatment-resistant, meaning other treatments for HIV no longer work for them. While leronlimab is still an experimental treatment, it may be extending or improving the lives of these patients. Without full access to its EDCs and clinical data, CytoDyn may be forced to terminate its studies, since the only alternative is to continue them with a gap in monitoring that is required by the study protocols and FDA rules and may make the study data unusable for FDA approval.

54. Accordingly, CytoDyn seeks the restoration of the status quo: access to the EDCs and clinical data that it owns, and that it needs to protect the patients receiving leronlimab in its studies.

CLAIMS FOR RELIEF

COUNT I

BREACH OF CONTRACT FOR FAILURE TO PROVIDE ACCESS TO EDCS AND DATA

55. Plaintiff realleges and incorporates by reference all the foregoing allegations as though fully set forth herein.

56. CytoDyn and Amarex are parties to a Master Services Agreement for the provision of clinical trial management and consulting services.

57. CytoDyn and Amarex have also executed a series of Project Work Orders pursuant to the MSA.

58. The MSA is a valid and enforceable contract "governed by the laws of the State of Maryland[.]" MSA Section 15.4.

59. Under the MSA, CytoDyn owns the clinical trial data, including the EDC, which is "information, materials, documents [or] raw data (i) supplied to Amarex, including without limitation clinical data, in connection with this Agreement; [or] (ii) developed by Amarex as a result of performing the Services, including without limitation any Deliverables[.]" MSA Section 5.2.

60. The MSA requires that Amarex, upon request, immediately return all Client Materials as defined by Section 4.2 of the MSA.

61. The EDC database for each study is part of the Client Materials under Section 4.2

62. CytoDyn has repeatedly requested that Amarex provide it with full access to the EDC and clinical data for each study.

63. Amarex has refused, and continues to refuse, to return the EDCs and data.

64. Amarex's refusal violates sections 4.1 and 5.2 of the MSA.

65. CytoDyn has already suffered harm to due to Amarex's breach. It has not been able to access the complete EDCs and study data its own to protect the integrity of its trials, to ensure FDA regulations are being followed, and to protect the safety of its patients.

66. In the absence of injunctive relief, CytoDyn will suffer immediate and irreparable harm including, but not limited to, inability to comply with FDA requirements for proper monitoring of clinical trials and handling of significant adverse events, a delayed ability to seek FDA approval of its therapies, a loss of goodwill, the loss of current and future market value and the loss of potential outside investment, all as a result of Amarex's breach of the MSA by failing to turn over CytoDyn's EDCs and data.

COUNT II

CONVERSION

67. Plaintiff realleges and incorporates by reference all foregoing allegations as if fully set forth herein.

68. All EDCs, clinical data from CytoDyn's clinical trials, and Client Materials as defined by Section 5.2 of the MSA, are the personal property of CytoDyn.

69. CytoDyn is the rightful owner of the clinical data from its clinical trials, including the EDC and Client Materials as defined by Section 5.2 of the MSA.

70. CytoDyn has revoked its permission for Amarex to possess the clinical data and the EDC.

71. Amarex has nevertheless refused to turn over the clinical data and EDC to CytoDyn.

72. This constitutes a conversion on the part of Amarex, which is exerting ownership and dominion over CytoDyn's personal property, in denial of or inconsistent with CytoDyn's property rights.

73. This also constitutes conversion because Amarex is retaining CtyoDyn's property longer than CytoDyn, as its rightful possessor, permits.

74. In the absence of injunctive relief, CytoDyn will suffer immediate and irreparable harm including, but not limited to, inability to comply with FDA requirements for proper monitoring of clinical trials and handling of significant adverse events, a delayed ability to seek FDA approval of its therapies, a loss of goodwill, the loss of current and future market value and the loss of potential outside investment, all as a result of Amarex's ongoing conversion of CytoDyn's personal property in the data that Amarex refuses to turn over.

COUNT III
TRESPASS TO CHATTELS

75. Plaintiff realleges and incorporates by reference all foregoing allegations as if fully set forth herein.

76. Plaintiff is entitled to rightful possession of its EDCs and clinical data and Client Materials as defined by Section 4.2 of the MSA.

77. Amarex has dispossessed CytoDyn of its EDCs and data.

78. In the absence of injunctive relief, CytoDyn will suffer immediate and irreparable harm including, but not limited to, inability to comply with FDA requirements for proper monitoring of clinical trials and handling of significant adverse events, a delayed ability to seek FDA approval of its therapies, a loss of goodwill, the loss of current and future market value and

the loss of potential outside investment, all as a result of Amarex's ongoing trespass to CytoDyn's chattels, namely the EDCs and data that Amarex refuses to turn over.

COUNT IV

BREACH OF CONTRACT FOR FAILURE TO PERMIT AUDIT

79. Plaintiff realleges and incorporates by reference all the foregoing allegations as though fully set forth herein.

80. CytoDyn and Amarex are parties to a Master Services Agreement for the provision of clinical trial management and consulting services.

81. CytoDyn and Amarex have also executed a series of Project Work Orders pursuant to the MSA.

82. The MSA is a valid and enforceable contract governed by Maryland law.

83. The MSA requires that Amarex "maintain accurate, complete, and current records relating to all Services," and "furnish to CytoDyn all data, information, and records maintained in connection with the Services as well as written reports of the process of the Services at reasonable times upon CytoDyn's request." MSA Section 2.4.

84. The MSA further provides that "CytoDyn shall be entitled, with at least 24 hours' prior notice, to audit and inspect records, facilities used, and the conduct of the Services relating to a Project Work Order under this Agreement." MSA Section 2.4.

85. CytoDyn requested that Amarex submit to an independent audit for the clinical trail work done pursuant to the MSA.

86. Amarex has breached the contract by refusing to submit to this audit.

87. Amarex's refusal violates section 2.4 of the MSA.

88. In the absence of injunctive relief, CytoDyn will suffer immediate and irreparable harm including, but not limited to, inability to comply with FDA requirements for proper monitoring of clinical trials and handling of significant adverse events, a delayed ability to seek FDA approval of its therapies, a loss of goodwill, the loss of current and future market value and the loss of potential outside investment, all as a result of Amarex's breach of the MSA by failing to cooperate with the audit required by the MSA, including making all books and records relating to CytoDyn's studies available to CytoDyn.

RELIEF REQUESTED

CytoDyn Inc. respectfully requests that this Court grant relief in its favor and against Amarex as follows:

a. Enter a preliminary and permanent injunction ordering Amarex to restore CytoDyn with access to the EDC databases for all of CytoDyn's Clinical Trials.

b. Order that Amarex must submit to an audit within 48 hours of this Order.

c. Declare that Amarex's acts and omissions described herein violated the Master Services Agreement;

d. Award attorneys' fees, costs, and other expenses as permitted by law;

e. Grant such other and further relief as the Court may deem just and proper.

DATED: October 4, 2021

Respectfully submitted,
/s/ Jacquelyn E. Fradette

Mark D. Hopson*
Benjamin M. Mundel*
Jacquelyn E. Fradette
Lucas W.E. Croslow*
Sidley Austin LLP
1501 K Street, N.W.
Washington, D.C. 20005
Telephone: (202) 736-8000

Counsel for Plaintiff CytoDyn, Inc.

**Pro hac vice* application forthcoming