UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

THERAPURE BIOPHARMA INC.

Plaintiff,

v.

DYNPORTE VACCINE COMPANY, LLC

Defendant.

Civil Action No. 1:19-cv-02092

AMENDED COMPLAINT

Plaintiff Therapure Biopharma Inc. (“Therapure” or “Plaintiff”), by and through undersigned counsel, for its Complaint against Defendant DynPort Vaccine Company, LLC (“DVC” or “Defendant”) alleges as follows:

INTRODUCTION

1. At issue in this lawsuit is the unlawful breach of Basic Ordering Agreement (“BOA”) No. S4501108 entered into between Therapure and Defendant DynPort Vaccine Company LLC (“Defendant” or “DVC”) in May 2013. Pursuant to the BOA, Therapure was subcontracted to provide certain goods and services in support of the development of an FDA licensed plasma-derived human butyrylcholinesterase (HuBChE) under Defendant’s prime contract with the Department of Defense (“DoD”) Medical Identification and Treatment Systems (“MITS”) Joint Product Management Office (“JPMO”). Known as Project Bioscavenger, the product being developed was designed to serve as an antidote for organophosphorus (“OP”) nerve agent poisoning by sequestering the OP nerve agent in the bloodstream and preventing it from reaching critical target organ systems. While there are obvious potential uses in military settings, there is an opportunity for broader commercial application, including for use by civilian first
responders in situations where nerve agent usage is suspected and for use combatting cocaine addiction.

2. It took several years for Therapure and DVC to negotiate an agreeable subcontract. As a contract development and manufacturing organization (“CDMO”), Therapure operates on the basis of a fee for service model within its available capacity and places a strong emphasis on profit enhancement. As such, return on investment (“ROI”) is a critical factor considered by Therapure. Among other things, in order to make this commitment and investment of resources worthwhile, Therapure insisted on the retention of certain commercial rights so that it could manufacture and sell commercially the Bioscavenger product once developed. Therapure calculated the annual revenue opportunity related to these rights as worth approximately $100 million per year. Absent retention of these rights, Therapure never would have executed the BOA.

3. Key to Bioscavenger’s success was a steady supply of quality materials, most critically, paste. In negotiating the terms of the BOA, Therapure went so far as to identify acceptable paste suppliers and to obtain suitable samples. Although Therapure originally proposed that it would supply the paste, Defendant insisted that it would do so.

4. Therapure relied on Defendant’s representations and its contractual obligation to deliver acceptable paste in a timely manner, without which it would not have executed the BOA. Clearly, Therapure’s reliance was misplaced; Defendant repeatedly failed and/or refused to provide proper paste. Not only was contract performance unnecessarily delayed, but Therapure incurred more than $12 million in unreimbursed costs as a result.

5. Throughout the course of subcontract performance over the past six years, despite various failures by Defendant to adhere to its relevant obligations, Therapure made significant strides in the development of the Bioscavenger product and had a product that could meet or exceed initial objectives and requirements of the program in terms of both yield and product quality. There
is no doubt that, with appropriate paste, in short order Therapure would have succeeded in completing those elements of the program that would have resulted in a product suitable for clinical and non-clinical applications and likely commercial and emergency settings, in accordance with the BOA. In fact, but for Defendant’s continuing failure to provide proper paste, as required by the contract, Therapure would have completed contract performance as originally envisioned and would have been in a position to commercially manufacture the Bioscavenger product.

6. In May 2018, Defendant issued to Therapure a 90-day stop work order. Nevertheless, Defendant directed Therapure to remain in a “stand ready” state whereby Therapure would be prepared to resume performance immediately at the lifting of the stop work order. Defendant issued additional stop work orders for a total stop-work period of ten months, during which Therapure was required to maintain a “stand ready” state. As Defendant was well aware, given the stage of contract performance, Therapure had significant personnel and other resources deployed at the time of the issuance of the stop work order. These resources remained in place for the entirety of the ten month stop work period and until the BOA was ultimately terminated by Defendant in March 2019.

7. From May 2018 until the termination of the BOA in March 2019, Defendant issued several stop work order notices to continually extend the relevant period. Defendant continued to direct Therapure to remain in a “stand ready” state, however. During this same time period, Therapure submitted no fewer than eight requests for equitable adjustment (“REAs”) in which it requested reimbursement for personnel, facilities, and other costs incurred as a result of maintaining the “stand ready” state. Therapure also had multiple written communications and in-person meetings to discuss the status of subcontract performance and payment of costs incurred as set forth in the REAs. As a result, Defendant was well aware of the level of Therapure’s resources that remained idle, including more than sixty-one full time equivalents (“FTEs”). Defendant never
took issue with or questioned that Therapure was entitled to reimbursement for personnel and fixed costs as well as overhead associated with the mandate to “stand ready.” In fact, Defendant conceded several times that it could easily recover payment for twenty-six FTEs. Defendant also did not take issue with the labor categories Therapure identified as required to “stand ready” Defendant requested documentation to support Therapure’s designation of the sixty-one FTEs, and Therapure provided appropriate documentation and support, but still Defendant has not paid Therapure. Despite Defendant never advising Therapure to scale down and commit its resources elsewhere during the ten month pendency of the stop work order, or any time thereafter, Defendant has completely failed to reimburse Therapure for any of its costs incurred in maintaining the “stand ready” state. Defendant was well aware of the significant detrimental impact that maintaining the “stand ready” state without payment was having on Therapure’s business, but still Defendants failed to pay Therapure. Indeed, Defendant falsely implied that it would reimburse Therapure for these significant costs.

8. By failing to reimburse Therapure for any of the $13,381,762.39 of costs incurred as a result of maintaining a “stand ready” state for ten months, as reflected in the eight REAs, Defendant has failed to adhere to its obligations under the BOA. As a result of its breach, Defendant has knowingly and with reckless disregard caused irreparable, and potentially ruinous and devastating harm to Therapure. Not only has Therapure been damaged by the loss of out-of-pocket costs incurred by maintaining the “stand ready” state, but its lost opportunity costs are substantial, as is the loss of its ability to exercise its commercial rights to the Bioscavenger product. Defendant’s actions, include: its breach of the BOA; its breach of its duties and covenants under the BOA; and its knowing acceptance of the benefit of Therapure remaining in a “stand ready” state without paying for that benefit. Defendant should compensate Therapure as a result.
THE PARTIES

9. Plaintiff Therapure is organized and existing under the laws of Ontario, Canada, with its headquarters and principal place of business in Mississauga, Ontario. Founded in 2008, Therapure is a privately held business consisting of two business units. The first is an integrated Contract Development and Manufacturing Organization (“CDMO”) that provides a range of therapeutic protein development manufacturing services including: technology transfer and process development; analytical development and testing; scale up and cGMP manufacturing; and aseptic fill/finish and lyophilization. The second is a product unit focused on commercializing plasma proteins derived primarily using its proprietary technology.

10. Upon information and belief, Defendant DVC is a corporation organized under the laws of Virginia, with its headquarters and principal place of business at 110 Thomas Johnson Drive, Frederick, MD 21702. Defendant manages product development programs for U.S. and international governmental entities and provides consulting services to biotechnology and pharmaceutical companies.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1332(a), in that: (a) Plaintiff is a foreign corporation located in Ontario, Canada; (b) upon information and belief, Defendant is a Virginia corporation with its principal place of business in Frederick MD; (c) there is complete diversity of citizenship between Plaintiff and Defendant; and (d) the amount in controversy exceeds the sum of $75,000, exclusive of interest and costs.

12. Venue is proper in this district, pursuant to 28 U.S.C. § 1391(a), in that DVC is a corporation that is headquartered and has its principal place of business within this judicial district and regularly conducts business within this judicial district. The acts and conduct complained of herein occurred in substantial part within this judicial district.
FACTUAL BACKGROUND

A. The Parties Negotiate and Execute the BOA

13. This action arises out of a basic ordering agreement ("BOA" or "subcontract") entered into by Therapure and Defendant in May 2013 whereby Therapure was tasked with certain efforts to provide human plasma-derived HuBChE to support clinical and non-clinical studies in support of the development of a FDA licensed HuBChE under Defendant’s prime contract with the DoD. DVC never provided Therapure a copy of DVC’s prime contract with the government and Therapure did not see that prime contract until DVC filed it with this Court on August 9, 2019. This Bioscavenger product is an antidote for OP nerve agent poisoning that sequesters the OP nerve agent in the bloodstream and prevents it from reaching critical target organ systems.

14. The parties originally endeavored in 2011 and 2012 to enter into a contract for the development of the Bioscavenger product, but had not been able to reach agreement on terms and the negotiations ultimately failed.

15. Because Defendant was unable to locate another entity qualified to develop the Bioscavenger product as required by Defendant’s DoD prime contract, Defendant re-engaged with Therapure in an effort to negotiate a contract. On or about March 6, 2012, Defendant issued Request for Proposal ("RFP") No. W911QY-12-R-056 to Therapure to enter into a process improvement, technology transfer and clinical manufacturing agreement in support of Defendant’s prime contract with DoD (No. W911QY-13C-0056) for the manufacture of materials to be used in clinical trials for the approval of HuBChE.

16. On or about July 17, 2012, Therapure responded to RFP No. W911QY-12-R-056 with a proposal that outlined an approach to developing Bioscavenger.

17. Thereafter, Therapure submitted a final Subcontractor’s Proposal on March 23, 2013, which was accepted by DVC. The final Subcontractor’s Proposal specified Therapure’s
assumptions regarding paste. These assumptions included that: DVC would deliver Cohn Fraction IV-4 paste, meeting acceptance criteria outlined by Therapure; DVC-procured Cohn Fraction IV-4 paste would be sourced from FDA-approved collection centers, would meet FDA requirements, and would have undergone testing for pathogens; and would meet certain requirements regarding average yield, failure rate, and purity. Subcontractor’s Proposal at 8-9, assumptions 8, 9 & 14. Moreover, at Milestone 1 the Subcontractor’s Proposal stated that “DVC shall provide Cohn Fraction IV-4 paste containing HuBChE starting material required for all manufacturing activities including technology transfer, process optimization, scale-up, Engineering Runs, process validation, and CGMP lots.” Id. at 13 (emphasis added). Relatedly, DVC’s Statement of Work (“SOW”), at §3.0, required DVC to provide Cohn IV-4 paste in accordance with the parties’ agreed specifications. DVC was aware that a “continual supply is required to support process development, process optimization, process validation, and CGMP manufacturing.” SOW § 1.0.

18. After almost ten months of negotiations regarding the terms of the subcontract agreement, on or about May 15, 2013, Therapure and DVC entered into Basic Ordering Agreement No. S4501108 (“BOA”).

19. The BOA specifically stated that this Subcontractors’ Proposal “shall be incorporated by reference into any resulting” task order, and that the Subcontractor’s Proposal and DVC’s Statement of Work “shall be attached to and form an integral part of” any task order. BOA, § A-1.

20. The BOA requires DVC to reimburse Therapure for certain performance-associated costs to the degree the parties agreed to them up-front through task orders (see, i.e., BOA § B-2, Type of Subcontract). The BOA also establishes procedures for Therapure to submit Requests for Equitable Adjustments (“REAs”) seeking recovery of additional unexpected costs for which it thinks DVC is liable. Specifically, the BOA incorporates by reference FAR §§ 252.243-7001 and
7002, which govern Contract Modifications and Requests for Equitable Adjustment. See BOA, § I, General Subcontract Clauses (incorporating these and other FAR provisions and specifying that the rights and duties specified in those clauses apply to Therapure and DVC, as obligor and obligee under the BOA subcontract, just as they would apply to a contractor and the government in a prime contract). Further, DVC agreed to pay Therapure the amounts specified by Therapure in duly prepared and submitted invoices. Id., § G-2.

21. The BOA also contains a “Quality Assurance” provision, which provides that “[t]he supplies and services being procured shall be developed according to the terms of [the BOA] and the applicable [task order].” Id., § E-3.

22. Additionally, the BOA contains a “Notice of Delay” provision and Invoice Instructions. The Notice of Delay provision states that “[i]n the event that DVC has knowledge that any actual situation may delay or threaten to delay the timely performance of this Subcontract or any of its TOs, DVC shall, within five (5) business days provide written notification to Therapure’s Project Manager of the nature of the anticipated delay.” Id., § F-6. Under the Invoice Instructions, DVC promised to pay Therapure “the amounts specified” by Therapure “in duly prepared and submitted invoices, subject to the resolution of any questions the Contractor may have about the services performed or amounts invoiced.”

23. The BOA identified procedures for the parties to resolve disputes. Under § H-12.4, any disputes that do not involve a decision by the contracting officer with respect to the prime contract “shall be decided by DVC,” unless Therapure notified DVC within thirty days that it disagreed with such decision, in which case Therapure “may proceed to have the dispute settled through appropriate legal action.” Moreover, pursuant to § H-13 of the BOA, DVC agreed to indemnify Therapure for all liabilities, including court costs and attorneys’ fees, “as a result of any breach” by DVC. § H-13.
24. The BOA cites and incorporates by reference multiple FAR and Department of Defense DFAR clauses. See BOA, § I. Conspicuously, however, the BOA does not cite, quote, contain, reference, or incorporate the “Disputes Clause” of Federal Acquisition Regulations, 48 C.F.R. § 52.233-1.

B. Therapure Retains Commercial Rights to the Bioscavenger Product

25. Because Therapure is a small company with limited bandwidth, it is careful in its decision-making regarding the opportunities it pursues. By dedicating its facilities and personnel to a particular project or business effort, Therapure necessarily makes tradeoffs and choices and foregoes certain opportunities in favor of another. For example, through a separately-executed license agreement attached to the BOA, Therapure insisted that Defendant agree that Therapure would retain certain commercial rights to manufacture the developed Bioscavenger product. Therapure calculated the annual revenue opportunity related to these rights as worth approximately $100 million per year. Absent retention of these commercial rights, Therapure would not have entered into the BOA and would not have been willing to commit the required resources to Bioscavenger and necessarily not be able to take advantage of other potential business opportunities during the pendency of performance of the BOA.

26. In determining to execute the BOA, Therapure made a calculated business decision based upon expected resulting revenues to commit its resources to the Bioscavenger Project and thereby necessarily forego other business opportunities.

C. Defendant Breaches the BOA by Failing to Provide Acceptable Supplies or Funding, and by Trying to Impose New Obligations on Therapure to Hide its own Misconduct

27. During the course of contract performance, Therapure encountered a number of delays that resulted, among other things, from Defendant’s failure to comply with the terms of the BOA. Some of the relevant delays were unnecessarily prolonged due to Defendant’s intransigence or general unwillingness to resolve outstanding issues, as well as a lack of knowledge or
understanding of Bioscavenger resulting from DVC’s significant staff turnover. Regardless of whether these delays were manufactured to address Defendant’s own cash flow, it is incontrovertible that there has long been a pattern and practice of Defendant’s failure to satisfy its obligations under the BOA and that Defendant’s failures have been borne by and have resulted in significant financial harm to Therapure.

28. During two particular periods of delay pursuant to which Defendant issued stop work orders, Therapure was obligated to maintain a “stand ready” state and was required to maintain the resources, including personnel, necessary to immediately recommence contract performance when so directed. In each instance, Therapure prepared and submitted an REA for which it was reimbursed by Defendant.

29. During the course of their contractual relationship, Therapure and DVC communicated about multiple REAs, at least four of which DVC submitted to DoD. It was the parties’ pattern, practice, and course of conduct that Therapure would submit REAs to DVC and then DVC would conduct due diligence, evaluating the basis for Therapure’s request. Once those discussions culminated in an agreement regarding Therapure’s REAs, Therapure would sign and execute them and then DVC would submit them to DoD for execution and payment.

30. Moreover, in 2015, it became apparent that the paste provided by Defendant was not viable and that contract performance could not continue absent obtaining a new paste product. Despite that Therapure completed the requisite research to determine the constitution of an appropriate paste and despite that the issue could have been resolved promptly, Defendant caused contract performance to be put on hold for more than nine months pending resolution of the issue. During this time, Therapure was required to maintain requisite personnel, facilities, and other resources at the ready despite not being paid by Defendant. Only after Therapure engaged legal counsel was the issue resolved, albeit temporarily. Therapure was also required to expend
resources in the preparation of an REA in order to recover the costs it had incurred as a result of this first paste-related delay caused by Defendant.

31. Unfortunately and despite the obvious adverse impact on Bioscavenger of deficient paste, Defendant continued to fail to provide an adequate supply of qualified paste. This was despite that Therapure’s proposal described in detail its assumptions regarding the supply of qualified fresh paste and that the BOA incorporates DVC’s acknowledgment of the properties of the paste it was to provide, which was critical to contract performance. Subcontractor’s Proposal at 8-9, assumptions 8, 9 & 14; SOW §§ 1.0, 3.0. By failing to provide the necessary paste, Defendant apparently sought to avoid incurring contract costs and instead tried to foist cost liability on Therapure for failed batches and/or lower yield. The direct results of Defendant’s breach included ongoing and continuing delays to contract performance, lower yield, and a cost impact to Therapure of more than $12 million.

32. At different times throughout the course of contract performance, DoD expressed frustration at the lack of progress. On information and belief, DoD was unaware of Defendant’s continuing failure to provide quality viable paste. Had DoD been aware of Defendant’s ongoing breach of the BOA, it would likely have issued to Defendant a show cause notice for its failure to comply with the obligations of its prime contract.

33. In or around mid-2016, Defendant required Therapure to stop work and subjected Therapure to the first of many lengthy alleged funding delays. These delays impacted Therapure’s ability to: utilize the dedicated program resources; manufacture consecutive batches; and meet planned revenues. During the pendency of these delays and stop work periods, Therapure was required to maintain at its own expense its personnel and other resources in a “stand ready” state. The level of the committed resources varied depending on the status of contract performance at the time of the delay or issuance of the relevant stop work order. During the periods of the relevant
delays, Therapure incurred significant costs for which it was only partially reimbursed after preparing, submitting, and negotiating relevant REAs.

34. In or around mid-2016, after apparently being cited for systemic unrelated regulatory non-compliances, Defendant endeavored to impose on Therapure compliance with the International Traffic in Arms Regulations (“ITAR”). On information and belief, as part of a compliance review mandated by the U.S. Department of State, Defendant realized that it had failed to designate the underlying Bioscavenger technical data package as ITAR-controlled and to so advise Therapure. Scrambling because it did not want the DoD to learn of its failure to properly handle Bioscavenger ITAR-controlled data, Defendant endeavored to impose on Therapure all sorts of new and untenable contract requirements. Ultimately, the issue was resolved because of a conveniently timed change in applicable law, which allowed the parties to conclude properly that no aspect of the BOA was ITAR-controlled. Nevertheless, Defendant’s negligence caused substantial delays, and Therapure was forced to incur significant legal expense, including fees for Canadian employment counsel that were necessitated by Defendant’s initial assertions of requisite changes to Therapure’s work force. Therapure has been required to simply absorb these fees; it has never been reimbursed by Defendant notwithstanding that Defendant’s own errors and noncompliance compelled the expenditure of legal fees. Because Therapure negotiated for post-development commercial rights and wanted to position the company for a possible sale in the future, Therapure would not have executed the BOA in the first place if any aspect of the contract had been ITAR controlled. As it is, Defendant interfered with an agreement that Therapure had to sell the company for $290 million.

35. More recently, and prior to the issuance of the latest stop work order, Defendant once again failed in its contractual obligation to provide viable paste required for successful contract performance. Because it was to its own short-term financial advantage, and without
regard to the longer-term impact on the BOA and in violation of its contractual obligation, Defendant continued to provide aged paste that had become or was close to becoming unsuitable and unstable, as demonstrated by the stability study conducted at Therapure’s expense. Despite objection from Therapure, Defendant insisted that Therapure employ the aged paste because Therapure, not Defendant, would then be required, for example, to absorb the cost of a failed experiment or failed GMP run and any associated delay. Therapure has repeatedly absorbed costs associated with Defendant’s relevant contract non-compliance without reimbursement by Defendant notwithstanding that the costs have resulted from Defendant’s contract breach. Upon information and belief, the delays and other performance issues linked to the poor quality paste provided by Defendant likely contributed to the DoD’s ultimate decision to terminate the Bioscavenger Program.

36. On or about July 13, 2018, Therapure submitted to Defendant an REA for the period of March 2017 to May 2018 for “Total Lost Opportunity Due to Paste Age and Quality and Funding Limitations” in the amount of $12,051,451.16. Defendant still has not reimbursed Therapure for amounts owed and resulting from Defendant’s refusal to provide proper quality paste.

D. Defendant’s Imposition of Costs on Therapure for Remaining in a “Stand-Ready” State for Ten Months and its Failure to Compensate Therapure for those Costs

37. On or about May 24, 2018, DVC issued a stop work order to Therapure. Defendant notified Therapure that due to limited funding from DoD, there was insufficient funding available to continue the contract. The stop work order directed Therapure to suspend all activities being performed under the subcontract for a period of 90 days with a possible extension. At the time of the issuance of the stop work order in May 2018, the contract was fairly close to completing manufacturing for Phase I clinical trials, and Therapure had almost successfully developed a viable Bioscavenger product.
38. On or about May 25, 2018, Defendant directed Therapure during a phone call to remain as-is in a “stand ready” state for re-initiation at any time upon removal of the stop work order by DVC. Therapure thereafter relied on Defendant’s admonition to remain in a “stand ready” state and, in so doing, incurred significant additional costs. Subsequently, during numerous meetings and in a multitude of written and verbal communications, Defendant reiterated and reinforced Therapure’s obligation to maintain a “stand ready” state. To date, Defendant has not reimbursed Therapure for any of these significant costs despite its clear and unequivocal contractual obligation to do so.

39. On or about July 13, 2018, Therapure submitted to Defendant the first of many REAs for costs incurred as a result of the stop work order and the requirement that Therapure maintain necessary contract resources in a “stand ready” state. This first REA was in the amount of $1,776,526.13 and covered resource costs and suite maintenance costs for the month of June 2018.

40. On or about August 1, 2018, Therapure submitted to Defendant an REA for costs incurred as a result of the stop work order and the requirement that Therapure maintain necessary contract resources in a “stand ready” state. This second such REA was in the amount of $1,914,650.22 and covered resource costs, suite maintenance costs, and expired material costs for the month of July 2018.

41. On August 14, 2018, Defendant posed some questions to Therapure relating to its REA. Therapure submitted a comprehensive response on August 21, 2018 and provided additional supporting documentation.

42. On or about August 23, 2018, Defendant issued to Therapure a Stop Work Order Notification Extension Letter, which extended the initial stop work order by 30 days (until
September 24, 2019). This Stop Work Order Notification Extension Letter authorized Therapure to work on certain identified activities.

43. On or about August 30, 2018, Therapure submitted to Defendant an REA for costs incurred as a result of the stop work order and the requirement that Therapure maintain necessary contract resources in a “stand ready” state. This REA was in the amount of $1,914,650.22 and covered resource costs, suite maintenance costs, and expired material costs for the month of August 2018.

44. On or about September 25, 2018, Defendant issued Therapure a second Stop Work Order Extension Letter, which extended the stop work order by 120 days (until January 25, 2019). Therapure could continue to work on the activities previously authorized in the second extension letter.

45. During September 2018, the parties met to discuss the status of contract performance and payment of the REAs. The parties discussed extensively Therapure’s REAs and the level of resources being maintained for the “stand ready” state. Throughout the pendency of the stop work period, there were frequent ongoing verbal and written communications between the parties during which the parties discussed the substance of the REAs and Therapure reiterated the need for payment. At no point during that meeting did Defendant object to Therapure’s determination of “stand ready” costs, or that Therapure was claiming personnel costs associated with sixty-one FTEs.

46. On or about October 1, 2018, Therapure submitted to Defendant a fourth REA for costs incurred as a result of the stop work order and the requirement that Therapure maintain necessary contract resources in a “stand ready” state. This REA was in the amount of $1,701,416.98 and covered resource costs, suite maintenance costs, and legal services costs for the month of September 2018.
47. On or about October 4, 2018, Defendant agreed to submit Therapure’s REAs to the DoD. It remains unclear why Defendant delayed so long before forwarding to DoD Therapure’s REAs, particularly given all of the relevant communications between the parties and Defendant’s knowledge of the financial hardship to Therapure of remaining in a “stand ready” state for such an extended period of time without receiving payment.

48. On or about October 16, 2018, Defendant sent a letter to Therapure requesting that Therapure provide additional documentation to substantiate the costs identified in the REAs. On or about October 29, 2018, Therapure provided to Defendant all of the requested supporting documentation. Therapure also thereafter continued to timely provide other documentation requested by Defendant.

49. On or about November 5, 2018, Therapure submitted an invoice proposal to Defendant for $6,401,836.77 in response to Defendant’s request that Therapure provide a proposal outlining the costs associated with maintaining the Resources and Suites in a “stand ready” state from the period October 2018 until January 25, 2019.

50. During November 2018, in response to Defendant’s requests, Therapure continued to provide timely documentation supporting the REA costs arising out of the requirement that Therapure maintain a “stand ready” state during the pendency of the stop work order.

51. On or about January 2, 2019 Therapure submitted another REA for costs incurred as a result of the stop work order and the requirement that Therapure maintain necessary contract resources in a “stand ready” state. This REA was for costs incurred in October 2018 and November 2018 and was in the amount of $3,364,464.36. It covered relevant resource costs, suite maintenance costs, legal services costs, and expired material costs.
52. In or around December 2018, Therapure issued an invoice to Defendant for $347,561.60 for 68 units of MS 9.1b. Therapure received payment approximately forty-five days later.

53. On or about January 8, 2019, Therapure issued an invoice to Defendant for $1,110,100.41 for costs relating to the performance of three units of MS 1.7 and one-hundred and ninety-two units of MS 9.1b under the BOA. Therapure received payment approximately forty-five days later.

54. On or about January 30, 2019, Defendant issued a third Stop Work Extension Letter, which extended the stop work order by 30 days (from January 25, 2019 until February 25, 2019).

55. On or about February 11, 2019, Therapure submitted to Defendant an REA for costs incurred as a result of the stop work order and the requirement that Therapure maintain necessary contract resources in a “stand ready” state. This REA covered the time periods of December 2018 and January 2019 and was in the amount of $2,676,143.30. It included and sought to recover resource costs, suite maintenance costs, and legal services costs.

56. As with the prior REAs submitted by DVC and consistent with the parties’ course of conduct, Therapure’s Chief Financial Officer was waiting to sign these eight REAs until after receiving confirmation that DVC agreed to the REAs. DVC refused to support Therapure’s eight REAs pertaining to the costs incurred while in DVC’s mandated “stand ready” state, however.

57. Each of these eight REAs contained a certification, however, attributed to David Long, Therapure’s Chief Financial Officer. That certification stated: “Pursuant to DFARS 252.243-7002, I certify that the request is made in good faith, and that the supporting data are accurate and complete to the best of my knowledge and belief.”
58. In the course of discussions with Therapure regarding these eight REAs, DVC never objected to Therapure’s failure to affix a signature. DVC also never cited the lack of a signature as a purported reason for DVC delaying their submission to the DoD. Indeed, the practice of Therapure submitting unsigned REAs was consistent with the parties’ pattern and practice for prior REAs. In fact, DVC ultimately partially paid one of the eight REAs at issue, even though that one too did not contain a signature.

59. DVC stated in its August 9, 2019 filing with this Court that, “[h]ad Therapure properly certified its REAs or termination settlement proposal to DVC, DVC could have and would have sponsored those claims.” This was the first time that DVC made such a statement. Nevertheless, Therapure has in fact “properly certified” the REAs at issue in this lawsuit, and therefore DVC should be compelled to sponsor Therapure’s DVC’s without further delay.

60. During the entirety of the stop work period, Therapure repeatedly requested payment from Defendant, underscoring that maintenance of the “stand ready” state had put Therapure in an untenable financial position. As of February 2019, Therapure had not received any money in response to the REAs and despite its continuing to provide all requested supporting information to Defendant.

61. By letter dated March 12, 2019, Therapure demanded payment from Defendant in the amount of $13,381,762.39 for outstanding amounts due as set forth in the eight REAs submitted for costs incurred as a result of the stop work order and the requirement that Therapure maintain necessary contract resources in a “stand ready” state. This letter specifically stated that the letter constituted “notice to DVC that, absent adjudication and payment of all outstanding REAs and the achievement of some understanding between the parties regarding a mutually agreeable path forward, [Therapure] will take immediate action to vindicate its rights under the BOA.”
On March 22, 2019, Therapure, DVC, and the DoD conducted a conference call to discuss Therapure’s REAs. At no point during this call did DVC object to Therapure’s REAs on the basis of their lack of signature, and it was clear during the discussion that DVC had in fact provided at least some of Therapure’s REAs and supporting documents to the DoD.

**E. Defendant Terminates the BOA, Fails to Reimburse Therapure for 10 Months of “Stand Ready” Costs, and Interferes with Therapure’s Commercial Rights**

On or about March 13, 2019, Defendant issued to Therapure a Notice of Termination for Convenience of the BOA. In the termination notice, Defendant demanded that Therapure deliver certain BuChE and other products developed pursuant to contract performance pursuant to FAR 52.249-2.

Subsequent to the issuance of the termination notice, the parties participated in several meetings and exchanged numerous verbal and written communications. During this period, Therapure continued to provide documents in support of its REAs, as requested by Defendant. This included personnel information and various types of auditable cost data. During this period, both DoD and Defendant promised Therapure that Defendant would begin payment of some of the costs identified in the REAs. This promise, which took nearly four months to fulfill and which resulted in a minor payment of only $126,882.27 in June 2019, has done nothing to alleviate the severe financial harm that has resulted from Defendant’s requirement that Therapure maintain necessary contract resources in a “stand ready” state for ten months without any meaningful payment.

On or about May 1, 2019, Therapure submitted to Defendant an Alternative Analysis REA for the period of May 2018 through January 2019, in the amount of $13,059,944.63 for costs associated with maintenance/facility costs, current loss recovery, and legal fees associated with the stop work and the associated requirement that Therapure remain in a “stand ready” state. Therapure also provided documentation and substantiation for all of its costs, despite that much of
the back-up data had been provided previously. In so doing, Therapure did not concede any shortcomings with the previous REAs for costs incurred as a result of the stop work order and the requirement that Therapure maintain necessary contract resources in a “stand ready” state. It performed this alternate analysis, which utilized a methodology that had been accepted previously by Defendant for other unrelated REAs, in order to demonstrate the legitimacy of Therapure’s original eight REAs. Employing the previously approved methodology, Therapure’s cost calculation still amounted to more than $13 million. Despite that Therapure’s Alternative Analysis REA substantiated its original REAs, Defendant has yet to make a single payment to Therapure for costs incurred as a result of maintaining the “stand ready” state during the pendency of the stop work order.

66. On May 15, 2019, after reviewing the inventory of items in its possession, Defendant advised Therapure which items needed to be produced to DVC pursuant to FAR 52.249-2. At Defendant’s instruction and convenience, all requisite items were delivered on or about May 30, 2019, well in advance of the deadlines set forth in FAR 52.249-2. Given the status of contract performance and how close Therapure was to completion, Defendant may potentially develop a viable Bioscavenger product with the delivered items further depriving Therapure of associated revenues, including those related to the reserved commercial rights.

67. On or about May 27, 2019, Therapure submitted to Defendant a Termination Proposal requesting additional compensation in the amount of $4,660,754.31, which included allowable and allocable termination costs associated with its subcontractor close-out costs, material destruction, equipment removal, transportation, storage, facility repairs, idle facilities, other continuing costs, accounting costs, legal costs, and clerical costs. Therapure provided documentation and substantiation for all of these costs.
68. To date, despite its clear contractual obligation to do so, Defendant has not reimbursed Therapure for the costs identified in Therapure’s Termination Proposal for any of the costs identified in the REAs incurred as a result of the stop work order and the requirement that Therapure maintain necessary contract resources in a “stand ready” state.

69. Defendant breached the BOA in multiple respects, causing Therapure significant damages. First, Defendant failed to provide Therapure adequate paste, and subjected Therapure to unjustified funding limitations, causing Therapure more than $12 million in damages and lost revenue opportunity related to the commercial rights to the Bioscavenger product of not less than $100 million. Second, Defendant’s own incompetence as it relates to the applicability of ITAR caused Therapure to incur thousands of dollars in legal and other fees. Third, Defendant’s imposition of requirements on and its ultimate scuttling of the sale of the business unit resulted in a loss of more than $290 million. Fourth, Defendant directed Therapure to remain in a “stand ready” state during pendency of a 10-month stop work order, resulting in more than $13 million of additional damages. Furthermore, once Defendant terminated the contract, Therapure documented an additional over $4 million in termination costs as well, which Defendant has likewise failed to pay. These damages do not include the profound harm to Therapure or the significant impact that Defendant’s failure to pay has had on the value of Therapure’s business.

70. Alternatively, if the BOA itself did not explicitly require Defendant to compensate Therapure for costs incurred during a “stand ready” state, then Defendant is liable to Therapure under the equitable doctrines of quantum meruit or unjust enrichment for failing to do so. Defendant has also been unjustly enriched because Therapure developed the Bioscavenger technology virtually to the point of commercial viability just before Defendant cancelled the BOA and took possession of the fruits of Therapure’s efforts.
COUNT I  
(Breach of Contract)

71. Paragraphs 1-70 are incorporated by reference herein.

72. Therapure has met all of its obligations under the BOA.

73. Defendant has failed to meet its obligations under the BOA, including its obligations to: (a) provide Therapure adequate paste as set forth in the Subcontractor’s Proposal, Section 3.0 of the SOW, and BOA § E-3; (b) provide adequate written notification to Therapure within five business days regarding its knowledge of delays, pursuant to the BOA § F-6; (c) reimburse Therapure for significant costs incurred during the ten month period of the stop work order during which Therapure remained at Defendant’s direction in a “stand ready” state for re-initiation at any time upon Defendant’s withdrawal of the stop work order, pursuant to its obligations with respect to REAs under FAR §§ 252.243-7001 and 7002 and pursuant to the BOA §§ F-6; G-2; and (d) compensate Therapure for termination costs which Therapure identified for Defendant.

74. Beginning in 2015, Defendant failed to provide an adequate supply of qualified paste to Therapure. The direct results of Defendant’s breach included ongoing and continuing delays to contract performance, lower yield, and significant cost impact to Therapure. Moreover, in mid-2016, Defendant subjected Therapure to many lengthy alleged funding delays which impacted Therapure’s ability to utilize the dedicated program resources; to manufacture consecutive batches; and to meet planned revenues.

75. On or about May 24, 2018, DVC issued a stop work order to Therapure. The next day, Defendant directed Therapure during a phone call to remain as-is in a “stand ready” state for re-initiation at any time upon removal of the stop work order by DVC. Therapure relied on this directive, which Defendant reiterated and reinforced multiple times since it first issued that directive, and as a result incurred significant additional costs. Defendant has not reimbursed
Therapure for any of these significant costs despite its clear and unequivocal contractual obligation to do so and despite Therapure having clearly identified, substantiated, and documented these costs at Defendant’s request.

76. During May 2019, after Defendant terminated the BOA, Therapure submitted a Termination Proposal requesting compensation for allowable and allocable termination costs associated with its close-out costs, material destruction, equipment removal, transportation, storage, facility repairs, idle facilities, other continuing costs, accounting costs, legal costs, and clerical costs. Therapure provided documentation and substantiation for all of these costs. Defendant has not reimbursed Therapure for any of them.

77. Defendants’ failure to reimburse Therapure for the costs it incurred as a result of the stop work orders and its ultimate termination of the BOA, as well as its failure to provide Therapure either with paste that met the age and quality requirements or with adequate funding, are also breaches of the implied contractual covenant of good faith and fair dealing. DVC, among other things, acted in bad faith, unreasonably, and unfairly when it directed Therapure to remain in a “stand ready” state but failed to reimburse Therapure the millions of dollars in costs for doing so, even when Therapure documented and substantiated those costs. DVC strung Therapure along for more than a year, purporting to engage in discussions with both Therapure and DoD regarding Therapure’s REAs and thus leading Therapure to believe DVC would support Therapure’s REAs and compensate Therapure, while at all times having no intention to actually pay Therapure and instead unreasonably demanding documentation that it knew did not exist and had no reason to exist. By this conduct DVC exhibited lack of faithfulness to the agreed common purpose of the parties’ contract and failed to act in accordance with Therapure’s justified expectations. DVC also acted in bad faith and unfairly when, without justification, it failed to provide Therapure with paste that met age and quality requirements, and when it failed and refused to provide Therapure with
adequate funding. Likewise, DVC violated the covenant of good faith and fair dealing when, because it did not want DoD to learn of its failure to properly handle Bioscavenger ITAR-controlled data, it sought to impose on Therapure new and untenable contract requirements which the parties never bargained for when they entered the BOA. This forced Therapure to incur significant legal expenses which Defendant never reimbursed. DVC’s actions were arbitrary and unreasonable.

78. Defendant has breached its obligations to provide reimbursement to Therapure of at least $13,381,762.39 in costs incurred as a result of the stop work orders issued by Defendant pursuant to BOA No. S4501108 and as detailed in the eight REAs submitted by Therapure in 2018 and 2019, as well as at least $12,051,451.16 for “Total Lost Opportunity Due to Paste Age and Quality and Funding Limitations.” Defendant has also breached its obligation to reimburse Therapure for at least $4,660,754.31 in termination costs.

79. As a direct and proximate cause of these breaches of the BOA, Therapure has incurred significant costs and disruption of its business and has suffered damages in an amount to be proven at trial, but which is not less than $30 million. Therapure has also incurred costs and attorneys’ fees as a result of DVC’s breaches of the BOA, for which DVC is liable pursuant to § H-13 of the BOA.

COUNT II
(Quantum Meruit)

80. Paragraphs 1-79 are incorporated by reference herein.

81. To the extent that the BOA does not expressly cover Therapure’s claims, Therapure asserts a claim under the equitable doctrine of quantum meruit.

82. In particular, and as alleged above, beginning in May 2018 and until DoD terminated DVC’s prime contract in March 2019, Defendant issued a stop work order, which it
renewed multiple times. Simultaneously, Defendant directed Therapure to remain in a “stand ready” state for re-initiation of contract performance at any time.

83. When DVC specifically directed Therapure to remain in a “stand ready” state, Therapure thereafter routinely notified DVC of the millions of dollars in costs it was incurring as a result. Therapure then both requested, and made clear that under the circumstances it reasonably expected, reimbursement.

84. When Therapure remained in a “stand ready” state, it rendered a valuable service to Defendant. This posture enabled Therapure to recommence contract performance if, at any time, Defendant had removed or repudiated the stop work order. Therapure’s full compliance with Defendant’s directive also allowed Defendant to ensure DoD that it was ready to fully perform its obligations to the government under Defendant’s contract with DoD.

85. DVC never corrected or contradicted Therapure’s reasonable expectation of payment. Never once before it terminated the BOA did DVC direct Therapure to halt or wind down its “stand ready” state, nor did it direct Therapure not to incur the costs associated with that “stand ready” state. On the contrary, on October 16, 2018, Defendant sent a letter to Therapure requesting that Therapure provide additional documentation to substantiate the costs identified in its REAs. That same month, Therapure provided the requested supporting documentation, and thereafter continued to timely provide documentation for future REAs. Defendant’s request for documentation directly implied that DVC would reimburse Therapure for these costs if it could document them.

86. Defendant accepted the benefit of Therapure remaining in a “stand ready” state, but has steadfastly refused to reimburse Defendant for the costs associated therewith and thereby received services for which Defendant has not provided payment.
87. Pursuant to the equitable doctrine of quantum meruit, Therapure is entitled to recover from Defendant an amount equal to the costs it incurred in order to remain in a “stand ready” state, but for which Defendant has not paid, in an amount to be proven at trial but which is not less than $13,000,000.

**COUNT III**

*(Unjust Enrichment – Therapure’s Stand Ready State)*

88. Paragraphs 1-87 are incorporated by reference herein.

89. To the extent that the BOA does not expressly cover Therapure’s claims, Therapure asserts a claim for unjust enrichment.

90. In particular, and as alleged above, Defendant requested that Therapure remain in a “stand ready” state during the pendency of stop work orders. Therapure then invested significant sums – over $13 million – in order to remain in that “stand ready” state.

91. Moreover, as alleged above, when it agreed to remain in a “stand ready” state during the pendency of stop work orders, Therapure necessarily was required to forego other business opportunities because its facilities and personnel remained in a “stand ready” state. Therapure suffered damages in the form of lost revenue that can never be recouped as a result of this reliance.

92. Defendant knew that Therapure was incurring multiple millions of dollars in costs each month that it remained in a “stand ready” state. Therapure submitted to Defendant a total of at least eight REAs during 2018 and 2019 identifying these costs. Therapure undertook these expenses at Defendant’s direction and for Defendant’s benefit. Defendant has never compensated Therapure for those expenses.

93. As a direct and proximate result of Defendant’s acts as alleged above, Therapure has been damaged in an amount to be proven at trial but which exceeds $13,000,000.
COUNT IV
(Unjust Enrichment – Commercial Rights in Bioscavenger Technology)

94. Paragraphs 1-93 are incorporated by reference herein.

95. Defendant has now taken possession of all of the Bioscavenger technology that Therapure developed pursuant to the BOA. At the time Defendant terminated the contract, Therapure was very close to upgrading the Bioscavenger technology it had developed into a marketable product. Indeed, absent Defendant’s failure to provide adequate paste, its multiple funding delays, and its stop work order, Therapure would have developed a marketable product long before Defendant terminated the contract. In any case, Defendant now may, with minimal effort, turn this technology into a marketable product and derive all of the commercial benefits that Therapure bargained for under the BOA. Defendant thus stands to reap significant rewards from Therapure’s hard work.

96. Defendant is well aware of the benefit this represents. When Therapure entered into the BOA, it insisted on the retention of certain commercial rights so that it could manufacture and sell commercially the Bioscavenger product once developed. Absent retention of these rights, Therapure never would have executed the BOA.

97. As alleged above, Therapure calculated the annual revenue opportunity related to these rights as worth approximately $100 million per year.

98. In addition to the lost opportunity of new business, as a result of the contract termination six years into performance and within months of achieving completion of the Bioscavenger product, Defendant has denied Therapure the commercial rights associated with future sales, rights that without which it would not have entered into the contract in the first place. Therapure relied on Defendant’s representations that it would retain these rights and has suffered significant damage and lost revenue as a result.
99. As a direct and proximate result of Defendant’s acts as alleged above, Defendant damaged Therapure in an amount to be proven at trial but which is not less than $100 million.

REQUEST FOR RELIEF

WHEREFORE, Therapure respectfully requests that this Court enter judgment in its favor and against Defendant and award Therapure the following relief:

1. An entry of judgment in favor of Therapure and against Defendant on all claims for relief;

2. An order awarding Therapure damages in an amount to be determined at trial, but amounting to no less than $100,000,000 exclusive of interest and costs.

3. An award of pre-judgment interest, attorney’s fees, costs, and post-judgment interest in favor of Therapure and against Defendant; and

4. An award of any further legal and equitable relief that the Court deems just and proper.

JURY DEMAND

Therapure requests a trial by jury on all issues so triable.

Dated: August 23, 2019

Respectfully submitted,

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