

**IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE**

In re:)	
)	
KALOBIOUS PHARMACEUTICALS, INC.,)	Chapter 11
)	
Reorganized Debtor.)	Case No. 15-12628 (LSS)
)	
<hr/> KALOBIOUS PHARMACEUTICALS, INC.,)	
)	
Plaintiff,)	
v.)	
SAVANT NEGLECTED DISEASES, LLC,)	Adv. Proc. No. 17-50898 (LSS)
)	
Defendant.)	
)	
<hr/>)	

**KALOBIOUS PHARMACEUTICALS, INC.’S
BRIEF IN SUPPORT OF ITS MOTION FOR A
TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION**

Dated: August 4, 2017
Wilmington, Delaware

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Pursuant to United States Bankruptcy Code § 105(a), Rule 65 of the Federal Rules of Civil Procedure, and Rule 7065 of the Federal Rules of Bankruptcy Procedure, Plaintiff KaloBios Pharmaceuticals, Inc. (“KaloBios”) hereby submits this memorandum of law in support of a motion for a temporary restraining order and preliminary injunction preventing Defendant Savant Neglected Diseases, LLC (“Savant”) from: taking any actions in furtherance of any alleged default; issuing any default notices; exercising remedies relating to any alleged default; attempting to collect on any of KaloBios’ Collateral; entering or visiting KaloBios’ premises without written permission from KaloBios; or conducting any sale of the Collateral.

PRELIMINARY STATEMENT

Emergency relief is necessary because Savant has issued a notice of foreclosure and sale to KaloBios, with the aim of destroying KaloBios and stealing its assets. In June 2016, when KaloBios emerged from bankruptcy in this Court, it executed an agreement with Savant to acquire assets associated with the manufacture, development and commercialization of benznidazole for the treatment of Chagas disease, a parasitic infection. Savant had represented that the assets it was selling were all that was needed to develop benznidazole for regulatory approval. Savant also agreed to assume responsibility for costs incurred in the development effort that exceeded the parties’ agreed-upon \$8 million joint development budget by more than \$500,000. KaloBios has made great strides over the last year in developing benznidazole for regulatory approval, in spite of the fact that Savant’s representations about the adequacy of its assets were not accurate. In doing so, KaloBios has incurred costs that Savant is obligated by contract to pay, an obligation Savant has refused to honor. Instead, Savant has unleashed a campaign of harassment against KaloBios, manufacturing defaults and threatening to seize KaloBios’ assets. Late on the night of August 2, 2017, Savant made good on its threats by

issuing a foreclosure notice, stating that, on August 9, 2017, KaloBios is to assemble and present to Savant for seizure the materials, contracts, inventory, records and information necessary to develop and commercialize benznidazole, and informing KaloBios that it intends to auction those assets at a public auction on September 1, 2017.

The factors governing temporary restraining orders and preliminary injunctions weigh considerably in favor of granting this motion.

KaloBios has demonstrated that it will likely succeed on the merits of its breach of contract and declaratory judgment claims. Savant has clearly breached its cost overage payment obligations to KaloBios, as provided in the parties' contract. The contract expressly authorizes KaloBios to credit any payments due Savant against cost overage amounts owed by Savant to KaloBios. Savant has also breached other provisions of the parties' contract including its failure to engage in dispute resolution discussions and its breach of a representation and warranty regarding the necessity, sufficiency and adequacy of the assets it sold to KaloBios.

Savant's demand for immediate possession of KaloBios' Collateral and impending foreclosure and sale also pose demonstrable irreparable harm to KaloBios. Benznidazole is far and away KaloBios' most significant product. If Savant guts KaloBios of the assets it is using to pursue regulatory approval for that drug, KaloBios will no longer be able to develop, manufacture and commercialize the drug and will be out of business.

The balance of harms also tips in KaloBios' favor. Unlike Savant, which has been leveling bad faith threats at KaloBios to put it in default, KaloBios has sought to focus the dispute on the merits of the parties' claims. Thus, at the very same time that KaloBios instituted this action, it made a motion, pursuant to Rule 67 of the Delaware Superior Court's Rules of Civil Procedure, to deposit disputed payments with the Court pending the outcome of this

litigation. The very money that Savant is complaining about would be safeguarded pending resolution of the case were the Rule 67 motion to be granted. On the other hand, if Savant is allowed to foreclose and sell KaloBios' assets, KaloBios will be finished as a business, its employees will be out of work, and affordable access to a promising new medication will be limited.

Finally, this case presents a stark example of the need for emergency relief to protect the public interest. Benznidazole is a very promising treatment for Chagas. Approximately one third of the individuals suffering from that disease develop severe cardiovascular complications. Currently, there is no approved drug for the treatment of that disease in the United States. The FDA has already approved two stages in KaloBios' efforts to obtain regulatory approval of benznidazole. The FDA has indicated that KaloBios is on the way toward obtaining regulatory approval for the drug next year. If Savant were to seize and sell the Collateral and prevent KaloBios from benznidazole development efforts, the approval process would most certainly be delayed and there is no indication that any new owner would complete the application process in any event.

In short, Savant's notice of foreclosure and sale poses serious threats to KaloBios and the efforts to obtain regulatory approval for benznidazole as a treatment for Chagas disease. Accordingly, KaloBios respectfully requests that the Court issue a temporary restraining order and preliminary injunction preventing Savant from continuing to issue default notices against KaloBios, and from taking any actions in furtherance of any alleged default, including possessing, foreclosing and selling the Collateral as it claims it states it intends to do in its August 2, 2017 notice of foreclosure and sale.

STATEMENT OF FACTS

A. KaloBios' Efforts at Developing Benznidazole

KaloBios is a biopharmaceutical company focused on developing medicines for patients with neglected and rare diseases.¹ Durrant Decl. ¶ 2. Over the past year, KaloBios has been working diligently to develop, manufacture and commercialize two drugs, benznidazole and lenzilumab. *Id.* Benznidazole is the recognized gold standard treatment for Chagas disease, a rare parasitic illness that can lead to severe cardiovascular, gastrointestinal and neurological problems. *Id.* Lenzilumab aims to be useful in treating multiple rare diseases including various forms of pediatric and adult leukemias. Benznidazole is the most advanced of KaloBios' products and could be approved for marketing in the United States next year. *Id.*

Benznidazole is a molecular antiprozoal compound. *Id.* ¶ 3. It has undergone clinical trials and studies, showing its efficacy at treating Chagas. The World Health Organization ("WHO"), the Center for Disease Control ("CDC") and the United States Federal Drug Administration ("FDA") have all designated Chagas as a neglected tropical disease. *Id.* Currently, there are no treatments for Chagas that have been approved in the United States. *Id.* ¶ 4. The FDA has indicated that benznidazole may qualify for priority review and potentially other FDA regulatory incentives. *Id.* Recently, the FDA designated Orphan Drug status to benznidazole, based on an application by KaloBios. *Id.*

B. Savant Induces KaloBios to Collaborate on Benznidazole Development

In the Fall of 2015, the now-notorious Martin Shkreli had taken control of KaloBios and appointed himself its CEO. *Id.* ¶ 5. At the time, Savant owned certain rights to manufacture,

¹ The facts cited are based on the Declaration of Dr. Cameron Durrant ("Durrant Decl.") with attached exhibits and the Declaration of Daniel D. Edelman ("Edelman Decl.") with attached Exhibits. A fuller description of the facts at issue in this case can be found in the Complaint, which is attached as Exhibit 1 to the Edelman Decl.

develop and commercialize benznidazole. *Id.* In December 2015, Shkreli executed a non-binding letter of intent with Stephen Hurst (“Hurst”), the CEO of Savant, regarding the development of benznidazole. *Id.* ¶ 6. This resulted in a non-refundable deposit being paid to Savant. *Id.*

Although the terms of the non-binding letter of intent were confidential, Shkreli publicly announced the potential transaction. He even boasted that he would inflate the price of benznidazole and potentially, together with Savant, make millions of dollars in profits once the drug was marketed to vulnerable populations.² *Id.* ¶ 7.

Shortly thereafter, in December, 2015, Shkreli was arrested and terminated as KaloBios’ CEO. *Id.* ¶ 8. After Shkreli’s indictment, KaloBios filed for bankruptcy, and Savant was left with no partner to develop benznidazole and no funding. *Id.* ¶ 10. It therefore sought to induce a group of new investors to fund KaloBios in developing benznidazole. *Id.* Savant and Hurst made representations to KaloBios and the potential investors concerning the status, quality and extent of testing and development of benznidazole, suggesting that the drug was near the final stages of obtaining approval from the FDA. *Id.* ¶ 11. Savant painted a picture of a drug program that was quite advanced. *Id.* Based on these representations, KaloBios agreed to fund approximately \$8 million toward the final stages for obtaining regulatory approval for benznidazole. *Id.* ¶ 12. KaloBios’ obligation was capped at this amount, and if the costs were higher, the additional costs shifted to Savant. *Id.*

² The Shkreli-Hurst partnership remained intact even after Shkreli was arrested at the end of 2015. In August 2016, Dorsey & Whitney issued a press release, announcing that Shkreli and Hurst had been invited to appear at a September 2016 symposium to discuss their efforts at forging a deal as to benznidazole. The press release stated: “Shkreli and Hurst will discuss how the KaloBios/Savant deal came together, their observations of KaloBios’ bankruptcy process and the impact of the public eye on pricing practices by life sciences companies.” See <http://www.businesswire.com/news/home/20160815006183/en/Dorsey-4D-Symposium-Adds-Martin-Shkreli-Steve> (last accessed on August 4, 2017).

C. Savant's Breach of the MDC's Cost Overage Obligations

On June 30, 2016, the day that KaloBios emerged from bankruptcy, KaloBios and Savant executed an "Agreement for the Manufacture, Development and Commercialization of Benznidazole for Human Use" (the "MDC"). Durrant Decl. *Id.* ¶ 15. Pursuant to the MDC and Savant's representations, KaloBios acquired certain assets (the "Acquired Assets"). *Id.* ¶ 16. In Section 8.7(b) of the MDC, Savant explicitly warranted and represented that "the Acquired Assets constitute all of the assets . . . necessary to the Exploitation" (including development) of benznidazole. *Id.*

In Section 4.3, the MDC defined the costs incurred as part of the parties' "Joint Development Plan" as the "Joint Development Program Costs." *Id.* ¶ 17. Section 4.3(b) provided that "KaloBios shall be responsible for funding" the Joint Development Program Costs, but "KaloBios shall have no responsibility to make any payment or reimbursement" for "costs or expenses that are not specified in, or exceed the amount set forth in, the budget." *Id.* Section 3.3 of the MDC provides for KaloBios to make "Milestone Payments" to Savant upon the occurrence of certain events in the regulatory approval process for benznidazole. *Id.* ¶ 18.

Section 4.8 of the MDC, however, authorizes cost shifting back to Savant once the Joint Development Program Costs exceed a specified budget set out in the Joint Development Plan. *Id.* ¶ 19. Specifically, Section 4.8 provides that, where the Joint Development Program Costs "result in expenses that exceed" the budget by more than a certain amount, Savant must assume the payment responsibilities. *Id.* Savant is required to pay KaloBios the cost overage amounts within thirty days. *Id.* But if Savant defaults on this payment obligation, KaloBios can credit the cost overage amounts owed by Savant against any payments KaloBios owes Savant, including any Milestone Payments that are due. *Id.* As Section 4.8 expressly states: Savant's

“failure to make such [cash] payment within thirty (30) days [is] deemed an election by [Savant] to allow the credit described in subsection (i) above” under which “KaloBios [is] to credit the payment of any such costs and expenses above Five Hundred Thousand Dollars (\$500,000) incurred by KaloBios . . . against any future payments to be made by KaloBios to [Savant] under this Agreement on a Dollar-for-Dollar basis.” *Id.*

During the time since the MDC was executed, KaloBios has learned that Savant’s representations concerning the adequacy of the Acquired Assets were untrue. *Id.* ¶ 21. Far more work was needed to prepare benznidazole for development and approval, requiring KaloBios to incur expenditures far exceeding the budgeted Joint Development Program Costs. *Id.* For example, KaloBios had to analyze and verify entirely new datasets, plan for and implement a comprehensive bioavailability study and rework the entire manufacturing process so as to ensure compliance with applicable federal regulations. *Id.* It also had to conduct extensive additional non-clinical studies mandated by the FDA. *Id.* KaloBios estimates that the total cost will now be approximately \$14 million, exceeding the total budget by approximately \$6 million. *Id.* ¶ 22.

Savant has refused to pay KaloBios cost overages incurred during the post-confirmation period that became due under Section 4.8 of the MDC. *Id.* ¶ 23. Instead, Savant started repeatedly threatening to hold KaloBios in default if it did not pay a First Milestone Payment while refusing even to acknowledge Savant’s obligation to pay the cost overage to KaloBios. *Id.* By the end of May 2017, Savant owed KaloBios \$2.7 million in cost overages. Savant, however, made clear it would not pay this obligation. *Id.* ¶ 24. KaloBios, therefore, credited a \$1 million First Milestone Payment due to Savant against the outstanding cost overages. *Id.* At that time, Savant made clear that it was refusing to pay the balance of \$1.7 million. Likewise, by the end of June 2017, Savant’s total cost overage responsibilities had risen to \$3.4 million, which it was

still refusing to pay. *Id.* ¶¶ 25-27. At the same time, in early July, a second milestone event had occurred such that there was a Second Milestone Payment due to Savant. *Id.* ¶ 25. This meant the total milestone payments amounted to \$2 million, with Savant being responsible to pay the balance of \$1.4 million, which it still refused to do. *Id.* ¶¶ 25-27.

D. Savant’s Breach of the MDC’s Dispute Resolution Obligations

The MDC also contains a dispute resolution provision in Section 14.2. Durrant Decl. ¶ 20. That provision states that: “in the event of a dispute, claim or controversy between the Parties arising under the or relating to [the MDC] or the breach, termination, enforcement, interpretation or validity thereof . . . the Party shall refer such Dispute to their respective Executive Officers, and such Executive Officers shall attempt in good faith to resolve such Dispute . . . within thirty days.” *Id.* Similarly, Section 6.1(e) provides that “disputes relating to . . . interpretation of this Agreement shall not be subject to any Party’s final decision-making authority and may be escalated pursuant to Section 14.2.” *Id.*

KaloBios and Durrant have made—and continue to make—efforts to engage Savant in the good faith dispute resolution discussions, but Savant has rebuffed all such attempts and continued to threaten KaloBios with foreclosure based on the first \$1 million Milestone Payment. *Id.* ¶¶ 30-45. Stephen Hurst even refused to hold a face-to-face meeting as suggested by KaloBios to try to resolve these issues, choosing instead to reiterate his threat of holding KaloBios in default if it did not pay the Milestone Payment by close of business on July 10, 2017. *Id.* ¶¶ 39-45.

E. KaloBios’ State Court Action and the Rule 67 Motion

Confronted with Savant’s impending default threat and its refusal to abide by the Section 14.2 dispute resolution process, KaloBios filed this Action in the Delaware Superior Court’s

Complex Commercial Litigation Division on the afternoon of July 10, 2017. KaloBios' complaint alleges four state law causes of action for breach of contract and declaratory judgment. Edelman Decl. Ex. ¶ 3; Ex. 1. These claims specifically pertain to Savant's breaches of its MDC Section 4.8 cost overage obligations and its Section 8.7(b) representation and warranty about the adequacy of the benzimidazole development efforts as well as Savant's failure to abide by the Section 14.2 dispute resolution obligations.

Given the dispute between the parties regarding the First Milestone Payment and the irreparable harm that might ensue from Savant's threatened default notice, KaloBios, simultaneously with filing its complaint, filed a motion with the Delaware Superior Court pursuant to Rule 67 of the Rules of Civil Procedure for the Superior Court of the State of Delaware for an order permitting KaloBios to deposit the Milestone Payment with the Court.³ *Id.* ¶ 4; Ex. 2. KaloBios also sought "expedited treatment" of this pending motion, stating that "KaloBios respectfully submits that the pending Rule 67 motion should be decided promptly given Savant's assertion that it intends to issue a default notice." *Id.* ¶ 5; Ex. 3. The case was assigned to Delaware Superior Court Judge Paul R. Wallace, who decided to hear the motion promptly, setting a hearing on the Rule 67 motion for July 24, 2017, with opposition papers to be filed by July 18. *Id.* ¶ 6; Ex. 4.

Savant's counsel acknowledged and agreed to the expedited Delaware Superior Court schedule on July 12, 2017. *Id.* ¶¶ 6-7; Ex. 4. A few hours later, however, Savant's counsel filed a Notice of Removal (the "Notice") to the United States District Court for the District of

³ When KaloBios filed this action, there had only been one milestone event. Since that time a second milestone event has occurred. Each of the First Milestone Payment and the Second Milestone Payment amounts are \$1 million. KaloBios is prepared to deposit both milestone payment amounts, totaling \$2 million, with the Court pending the outcome of this litigation pursuant to its Rule 67 motion. Durrant Decl. ¶¶ 46-47.

Delaware. *Id.* ¶ 8; Ex. 5. The case was transferred to the United States Bankruptcy Court for the District of Delaware on July 19, 2017. *Id.* ¶ 9; Ex. 6.

F. Savant's Default Accusations

Immediately after KaloBios' complaint was filed, Savant's counsel indicated that Savant was considering consenting to the Rule 67 motion. Edelman Decl. ¶¶ 6-7; Ex. 4. Early in the morning of July 11, however, Savant's counsel sent KaloBios a "notice of default and reservation of rights," under a Security Agreement that was entered into at the same time as the MDC. *Id.* ¶¶ 13; Ex. 9. Savant's counsel claimed that, pursuant to Section 10(a) of the Security Agreement, an Event of Default would occur if the milestone payment were not made by July 20, 2017. *Id.* Ex. 9.

KaloBios' counsel responded that same day, July 11, identifying several bases for invalidating Savant's July 11 default notice. *Id.* ¶ 14; Ex. 10. These reasons included: (1) there had been no default; (2) KaloBios filed a Rule 67 motion obviating the Savant's default accusation because KaloBios requested that the disputed Milestone Payment amounts be deposited with the Court; (3) the notice is inconsistent with other actions taken Savant's counsel, such as seeking more time to consider consenting to the Rule 67 motion; (4) the notice violates the dispute resolution obligations set out in Section 14.2 of the MDC; (5) the supposed "Event of Default Date" is incorrect for, among other reasons, failing to factor in the 60-day cure period; and (6) the notice was issued in bad faith in an attempt to harm KaloBios. *Id.* Ex. 10. Savant ignored KaloBios' July 11 letter, choosing neither to address KaloBios' arguments rejecting the notice of default nor to engage in good faith dispute resolution discussions as is mandated by Section 14.2 of the MDC.

Instead, Savant began to assert more claims and impose more obligations on KaloBios. On Wednesday July 12, 2017, Savant sent KaloBios a “Notice and Request for Inspection” pursuant to Section 8 of the parties’ Security Agreement. Savant sought inspection and examination of KaloBios’ “Collateral” as that term is defined within the Security Agreement to refer generally to the Acquired Assert at two locations in California and the United Kingdom, respectively, starting on Monday, July 17, 2017. *Id.* ¶ 15; Ex. 11. KaloBios’ counsel responded on July 14, 2017, objecting to the inspection request as a retaliatory measure on Savant’s part and identifying various defective features about the notice. *Id.* ¶ 16; Ex. 12. Nevertheless, KaloBios agreed to coordinate the timing, scope and other logistics as to the inspection with Savant. *Id.* Counsel for KaloBios and Savant continued to communicate about the inspection, with KaloBios reiterating on July 20, 2017 that, notwithstanding its continued objections to the inspection notice, it was prepared to schedule an inspection for the end of August. *Id.* ¶¶ 17-18; Exs. 13-14.

At the same time, KaloBios’ counsel sought to confirm with Savant’s counsel that Savant would be keeping to the Rule 67 motion schedule. *Id.* ¶ 19; Ex. 15. KaloBios’ counsel wrote: “As you know, KaloBios has made an expedited motion pursuant to Rule 67. The exigent circumstance continues, and your purported removal of the case has not diminished the exigent circumstances.” *Id.* Savant’s counsel responded that “Savant will not submit a response to KaloBios’ Rule 67 motion until KaloBios’ apparently forthcoming remand application is decided.” *Id.* ¶ 20; Ex. 16. Savant’s counsel also asserted “nor are there any exigent circumstances.” *Id.*

In addition, while Savant’s counsel never responded to KaloBios’ counsel’s July 11 letter detailing the deficiencies in Savant’s initial default notice of that same day, on July 21, 2017,

Savant's counsel sent to KaloBios' counsel a second "Events of Default; Reservation of Rights." *Id.* ¶ 21; Ex. 17. In it, Savant claimed that, KaloBios' failure to pay the First Milestone Payment by July 20, 2017 meant that there had been an alleged Event of Default under Section 10(a) of the Security Agreement. *Id.* Savant also claimed that KaloBios was purportedly in default of three other matters: (1) that KaloBios had allegedly misrepresented its financial condition at the time of the MDC's execution on June 30, 2016; (2) that KaloBios had supposedly violated Section 4 of the Security Agreement by granting a security interest to Black Horse Capital; and (3) that KaloBios had purportedly violated Section 8 of the Security Agreement by allegedly failing to permit inspection of the Collateral. *Id.*

On July 23, 2017, KaloBios' counsel wrote to Savant's counsel, suggesting that the parties enter into a standstill agreement. *Id.* ¶ 22; Ex. 18. KaloBios proposed that, until the Rule 67 motion is decided, the parties agree (1) not to take any actions pursuant to any default or enforce and default notice, (2) issue any new default notices, (3) refrain from exercise any remedies under the MDC or the Security Agreements, and (4) stay all time periods under the MDC or the Security agreement. *Id.* On July 24, 2017, Savant's counsel rejected KaloBios' request for a standstill agreement. *Id.* ¶ 23; Ex. 19.

G. Savant's Counterclaims and Notice of Foreclosure

On July 27, Savant filed an Answer and Counterclaims. *Id.* ¶ 10; Ex. 7. The Counterclaims primarily allege breach of contract allegations that mirror the default accusations made by Savant in its two default notices. *Id.* Ex. 7. On August 1, 2017, KaloBios moved to remand this case to Delaware Superior Court. *Id.* ¶ 11; Ex. 8.⁴

⁴ KaloBios continues to seek remand and does not, in making this motion for emergency relief, consent to the Bankruptcy Court's jurisdiction over the matters alleged in its complaint. Savant has engaged in manipulation by removing this action to this Court so as to delay a hearing on KaloBios' Rule 67 Motion, and unleash its

Late in the evening of August 2, 2017, Savant’s counsel sent to KaloBios’ counsel a “Notice of Foreclosure and Sale.” *Id.* ¶ 24; Ex. 20. Savant claims that KaloBios had committed a payment default by not paying the First Milestone Payment by July 20, 2017 and that, therefore, Savant was exercising its rights under Section 11 of the parties’ Security Agreement to assemble and make available to Savant by one week later, August 9, 2017, the “Collateral” identified in a schedule attached to the notice. *Id.* Ex. 20. The notice stated that Savant intended to sell the Collateral at a public sale on September 1, 2017. *Id.*

ARGUMENT

I. THE COURT SHOULD GRANT A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION PREVENTING SAVANT FROM CONTINUING TO ISSUE DEFAULT NOTICES OR TAKING ANY ACTIONS IN FURTHERANCE OF ANY ALLEGED DEFAULT INCLUDING POSSESSING, FORECLOSING ON AND SELLING THE COLLATERAL

Temporary restraining orders and preliminary injunctions are appropriate where the movant demonstrates “(i) a reasonable likelihood of success on the merits; (ii) a likelihood that it will suffer irreparable harm if relief is denied; (iii) that the non-moving party will not suffer even greater harm if the injunction is granted; and (iv) that the public interest favors such relief.” *Broadstripe, LLC v. Nat’l Cable Television Cooperative, Inc. (In re Broadstripe, LLC)*, 402 B.R. 646, 655 (Bankr. D. Del. 2009) (citation omitted). The Court “must engage in a delicate balancing of the probabilities of ultimate success at final hearing with the consequences of immediate and irreparable injury . . . weigh[ing], rather than mechanically appl[y]ing,” the relevant factors. *Id.* (internal citations omitted). Generally, courts follow the same standard in granting temporary restraining orders as they do in granting preliminary injunctions. *See, e.g.,*

accusations of default. Savant’s August 2nd notice of foreclosure has made it clear that only a court order can ensure that Savant’s threats and recklessly damaging conduct will stop.

Tootsie Roll Indus. v. Sathers, Inc., 666 F. Supp. 655, 658 (D. Del. 1987); *Olde Discount Corp. v. Tupman*, 805 F. Supp. 1130, 1135 (D. Del. 1992).

A. KaloBios is Likely to Succeed on the Merits of its Claims Against Savant

In order to demonstrate a sufficient likelihood of success on the merits sufficient to sustain a request for emergency relief, a movant should make “a prima facie case showing a reasonable probability that it will prevail on the merits.” *GTE Sylvania Inc. v. Consumer Prod. Safety Comm’n*, 404 F. Supp. 352, 369 (D. Del. 1975) (citation omitted). The movant does not need to demonstrate a certainty that it will win—or even that it is more likely to win than not. *See Issa v. Sch. Dist. of Lancaster*, 847 F.3d 121, 131 (3d Cir. 2017) (“To satisfy this requirement for preliminary relief, the movant need only prove a prima facie case, not a certainty We do not require that the right to a final decision after trial be wholly without doubt; the movant need only show a reasonable probability of success.”) (internal citations and quotation marks omitted); *Singer Mgmt. Consultants, Inc. v. Milgram*, 650 F.3d 223, 229 (3d Cir. 2011) (en banc) (explaining that that a party moving for a preliminary injunction “needs only to show a likelihood of success on the merits . . . that is, a reasonable chance, or probability, of winning . . . to be granted relief. A ‘likelihood’ does not mean more likely than not.”) (internal citations omitted). Furthermore, “in a situation where factors of irreparable harm, interests of third parties and public considerations strongly favor the moving party,” emergency relief may be appropriate even though a movant “does not demonstrate as strong a likelihood of ultimate success as would generally be required.” *In re Revel AC, Inc.*, 802 F.3d 558, 569–70 (3d Cir. 2015) (citation omitted).

As detailed below, KaloBios is likely to succeed on the merits of its claims against Savant.

1. Savant Breached Section 4.8 of the MDC and KaloBios is Therefore Entitled to a Declaratory Judgment that it May Credit Overages Against the Milestone Payments

Savant clearly breached Section 4.8 of the MDC. That provision unambiguously requires cost shifting, whereby Savant is required to assume responsibility for the Section 4.3 Joint Development Program Costs when those costs exceed the Joint Development Plan's \$8 million budget by \$500,000. Durrant Decl. ¶ 19. Pursuant to Section 4.8, Savant must either pay KaloBios the cost overage amounts within thirty days or allow KaloBios to credit the cost overages against payments KaloBios owes to Savant, including any Milestone Payments. Section 4.8 is clear on its face that, if Savant does not make the cost overage payment within thirty days, it is deemed to have elected to allow KaloBios to credit the owed cost overages against payments owed to Savant. Section 4.8 expressly states that Savant's "failure to make such [cash] payment within thirty (30) days is deemed an election by Savant to allow the credit described in subsection (i) above" under which "KaloBios [is] to credit the payment of any such costs and expenses above Five Hundred Thousand Dollars (\$500,000) incurred by KaloBios . . . against any such future payments to be made by KaloBios to Savant under the Agreement on a Dollar-for-Dollar basis." *Id.*

There is no question that the Joint Development Costs have exceeded the budget. Indeed, KaloBios has presented back-up detail showing that, as of June 30, 2017, the costs over budget equal \$3,942,058. Durrant Decl. Ex. 4. Pursuant to Section 4.8, therefore, Savant is responsible to pay KaloBios \$3,442,058, representing the cost overages incurred to date that exceed the \$500,000 threshold. Because Savant has made clear that it will not pay the cost overages, KaloBios is authorized by Section 4.8 to credit the \$2 million in Milestone Payments owed to Savant such that Savant owed KaloBios \$1,442,058.

Whether viewed as a breach or an anticipatory breach, Savant has clearly demonstrated its refusal to comply with Section 4.8. Moreover, KaloBios is entitled to a declaratory judgment that it is permitted to credit the cost overages against the Milestone Payments, as the parties agreed and intended. *See, e.g., Tenneco Auto., Inc. v. El Paso Corp.*, No. CIV.A. 18810-NC, 2007 WL 92621, at *6 (Del. Ch. Jan. 8, 2007) (a “clear statement” of a refusal to perform contractual obligations “constitutes a repudiation of the contract and an anticipatory breach of the agreement.”); *Stone St. Asset Tr. v. Blue*, 821 F. Supp. 2d 672, 676 (D. Del. 2011) (declaratory judgment clarifying contractual obligations is appropriate “to avoid accrual of avoidable damages to one not certain of his rights and to afford him an early adjudication without waiting until his adversary should see fit to begin suit, after damage had accrued”).

Savant’s likely arguments will not change this conclusion. Savant has tried to suggest, in the past, that there is no “linkage” between its obligations to pay the cost overages and the Milestone Payments. Durrant Decl. ¶ 38. This claim, however, is belied by the terms of Section 4.8, which specifically provides that the “Milestone Payments” are among the “future payments” against which cost overages may be credited. *Id.* ¶ 19. Savant also may contend, as it has previously, that it is not required to pay any cost overages until all FDA regulatory approval steps have been met. This argument is also at odds with Section 4.8, which requires Savant to pay cost overage invoices “within the calendar year in which such invoice is delivered.” Far from supporting Savant’s position, these provisions demonstrate that KaloBios was permitted to credit its cost overages against the Milestone Payments, and that Savant’s continuing refusal to recognize the validity of these payments (and now, to attempt to foreclose on KaloBios’ Collateral as a result) constitutes a breach or an anticipatory breach of the MDC. KaloBios is therefore likely to succeed on the merits of its claims under Section 4.8.

2. KaloBios is Likely to Succeed on its Claim for Declaratory Judgment that Savant Breached Section 14.2 of the MDC

Savant has consistently shown disregard for the dispute resolution provisions contained in Section 14.2 of the MDC. That provision states clearly: “in the event of a dispute, claim or controversy between the Parties arising under or relating to this Agreement or the breach . . . interpretation or validity thereof, . . . the Party shall refer the Dispute to their respective Executive Officers, and such Executive Officers shall attempt to in good faith to resolve such Dispute . . . within thirty (30) days.” Durrant Decl. ¶ 20. The MDC defines the term “Executive Officers” to mean Stephen Hurst on behalf of Savant and Cameron Durrant on behalf of KaloBios. Moreover, both Dr. Durrant and Hurst were members of the “Joint Steering Committee” described in the MDC. *Id.* ¶ 31. Section 6.1 identifies the obligations of that committee. It provides that: “disputes relating to . . . material breach or interpretation of this Agreement shall *not* be subject to any Party’s final decision-making authority and may be escalated pursuant to Section 14.2.” *Id.* ¶ 20. (emphasis added).

Dr. Durrant has made extensive effort to engage Hurst in good faith discussions and dispute resolution efforts about the cost overages. *Id.* ¶¶ 30-45. These efforts began in January 2017 when Dr. Durrant first attempted to engage Hurst on the subject at a Joint Steering Committee meeting. *Id.* ¶ 31. Hurst rebuffed Dr. Durrant and continued to do so every time Dr. Durrant tried to raise the subject. In mid-June, Dr. Durrant wrote to Hurst about the need to discuss the budget and the milestones. *Id.* ¶¶ 33-34. Hurst responded that he did not see much point in having the discussions. *Id.* ¶ 33. During the week of June 26, 2017, Dr. Durrant even more directly stated: “I have been seeking a discussion with you to discuss submitting an invoice as per our agreement to credit KaloBios for the R&D costs over the original benznidazole Joint Development Plan budget.” *Id.* ¶ 34. Here too, Hurst rejected the discussion. *Id.*

Then, after KaloBios sent Savant the first invoice on July 28, 2017, Hurst became even more adamant that he would not hold dispute resolution discussions and would threaten KaloBios with default. On June 29, 2017, for example, Hurst rejected the June 28 invoice, imposed a deadline on July 10 for KaloBios to pay the First Milestone Payment and set out a clear refusal to talk, stating: “Your invoice is hereby rejected,” and “Savant will not engage on the topic of the budget overruns until the milestone issue has been resolved to our satisfaction.” *Id.* ¶¶ 35-38.

Nevertheless, Dr. Durrant tried again to get Hurst to engage in dispute resolution discussions, to no avail. For example, Dr. Durrant suggested that the two have a face-to-face meeting, which Hurst rejected. *Id.* ¶ 39. Dr. Durrant asked Hurst to confer after Hurst met with the Savant board, but Hurst refused to do so. *Id.* ¶¶ 39-40. As Savant’s continued threat of issuing a default notice to KaloBios on July 10 loomed, Dr. Durrant made further requests of Hurst to engage in dispute resolution talks but Hurst continued to ignore Dr. Durrant. *Id.* ¶¶ 41-45.

Thus, the record clearly demonstrates that KaloBios will likely succeed on its declaratory judgment claim that Savant breached its Section 14.2 obligation to engage in good faith attempts to resolve the dispute over Savant’s responsibilities to pay the cost overages.

3. KaloBios is Likely to Succeed on its Claim that Savant Breached Section 8.7(b) of the MDC

After Shkreli was arrested and terminated by KaloBios, Savant and Hurst sought to find new investors to pursue a partnership with KaloBios in developing, manufacturing and commercializing benznidazole. Durrant Decl. ¶ 10. To do so, Hurst and Savant made representations about the assets they were prepared to sell KaloBios as being all of the assets necessary for accomplishing those results. *Id.* ¶ 11. Those representations were included in the

Section 8.7(b) of the MDC in which Savant expressly warranted and represented that the “Acquired Assets constitute all of the assets . . . necessary to the Exploitation of the Compound and Product.” *Id.* ¶ 16. The “Acquired Assets” refers to the variety of materials and documents that KaloBios bought from Savant through the MDC. And the MDC defines “Exploitation” to refer to the full ranges of activities associated with the research, development, commercialization and manufacture of benznidazole. Durrant Decl. Ex. 1 at 3, 17.

It became clear, however, over the last year since the MDC was signed that Savant has misrepresented the necessity, sufficiency and adequacy of the Acquired Assets. KaloBios has made great strides in developing benznidazole and the effort to obtain FDA approval but it has had to do so notwithstanding the inadequacy of Savant’s assets. Savant may try to deflect attention away from the insufficiency of the assets it sold by claiming that KaloBios and not Savant is incurring the costs at this time. But that is a ploy and a distraction. The issue is not who is doing the work but the status and sufficiency of the Acquired Assets. Thus, the Section 4.8 cost shifting provision makes quite clear that it applies where the cost overages occurred “due to the insufficiency or inadequacy of the Acquired Assets.”

KaloBios has submitted detailed back up as to the cost overages in connection with this motion that demonstrates the extra work that has had to be accomplished because of the insufficiency of the Acquired Assets. Durrant Decl. Ex. 4. This and other information confirms that Savant misrepresented the necessity, adequacy and sufficiency of the Acquired Assets to the development efforts and KaloBios will likely succeed on its claim that Savant breached its MDC Section 8.7(b) representation and warranty.

B. KaloBios Will Suffer Irreparable Harm if the Court Does not Enjoin Savant From Foreclosing Upon and Selling the Collateral

It is well settled that “the potential loss or destruction of one’s business constitutes irreparable harm.” *Sarwari v. BP Products N. Am., Inc.*, No. 06-2976 (DMC), 2006 WL 8417396, at *6 (D.N.J. Sept. 15, 2006). Emergency relief is therefore warranted where, without such relief, “a substantial loss of business and perhaps even bankruptcy” would ensue. *Doran v. Salem Inn, Inc.*, 422 U.S. 922, 932 (1975); accord, e.g., *N.W. Controls, Inc. v. Outboard Marine Corp.*, 317 F. Supp. 698, 703 (D. Del. 1970); *Minard Run Oil Co. v. U.S. Forest Service*, No. 09-125 Erie, 2009 WL 4937785, at *32 (W.D. Pa. Dec. 15, 2009) (quoting *N.W. Controls*, 317 F. Supp at 703); *Emergency Accessories & Installation, Inc. v. Whelen Engineering Co., Inc.*, No. 09-2652 (JEI/AMD), 2009 WL 1587888, at *6-7 (D.N.J. June 3, 2009) (preliminarily enjoining defendant from terminating contract with plaintiff because termination would be “the death knell” for plaintiff’s business); Dr. Durrant’s affidavit makes clear the severe—if not fatal—impact Savant’s impending foreclosure and sale of the collateral would have on KaloBios. See Durrant Decl. ¶¶ 48-57. To be blunt, KaloBios’ business will be decimated, and almost certainly will fail, unless this Court maintains the *status quo* during the pendency of this case. The Collateral upon which Savant intends to claim possession on August 9, 2017 and foreclose and auction on September 1, 2017 constitutes the materials, contracts, inventory, records and information used to develop and obtain regulatory approval for benznidazole. In other words, Savant wants to gut KaloBios, absconding with of all the work KaloBios has done over the last year while developing its central product.

Benznidazole is KaloBios’ only meaningful source of anticipated revenue in the near to medium term and comprises the vast majority of KaloBios’ value. *Id.* ¶¶ 25-27. If Savant is permitted to foreclose on the Collateral, however, KaloBios will lose any right to develop and

commercialize benznidazole. This loss would ensure the demise of KaloBios and would result in its employees losing their jobs, and in patients losing prompt and affordable access to benznidazole, all before KaloBios ever can be heard on the merits of its claims. There is little chance that KaloBios could survive such a drastic attack on its business operations and Savant knows that. Savant's desire for a foreclosure is, in fact, targeted at irreparably harming KaloBios rather than addressing the merits of the dispute, and to this end Savant has done everything to resist prompt resolution of the substantive issues, such as removing to Bankruptcy Court in order to prevent the Superior Court from hearing the Rule 67 motion on an expedited schedule.

The impending foreclosure will most certainly irreparably damage and even destroy KaloBios' business, supporting the need for this Court granting KaloBios' motion for temporary order and preliminary injunction.

C. The Balance of Harms Tips Decidedly in Favor of Injunctive Relief

The balance of hardships also strongly supports injunctive relief. KaloBios is simply requesting that this Court maintain the *status quo* pending a determination of claims in this action. As noted above, if this injunction is not granted, it is likely that KaloBios will fail, the jobs of its many employees will be lost, and affordable access to a promissory treatment for a parasitic disease will be compromised.

By contrast, an injunction maintaining the *status quo* will impose no hardship on Savant whatsoever. Indeed, KaloBios already has committed to deposit the First Milestone Payment into an interest-bearing account with the Court, and has filed an expedited motion to obtain permission to do so. With the Court's permission, KaloBios also stands ready to deposit the Second Milestone Payment into that same interest-bearing account. Durrant Decl. ¶¶ 46-47. KaloBios' motion remains pending only because Savant removed this case from the Superior Court. Once KaloBios is able to obtain the requisite order from the appropriate court, however,

KaloBios will deposit both the First and Second Milestone Payments pending the outcome of this case. Thus, even in the unlikely event that Savant prevails in this litigation, it will be made whole.

D. The Public Interest Favors Granting a Temporary Restraining Order and Preliminary Injunction

This case presents a prime example of a dispute in which the public interest weighs more heavily in favor of granting injunctive relief. Benznidazole is a promising treatment for Chagas disease, a chronic, potentially life-threatening infectious disease that affects 350,000 in the United States alone. Durrant Decl. ¶ 53. Approximately one third of individuals infected with Chagas develop severe cardiovascular complications, including sudden cardiac arrest. *Id.* Currently, there is no FDA-approved treatment for Chagas, but KaloBios has made significant progress in obtaining interim approvals from the FDA and hopes to submit a new drug application for benznidazole early next year. *Id.* ¶ 24. If Savant were to sell the Collateral (or keep it for itself), however, then this timeline would almost certainly be delayed, and there would be no guarantee that the new owner would have the wherewithal to complete the application process in any event. *Id.* ¶¶ 55-56.

Of equal if not greater importance, the sale of the Collateral to another party may restrict benznidazole's availability from those who need it most. KaloBios has adopted a Responsible Pricing Model for all of its current and future products, including benznidazole. *Id.* ¶ 55. Under that model, KaloBios has committed to price its products at cost plus a modest profit margin that it will determine after consultations with key stakeholders. *Id.* KaloBios has further committed to limit the increase in price to no more than the rate of inflation or Consumer Price Index, to forswear predatory pricing or "price-gouging," and to ensure that patients have access to benznidazole irrespective of their ability to pay. *Id.* There is no guarantee that the purchaser of

the Collateral (or Savant, if it elects to keep the Collateral for itself) would make the same commitments. *Id.* ¶ 56. In fact, Savant and its CEO, Stephen Hurst, previously partnered with Martin Shkreli to develop benznidazole even though Shkreli already was notorious for engaging in predatory pricing of other pharmaceuticals. *Id.* Were Savant and Hurst to sell to or partner with someone with a similar strategy again, the results could be catastrophic for those suffering from Chagas.

In sum, all of the factors this Court should consider on a motion for temporary restraining order and preliminary injunction weigh decidedly in favor of granting the motion. KaloBios respectfully requests that this Court enjoin Savant from continuing to issue default notices to KaloBios and from pursuing its threatened foreclosure and sale of the Collateral.

II. KALOBIOS SHOULD NOT BE REQUIRED TO POST SECURITY BECAUSE IT ALREADY HAS COMITTED TO DEPOSIT THE MILESTONE PAYMENTS WITH THE COURT

While Federal Rule of Civil Procedure 65 (made applicable by Bankruptcy Rule 7065) generally requires the movant to post security in an amount determined by the Court, courts have discretion under Rule 65(c) to waive a bond requirement “where the nature of the action necessarily precludes any monetary harm to the defendant.” *Zambelli Fireworks Mfg. Co., Inc. v. Wood*, 592 F.3d 412, 426 (3d Cir. 2010). KaloBios respectfully submits that no bond is required of it (*see* Fed. R. Bankr. P. 7065) or that the Court should exercise its discretion to waive any bond requirement here. As noted above, KaloBios already has moved for permission to deposit the First Milestone Payment into Court and has committed to depositing the Second Milestone Payment as well. Those deposits, once made, will ensure that Savant will not face any


injury or damages even if it ultimately is “found to have been wrongfully enjoined or restrained.”
Fed. R. Civ. P. 65(c).⁵

CONCLUSION

For the foregoing reasons, KaloBios’ motion for a temporary restraining order and preliminary injunction preventing Savant from taking any actions in furtherance of any alleged default, issuing any default notices, exercising remedies relating to any alleged default, attempting to collect on any of KaloBios’ Collateral, entering or visiting KaloBios’ premises without written permission from KaloBios, or conducting any sale of the Collateral, should be granted in its entirety.

⁵ If the Court nonetheless requires KaloBios to post security, then KaloBios respectfully submits that a nominal bond will suffice. *See Neo Gen Screening, Inc. v. TeleChem Int’l, Inc.*, 69 F. App’x 550, 557 (3d Cir. 2003); *Blanchette v. Providence & Worcester Co.*, 428 F. Supp. 347, 358 (D. Del. 1977).

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