# UNITED STATES OF AMERICA Before the SECURITIES AND EXCHANGE COMMISSION

ADMINISTRATIVE PROCEEDING File No. 3-20550

In the Matter of

**Calmare Therapeutics Incorporated,** 

Respondent.

# RESPONDENT'S BRIEF IN OPPOSITION TO DIVISION OF ENFORCEMENT'S MOTION FOR SUMMARY DISPOSITION

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#### INTRODUCTION

Calmare Therapeutics Incorporated ("Respondent" or "Calmare"), by and through its undersigned counsel, opposes the Motion for Summary Disposition filed by Division of Enforcement ("Division") requesting revocation of the registration of each class of securities of Calmare registered pursuant to Securities Exchange Act of 1934 ("1934 Act"), Section 12. In order to grant a Motion for Summary Disposition, determination under Rule 250 of the Commission's Rules of Practice, 17 C.F.R. § 201.250, the Commission must determine "that no public hearing is necessary." *Calmare Therapeutics Inc.*, Exchange Act Release No. 92977, 2021 WL 4202234, at \*4 (Sept. 14, 2021). Specifically, the Commission must consider a number of factors established by precedent and determine that no genuine issue of fact concerning these factors exists. *In the Matter of Can-Cal Res. Ltd., China Fruits Corp., & Skystar Bio-Pharm. Co.*, Release No. 6525, 2019 WL 2296498, at \*3 (Mar. 28, 2019)

Calmare's business depends on the viability of certain contracts between Calmare and the U.S. federal government. Given the nature of Calmare's business in the medical field and that its revenue comes from contracts for its proprietary technology, Calmare's financial health and corresponding ability to return to compliance with SEC filing obligations has been significantly impacted due a number of factors including the COVID-19 Pandemic. Considering these unique circumstances, a number of genuine issues of fact exist, and a public hearing is necessary to determine the appropriate remedy for the protection of investors.

Calmare has taken steps to become compliant with its reporting obligations, and has made credible assurances that it will be able to maintain compliance with these obligations. Calmare has been advised by its government contract consultant that revocation of its 1934 Act registration will in all probability result in the loss of the contracts that the Company has with U.S. federal

government agencies, and thereby have a material negative impact on its business and its public shareholders.

There are material questions of fact remaining as to the appropriate remedy for Calmare's reporting violations, and, when these facts are considered in the light most favorable to Calmare, it is clear that the Division has not met the standard needed for the Commission to grant summary disposition and there is no showing that revocation of Calmare's registration is necessary for the protection of investors. Accordingly, a public hearing is necessary before the Commission can make a final determination in this proceeding.

#### **ARGUMENT**

#### A. Standards applicable to the Division's Summary Disposition Motion

Under Rule 250(b), summary disposition is appropriate only where there is **no** genuine issue as to **any** material fact and the movant is entitled to summary disposition as a matter of law. In the Matter of Can-Cal Res. Ltd., China Fruits Corp., & Skystar Bio-Pharm. Co., Release No. 6525, 2019 WL 2296498, at \*3 (Mar. 28, 2019) (emphasis added). In assessing the summary disposition record, the facts, as well as the reasonable inferences that may be drawn from them, must be viewed in the light most favorable to the non-moving party. Id. (denying Division's motion for summary disposition because it failed to show there was no genuine issue with regard to any material fact and that it was entitled to summary disposition as a matter of law).

To determine whether a sanction or revocation is in the public interest, the Commission "consider[s], among other things, the seriousness of the issuer's violations, the isolated or recurrent nature of the violations, the degree of culpability involved, the extent of the issuer's efforts to remedy its past violations and ensure future compliance, and the credibility of its assurances, if any, against further violations." *Can-Cal*, 2019 WL 2296498, at \*3 (quoting *Gateway Int'l* 

Holdings, Inc., Exchange Act Release No. 53907, 2006 WL 1506286, at \*4 (May 31, 2006)). Here, disputed material facts exist as to whether revocation of Calmare's 1934 Act registration is in the public interest, and therefore, summary disposition must be denied.

## **B.** Disputed Issues of Material Fact and Law

- 1. Calmare is a medical device company holding patents and other designations providing it the exclusive right to sell those devices.<sup>1</sup>
- 2. Calmare has government contracts to supply its devices, including a five-year contract with the U.S. Veterans Hospital for \$2.5 million of purchases entered into in June 2020.<sup>2</sup>
- 3. Calmare has experienced past financial challenges due in part to the circumstances presented by the pandemic.<sup>3</sup>
- 4. Calmare has taken steps to become compliant but has been unable to become compliant due to past financial hardship.<sup>4</sup>
- 5. The financial health of Calmare is dependent on the viability of its federal government contracts.<sup>5</sup> If these contracts remain viable, they, together with other revenue sources, will provide more than adequate revenue to bring Calmare compliant, and maintain compliance, with its 1934 Act reporting requirements.<sup>6</sup>
- 6. Calmare has been advised that its federal government contracts will be terminated if Calmare's 1934 Act stock registration is revoked as a result of this proceeding pursuant to "Responsible Contractor" requirements contained in such contracts.<sup>7</sup>

<sup>&</sup>lt;sup>1</sup> See Declaration of Conrad Mir In Support of Respondent's Brief in Opposition to Division of Enforcement's Motion for Summary Disposition ("Mir Dec.") at  $\P$  3 and 4.

<sup>&</sup>lt;sup>2</sup> See Mir Dec. at ¶ 5.

<sup>&</sup>lt;sup>3</sup> See Mir Dec. at  $\P$ ¶ 6 and 7.

<sup>&</sup>lt;sup>4</sup> See Mir Dec. at ¶¶ 10 and 12.

<sup>&</sup>lt;sup>5</sup> See Mir Dec. at ¶ 8.

<sup>&</sup>lt;sup>6</sup> See Mir Dec. at ¶ 11.

<sup>&</sup>lt;sup>7</sup> See Declaration of Peter Brennan In Support of Respondent's Brief in Opposition to Division of Enforcement's Motion for Summary Disposition ("Brennan Dec.") at p. 3; See also Mir Dec. at ¶ 7.

### C. Revocation is Not in the Public Interest

In applying the *Gateway* factors, the Commission must determine whether it is in the public interest to revoke Calmare's 1934 Act registration. In the Matter of Erhc Energy, Inc. & Iddriven Inc., Respondents., Release No. 90517, 2020 WL 6891409 (Nov. 24, 2020)(citing Gateway). Even if the Division has established that a filer is delinquent, the Commission and the courts have made clear that revocation cannot automatically result from that alone—"otherwise there would be no need for this proceeding—and an individual assessment of the public interest in each case is required." In the Matter of Martin Shkreli, Release No. 5233, 2017 WL 11393793, at \*4 (Nov. 17, 2017)(denying the Division's motion for summary disposition where the Division failed to show that "the public interest supports" the sanction sought). Moreover, the Commission's inquiry into the appropriate sanction to protect the public interest is flexible, and no one factor is dispositive. In the Matter of John T. Lynch, Jr., Release No. 4989, 2017 WL 11180603 (Aug. 22, 2017)(denying summary disposition because "a hearing is necessary to determine what sanction, if any, is in the public interest."). Here, based on the summary disposition record taken in the light most favorable to Calmare, the Division has not met its burden of showing that revocation is in the public interest - particularly because the public interest is being protected by the prohibition on trading in Calmare's stock.

In *Can-Cal*, 2019 WL 2296498, at \*3, the Division's motion for summary disposition was denied despite the Commission finding that the first and second *Gateway* factors—the seriousness of the issuer's violations, and the isolated or recurrent nature of the violations—weighed against the respondent company and in the Division's favor. In its consideration of the remaining *Gateway* factors, the Commission noted that the evidence in the summary disposition record supported the respondent company's argument that its return to compliance "was precipitated not by the [12(j)]

proceeding," but by the viability of a third party on which the respondent company was dependent for the "financial health" necessary to become and remain compliant. *See Can-Cal*, 2019 WL 2296498, at \*4. Pursuant to a contract between the third party and the respondent company, the respondent company would be paid \$150,000 each year for at least 20 years. Because the respondent company's "financial health" was dependent on the viability of that contract, there were "material questions of fact concerning the third party's solvency that needed to be addressed at a hearing." *Id.* (modified for clarity). Similarly here, Calmare's financial health is dependent on the viability of certain government contracts. At least one of these contracts involves \$2.5 million of payments over a five-year period, and therefore, there are material questions of fact and law concerning these government contracts that need to be addressed at a hearing.

Calmare's business is in the medical field and primarily focuses on the sale of medical equipment featuring its proprietary technology, which has various applications in treating patients suffering from chronic pain. <sup>10</sup> In June 2020, Calmare was awarded a five-year contract providing for payments of \$2.5 million by the U.S. Department of Veteran Affairs. Under normal circumstances, after being awarded such a contract, Calmare would have begun receiving orders for its medical equipment and the corresponding revenue that should be more than what is needed to adequately cover the costs of becoming and remaining compliant. <sup>11</sup> Under the circumstances presented by the COVID-19 Pandemic, however, most elective medical treatments were discontinued. <sup>12</sup> In a socially distanced world, it became common-place (sometimes required) to be treated by a physician via video, not in-person as needed for the use of Calmare's medical

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<sup>&</sup>lt;sup>8</sup> See Mir Dec. at ¶ 8.

<sup>&</sup>lt;sup>9</sup> See Mir Dec. at ¶ 5.

<sup>&</sup>lt;sup>10</sup> See Mir Dec. at ¶ 4.

<sup>&</sup>lt;sup>11</sup> See Mir Dec. at ¶ 4-8.

<sup>&</sup>lt;sup>12</sup> See Mir Dec. at ¶ 6.

equipment.<sup>13</sup> Although these circumstances have significantly impacted Calmare's financial health and corresponding ability to become compliant,<sup>14</sup> they are temporary. As long as Calmare's contracts are allowed to remain viable and not cancelled as a result of revocation of Calmare's 1934 Act registration, the revenue that they provide will more than adequately cover the costs of becoming and remaining compliant.<sup>15</sup> An evidentiary hearing is therefore necessary to address these material questions of fact.

## D. Calmare's Assurances of Future Compliance are Credible

A company's recurrent failure to file reports is so serious that only a strongly compelling showing on the remaining factors—its remedial efforts and assurances against future violations—"will save it from revocation." *Can-Cal*, 2019 WL 2296498, at \*3 ("[r]evocation is not automatic"). Although the Commission demands strict compliance with Section 13(a) and its rules, a company's "subsequent filing history is an important factor to be considered in determining whether revocation is necessary or appropriate for the protection of investors." *Id.* (quoting *e-Smart, Techs., Inc.*, Exchange Act Release No. 50514, 2004 WL 2309336, at \*2 (Oct. 12, 2004)). Here, the circumstances presented substantially resemble those in *Can-Cal*, where the Commission found that the evidence in the summary disposition record supported the respondent company's argument that its financial health and corresponding ability to become and remain compliant depended on the viability of a contract with a third party, and, accordingly, a hearing was necessary to determine questions concerning that contract. *See Can-Cal*, 2019 WL 2296498 at \*4.

Calmare has engaged two accounting firms for the purpose of bringing it into compliance in the foreseeable future.<sup>16</sup> One accounting firm to work with Calmare in preparation of its

<sup>14</sup> See Mir Dec. at ¶¶ 7 and 12.

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<sup>&</sup>lt;sup>13</sup> See Mir Dec. at ¶ 6.

<sup>&</sup>lt;sup>15</sup> See Mir Dec. at ¶ 11.

<sup>&</sup>lt;sup>16</sup> *See* Mir Dec. at ¶ 10.

financial statements, and the other firm to audit those statements. That is only possible because of the revenue that Calmare generates from the sale of devices utilizing its proprietary technology with certain federal government agencies.<sup>17</sup> Calmare has been advised that if its registration is revoked, in all probability (or even for certain) those contracts will be lost, along with the financial health they provide for Calmare, thereby making Calmare's ability to become and remain compliant not possible in the immediate future. 18

In Can-Cal, the Commission found credible the respondent company's assurances of future compliance where its chairman declared that the payments the respondent company would receive pursuant to its contracts with a third party would "more than adequately cover the costs to pay [the respondent company's] audit firm' to prepare documents necessary for its securities filings. Can-Cal, 2019 WL 2296498, at \*4 (concluding that "viewing the record in the light most favorable" to the respondent company, the Commission "cannot say that its assurances of future compliance are not credible."). Similarly here, viewing the summary disposition record in the light most favorable to Calmare, the credibility of its assurances that it will become and remain complaint depend on the viability of certain government contracts. As in Can-Cal, this presents material questions of fact and law that must be addressed at a hearing. Accordingly, summary disposition must be denied.

#### **CONCLUSION**

Based on the summary disposition record taken in the light most favorable to the Respondent, the Division has not met, and cannot meet, its burden of demonstrating that revocation is the appropriate remedy. Before the Commission makes a final determination in this proceeding,

<sup>&</sup>lt;sup>17</sup> See Mir Dec. at ¶ 8

<sup>&</sup>lt;sup>18</sup> See Mir Dec. at ¶ 8.

a hearing is necessary to address the outstanding material issues of fact and law. Accordingly, the
Division's Motion for Summary Disposition must be denied.

### **CERTIFICATE OF SERVICE**

I hereby certify that I caused true copies of the Respondent's Brief in Opposition to the Division of Enforcement's Motion for Summary Disposition to be served on the following on March 7, 2022 in the manner indicated below:

/s/\_Paul L. Vorndran
Paul L. Vorndran

Via eFap:

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## **CERTIFICATE AS TO LENGTH**

This Motion and Brief is less than 10 pages, and therefore it complies with SEC Rule of Practice 154.

/s/ Paul L. Vorndran
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