UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SECURITIES AND EXCHANGE COMMISSION,

Plaintiff,

v.

CARL RAUSCH,

Defendant.

Civil Action No. 06-10642 PBS

COMPLAINT

Plaintiff Securities and Exchange Commission (the "Commission") alleges:

Summary

1. In 2003, Defendant Carl Rausch ("Rausch"), the Senior Technology Officer of Biopure Corporation ("Biopure") and Vice Chairman of Biopure's Board of Directors, aided and abetting Biopure in filing materials with the Commission that misled investors about the truth about Biopure's applications for Food and Drug Administration ("FDA") approval of Hemopure.

2. Hemopure is a biotechnology product that is designed to deliver oxygen to tissues as a substitute for red blood cells. To date, Hemopure has not been approved by the FDA for use in humans. Since its founding in 1984, defendant Biopure has devoted substantially all of its resources toward developing Hemopure for human use. In July 2002, Biopure submitted a biologics license application ("BLA") to the FDA for approval to use Hemopure for the treatment of acutely anemic patients undergoing orthopedic surgery. In March 2003, the company also applied for FDA approval to perform clinical trials of Hemopure on human trauma victims in hospitals.

3. In April 2003, Biopure began receiving negative information from the FDA. On

or about April 9, 2003, the FDA imposed a clinical hold barring the company from conducting clinical trials of Hemopure on trauma victims because of "safety concerns" arising out of the FDA's preliminary assessment of Biopure's BLA. In or about May 2003, the FDA denied Biopure's request to lift the clinical hold. Then, on or about July 30, 2003, Biopure received two lengthy and detailed letters from the FDA. In one letter, the FDA again refused to allow the clinical trials because of "an unreasonable and significant risk of illness or injury" to human subjects. The other letter was the FDA's complete response letter to the BLA, in which the FDA informed Biopure that it was not approving Biopure's BLA at that time because of extensive and significant deficiencies in Biopure's application and because of concerns about the lack of safety and efficacy of Hemopure. Receipt of the complete response letter meant that the FDA had completed its review of the BLA and would have an additional six months to review a resubmission by the company, if and when the company addressed all deficiencies identified by the FDA. One year later, the company still had not addressed all deficiencies raised in the complete response letter and decided instead to shift its focus to developing Hemopure for a different application.

4. Throughout 2003, Biopure was also in need of additional capital to satisfy its continuing financial needs. Biopure had not been profitable at any point since its founding. Several times during 2003, as it had done previously and since, Biopure was seeking to raise money by accessing public and private capital markets through the sale of additional shares of stock.

5. For more than eight months from April 9 until December 24, 2003, Biopure concealed the clinical hold from investors while touting a potential use of Hemopure by trauma victims in multiple securities offerings, public filings, press releases and investor conference calls. Moreover, on August 1, 2003, two days after receiving the complete response letter from the FDA, Biopure issued a fraudulent and misleading press release that gave the false impression the company had received positive news from the FDA. That day, Biopure's stock closed at $7.30 per share, a 22% increase over its previous day close. For four additional months from August until December 11, 2003, Biopure continued to conceal from investors that it had received a complete response letter from the FDA, continued to make false statements about its dealings with the FDA and failed to disclose the true scope and nature of the deficiencies with the BLA identified by the FDA.

6. As the truth about Biopure's applications for FDA approval gradually became public, through a series of incomplete disclosures, the market reacted. As of year-end 2003, Biopure stock was trading below $3.00 per share.

7. By participating in the scheme set forth in this Complaint, defendant Rausch aided and abetting Biopure's violations of Section 13(a) of the Securities Exchange Act of 1934 ("Exchange Act") and Rules 12b-20, 13a-11 and 13a-13 thereunder.

8. Unless restrained and enjoined, defendant will continue to engage in acts, practices, and courses of business as set forth in this Complaint or in acts, practices, and courses of business of similar object and purpose. Accordingly, the Commission seeks: (i) entry of a permanent injunction prohibiting defendant from further violations of the relevant provisions of the federal securities laws; (ii) the imposition of a civil monetary penalty against defendant ; and

(iv) other equitable relief as the Court in its discretion deems just.

Jurisdiction

9. The Commission brings this action pursuant to Sections 20(e) and 21(d) of the Exchange Act [15 U.S.C. §§ 78t(e) and 78u(d)].

10. This Court has jurisdiction over this action pursuant to Sections 21 and 27 of the Exchange Act [15 U.S.C. §§ 78u and 78aa]. Additionally, many of the acts and practices set forth in this Complaint occurred in this District.

11. In connection with the conduct described in this Complaint, defendant directly and indirectly made use of the mails or the means or instruments of transportation or communication in interstate commerce.

The Defendant

12. **Carl Rausch,** age 57, was Biopure's co-founder and the developer of the scientific technology for its artificial blood product, Hemopure. Until September 6, 2005, Rausch was Vice Chairman of Biopure's Board of Directors and the company's Senior Technology Officer. From 1984-2001, Rausch was the Biopure's CEO and Chairman of the Board of Directors. Defendant Rausch resides in Belmont, Massachusetts.

BACKGROUND

13. The Commission hereby realleges and incorporates by reference the allegations set forth in the Complaint, dated September 14, 2005, in SEC v. Biopure, Civ. A. No. 05-11853-PBS (D. Mass.) ("Related Complaint") as if set forth fully herein. Defined terms used herein have the same meaning as in the Related Complaint.

14. In April 2003, defendant Rausch became aware that the FDA had imposed a

clinical hold on Biopure's proposed trials of Hemopure on trauma patients because of safety concerns. In late July 2003, defendant Rausch received a copy of the Complete Response Letter to Biopure's BLA in which the FDA informed Biopure that its BLA was not approved and summarized the deficiencies of Biopure's BLA.

15. Nonetheless, defendant Rausch knowingly rendering substantial assistance in drafting, reviewing, signing and/or approving the following materials that Biopure filed with the Commission, including the April Offering Documents, Summer 2003 Shelf Registration, June 16 Form 10-Q, August 1 Form 8-K, August 21 Form 8-K, September 15 Form 10-Q, and December 11 Form 8-K, each of which contained material misstatements or omissions concerning the status of Biopure's applications for FDA approval of Hemopure.

CLAIM

(Aiding and Abetting Biopure's Violations of
Exchange Act Section 13(a) and Exchange Act Rules 12b-20, 13a-11 and 13a-13)

16. The Commission repeats and incorporates by reference the allegations in paragraphs 1-15 of the Complaint as if set forth fully herein.

17. Section 13(a) of the Exchange Act and Rules 13a-11 and 13a-13 thereunder require issuers of registered securities to file with the Commission factually accurate current and quarterly reports. Exchange Act Rule 12b-20 provides that in addition to the information expressly required to be included in a statement or report, there shall be added such further material information, if any, as may be necessary to make the required statements, in the light of the circumstances under which they are made, not misleading.

18. As set forth herein, one or more of Biopure's filings with the Commission

fraudulently misled investors about the truth regarding Biopure's efforts to gain FDA approval of Hemopure in connection with the company's trauma IND and its BLA in violation of Section 13(a) of the Exchange Act and Rules 12b-20, 13a-11, and 13a-13 thereunder.

19. By knowingly rendering substantial assistance to one or more of Biopure's violations, defendant Rausch aided and abetted Biopure's violations of Section 13(a) of the Exchange Act, and Rules 12b-20, 13a-11, and 13a-13 thereunder.

PRAYER FOR RELIEF

WHEREFORE, the Commission respectfully requests that this Court:

I.

Issue a Final Judgment of Permanent Injunction permanently restraining and enjoining defendant Rausch and all persons in active concert or participation with him who receive actual notice of the Final Judgement by personal service or otherwise, from violating or aiding and abetting violations of Section 13(a) of the Exchange Act [15 U.S.C. § 78m(a)] and Rules 12b-20, 13a-11 and 13a-13 promulgated thereunder [17 C.F.R §§ 240.12b-20, 240.13a-11 and 240.13a-13].

II.

Issue an Order requiring defendant Rausch to pay a civil penalty in an appropriate amount pursuant to Section 21(d)(3) [15 U.S.C. §§ 77t(d) and 78u(d)(3)].

III.

Grant such other relief as this Court deems just and appropriate under the circumstances.

Respectfully submitted,

By: _____

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