

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
SOUTHERN DIVISION**

DAVID STARR, BERNADETTE
MAVRIKOS, EDMUND QUIMBAO,
JAMES TETTENHORST, JEREMY
HANSEN, KRISTA KARO, ARLENE
REED-COSSAIRT, PETER STAVROS,
HEATHER FARKAS,

on behalf of themselves and all others
similarly situated,

Plaintiffs,

v.

VSL PHARMACEUTICALS, INC.;
LEADIANT BIOSCIENCES, INC.; F/K/A
SIGMA-TAU PHARMACEUTICALS, INC.;
and ALFASIGMA USA, INC.

Defendants.

No.: 8:19-CV-02173-LKG

**[PROPOSED] ORDER GRANTING
PRELIMINARY APPROVAL OF CLASS SETTLEMENT**

Before the Court is Plaintiffs' Motion for Preliminary Approval of Class Settlement and Direction of Notice Under Rule 23(e) (the "Motion"). Plaintiffs David Starr, Bernadette Mavrikos, Edmund Quimbao, James Tettenhorst, Jeremy Hansen, Krista Karo, Arlene Reed-Cossairt, Peter Stavros, and Heather Farkas (collectively, "Settlement Class Representatives") and Defendants Alfasigma USA, Inc. ("Alfasigma"), Leadiant BioSciences, Inc. ("Leadiant"), and VSL Pharmaceuticals, Inc. ("VSL") have entered into a Class Action Settlement Agreement and Release, dated March 31, 2026 (the "Settlement Agreement").

Having thoroughly reviewed the Settlement Agreement, including the proposed forms of class notice and other exhibits thereto, the Motion, and the papers and arguments in connection therewith, THE COURT HEREBY FINDS, CONCLUDES, AND ORDERS THE FOLLOWING:

1. Capitalized terms not otherwise defined herein have the meanings set forth in the Settlement Agreement.

2. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. § 1332(d) and has personal jurisdiction over the Parties and the Settlement Class Members. Venue is proper in this District.

3. The Motion is GRANTED.

4. The Court hereby provisionally certifies, for settlement purposes only, a “Settlement Class,” pursuant to Rule 23(b)(3), consisting of

All persons who purchased a VSL#3 Class Product in the United States beginning June 1, 2016, and ending June 19, 2019. The following individuals are excluded from the Settlement Class: officers and directors of Defendants Alfasigma, Leadiant, and VSL, and their parents, subsidiaries, affiliates, and any entity in which they have a controlling interest. Also excluded from the Class are any persons or entities that purchased VSL#3 Class Products exclusively for the purpose of reselling the VSL#3 Class Product to a consumer. Finally, also excluded from the Class are all judges assigned to hear any aspect of the Litigation, as well as their staff and immediate family; and Settlement Class Counsel, their staff members, and their immediate family.

5. The Court hereby preliminarily approves the Settlement Agreement and the terms embodied therein pursuant to Rule 23(e)(1). The Court finds that it will likely be able to approve the Settlement Agreement under Rule 23(e)(2) and to certify the Settlement Class for purposes of judgment on the proposed Settlement. The Court preliminarily finds that the Settlement is fair, reasonable, and adequate as to the Settlement Class Members under the relevant considerations. The Court finds that proposed Settlement Class Representatives and proposed Settlement Class Counsel have adequately represented, and will continue to adequately represent, the Settlement Class. The Court further finds that the Settlement Agreement is the product of arm’s length negotiations by the Parties through an experienced mediator, Robert A. Meyer, Esq., and comes

after adequate investigation of the facts and legal issues, filing of three complaints and other briefing (including class certification briefing) in federal district court, fact and expert discovery, and a day-long mediation session. The Court preliminarily finds that the relief provided to the Settlement Class is adequate, taking into account, *inter alia*, the costs, risks, and delay of trial and appeal and the proposed method of distributing compensation to the Settlement Class. The Court further finds that the Settlement Agreement treats the Settlement Class Members equitably relative to one another. As set forth more fully in the Settlement Agreement, Settlement Class Members that submit a timely and valid Claim Form will be sent Claim Payments, the number of which will be based on the number of VSL#3 Class Products the Settlement Class Member purchased (or, in the case of Class Members without Proof of Purchase, no more than one (1) Unit per Household), as provided on the Settlement Class Member's submitted Claim Form and consistent with the terms of the Settlement Agreement. The Court will fully assess any request for any Settlement Class Counsel Attorneys' Fees and Costs Award, and any Service Awards for the Settlement Class Representatives, after receiving a motion from proposed Settlement Class Representatives and Settlement Class Counsel supporting such a request. At this stage, the Court finds that the plan to request such an award creates no reason not to direct notice to the Settlement Class, especially because any motion for any such award must be filed before the deadline to object or opt-out of the Settlement.

6. The Court finds that, for settlement purposes only, the Settlement Class, as defined above, meets the requirements for class certification under Federal Rules of Civil Procedure 23(a) and 23(b)(3). Specifically, the Court finds that (1) the Settlement Class Members are sufficiently numerous such that joinder is impracticable; (2) there are questions of law and fact common to Settlement Class Members; (3) proposed Settlement Class Representatives' claims are typical of

those of the Settlement Class Members; (4) proposed Settlement Class Representatives and Settlement Class Counsel have fairly and adequately represented, and will continue to fairly and adequately represent, the interests of the Settlement Class Members; and (5) for purposes of settlement only, the Settlement Class meets the predominance and superiority requirements of Rule 23(b)(3).

7. Certification of the Settlement Class shall be solely for settlement purposes and without prejudice to the Parties in the event the Settlement is not finally approved by this Court or otherwise does not take effect, and the Parties preserve all rights and defenses regarding class certification in the event the Settlement is not finally approved by this Court or otherwise does not take effect. In the event this Settlement is not approved or for any reason the Effective Date never occurs, the parties shall revert to their positions immediately prior to January 7, 2026 (including with respect to this Court's orders certifying classes in this matter) and retaining whatever rights they may have pursuant to Rule 23 or on appeal to seek to modify or otherwise challenge the Court's prior class certification order.

8. The Court hereby approves Plaintiffs David Starr, Bernadette Mavrikos, Edmund Quimbao, James Tettenhorst, Jeremy Hansen, Krista Karo, Arlene Reed-Cossairt, Peter Stavros, and Heather Farkas as Settlement Class Representatives to represent the Settlement Class.

9. The Court hereby appoints the following lawyers at the following firms as Settlement Class Counsel for the Settlement Class: Jeremy W. Schulman and Jeffrey S. Gavenman of Hughes Hubbard & Reed; and Edward F. Haber, Michelle H. Blauner, Ian J. McLoughlin, and Patrick J. Vallely of Shapiro Haber & Urmy LLP.

10. The Court hereby appoints Angeion Group LLC as Settlement Administrator and directs Angeion Group LLC to carry out all duties and responsibilities of the Settlement Administrator as specified in the Settlement Agreement and herein.

Notice Program

11. Pursuant to Rule 23(e)(1) and Rule 23(c)(2)(B), the Court approves the proposed Notice program set forth in Section 4.2 of the Settlement Agreement, including the form and content of the proposed forms of class notice attached as Exhibits 4, 5, and 6 to the Settlement Agreement. The Court finds that the proposed Notice program meets the requirements of due process under the U.S. Constitution and Rule 23; and that such Notice program, which includes providing direct notice to class members whose information Settlement Class Counsel have obtained from Defendants and Retailers, the establishment of a Settlement Website, the establishment of a toll-free telephone helpline, online display advertising, and advertising on search engines and social media, is the best notice practicable under the circumstances and shall constitute due and sufficient notice to all persons entitled thereto. The Court further finds that the proposed form and content of the Notice are adequate and will give the Settlement Class Members sufficient information to enable them to make informed decisions as to the Settlement Class, the right to object or opt out, and the proposed Settlement and its terms. The Court finds that the Notice clearly and concisely states in plain, easily understood language, *inter alia*: (i) the nature of the Litigation; (ii) the definition of the Settlement Class; (iii) the class claims and issues; (iv) that a Settlement Class Member may enter an appearance through an attorney if the member so desires; (v) that the Settlement Class Member must submit a timely claim via a valid Claim Form to be eligible to receive compensation under the Settlement; (vi) the time and manner for submitting a Claim Form; (vii) that the Court will exclude from the Settlement Class any member

who timely and validly requests exclusion; (viii) the time and manner for requesting exclusion; and (ix) the binding effect of a class judgment on Settlement Class Members under Rule 23(c)(3). The parties may make non-material changes to the proposed Notice program, including the form and content of the Notice, without seeking further approval of the Court.

12. The Court directs the Settlement Administrator and the Parties to implement the Notice program as set forth in the Settlement Agreement. As soon as practicable and no later than 45 days after entry of this Preliminary Approval Order, the Settlement Administrator shall do the following:

a. Settlement Website: The Settlement Administrator shall establish and maintain a Settlement Website hosted at www.vsl3lawsuit.com (or another URL agreed-upon by the Parties) that is dedicated to the Settlement. The Settlement Website shall contain the Long Form Notice (in substantially the same form attached as Exhibit 4 to the Settlement Agreement), in both downloadable PDF format and HTML format; a Contact Information page that includes the address for the Settlement Administrator and addresses and telephone numbers for Settlement Class Counsel; the telephone helpline number; the Settlement Agreement; this Order, a downloadable and online version of the Claim Form; and all other material filings by the Parties or the Court regarding the Settlement, including Settlement Class Counsel's application for an Attorneys' Fees and Costs Award, the motion for final approval of the Settlement, and any orders with respect to such applications and motions. The Settlement Website shall remain accessible until at least 180 days after all Claim Payments to eligible Settlement Class Members have been distributed.

b. Toll-free telephone helpline: The Settlement Administrator shall establish and maintain a toll-free telephone helpline, which shall be posted on the Settlement Website, and

to which Settlement Class Members may refer for information about the Litigation and the Settlement Agreement. The toll-free helpline shall remain active until at least 180 days after all Claim Payments to eligible Settlement Class Members have been distributed.

c. Direct notice: Settlement Class Counsel has obtained from the Retailers and Defendants Retail Transaction Records reflecting Settlement Class Members' purchases of VSL#3 Class Products during the Class Period, or commitments to produce such Retail Transaction Records to the Settlement Administrator. The Settlement Administrator will analyze Retail Transaction Records to identify individuals who are Settlement Class Members as defined in this Settlement Agreement. The Settlement Administrator shall send via email the Email Notice to all Settlement Class Members for whom the Settlement Administrator has a valid email address and shall send via U.S. mail the Mailed Notice to all Settlement Class Members for whom the Settlement Administrator has a valid U.S. mailing address but no valid email address. Direct Notice will be sent on the Notice Date.

d. Media Campaign: The Settlement Administrator shall implement the Media Campaign, including programmatic display advertising, social media advertising, and search engine marketing, substantially in the form of and using the methods proposed by the Settlement Class Representatives in their Motion for Preliminary Approval.

13. Within 14 days after entry of the Preliminary Approval Order, Defendants shall pay the Settlement Fund into the Escrow Account.

14. By no later than 35 days before the Final Approval Hearing, the Settlement Administrator shall file (or provide to Settlement Class Counsel for filing) an affidavit affirming that the Notice program has been implemented in accordance with the Settlement Agreement and

this Order (including Class Action Fairness Act notice) and identifying any Settlement Class Members who timely and validly requested exclusion from the Settlement Class.

Opt-Out and Objection Procedures

15. Settlement Class Members may exclude themselves from the Settlement Class by mailing to the Settlement Administrator a written request for exclusion that is postmarked no later than 105 days after the entry of this Preliminary Approval Order (the “Exclusion/Objection Deadline”). To be effective, the request for exclusion must include (a) the Settlement Class Member’s full name, telephone number, and mailing address; (b) a clear and unequivocal statement that the Settlement Class Member wishes to be excluded from the Settlement Class; (c) the name of the Litigation: “*Starr et al. v. VSL Pharmaceuticals, Inc., et al.*, Case No. 8:19-cv-02173”; and (d) the Settlement Class Member’s signature, or the like signature or affirmation of an individual authorized to act on the Settlement Class Member’s behalf. Upon the Settlement Administrator’s receipt of a timely and valid exclusion request, the Settlement Class Member shall be deemed excluded from the Settlement Class and shall not be entitled to any benefits of this Settlement. A Settlement Class Member may request to be excluded from the Settlement only on the Settlement Class Member’s own behalf; a Settlement Class Member may not request that other Settlement Class Members (or a group or subclass of Settlement Class Members) be excluded from the Settlement.

16. Any Settlement Class Member who does not request exclusion from the Settlement Class has the right to object to the proposed Settlement and/or to any motion for Settlement Class Counsel Attorneys’ Fees and Costs Award. To be considered valid, an objection must be writing, must be filed with or mailed to the Court, must be postmarked or filed no later than 105 days after entry of this Preliminary Approval Order (the “Exclusion/Objection Deadline”), and must include

the following: (a) the name of the Litigation: “*Starr et al. v. VSL Pharmaceuticals, Inc., et al.*,” Case No. 8:19-cv-02173”; (b) the full name, mailing address, and telephone number of the Settlement Class Member objecting to the Settlement (the “Objector”); (c) the Objector’s signature, or the like signature or affirmation of an individual authorized to act on the Objector’s behalf; (d) a statement of the specific grounds for the objection; (e) a statement whether the objection applies only to the Objector, to a specific subset of the class, or to the entire class; (f) the name, address, bar number, and telephone number of counsel for the Objector, if represented by an attorney in connection with the objection; and (g) a statement whether the Objector intends to appear at the Final Approval Hearing, either in person or through counsel. If the Objector or his or her attorney intends to present evidence at the Final Approval Hearing, the objection must contain the following information: a detailed description of all evidence the Objector will offer at the Final Approval Hearing, including copies of any and all exhibits that the Objector may introduce at the Final Approval Hearing. If an objection is not submitted in accordance with this paragraph, this Court may in the exercise of its discretion refuse to consider it. Any Settlement Class Member who does not timely submit an objection in accordance with this paragraph shall waive the right to object or to be heard at the Final Approval Hearing and shall be forever barred from making any objection to the proposed Settlement or to any motion for Settlement Class Counsel Attorneys’ Fees and Costs Award.

17. By no later than 75 days after the entry of this Preliminary Approval Order, Settlement Class Counsel shall file their motion for an Attorneys’ Fees and Costs Award. Any such motion shall be posted to the Settlement Website within one business day after its filing.

Final Approval Hearing

18. The Court will hold a Final Approval Hearing on _____, 2026 [*at least 165 days after entry of this Preliminary Approval Order*] at _____ a.m./p.m., in the United States District Court for the District of Maryland, 6500 Cherrywood Lane Greenbelt, MD 20770. The purposes of the Final Approval Hearing will be to: (i) determine whether the proposed Settlement Agreement should be finally approved by the Court as fair, reasonable, adequate, and in the best interests of the Settlement Class; (ii) determine whether judgment should be entered pursuant to the Settlement Agreement, dismissing the claims in the Litigation with prejudice and releasing all Released Claims; (iii) determine whether the Settlement Class should be finally certified; (iv) rule on Settlement Class Counsel's motion for an Attorneys' Fees and Costs Award; (v) consider any properly filed objections; and (vi) consider any other matters necessary in connection with the final approval of the Settlement Agreement. If the Court subsequently determines that the Final Approval Hearing should not occur at an in-person hearing but rather through remote means, the Court will issue a subsequent order.

19. By no later than 30 days before the Final Approval Hearing, Settlement Class Counsel shall file their motion for final approval of the Settlement Agreement.

20. Any oppositions (if any) to the motion seeking the Court's entry of the Final Approval Order shall be filed 14 days before the Final Approval Hearing.

21. Any replies in further support of the motion seeking the Court's entry of the Final Approval Order (if any) shall be filed 7 days before the date of the Final Approval Hearing.

22. The Court may, in its discretion, modify the date, time, and/or location of the Final Approval Hearing. In the event the Court changes the date, time, and/or location of the Final Approval Hearing, the new date and time shall be posted on the Settlement Website.

23. If the Settlement Agreement, including any amendment made in accordance therewith, is not approved by the Court or shall not become effective for any reason whatsoever, the Settlement Agreement and any actions taken or to be taken in connection therewith (including this Preliminary Approval Order and any judgment entered herein), shall be terminated and shall become null and void and of no further force and effect except for (i) any obligations to pay for any expense incurred in connection with Notice and administration as set forth in the Settlement Agreement, and (ii) any other obligations or provisions that are expressly designated in the Settlement Agreement to survive the termination of the Settlement Agreement.

24. Other than such proceedings as may be necessary to carry out the terms and conditions of the Settlement Agreement, including matters relating to Settlement Class Counsel's motion for an Attorneys' Fees and Costs Award, all proceedings in the Litigation are hereby stayed and suspended until further order of this Court.

25. Pending final determination of whether the Settlement Agreement should be finally approved, Settlement Class Representatives, all Settlement Class Members, and Releasing Parties (and any persons purporting to act on their behalf) are barred and enjoined from filing, commencing, prosecuting, maintaining, or enforcing any Released Claims against the Released Parties, directly or indirectly (including in any action purportedly brought on behalf of the general public of the United States or of a particular state, district, or territory therein), in any judicial, administrative, arbitral, or other forum. This bar and injunction are necessary to protect and effectuate the Settlement Agreement and this Preliminary Approval Order, and this Court's authority to effectuate the Settlement, and is ordered in aid of this Court's jurisdiction.

26. This Preliminary Approval Order, the Settlement Agreement, and all negotiations, statements, agreements, and proceedings relating to the Settlement, and any matters arising in

connection with settlement negotiations, proceedings, or agreements, shall not constitute, be described as, construed as, offered, or received against Defendants or the Released Parties as evidence or an admission of: (a) the truth of any fact alleged by any plaintiff in the Litigation; (b) any liability, negligence, fault, or wrongdoing of Defendants or the Released Parties; or (c) that this or any other action may be properly certified as a class action for litigation, non-settlement purposes.

27. The Parties are directed to take all necessary and appropriate steps to establish the means necessary to implement the Settlement Agreement according to its terms should it be finally approved.

28. The Court may, for good cause, extend any of the deadlines set forth in this Preliminary Approval Order without further notice to Settlement Class Members. Without further order of the Court, the Parties may agree to make non-material modifications in implementing the Settlement that are not inconsistent with this Preliminary Approval Order.

29. The following chart summarizes the dates and deadlines set by this Preliminary Approval Order:

Notice Date	<u> </u> , 2026, which is 45 days after entry of this Preliminary Approval Order
Last day for Settlement Class Counsel to file motion for Settlement Class Counsel Attorneys' Fees and Costs Award	<u> </u> , 2026, which is 75 days after entry of this Preliminary Approval Order
Claims Submission Deadline	<u> </u> , 2026, which is 105 days after entry of this Preliminary Approval Order
Exclusion/Objection Deadline	<u> </u> , 2026, which is 105 days after entry of this Preliminary Approval Order
Last day for Settlement Class Counsel to file motion for final approval of the Settlement	<u> </u> , 2026, which is 30 days before Final Approval Hearing

Last day to file oppositions (if any) to the motion for final approval of the Settlement	_____, 2026, which is 14 days before the Final Approval Hearing
Last day to file any replies in further support of the motion for final approval of the Settlement and the motions for Settlement Class Counsel Attorneys' Fees and Costs Award	_____, 2026, which is 7 days before the date of the Final Approval Hearing
Final Approval Hearing	_____, 2026, which is at least 165 days after entry of this Preliminary Approval Order

IT IS SO ORDERED.

DATED: _____.

Honorable Lydia Kay Griggsby
United States District Judge