BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

In the Matter of the Accusation Against:

ACROTECH BIOPHARMA LLC, DBA ACROTECH BIOPHARMA INC.; ASHISH ANVEKAR, PRESIDENT; KIRAN NAGABANDHI, TRES/CFO; WILLIAM H. REISS, DRIC

Out of State Distributor License No. OSD 7659,

and

WILLIAM HERMAN REISS,

Designated Representative License No. EXC 26864,

Respondents.

Agency Case No. 7468

OAH No. 2023100078

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on June 19, 2024.

It is so ORDERED on May 20, 2024.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

By

Seung W. Oh, Pharm.D. Board President

1	ROB BONTA Attorney General of California		
2	KAREN R. DENVIR Supervising Deputy Attorney General		
3	Malissa N. Siemantel Deputy Attorney General		
4	State Bar No. 240157 1300 I Street, Suite 125		
5	P.O. Box 944255 Sacramento, CA 94244-2550		
6 7	Telephone: (916) 210-7555 Facsimile: (916) 324-5567 Attorneys for Complainant		
8			
9	BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
10			
11	STATE OF CAL	IFORNIA	
12		LC N 7460	
13	In the Matter of the Accusation Against:	Case No. 7468	
14	ACROTECH BIOPHARMA LLC, DBA ACROTECH BIOPHARMA INC.;	OAH No. 2023100078	
15	ASHISH ANVEKAR, PRESIDENT; KIRAN NAGABANDHI, TRES/CFO;	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR	
16	WILLIAM H. REISS, DRIC 279 Princeton Hightstown Rd., Ste. 103 East Windsor, NJ 08520	PUBLIC REPROVAL AS TO RESPONDENT ACROTECH BIOPHARMA LLC, DBA ACROTECH	
17	Out of State Distributor License No. OSD 7659	BIOPHARMA INC. ONLY	
18	WILLIAM HERMAN REISS	[Bus. & Prof. Code § 495]	
19	279 Princeton Hightstown Rd, #103 East Windsor, NJ 08563		
20	Designated Representative License No. EXC 26864		
21	Respondents.		
22 23	Respondents.		
24	IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-		
25	entitled proceedings that the following matters are true:		
26	PARTIES		
27	1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy		
28	(Board). She brought this action solely in her official capacity and is represented in this matter by		
20			

Rob Bonta, Attorney General of the State of California, by Malissa N. Siemantel, Deputy Attorney General.

 Acrotech Biopharma LLC, doing business Acrotech Biopharma Inc. (Respondent Acrotech) is represented in this proceeding by attorney Michael A. Gawley, whose address is: 50 California Street, 34th Floor, San Francisco, CA 94111.

JURISDICTION

- 3. On or about November 18, 2019, the Board issued Out of State Distributor License Number OSD 7659 to Respondent Acrotech. The Board's records indicate that Ashish Avenkar has been President since September 14, 2019, Krian Nagabandhi has been the Treasurer and Chief Financial Officer since September 14, 2019, and William H. Reiss (Respondent Reiss), is and has been the Designated Representative-in-Charge (DRIC) since November 23, 2022. The Out of State Distributor License was in full force and effect at all times relevant to the charges brought herein and will expire on November 1, 2025, unless renewed.
- 4. Accusation No. 7468 was filed before the Board and is currently pending against Respondent Acrotech. The Accusation and all other statutorily required documents were properly served on Respondent on May 15, 2023. Respondent Acrotech timely filed its Notice of Defense contesting the Accusation. A copy of Accusation No. 7468 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

- 5. Respondent Acrotech has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 7468. Respondent Acrotech has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.
- 6. Respondent Acrotech is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to

reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

7. Respondent Acrotech voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

- 8. Respondent Acrotech admits the truth of each and every charge and allegation in Accusation No. 7468.
- 9. Respondent Acrotech agrees that its Out of State Distributor License is subject to discipline and they agree to be bound by the Disciplinary Order below.

CONTINGENCY

- 10. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent Acrotech understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent Acrotech understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.
- 11. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.
- 12. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified,

supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

13. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Out of State Distributor License No. OSD 7659 issued to Respondent Acrotech Biopharma LLC, doing business Acrotech Biopharma Inc., shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of Accusation No. 7468, attached as exhibit A.

Cost Recovery. No later than twelve (12) months from the effective date of the Decision, Respondent Acrotech shall pay \$5,756.25 to the Board for its costs associated with the investigation and enforcement of this matter pursuant to Business and Professions Code Section 125.3. If Respondent Acrotech fails to pay the Board costs as ordered, Respondent Acrotech shall not be allowed to renew their Out of State Distributor License until Respondent Acrotech pays costs in full. In addition, the Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

VAWD Accreditation and Reports. No later than 60 days from the effective date of the Decision, Respondent Acrotech shall provide to the Board proof of drug distributor accreditation by the Verified-Accredited Wholesale Distributors (VAWD) Program through the National Association of Boards of Pharmacy (NABP). Further, Respondent Acrotech shall submit to the Board, for three (3) years from the effective date of the Decision, any and all reports, including, but not limited to, inspection reports, issued to Respondent Acrotech by VAWD within five (5) days of Respondent Acrotech's receipt of the report(s).

Full Compliance. As a resolution of the charges in Accusation No. 7468, this stipulated settlement is contingent upon Respondent Acrotech's full compliance with all conditions of this Order. If Respondent Acrotech fails to satisfy any of these conditions, such failure to comply ///

1	constitutes cause for discipline, including outright revocation, of Respondent Acrotech's Out of			
2	State Distributor License No. OSD 7659.			
3	<u>ACCEPTANCE</u>			
4	I, Ashish Anvekar, as President of Acrotech Biopharma LLC, doing business Acrotech			
5	Biopharma Inc., have carefully read the above Stipulated Settlement and Disciplinary Order for			
6	Public Reproval and have fully discussed it with my attorney, Michael A. Gawley. I, on behalf of			
7	Acrotech Biopharma LLC, doing business Acrotech Biopharma Inc., understand the stipulation			
8	and the effect it will have on the Out of State Distributor License. I am authorized to enter into			
9	this Stipulated Settlement and Disciplinary Order for Public Reproval on behalf of Acrotech			
10	Biopharma LLC, doing business Acrotech Biopharma Inc. Acrotech Biopharma LLC, doing			
11	business Acrotech Biopharma Inc., enters into this Stipulated Settlement and Disciplinary Order			
12	for Public Reproval voluntarily, knowingly, and intelligently, and agrees to be bound by the			
13	Decision and Order of the Board of Pharmacy.			
14				
15	DATED:			
16	ACROTECH BIOPHARMA LLC, DBA ACROTECH BIOPHARMA INC.,			
17	ASHISH ANVEKAR, PRESIDENT Respondent			
18	respondent			
19	I have read and fully discussed with Ashish Anvekar as an authorized representative of			
20	Acrotech Biopharma LLC, doing business Acrotech Biopharma Inc., the terms and conditions and			
21	other matters contained in the above Stipulated Settlement and Disciplinary Order for Public			
22	Reproval. I approve its form and content.			
23				
24	DATED:			
25	MICHAEL A. GAWLEY Attorney for Respondent			
26				
27				
28				
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1	constitutes cause for discipline, including outright revocation, of Respondent Acrotech's Out of		
2	State Distributor License No. OSD 7659.		
3	<u>ACCEPTANCE</u>		
4	I, Ashish Anvekar, as President of Acrotech Biopharma LLC, doing business Acrotech		
5	Biopharma Inc., have carefully read the above Stipulated Settlement and Disciplinary Order for		
6	Public Reproval and have fully discussed it with my attorney, Michael A. Gawley. I, on behalf of		
7	Acrotech Biopharma LLC, doing business Acrotech Biopharma Inc., understand the stipulation		
8	and the effect it will have on the Out of State Distributor License. I am authorized to enter into		
9	this Stipulated Settlement and Disciplinary Order for Public Reproval on behalf of Acrotech		
10	Biopharma LLC, doing business Acrotech Biopharma Inc. Acrotech Biopharma LLC, doing		
11	business Acrotech Biopharma Inc., enters into this Stipulated Settlement and Disciplinary Order		
12	for Public Reproval voluntarily, knowingly, and intelligently, and agrees to be bound by the		
13	Decision and Order of the Board of Pharmacy.		
14 15	DATED: Ashish Anvekar DN: cn=Ashish Anvekar, o=Acrotech Biopharma, ou, email=aanvekar@acrotechbiopharma.com, c=US Date: 2024.02.21 15:44:00 -05'00'		
16 17	ACROTECH BIOPHARMA LLC, DBA ACROTECH BIOPHARMA INC., ASHISH ANVEKAR, PRESIDENT		
18	Respondent		
19	I have read and fully discussed with Ashish Anvekar as an authorized representative of		
20	Acrotech Biopharma LLC, doing business Acrotech Biopharma Inc., the terms and conditions and		
21	other matters contained in the above Stipulated Settlement and Disciplinary Order for Public		
22	Reproval. I approve its form and content.		
23			
24	DATED:		
25	MICHAEL A. GAWLEY Attorney for Respondent		
26			
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	5		

ENDORSEMENT The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs. DATED: Respectfully submitted, **ROB BONTA** Attorney General of California KAREN R. DENVIR Supervising Deputy Attorney General MALISSA N. SIEMANTEL Deputy Attorney General Attorneys for Complainant SA2023300847 37885527.docx

ENDORSEMENT 1 The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby 2 respectfully submitted for consideration by the Board of Pharmacy of the Department of 3 Consumer Affairs. 4 5 Respectfully submitted, 6 DATED: February 26, 20204 7 ROB BONTA Attorney General of California 8 KAREN R. DENVIR Supervising Deputy Attorney General Digitally signed by 9 Malissa N. Siemantel Date: 2024.02.26 10 11:55:11 -08'00' MALISSA N. SIEMANTEL 11 Deputy Attorney General Attorneys for Complainant 12 13 14 15 SA2023300847 16 37885527.docx 17 18 19 20 21 22 23 24 25 26 27 28

Exhibit A

Accusation No. 7468

1	ROB BONTA Attorney General of California			
2	KAREN R. DENVIR Supervising Deputy Attorney General			
3	Supervising Deputy Attorney General MALISSA N. SIEMANTEL Deputy Attorney General			
4	State Bar No. 240157 1300 I Street, Suite 125 P.O. Box 944255 Sacramento, CA 94244-2550			
5				
6 7	Telephone: (916) 210-7555 Facsimile: (916) 324-5567 Attorneys for Complainant			
8				
9	BEFORE THE BOARD OF PHARMACY			
10	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA			
11				
12	In the Matter of the Accusation Against:	Case No. 7468		
13	ACROTECH BIOPHARMA LLC,			
14	DBA ACROTECH BIOPHARMA INC.; ASHISH ANVEKAR, PRESIDENT;	ACCUSATION		
15	KIRAN NAGABANDHI, TRES/CFO; WILLIAM H. REISS, DRIC			
16	279 Princeton Hightstown Rd., Ste. 103 East Windsor, NJ 08520			
17	Out of State Distributor License No. OSD 7659			
18 19	WILLIAM HERMAN REISS 279 Princeton Hightstown Rd, #103 East Windsor, NJ 08563			
20	Designated Representative License No.			
21	EXC 26864			
22	Respondents.			
23				
24	D A D/TH			
25	PARTIES 1. Annu Sudamum (Complainment) being a thin Acceptation and above the sum of sixth acceptance of the sum of the			
26	1. Anne Sodergren (Complainant) brings this Accusation solely in her official capacity			
27	as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Board).			
28	1			

2. On or about November 18, 2019, the Board issued Out of State Distributor License
Number OSD 7659 to Acrotech Biopharma LLC, doing business Acrotech Biopharma Inc.
(Respondent Acrotech). The Board's records indicate that Ashish Avenkar has been President
since September 14, 2019, Krian Nagabandhi has been the Treasurer and Chief Financial Officer
since September 14, 2019, and William H. Reiss (Respondent Reiss), is and has been the
Designated Representative-in-Charge (DRIC) since November 22, 2023. The Out of State
Distributor License was in full force and effect at all times relevant to the charges brought herein
and will expire on November 1, 2023, unless renewed.

On or about November 23, 2022, the Board issued Designated Representative License Number EXC 26864 to Respondent Reiss. The Designated Representative License will expire on

- This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise
- Code section 118, subdivision (b), provides that the suspension, expiration, surrender, cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or
- Code section 4300, subdivision (a), provides that every license issued by the Board

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render

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STATUTORY AND REGULATORY PROVISIONS

8. Code section 4022.5 states:

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- (a) "Designated representative" means an individual to whom a license has been granted pursuant to Section 4053. A pharmacist fulfilling the duties of Section 4053 shall not be required to obtain a license as a designated representative.
- (b) "Designated representative-in-charge" means a designated representative or designated representative-reverse distributor, or a pharmacist licensed in the home state proposed by a wholesaler or veterinary food-animal drug retailer and approved by the board as the supervisor or manager responsible for ensuring the wholesaler's or veterinary food-animal drug retailer's compliance with all state and federal laws and regulations pertaining to practice in the applicable license category.

9. Code section 4053, subdivision (a), states¹:

Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer. The designated representative shall protect the public health and safety in the handling, storage, and shipment of dangerous drugs and dangerous devices in the wholesaler or veterinary food-animal drug retailer.

10. Code section 4161 states, in pertinent part:

- (a) A person located outside this state that (1) ships, sells, mails, warehouses, distributes, or delivers dangerous drugs or dangerous devices into this state or (2) sells, brokers, warehouses, or distributes dangerous drugs or devices within this state shall be considered a nonresident wholesaler or a nonresident third-party logistics provider.
- (b) A nonresident wholesaler or nonresident third-party logistics provider shall be licensed by the board prior to shipping, selling, mailing, warehousing, distributing, or delivering dangerous drugs or dangerous devices to a site located in this state or selling, brokering, warehousing, or distributing dangerous drugs or devices within this state.

• • •

(i) (1) The board shall not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.

• • •

(j) The designated representative-in-charge shall be responsible for the compliance of the nonresident wholesaler with state and federal laws governing wholesalers. The responsible manager shall be responsible for the compliance of the nonresident third-party logistics provider's place of business with state and federal laws governing third-party logistics providers. A nonresident wholesaler or

¹ Effective January 1, 2022, Code section 4053 was amended. However, the amendment did not change the language of subdivision (a).

COST RECOVERY

14. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licensee found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case, with failure of the licensee to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

FACTUAL ALLEGATIONS

- 15. On or about October 27, 2022, the Board received an "Application for Change of Designated Representative-in-Charge (DRIC)" (the application) for Respondent Acrotech. The application was signed on October 18, 2022, under penalty of perjury by Kiran K. Nagabandi, as the corporate officer, and William Herman Reiss, as the new DRIC. The application stated that Steve Lucas stopped acting as DRIC for Acrotech on November 3, 2021, and that Respondent Reiss started acting as the new DRIC on November 4, 2021. Respondent Reiss was not licensed as a Designated Representative at that time.
- 16. On or about November 23, 2022, the Board issued Designated Representative License Number EXC 26864 to Respondent Reiss. The Designated Representative License will expire on November 1, 2023, unless renewed.

FIRST CAUSE FOR DISCIPLINE

(Failure to Have a Designated Representative-in-Charge)

17. Respondent Acrotech is subject to disciplinary action under Code section 4301, subdivisions (o) and (p), in conjunction with Code section 4161 and Regulations section 1781, subdivision (a), in that on or about and between November 4, 2021, and November 22, 2022, Respondent Acrotech failed to have a DRIC who was properly licensed in accordance with Code sections 4022.5 and 4161, as set forth in paragraphs 15 and 16, above.

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SECOND CAUSE FOR DISCIPLINE

(Failure to Notify Board of Change in Designated Representative-in-Charge)

18. Respondent Acrotech is subject to disciplinary action under Code section 4301, subdivisions (o) and (p), in conjunction with Code section 4161, subdivision (j), in that Respondent Acrotech failed to notify the Board of a new, properly licensed DRIC within 30 days of the date that the prior DRIC ceased to be the DRIC, as set forth in paragraph 15, above.

THIRD CAUSE FOR DISCIPLINE

(Acting as a Designated Representative-in-Charge without a License)

19. Respondent Reiss is subject to disciplinary action under Code section 4301, subdivisions (o) and (p), in conjunction with Code sections 4053 and 4161, and Regulations section 1781, subdivision (a), in that Respondent Reiss acted as a DRIC without having a valid Designated Representative License, as set forth in paragraphs 15 and 16, above.

DISCIPLINE CONSIDERATIONS

20. To determine the degree of discipline, if any, to be imposed on Respondent Acrotech, Complainant alleges that on or about August 24, 2021, in a prior action, the Board of Pharmacy issued Citation Number CI 2020 91731 and ordered Respondent Acrotech to pay a civil penalty in the amount of \$750. The circumstances are that Respondent Acrotech failed to notify the Board in writing within 30 days of the date when a DRIC ceased to act as the DRIC when Respondent Acrotech notified the Board of the change in DRIC 434 days later. Further, Respondent Acrotech operated without a DRIC for 189 days. That Citation is now final.

OTHER MATTERS

21. Pursuant to Code section 4307, if discipline is imposed on Out of State Distributor License Number OSD 7659 issued to Acrotech Biopharma LLC, doing business as Acrotech Biopharma Inc., it shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee for five years if Out of State Distributor License Number OSD 7659 is placed on probation or until Out of State Distributor License Number OSD 7659 is reinstated if it is revoked.

- 22. Pursuant to Code section 4307, if discipline is imposed on Out of State Distributor License Number OSD 7659 issued to Acrotech Biopharma LLC, doing business as Acrotech Biopharma Inc., while Krian Nagabandhi has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control and had knowledge or knowingly participated in any conduct for which the licensee was disciplined, Krian Nagabandhi shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee for five years if Out of State Distributor License Number OSD 7659 is placed on probation or until Out of State Distributor License Number OSD 7659 is reinstated if it is revoked.
- 23. Pursuant to Code section 4307, if discipline is imposed on Out of State Distributor License Number OSD 7659 issued to Acrotech Biopharma LLC, doing business as Acrotech Biopharma Inc., while William Herman Reiss has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control and had knowledge or knowingly participated in any conduct for which the licensee was disciplined, William Herman Reiss shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee for five years if Out of State Distributor License Number OSD 7659 is placed on probation or until Out of State Distributor License Number OSD 7659 is reinstated if it is revoked.

<u>PRAYER</u>

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

- 1. Revoking or suspending Out of State Distributor License Number OSD 7659, issued to Acrotech Biopharma LLC, doing business as Acrotech Biopharma Inc.;
- 2. Revoking or suspending Designated Representative License Number EXC 26864, issued to William Herman Reiss;

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