UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND
(Southern Division)

_, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. REGENXBIO, INC. 9804 Medical Center Drive Rockville, MD 20850 Montgomery County KENNETH T. MILLS 9804 Medical Center Drive Rockville, MD 20850 Montgomery County CURRAN SIMPSON 9804 Medical Center Drive Rockville, MD 20850 Montgomery County STEPHEN PAKOLA 9804 Medical Center Drive Rockville, MD 20850 Montgomery County Defendants.	Case No. **COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **CLASS ACTION** Demand for Jury Trial

Plaintiff _ ("Plaintiff"), individually and on behalf of all other persons similarly situated, by his undersigned attorneys, alleges in this complaint for violations of the federal securities laws (the "Complaint") the following based upon knowledge with respect to his own acts, and upon facts obtained through an investigation conducted by his counsel, which included,

inter alia: (a) review and analysis of relevant filings made by REGENXBIO Inc. ("REGENXBIO" or the "Company") with the United States Securities and Exchange Commission (the "SEC"); (b) review and analysis of REGENXBIO's public documents, conference calls, press releases, and stock chart; (c) review and analysis of securities analysts' reports and advisories concerning the Company; and (d) information readily obtainable on the internet.

Plaintiff believes that further substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery. Most of the facts supporting the allegations contained herein are known only to the defendants or are exclusively within their control.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all investors who purchased or otherwise acquired REGENXBIO securities between February 9, 2022 and January 27, 2026, inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws (the "Class").

2. Defendants provided investors with material information concerning REGENXBIO's plan to develop and commercialize its product candidate RGX-111, a one-time gene therapy for the treatment of severe Mucopolysaccharidosis Type I (MPS I), also known as Hurler syndrome. Defendants' statements included, among other things, REGENXBIO's positive assertions of RGX-111's future trial success based on continuing positive biomarker and safety data from the ongoing PhaseI/II study.

3. Defendants provided these overwhelmingly positive statements to investors while, at the same time, disseminating false and misleading statements and/or concealing material adverse

facts concerning the efficacy and safety of its RGX-111 trial study. This caused Plaintiff and other shareholders to purchase REGENXBIO's securities at artificially inflated prices.

4. The truth began to emerge on January 28, 2026, when REGENXBIO issued a press release announcing that the FDA placed a clinical hold on its investigational gene therapy RGX-111. In pertinent part, Defendants announced that an intraventricular CNS tumor was found in a participant treated in its RGX-111 Phase I/II study.

5. Investors and analysts reacted immediately to REGENXBIO's revelation. The price of REGENXBIO's common stock declined from a closing market price of $13.41 per share on January 27, 2026, REGENXBIO's stock price fell to $11.01 per share on January 28, 2026, a decline of 17.8% in the span of just a single day.

JURISDICTION AND VENUE

6. Plaintiff brings this action, on behalf of himself and other similarly situated investors, to recover losses sustained in connection with Defendants' fraud.

7. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. §78aa.

9. Venue is proper in this District pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b), as a significant portion of Defendant REGENXBIO's business, actions, and the subsequent damages to Plaintiff and the Class, took place within this District.

10. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce,

including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

THE PARTIES

11. Plaintiff purchased REGENXBIO common stock at artificially inflated prices during the Class Period and was damaged upon the revelation of the Defendants' fraud. Plaintiff's certification evidencing his transaction(s) in REGENXBIO is attached hereto.

12. REGENXBIO, Inc. is a Delaware corporation with its principal executive offices located at 9804 Medical Center Drive, Rockville, Maryland 20850. During the Class Period, the Company's common stock traded on the NASDAQ under the symbol "RGNX."

13. Defendant Kenneth T. Mills ("Mills") was the President and Chief Executive Officer of REGENXBIO from September 22, 2015 until July 1, 2024.

14. Defendant Curran Simpson ("Simpson") was the President and Chief Executive Officer beginning on July 1, 2024 and all relevant times thereafter.

15. Defendant Stephen Pakola, M.D. ("Pakola") was, at all relevant times, the Executive Vice President and Chief Medical Officer of REGENXBIO.

16. Defendants Mills, Simpson, and Pakola are sometimes referred to herein as the "Individual Defendants." REGENXBIO together with the Individual Defendants are referred to herein as the "Defendants."

17. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of REGENXBIO's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. Each Individual Defendant was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance

and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of these Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

18. REGENXBIO is liable for the acts of the Individual Defendants, and its employees under the doctrine of respondeat superior and common law principles of agency as all the wrongful acts complained of herein were carried out within the scope of their employment with authorization.

19. The scienter of the Individual Defendants, and other employees and agents of the Company are similarly imputed to REGENXBIO under respondeat superior and agency principles.

SUBSTANTIVE ALLEGATIONS

Company Background

20. REGENXBIO is a clinical-stage biotechnology company providing gene therapies that deliver functional genes to cells with genetic defects in the United States. Its gene therapy product candidates are based on NAV Technology Platform, a proprietary adeno-associated virus (AAV) gene delivery platform.

The Defendants Materially Misled Investors Concerning the Viability and Safety of REGENXBIO's RGX-111 Study

February 9, 2022

21. On February 9, 2022, Defendants published a press release announcing positive initial data in the ongoing Phase I/II trial of RGX-111 and notably, no serious adverse events were observed. The press release detailed the pertinent results as follows:

- RGX-111, a potential one-time gene therapy for MPS I, is well-tolerated across two dose levels, with no drug-related serious adverse events
- Biomarker and neurodevelopmental assessments indicate encouraging CNS profile in patients dosed with RGX-111
- Evidence of systemic biomarker activity observed
- Phase I/II trial data are consistent with positive results from an RGX-111 single-patient IND
- Completed dosing of three patients in Cohort 2; Cohort 2 has been expanded to enroll up to 6 additional patients

22. As part of the press release, Defendant Pakola was optimistic about RGX-111's trajectory, stating, in relevant part:

> This marks our first data presentation from the Phase I/II trial evaluating RGX-111 as a potential one-time gene therapy delivered directly to the central nervous system (CNS) for the treatment of severe MPS I. We are encouraged to see that RGX-111 has been well-tolerated with emerging evidence of CNS biomarker activity and improvements in neurodevelopmental function, which suggest biological activity in the CNS following one-time administration of RGX-111. We also saw emerging evidence of biomarker activity outside of the CNS. We plan to enroll additional patients in the Phase I/II trial and look forward to providing additional updates.

February 24, 2023

23. On February 24, 2023, Defendants issued a press release announcing continuing positive data from the Phase I/II trial of RGX-111, including the absence of any serious adverse events. The press release stated in relevant part:

> **Data Summary and Safety Data**
> ***As of January 17, 2023, RGX-111 was reported to be well tolerated in the eight patients enrolled in the Phase I/II clinical trial with no drug-related serious adverse events (SAEs).*** Time of post-administration follow-up ranged from seven to 103 weeks. Two patients in Cohort 1 and three patients in Cohort 2 have completed the 48-week immunosuppression regimen, per the study protocol.
> ***RGX-111 continued to be well-tolerated in the single-patient IND with no drug-related SAEs as of December 12, 2021***. Time of post-administration follow-up was 87 weeks. This patient has completed the 48-week immunosuppression regimen, per the study protocol, and continues to receive weekly ERT.
>
> **CSF Biomarker Data**
> Data from patients in the Phase I/II trial and the single-patient IND indicate positive IDUA biomarker activity in the CNS following one-time administration of RGX-111. Heparan sulfate (HS) is a glycosaminoglycan (GAG) that is a key biomarker

of IDUA enzyme activity. In the Phase I/II trial, a decrease in CSF HS was observed through the last timepoint available in the majority of patients following administration of RGX-111. Measurable CSF IDUA enzyme activity was detected after RGX-111 administration in four of the five Phase I/II trial patients and in the single patient IND participant.

Neurodevelopmental Data
Patients in the Phase I/II trial and the single-patient IND demonstrated encouraging continued neurodevelopmental skill acquisition, as measured by age and developmentally appropriate validated instruments for neurodevelopmental testing, including the Bayley Scales of Infant Development (BSID-III) for chronological or developmental ages 0-42 months, Wechsler Abbreviated Scale of Intelligence (WASI-II) for chronological and developmental age greater than six years, and the Vineland Adaptive Behavior Scale (VABS-III; across all age groups).

All five patients assessed with BSID-III demonstrated continued developmental skill acquisition on all subsets (cognition, expressive language and fine motor). At the last assessment, four of the five patients had function ≥ -2 standard deviations of the normative mean on the cognition, expressive language and fine motor subtests. Cognitive function in a Phase I/II trial patient and the single IND patient was higher than the age equivalent scores in the available natural history data.

(Emphasis added).

24. As part of the Company's press release, Defendant Mills expressed confidence in the RGX-111 study, stating, in pertinent part:

> ***RGX-111 is our second-most advanced clinical candidate in our neurodegenerative disease pipeline and is part of our '5x'25' strategy to have five gene therapies either on the market or in late-stage development by 2025. We are encouraged to see that this potential one-time gene therapy using our NAV AAV9 vector continues to demonstrate compelling evidence of CNS biomarker activity.*** In connecting with MPS I families, we understand the need for new treatment options that can impact daily living, and we're pleased to see that most patients in this trial demonstrated continued skill acquisition across multiple neurodevelopmental assessments.
>
> (Emphasis added).

25. On February 28, 2023, during the Company's Fourth Quarter 2022 earnings call, Defendant Pakola touted RGX-111's positive results presented at the 19th Annual WORLD*Symposium*™, stating, in relevant part:

At World, we also shared additional positive interim data from the Phase I/II trial of RGX-111 for the treatment of severe MPS I. As of January 17, 2023, RGX-111 was reported to be well tolerated, with no drug-related serious adverse events. Patients demonstrated positive IDUA biomarker activity in the CNS and encouraging continued neurodevelopmental skill acquisition as measured by age and developmentally appropriate validated instruments for neurodevelopmental testing.

[Emphasis added].

May 3, 2023

26. On May 3, 2023, Defendants issued a press release announcing first quarter 2023 financial results. Most notably, the press release highlighted RGX-111's continued positive progress and recent completion of the manufacture of commercial-scale cGMP material using the NAVXpress platform process to support the continued development of RGX-111. In pertinent part:

- A Phase I/II trial of RGX-111 for the treatment of MPS I is fully enrolled with follow-up ongoing.

- ***REGENXBIO has recently completed the manufacture of commercial-scale cGMP material using the NAVXpress platform process at the REGENXBIO Manufacturing Innovation Center to support the continued development of RGX-111.***

- In February 2023, REGENXBIO announced additional positive interim data from the Phase I/II trial demonstrating that RGX-111 was well tolerated in eight patients. Biomarker and neurodevelopmental assessments indicated an encouraging CNS profile in patients dosed with RGX-111.

- ***REGENXBIO expects to complete analytical characterization of the commercial-scale cGMP material and share additional updates on program plans in the second half of 2023.***

[Emphasis added].

27. On the accompanying earnings call, Defendant Pakola reiterated the positive results from its Phase I/II trial of RGX-111 presented at results announced at the 2023 Annual WORLD*Symposium*™ in February, stating, in relevant part:

Moving to RGX-111, an investigational onetime AAV therapeutic for the treatment of severe MPS I using the NAV AAV9 vector to deliver the IDUA gene. We have completed enrollment of the Phase I/II trial of RGX-111 for the treatment of MPS I and plan to use commercial-scale cGMP material being manufactured at our Manufacturing Innovation Center using the NAVXpress platform process to support its continued development.

We recently announced additional positive interim data from the Phase I/II trial at the 2023 WORLDSymposium in February, demonstrating that RGX-111 was well tolerated in 8 patients. Biomarker and neurodevelopmental assessments indicated an encouraging CNS profile in patients dosed with RGX-111. We expect to share additional updates on plans for this program in the second half of 2023.

[Emphasis added].

November 8, 2023

28. On November 8, 2023, Defendants published third quarter 2023 financial results and "Updated Strategic Plans" focusing on the Company's AAV therapeutic product candidates with the largest "commercial opportunities and value generation." Notably, the press release stated RGNX that its RGX-111 study would not be included among its highest-priority clinical programs going forward, stating, in pertinent part:

PIPELINE PRIORITIZATION AND CORPORATE RESTRUCTURING

The following key strategic decisions support the pipeline prioritization and corporate restructuring related to product candidates that are differentiated, can be expedited, and support near-term and long-term value generation.

* * *

- Pursuing strategic alternatives, including potential partnering, for its other rare neurodegenerative disease clinical stage programs: RGX-111 for the treatment of severe Mucopolysaccharidosis Type I, RGX-181 for the treatment of late-infantile neuronal ceroid lipofuscinosis type 2 (CLN2) disease, a form of Batten disease and RGX-381 for the treatment of the ocular manifestations of CLN2 disease.

29. On the accompanying earnings call, Chief Medical Officer Pakola reiterated that the company was de-prioritizing its RGX-111 study and seeking "strategic alternatives" for the program going forward, stating, in pertinent part:

> While we are no longer moving forward with our RGX-111, 181 and 381 rare neurodegenerative programs, we believe in the potential of these therapies and are committed to finding strategic alternatives for them, including potential partners or leveraging public private partnerships.

30. CEO Kenneth T. Mills, added, in relevant part:

> So with respect to 111 and other things, that's going to be a discontinuation of any clinical development work and exercise that will result in looking for opportunities in the short term for partnering, but it won't become something that will be viewed as a meaningful contribution to the operating plans going forward.

January 14, 2025

31. Over a year later, on January 14, 2025, Defendants issued a press release announcing its strategic partnership between RGNX and Nippon Shinyaku Co., Ltd. for "RGX-111 for Mucopolysaccharidosis I (MPS I)" reiterating "[p]ositive interim data from a Phase I/II trial of RGX-111 were reported in February 2023" and that "RGX-111 has received orphan drug product, rare pediatric disease and Fast Track designations from the U.S. Food and Drug Administration (FDA)."

32. RGNX's newly appointed CEO Curran M. Simpson commented on the Company's partnership with Nippon, stating, in relevant part:

> This partnership with Nippon Shinyaku is exciting in that it maximizes our collective strengths and enables access of two potentially transformational medicines to key markets. The structure of the agreement allows us to leverage our expertise in gene therapy manufacturing while also capturing milestones and a meaningful share of future product revenues. RGX-121 is poised to be the first gene therapy for MPS II with potential FDA approval as early as late 2025, and ***RGX-111 has demonstrated very promising results in Phase 1/2 study. With Nippon Shinyaku's expertise in rare disease and strong commercial capabilities, we look forward to working together to get both of these promising candidates across the finish line for patients.***

(Emphasis added).

33. The above statements in Paragraphs 21 to 33 were false and/or materially misleading. Defendants continually touted RGX-111 as one of its lead clinical-stage AAV therapeutic product candidate RGX-111 for the treatment of MPS I using its proprietary NAV AAVP vector. Further, Defendants announced in 2018 that RGX-111 had been granted Fast Track designation by the FDA and repeatedly represented that the Phase I/II RGX-111 studies were reporting positive results consistently highlighting "positive interim safety, tolerability, and biomarker data." In truth, Defendants were aware of the serious safety issues relating to the RGX-111 study including the potential for CNS neoplasm and in November 2023 abruptly decided to de-prioritize its second-most advanced clinical candidate, RGX-111, and seek "strategic alternatives" for the program.

The Truth Emerges

January 28, 2026

34. Defendants announced that the FDA placed a clinical hold on its investigational gene therapy RGX-111 following preliminary analysis of a single case of neoplasm (intraventricular CNS tumor) in a participant treated in its Phase I. Further, the FDA also placed a clinical hold on RGX-121 citing "the similarities in products, study populations, and shared risk between the clinical studies." In pertinent part, the release added:

> The case was identified during a routine brain MRI of an asymptomatic five-year-old participant who received intracisternal RGX-111 four years prior. Preliminary genetic analysis of the resected tumor detected an AAV vector genome integration event associated with overexpression of a proto-oncogene (PLAG1), which is known to be susceptible to chromosomal rearrangements. The investigation to determine if this SAE is drug related is ongoing. The causality has not been established. The participant continues to be asymptomatic, with positive developmental advancements noted by the treating physician. No evidence of neoplasm has been reported in the nine other participants treated with RGX-111 nor in the 32 participants treated with RGX-121.

35. The aforementioned press releases and statements made by the Individual Defendants are in direct contrast to statements they made during the above-referenced earnings calls and press releases. On those calls, Defendants continually praised RGX-111 as its second-most advanced clinical-stage AAV therapeutic product candidate for gene therapies consistently highlighting positive interim data with "no drug-related serious adverse events," while simultaneously minimizing the serious safety risks associated with the RGX-111 study including the potential for CNS neoplasm.

36. Investors and analysts reacted immediately to REGENXBIO's revelation. The price of REGENXBIO's common stock declined from a closing market price of $13.41 per share on January 28, 2026 to $11.01 per share on January 28, 2026, a decline of 17.8% in the span of just a single day.

Additional Scienter Allegations

37. During the Class Period, Defendants acted with scienter in that they knew, should have known, or otherwise were deliberately reckless in not knowing that the public statements disseminated on behalf of REGENXBIO were materially false and misleading at the time they were made. Defendants had actual knowledge of, or access to, non-public information concerning the serious safety risks associated with REGENXBIO's RGX-111 gene therapy candidate for the treatment of MPS I, including the potential for intraventricular CNS tumors. Despite such knowledge, Defendants repeatedly conveyed to investors that the Phase I/II clinical trials for RGX-111 were on track to produce positive results without the risk of any serious adverse events.

38. In fact, Defendants knew or deliberately disregarded the risks associated with AAV-based gene therapy administered intracisternally, a type of treatment that carries a recognized risk of delayed genome integration and potential cancer-related effects. In particular,

Defendants repeatedly described RGX-111 as demonstrating "very promising" results in its Phase I/II study and touted the "potentially transformational medicines" in its strategic partnership announcement with Nippon while omitting the material safety concerns with the study.

39. Defendants' knowledge concerning the serious safety issues relating to the RGX-111 study, including the potential for CNS neoplasm, is also evident from the fact that in November 2023 they abruptly decided to de-prioritize its second-most advanced clinical candidate, RGX-111, and seek "strategic alternatives" for the program.

Loss Causation and Economic Loss

40. During the Class Period, as detailed herein, Defendants made materially false and misleading statements and engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of REGENXBIO's common stock and operated as a fraud or deceit on Class Period purchasers of REGENXBIO's common stock by materially misleading the investing public. Later, Defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the price of REGENXBIO's common stock materially declined, as the prior artificial inflation came out of the price over time. As a result of their purchases of REGENXBIO's common stock during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages under federal securities laws.

Presumption of Reliance; Fraud-On-The-Market

41. At all relevant times, the market for REGENXBIO's common stock was an efficient market for the following reasons, among others:

(a) REGENXBIO's common stock met the requirements for listing and was listed and actively traded on the NASDAQ during the Class Period, a highly efficient and automated market;

(b) REGENXBIO communicated with public investors via established market communication mechanisms, including disseminations of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

(c) REGENXBIO was followed by several securities analysts employed by major brokerage firms who authored reports that were distributed to the sales force and certain customers of their respective brokerage firms during the Class Period. Each of these reports was publicly available and entered the public marketplace; and

(d) Unexpected material news about REGENXBIO was reflected in and incorporated into the Company's stock price during the Class Period.

42. As a result of the foregoing, the market for REGENXBIO's common stock promptly digested current information regarding the Company from all publicly available sources and reflected such information in REGENXBIO's stock price. Under these circumstances, all purchasers of REGENXBIO's common stock during the Class Period suffered similar injury through their purchase of REGENXBIO's common stock at artificially inflated prices, and a presumption of reliance applies.

43. Alternatively, reliance need not be proven in this action because the action involves omissions and deficient disclosures. Positive proof of reliance is not a prerequisite to recovery pursuant to ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense

that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security.

No Safe Harbor; Inapplicability of Bespeaks Caution Doctrine

44. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the material misrepresentations and omissions alleged in this Complaint. As alleged above, Defendants' liability stems from the fact that they provided investors with revenue projections while at the same time failing to maintain adequate forecasting processes. Defendants provided the public with forecasts that failed to account for this decline in sales and/or adequately disclose the fact that the Company at the current time did not have adequate forecasting processes.

45. To the extent certain of the statements alleged to be misleading or inaccurate may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

46. Defendants are also liable for any false or misleading "forward-looking statements" pleaded because, at the time each "forward-looking statement" was made, the speaker knew the "forward-looking statement" was false or misleading and the "forward-looking statement" was authorized and/or approved by an executive officer of REGENXBIO who knew that the "forward-looking statement" was false. Alternatively, none of the historic or present-tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any

of the projections or forecasts made by the defendants expressly related to or stated to be dependent on those historic or present-tense statements when made.

CLASS ACTION ALLEGATIONS

47. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired REGENXBIO's common stock during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosure. Excluded from the Class are defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

48. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, REGENXBIO's common stock were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by REGENXBIO or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions. As of March 7, 2025, there were 50 million shares of the Company's common stock outstanding. Upon information and belief, these shares are held by thousands, if not millions, of individuals located throughout the country and possibly the world. Joinder would be highly impracticable.

49. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

50. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

51. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of REGENXBIO;

(c) whether the Individual Defendants caused REGENXBIO to issue false and misleading financial statements during the Class Period;

(d) whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

(e) whether the prices of REGENXBIO's common stock during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

(f) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

52. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I

Against All Defendants for Violations of Section 10(b) and Rule 10b-5 Promulgated Thereunder

53. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

54. This Count is asserted against defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

55. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon. Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of REGENXBIO common stock; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire REGENXBIO's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

56. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for REGENXBIO's securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company.

57. By virtue of their positions at the Company, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

58. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within defendants' knowledge and control. As the senior managers and/or directors of the Company, the Individual Defendants had knowledge of the details of REGENXBIO's internal affairs.

59. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of the

Company. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to REGENXBIO's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of REGENXBIO's common stock was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning the Company which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired REGENXBIO's common stock at artificially inflated prices and relied upon the price of the common stock, the integrity of the market for the common stock and/or upon statements disseminated by Defendants, and were damaged thereby.

60. During the Class Period, REGENXBIO's common stock was traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of REGENXBIO's common stock at prices artificially inflated by defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said common stock, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of REGENXBIO's common stock was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of REGENXBIO's common stock declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

61. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

62. As a direct and proximate result of defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's common stock during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

Against the Individual Defendants
for Violations of Section 20(a) of the Exchange Act

63. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

64. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information about REGENXBIO's misstatements.

65. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information, and to correct promptly any public statements issued by REGENXBIO which had become materially false or misleading.

66. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which REGENXBIO disseminated in the marketplace during the Class Period concerning the misrepresentations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause REGENXBIO to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of REGENXBIO's common stock.

67. Each of the Individual Defendants, therefore, acted as a controlling person of the Company. By reason of their senior management positions and/or being directors of the Company, each of the Individual Defendants had the power to direct the actions of, and exercised the same

to cause REGENXBIO to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of the Company and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

68. By reason of the above conduct, the Individual Defendants and/or REGENXBIO are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demand judgment against defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representatives;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class pre-judgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated:

Respectfully submitted,

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