UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. VIATRIS INC., SCOTT ANDREW SMITH, and THEODORA MISTRAS, Defendants.	Case No. **COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **CLASS ACTION** Jury Trial Demanded

Plaintiff , individually and on behalf of all other persons similarly situated, by her undersigned attorneys, alleges in this Complaint for violations of the federal securities laws the following based upon knowledge with respect to her own acts, and upon facts obtained through an investigation conducted by her counsel, that included, *inter alia*: (a) review and analysis of relevant filings made by Viatris Inc. ("Viatris" or the "Company") with the United States Securities and Exchange Commission; (b) review and analysis of Viatris' 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 Viatris securities between August 8, 2024, to February 26, 2025, inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws.

2. Defendants provided investors with material information concerning the failed inspection of Viatris' Indore, India facility. Defendants' statements, albeit made months after the initial inspection and Defendants' initiation of remediation efforts included, among other things, the disclosure of the FDA's issuance of a warning letter and import alert which would prevent Viatris from shipping eleven products from the Indore facility, though four of such were exempt from the limitations (the "Warning Letter"). Defendants routinely referred to the impact of the Warning Letter as a mere "minor headwind" for the Company.

3. Defendants provided these disclosures to investors while, at the same time, disseminating materially false and misleading statements and/or concealing material adverse facts concerning the true state impact of the Warning Letter on Viatris' financials; notably, Defendants did not disclose precisely when the inspection occurred, how long the remediation efforts had been implemented, or the financial impact of the existing and continued remediation efforts; Defendants further notably failed to disclose which products were subject to the FDA Warning Letter, which products were subject to exemptions, and the significance of the restricted products with respect to the Company's existing financials and future projections, and for which the company believed it would obtain exemptions. Such statements, absent these material facts, caused Plaintiff and other shareholders to purchase Viatris' securities at artificially inflated prices.

4. On February 27, 2025 Viatris announced its financial results for the fourth quarter and full fiscal year 2024 and provided disappointing fiscal 2025 guidance. The Company attributed below-expectation guidance on "the expected financial impact from Indore facility warning letter and import alert."

5. Investors and analysts reacted immediately to Viatris' revelation. The price of Viatris' common stock declined dramatically. From a closing market price of $11.24 per share on February 26, 2025, Viatris' stock price fell to $9.53 per share on February 27, 2025, a decline of about 15.21% in the span of just a single day.

JURISDICTION AND VENUE

6. Plaintiff brings this action, on behalf of herself 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 Defendant Viatris is headquartered in this District and a significant portion of its business, actions, and the subsequent damages to Plaintiff and the Class, occurred 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 Viatris common stock at artificially inflated prices during the Class Period and was damaged upon the revelation of Defendants' fraud. Plaintiff's certification evidencing her transactions in Viatris is attached hereto.

12. Viatris is a Pennsylvania corporation with its principal executive offices located at 1000 Mylan Boulevard, Canonsburg, PA 15317. During the Class Period, the Company's common stock traded on the NASDAQ Stock Market (the "NASDAQ") under the symbol "VTRS."

13. Defendant Scott Andrew Smith was at all relevant times the Chief Executive Officer and Director of Viatris.

14. Defendant Theodora Mistras was at all relevant times the Chief Financial Officer.

15. Defendants Smith and Mistras are sometimes referred to herein as the "Individual Defendants." Viatris, together with the Individual Defendants, are referred to herein as the "Defendants."

16. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Viatris' 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, the issuance thereof 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.

17. Viatris 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 wrongful acts complained of herein were carried out within the scope of their employment with authorization.

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

SUBSTANTIVE ALLEGATIONS

Company Background

19. Viatris is a global healthcare company that supplies medicines to about 1 billion patients across more than 165 countries and territories via its 26 manufacturing and packaging sites worldwide.

20. The Company is headquartered in Pittsburgh, Pennsylvania with global centers in Shanghai, China and Hyderabad, India.

The Defendants Materially Misled Investors Concerning the Significance and Impact of the Failed FDA Inspection at the Indore, India Facility

August 8, 2024

21. On August 8, 2024 Defendants issued their quarterly report for the second quarter of fiscal year 2024, covering the period that ended on July 30, 2024. In the 10-Q filing, Defendants reiterated the following pertinent entry among the list of risk factors that could affect the company's future financials:

> Any changes in or difficulties with the Company's manufacturing facilities, ***including with respect to inspections, remediation and restructuring activities***, supply chain or inventory or the ability to meet anticipated demand

(Emphasis added).

22. Despite acknowledgment of this risk factor, Defendants made no mention of any inspection, failed or otherwise, of its Indore, India facility in either its press release, 10-Q filing, or earnings call corresponding to the second quarter fiscal year 2024 results. In the same vein, Defendants further made no mention of any ongoing remediation efforts with respect to the Indore facility.

23. Viatris' 10-Q for the second quarter of fiscal year 2024, in pertinent part, directs investors "[f]or more detailed information on the risks and uncertainties associated with Viatris, [to] see the risks described in Part I, Item 1A in the 2023 Form 10-K."

24. In the Company's 2023 10-K as filed on February 28, 2024, Viatris' expanded on the risks associated with FDA inspections, stating, in pertinent part:

> ***We believe all our facilities are in good operating condition, the machinery and equipment are well-maintained, the facilities are suitable for their intended purposes, and they have capacities adequate for the current operations.***
>
> ***Facilities and records related to our products are subject to periodic inspection by the FDA***, the EMA and other regulatory authorities in jurisdictions where our products are marketed. In addition, ***authorities often conduct pre-approval plant inspections to determine whether our systems and processes comply with current GMP and other regulations, and clinical-trial reviews to evaluate regulatory compliance and data integrity.*** Our suppliers, contract manufacturers, clinical trial partners and other business partners are subject to similar regulations and periodic inspections. ***The Company remains committed to maintaining the highest quality manufacturing standards at its facilities around the world and to continuous assessment and improvement in a time of evolving industry dynamics and regulatory expectations.***
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> . . .
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> ***The pharmaceutical industry is subject to regulation by various governmental authorities in the jurisdictions in which we operate, including the U.S., EU,***

China and India. For instance, ***we must comply with applicable laws and requirements of the FDA and other regulatory agencies,*** including foreign authorities, with respect to the research, development, manufacture, quality, safety, effectiveness, approval, labeling, tracking, tracing, authentication, storage, record-keeping, reporting, pharmacovigilance, sale, distribution, import, export, marketing, advertising, and promotion of pharmaceutical products. We are committed to conducting our business, including the sale and marketing of our products, in compliance with all applicable laws and regulations. These laws and regulations, however, are numerous, complex and continue to evolve, and it is possible that a governmental authority may challenge our activities, or that an employee or agent could violate these laws and regulations without our knowledge. ***Failure to comply with these laws, regulations or expectations could result in a range of consequences, including, but not limited to, fines, penalties, disgorgement, exclusion from U.S. federal healthcare reimbursement programs, unanticipated compliance expenditures, suspension of review of applications or other submissions, rejection or delay in approval of applications, recall or seizure of products, total or partial suspension of production and/or distribution, our inability to sell products, the return by customers of our products, injunctions, and/or criminal prosecution***. Under certain circumstances, a regulator may also have the authority to revoke or vary previously granted drug approvals.

The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If such regulatory authorities become aware of new safety information about any of our marketed or investigational products, those authorities may require further inspections, enhancements to manufacturing controls, labeling changes, establishment of a risk evaluation and mitigation strategy or similar strategy, restrictions on a product's indicated uses or marketing, or post-approval studies or post-market surveillance. In addition, we are subject to regulations in various jurisdictions, including the Federal Drug Supply Chain Security Act in the U.S., the Falsified Medicines Directive in the EU and several other such regulations in other countries that require us to develop electronic systems to serialize, track, trace and authenticate units of our products through the supply chain and distribution system. Compliance with these regulations has in the past and may in the future result in increased expenses for us or impose greater administrative burdens on our organization, and failure to meet these requirements could result in fines or other penalties.

. . .

The FDA and comparable foreign regulatory authorities also regulate the facilities and operational procedures that we use to manufacture our products. We must register our facilities with the FDA and similar regulators in other countries. Products must be manufactured in our facilities in accordance with cGMP or similar standards in each territory in which we manufacture. Compliance with such regulations and with our own quality standards requires substantial

expenditures of time, money, and effort in multiple areas, including training of personnel, record-keeping, production, and quality control and quality assurance. ***The FDA and other comparable regulatory authorities, including foreign authorities, periodically inspect our manufacturing facilities for compliance with cGMP or similar standards in the applicable territory. Regulatory approval to manufacture a drug is granted on a site-specific basis. Failure to comply with cGMP and other regulatory standards at one of our or our partners' or suppliers' manufacturing facilities could result in an adverse action brought by the FDA or other regulatory authorities, which has resulted and could in the future result in the receipt of an untitled or warning letter, fines, penalties, disgorgement, unanticipated compliance expenditures, rejection or delay in approval of applications, suspension of review of applications or other submissions, suspension of ongoing clinical trials, recall or seizure of products, total or partial suspension of production and/or distribution, our inability to sell products, the return by customers of our products, orders to suspend, vary, or withdraw marketing authorizations, injunctions, consent decrees, requirements to modify promotional materials or issue corrective information to healthcare practitioners, refusal to permit import or export, criminal prosecution and/or other adverse actions.***

Our business could be adversely affected if any regulatory body were to delay, withhold, or withdraw approval of an application; require a recall or other adverse product action; ***require one of our manufacturing facilities to cease or limit production***; or suspend, vary, or withdraw related marketing authorization. ***Delay and cost in obtaining FDA or other regulatory approval to manufacture at a different facility also could have a material adverse effect on our business.***

Although we have established internal quality and regulatory compliance programs and policies, there is no guarantee that these programs and policies, as currently designed, will meet regulatory agency standards in the future or will prevent instances of non-compliance with applicable laws and regulations. Additionally, despite our compliance efforts, we or our partners have in the past and may in the future receive notices of manufacturing and quality-related observations following inspections by regulatory authorities around the world, as well as official agency correspondence regarding compliance. ***If we are unable to resolve these observations and address regulatory concerns in a timely fashion, our business, financial condition, results of operations, cash flows, ability to pay dividends and/or stock price could be materially adversely affected***.

(Emphasis added)

25. Despite incorporating the elaborated risks in the Company's 10-K filing into the August, 23, 2024 10-Q, Defendants made no effort to alert its investors as to the failed inspection at its Indore, India facility, the ongoing remediation efforts, or the extent to which additional

remediation efforts and potential punitive measures were likely to be implemented before the facility could begin to operate normally again.

November 7, 2024

26. On November 7, 2024 Defendants issued their quarterly report for the third quarter of fiscal year 2024, covering the period which ended on September 30, 2024. In the corresponding 10-Q filing, Defendants again reiterated that inspections and remediation activities could impact their financials, again stating in pertinent part:

> Any changes in or difficulties with the Company's manufacturing facilities, ***including with respect to inspections, remediation and restructuring activities***, supply chain or inventory or the ability to meet anticipated demand.

(Emphasis added).

27. Yet again, despite acknowledgment of this risk factor, Defendants did not mention the Indore facility inspection, subsequent remediation measures, or otherwise posit the risk of the potential Warning Letter and its ramifications to Viatris' finances.

December 23, 2024

28. On December 23, 2024 Defendants issued a press release speaking, for the first time, about the inspection at the Indore, India facility. Defendants announced that the FDA had issued a Warning Letter following a failed inspection at the facility, stating, in pertinent part:

> ***Following an inspection by the U.S. FDA at our oral finished dose manufacturing facility in Indore, India earlier this year***, the ***Agency has issued a warning letter, and an Import Alert*** related to this facility.

(Emphasis added).

29. Despite that the import alert "***affects 11 actively distributed products that will no longer be accepted into the U.S. until the Warning Letter is lifted***," the Company highlighted that there were "four products" excepted from the ban "on shortage concerns," and added that "***[t]here***

could be potential for additional exceptions based on further discussions with the Agency"

(Emphasis added).

30. The press release further disclosed that ongoing remediation efforts had been occurring at the facility since Viatris first learned of the inspection results at an undisclosed time earlier in the year and, despite such work, there would be no impact to the current-year's financials, stating in pertinent part:

> ***Following the substance of FDA's original inspection observations, we immediately implemented a comprehensive remediation plan at the site***. The necessary corrective and preventive actions are well underway, including but not limited to related personnel actions. Additionally we have engaged independent third-party subject matter experts to support the remediation plan.
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> ***At this time, we do not anticipate these actions impacting our current 2024 guidance ranges***. We will incorporate potential future financial impact in our 2025 guidance ranges when we provide these in early 2025.

(Emphasis added).

January 14, 2025

31. On January 14, 2025 Viatris presented at the 43rd Annual J.P. Morgan Healthcare Conference 2025. During the Company's panel presentation, Defendants Smith and Mistras, in pertinent part, spoke to the FDA Warning Letter, downplaying its impact on the Company's financials:

> <Q: Christopher Thomas Schott – JPMorgan Chase & Co. – Senior Analyst> Maybe one last bigger picture one. Just -- I know, you're not giving formal guidance for 2025. But just headwinds and tailwinds, what are the things we should watch for as we go for this year?
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> <A: Scott Andrew Smith> So headwinds and tailwinds. So just 1 thing, and I'll let Doretta take on the headwinds and tailwinds from a finance perspective. ***One of the things that was announced was an Import Alert from our facility in Indore***, and she will address that, I think, ***a little bit as a headwind for us***. And I just wanted to say before she gets into the headwinds and tailwinds. ***So we take it very seriously.***

The Indore facility is 1 of 26 manufacturing facilities. It's an important facility within our global network. It's focused on oral solid doses. The Warning Letter and Import Alert are a result of an inspection which happened about 8 months ago. And we're in close communication with the FDA and receiving initial FDA feedback some months ago. We -- when we got that feedback, we agreed to immediate remediation at that time of the issues that they had.

And the ***Import Alert involves 11 products in the U.S., however, 4 products of the 11 are on an exempt list, and we're in active discussions with the FDA to add more products to that exempt list.*** So that was one of the things and Doretta go into it a little bit more to ***provide a little bit of headwind for us as we move into 2025***.

<A: Theodora Mistras> Yes. Just to give some additional color regarding our headwinds and our tailwinds. There are some pushes and pulls as to consider as we think about 2025. From a tailwind perspective, we currently expect strong performance from Europe and China, contributions from our Complex Generics portfolio as well as our broad portfolio of new product launches are expected to contribute somewhere between $450 million and $550 million of new product revenue next year.

From a headwind perspective, as Scott mentioned, specifically with respect to Indore, currently, we're having ongoing discussions, both with the FDA as well as current customers. And so we're not in a position right now to disclose specific products, and we're continuing to assess the potential impact from Indore and lastly, just from a headwind perspective, we're continuing to monitor just given the strength of the U.S. dollar FX across our key currencies. About 70% of our business is outside of the U.S. And just to give some perspective, if you were to apply '24 rates to -- the spot rates to kind of the average rate over '24, that would have had a 2% to 3% impact to our '24, just to give some connection.

And so we plan, ultimately, intention is when we kind of consistent with historical precedent to provide our outlook when we give Q4 results and guidance end of February, early March.

<Q: Christopher Thomas Schott> I know the specific products aren't disclosed and you're still working on it. Just any -- just to quantify just how big is this facility from a revenue perspective?

<A: Theodora Mistras> So as Scott -- ***it's 1 of 26 facilities. It's an oral dose manufacturing facility. It services our network across the world. So it's a global facility for us as it relates to Indore.***

(Emphasis added).

32. The above statements in Paragraphs 21 to 31 were false and/or materially misleading. Defendants created the false impression that they possessed reliable information pertaining to the headwinds impacting the Company's projected revenue outlook and anticipated growth while also minimizing the significance and risk associated with the impact of the failed inspection and corresponding Warning Letter. In truth, Viatris' efforts to downplay the ramifications of the Indore facility's failed FDA inspection fell short of reality; the impact to the Company's projected fiscal year 2025 finances from the combination of the ongoing remediation efforts at the facility, the inability for the facility to manufacture and ship key products for the Company, particularly Lenalidomide, the inability for Viatris to convince the FDA to expand the exempt list to include such drugs, and an associated impact on shipments to other regions from the Indore facility was significant and resulted in much more than "a little bit" of a headwind.

The Truth Emerges during Viatris' Fourth Quarter Earnings Report

February 27, 2025

33. On February 27, 2025 Defendants released their fourth quarter, fiscal year 2024 results and provided guidance for fiscal year 2025. Defendants updated their annual 10-K filing and provided disclosures regarding the FDA inspection of the Indore facility, stating, in pertinent part:

> ***Facilities and records related to our products are subject to periodic inspection by the FDA, the EMA and other regulatory authorities in jurisdictions where the Company's products are marketed. In addition, authorities often conduct pre-approval plant inspections to determine whether the Company's systems and processes comply with current GMP and other regulations, and clinical-trial reviews to evaluate regulatory compliance and data integrity.*** Our suppliers, contract manufacturers, clinical trial partners and other business partners are subject to similar regulations and periodic inspections. ***The Company remains committed to maintaining the highest quality manufacturing standards at its facilities around the world and to continuous assessment and improvement in a time of evolving industry dynamics and regulatory expectations.***

> ***Following an inspection by the FDA at our oral finished dose manufacturing facility in Indore, India in 2024, the FDA has issued a warning letter, and an import alert related to this facility. The import alert affects 11 actively distributed products that will no longer be accepted into the U.S. until the warning letter is lifted***. It makes exceptions, subject to certain conditions, for four products based on shortage concerns. Following recently concluded discussions with the FDA, the Company does not expect additional product exceptions to be granted by the FDA.
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> ***Following the substance of FDA's original inspection observations, the Company immediately implemented a comprehensive remediation plan at the site. The necessary corrective and preventive actions are well underway, including but not limited to related personnel actions***. Additionally, we have engaged independent third-party subject matter experts to support the remediation plan.
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> ***We have been in regular communication with FDA during this process and will continue to work to ensure that the FDA is satisfied with the steps we have taken to resolve all the points raised***. Our responses to the warning letter and import alert were submitted within the required time periods.
>
> ***While product continues to be shipped from the Indore facility to markets outside the U.S., some impact in other markets, including the ARV business in Emerging Markets and select generic products in Europe, is anticipated. The Company currently estimates the negative impact to 2025 total revenues to be approximately $500 million and to 2025 earnings from operations to be approximately $385 million.***
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> We take very seriously our continued and comprehensive oversight of our entire manufacturing network. Patient safety remains our primary and unwavering focus. We will work closely with our customers to mitigate any possible supply disruptions and meet the needs of the patients we serve.

(Emphasis added).

34. During the same-day earnings call, Defendant Smith provided multiple revelations regarding the FDA's action at the Indore facility. In pertinent part, Defendant Smith unveiled that the FDA inspection occurred in June 2024, that the Company was half-way completed with its remediation efforts, that no other products would be granted exceptions as previously suggested, and that the headwinds in 2025 from the FDA's Warning Letter would be significant:

> Before we dive into our 2025 priorities, I want to give you an update on the remediation efforts at our facility in Indore, India, and the estimated impact for this year. ***The FDA inspected the facility in June. Following the inspection, we***

immediately began implementing a comprehensive remediation plan to address the FDA feedback. The necessary corrective actions are well underway, including, but not limited to related personnel actions, and we have engaged independent third-party subject matter experts to support our efforts.

I assure you we take these matters very seriously as well as our commitment to quality across our entire network. We recently traveled to Indore to review the progress***. I can tell you we are more than halfway through our efforts. We expect to be completed in a few months, at which time we anticipate asking the FDA to conduct a reinspection of the facility***. We received a warning letter and import alert from the FDA at the end of December. The important alert affects 11 actively distributed products in the U.S., including lenalidomide.

The FDA made exceptions subject to certain conditions for 4 products based on shortage concerns. We recently finished interactions with the FDA about potential additional product exceptions, and we do not expect any additional exceptions will be granted at this time. While product continues to be shipped from the facility to markets outside the U.S., ***we currently anticipate some impact in other markets, including parts of our ARV business and emerging markets and to select generic products in Europe.***

We currently estimate the negative impact on 2025 total revenues to be approximately $500 million and on 2025 adjusted EBITDA to be approximately $385 million. To meet the needs of the patients we serve, we are working closely with our customers to mitigate any supply disruptions, including potential site transfers and third-party arrangements.

(Emphasis added).

35. The question-and-answer portion of the call followed, during which the Defendants fielded multiple questions surrounding their prior disclosures regarding the Warning Letter and its associated impact on the Viatris' projections, pertinently, in the following exchanges:

<Q: David A. Amsellem – Piper Sandler & Co. – MD & Senior Research Analyst> So first, I guess, on the warning letter and the remediation. I guess any time there is a warning letter you can't help but wonder are there potential issues with quality control at other facilities. So I guess, can you just talk about your level of confidence that this is something that is contained to Indore and not something that you're worried about in terms of 483s and potential warning letters at other sites?

. . .

<A: Scott Andrew Smith> So thank you, David. Thanks for the questions. So first of all, your first question around security and thoughts around other facilities. There

were 3 facilities inspected in '24. ***We've talked about Indore here, where we got the warning letter and import letter. There was also an inspection in Carole Park in Australia, and that has been closed out***. No voluntary issues there for us to be able to handle. No warning letter issued there at all. So that was -- that's closed out in terms of Carole Park.

The third facility is in Nashik, India, and there was an inspection there. The classification of that is pending. And so we're waiting to hear back there. All other facilities within the network -- and there's 26 facilities in our network, all other facilities are within acceptable compliance status with all the relevant health authorities. So that's where we stand. We're waiting to hear back on Nashik, but everything else is in compliance at this point in time.

And again, this is -- the Indore situation was 1 out of 26 facilities in our network, an important one, not to diminish that, but 1 in 26 within the network.

. . .

<Q: Ashwani Verma – UBS Investment Bank – Director of Americas Equity Research & US Specialty Pharma Analyst> So I wanted to understand the implications for 2026. So typically, these type of warning letters can take a minimum of 2 years to resolve. I know you said that Revlimid was already going to go off, but did you have some offsets planned for it already?

. . .

<A: Scott Andrew Smith> ***So the remediation efforts in Indore are, I would say, more than halfway done. We expect to be done as we get to the late spring, early summer with the remediation.*** At that point, we'll ask the FDA to come in and reinspect the facility, which we -- ***relative to lenalidomide, we talked extensively with the FDA and thought we had a really good case to get it on the exempt list because of the critical nature of that particular medicine. We were unable to do so***.

We looked for alternate sources of lenalidomide and continue to do so. However, lenalidomide is scheduled to hit a secondary patent cliff, I'll say, or expected to -- the economics of it are expected to significantly diminish as we get into January of '26. So from a lenalidomide perspective, this just brought that event up earlier for us, 10 to 12 months earlier. I certainly would have liked to have that capital to deploy as part of our revenue and EBITDA, but it was an event that was going to happen within 10 to 12 months. ***We are looking high and low for alternate ways to be able to fill that. At this point, we don't have any***

. . .

<Q: Christopher Thomas Schott – JPMorgan Chase & Co – Senior Analyst> Can you just maybe walk through a little bit when we think about the year-over-year step down in gross margins how much of that is coming from Indore and how much of that is coming from some of the factors that you cited?

<A: Theodora Mistras> And to your question, Chris, around gross margin. There were a couple of components, as I mentioned, that we're factoring into the step-down. ***The largest component is Indore. Just given the high-margin nature of both the penalties as well as lenalidomide, the margin impact of Indore is about -- kind of close to 80% margin***. And then in addition to that, we just have normal kind of base business price erosion and increase in some product supply cost. And that has been offset with kind of benefits from just ongoing segment mix in our business.

. . .

<Q: Jason Matthew Gerberry – BofA Securities – Managing Director in US Equity Research> So just for me, maybe I missed this, but why does the Indore facility issues have an impact on revenues outside the United States?

<A: Scott Andrew Smith> So just on the first question, ***I think when you get a situation like Indore and warning letter and an active remediation that's ongoing right now, that active remediation sometimes can cause you to have a pause in manufacturing, supply issues in certain cases. Even though the product can go into Europe, there might be shortages of certain products, as we work through that plan and remediate.***

We look for alternate sources of products while we're doing the remediation. So you can see some shortages with some products, but certainly not across the board, and it's very specific to product and location. But it has to do with the remediation of the facility. And again, we've got a network of facilities here from a manufacturing perspective, 26 globally, and we look for alternate sources when we have a shutdown for remediation or a slowdown for remediation like we do at Indore.

. . .

<Q: Umer Raffat – Evercore ISI Institutional Equities – Senior MD & Senior Analyst of Equity Research> First, Scott, Doretta, for you, at the conference in January, you guys talked about -- ***for the Indore warning letter, you guys mentioned it's 11 products and most -- and 4 of the 11 were exempt and more could get exempt. So most folks listening in just assumed, you know what, hundreds of products, 11 -- 100 of products in this company, 11 of them, so probably not so much. But the top of EBITDA hit we learned about today, considering also that you knew generic Revlimid was one of them, I'm just***

> ***curious about the thought process around how you guys communicated that to investors previously***.
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> . . .
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> <A: Scott Andrew Smith> Yes. So relative to disclosure, JPMorgan, it was a very dynamic situation at that time. ***There were some products which were excluded, others in which we had agreement from the FDA that we could go ahead and ask for exclusion and put our case together, why. So we were unsure exactly what that would look like. We were also exploring alternate forms of lenalidomide from other companies to help fill that shortage gap. So it was a very dynamic situation at that time.***
>
> ***We didn't even have a good view on exactly whether lenalidomide will be excluded or not until just a few days ago. So it's been very dynamic. We thought we had a great case because of the importance of the medication. It just did not materialize.*** And so, for me, JPMorgan to start to say, well, this is this product and not that product without being able to give the whole picture, I think, gets to our credibility. ***What was really concerning to me was to be accurate, to be credible to when I understood what exactly that list would look like and what exactly the impacts would look like that I could share that.***
>
> And I think it's only been in the last couple of days that it's been very clear to us what the U.S. and non-U.S. impacts are, including lenalidomide. ***I think the distortion that you see in terms of the magnitude from a revenue and EBITDA perspective is because specifically of lenalidomide and the profit profile of that particular product.***

(Emphasis added).

36. The aforementioned press releases and statements made by the Individual Defendants are in direct contrast to statements they made during the August 8, 2024, November 7, 2024, December 23, 2024, and January 14, 2025 filings, releases, and investor presentations. During those communications with their investors, Defendants (1) failed to provide a firm date for the inspection at the Indore, India facility, (2) repeatedly gave the impression they would be able to get more products on the exemption list, (3) did not articulate the significance of the products that were or could have been subject to the restrictions (particularly lenalidomide) and (4) otherwise repeatedly downplayed the significance and financial impact of the failed inspection and

Warning Letter by telling investors they caused a mere "minor headwind" for fiscal year 2025 and never previously mentioning any additional impact on the shipment of products outside the United States or the potential for the issue to continue into fiscal year 2026.

37. Investors and analysts reacted immediately to Viatris' revelation. The price of Viatris' common stock declined dramatically. From a closing market price of $11.24 per share on February 26, 2025, Viatris' stock price fell to $9.53 per share on February 27, 2025, a decline of about 15.21% in the span of just a single day.

38. A number of well-known analysts who had been following Viatris lowered their price targets in response to Viatris' disclosures. For example, J.P. Morgan, while reiterating their neutral rating post drop summarized that,

> Overall, 2025 guidance came in below expectations largely due to the company's Indore manufacturing plant warning letter, which is particularly impacting gRevlimid sales. ***While VTRS had talked about this warning letter at the JPMorgan Healthcare Conference, the size of the impact is larger than we/the Street expected and we see Indore as a setback for the VTRS story***.

(Emphasis added).

39. The analyst went on to highlight the details of the impact of the Indore facility's failed inspection, stating:

> ***Indore impact bigger than expected and could take time to resolve***. VTRS is expecting the import restrictions at Indore to reduce revenues by $500mm and EBITDA by $385mmthis year. Revlimid is driving ~50% of this impact with VTRS estimating a $200mm revenue/$190mm EBITDA headwind from this product . . . VTRS is also expecting a $75mm impact in Europe and a $125mm impact in Emerging Markets . . . ***VTRS is working on remediating the plant, although this could take some time (mgmt. hoping for an FDA inspection in late 2025/2026) and we would not be surprised for this issue to persist into 2026***.

(Emphasis added).

40. Similarly, Morningstar highlighted their surprise as to the significance of the headwinds, pertinently stating:

> Headwinds from facility inspections in Indore, India, were revealed at a conference in January but look much more significant than we had originally anticipated. The import alert affects seven products mainly distributed in the US and is to create $500 million sales and $385 million EBITDA headwinds for 2025. Importantly, lenalidomide is included in the seven impacted products and is responsible for a majority of the headwinds. This was especially discouraging since 2025 was the last full year that Viatris, along with other key generic manufacturers, would have enjoyed meaningful contributions from the drug before additional competition is expected starting in 2026. The profit impact is also disappointing since the firm's consolidated EBITDA margin of 35% (average of the past three years) is likely to see meaningful headwinds given the margin impact of the facility looks to be close to 80%.
>
> 2025 full-year guidance of $13.8 billion in revenue and $2.19 EPS, both at midpoint, fall short of our original assumptions by 5% and almost 18%, respectively.

41. The fact that these analysts, and others, discussed Viatris' shortfall and below-expectation projections suggests that the public placed significant weight on Viatris' prior revenue and sales estimates. The frequent, in-depth discussion of Viatris' guidance confirms that Defendants' statements during the Class Period were material.

Loss Causation and Economic Loss

42. Defendants made materially false and misleading statements during the Class Period and engaged in a scheme to deceive the market. Defendants' acts and omissions artificially inflated the price of Viatris' common stock and operated as a fraud or deceit on Class Period purchasers of Viatris' common stock. When Defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the price of Viatris' common stock suffered a material decline, as the prior artificial inflation came out of the price over time. As a result of their purchases of Viatris' common stock during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages under federal securities laws.

43. Viatris' stock price fell in response to the corrective event on February 27, 2025, as alleged *supra*. On February 27, 2025, Defendants disclosed information that was directly related

to their prior misrepresentations and material omissions concerning Viatris' disclosures and suggested impact of the FDA's inspection and subsequent actions regarding the Indore, India manufacturing facility

44. In particular, on February 27, 2025 Viatris announced significantly below-market growth expectations, estimating an impact on 2025 revenue and earnings of approximately $500 million and $385 million, respectively.

Presumption of Reliance; Fraud-On-The-Market

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

(a) Viatris' 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) Viatris 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) Viatris was followed by several securities analysts employed by major brokerage firms who wrote 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 Viatris was reflected in and incorporated into the Company's stock price during the Class Period.

46. As a result of the foregoing, the market for Viatris' common stock promptly digested current information regarding the Company from all publicly available sources and

reflected such information in Viatris' stock price. Under these circumstances, all purchasers of Viatris' common stock during the Class Period suffered similar injury through their purchase of Viatris' common stock at artificially inflated prices, and a presumption of reliance applies.

47. 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

48. 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 failed to timely provide investors with appropriate disclosures related to the FDA's inspection of the Indore, India facility, the Company's subsequent and ongoing remediation efforts the followed, the potential for additional action from the FDA and, once disclosed, minimizing the potential impact of the FDA's actions on the Company's future profitability. Defendants ultimately provided the public with disclosures that routinely downplayed the significance of the ongoing remediation efforts, the scope of the restrictions and, generally, the size and scope of the headwinds caused by the Company's mismanagement of the Indore, India manufacturing facility. Defendants' disclosures further omitted key details related to the specific drugs at risk of being restricted by the FDA's actions and the tangential impact on products shipped outside the United States.

49. 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.

50. 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 Viatris who knew that the "forward-looking statement" was false. Alternatively, none of the historic or present-tense statements made by Defendants was an assumption 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

51. 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 Viatris' 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.

52. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Viatris' 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 Viatris 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 February 21, 2025, there were 1.194 billion 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.

53. 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.

54. 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.

55. 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 Viatris;

(c) whether the Individual Defendants caused Viatris 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 Viatris' 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.

56. 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

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

58. 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.

59. 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 Viatris common stock; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Viatris' 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.

60. 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 Viatris' 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.

61. 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.

62. 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 Viatris' internal affairs.

63. 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 Viatris' 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 Viatris' 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 Viatris' 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.

64. During the Class Period, Viatris' 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 Viatris' 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 Viatris' common stock was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Viatris' common stock declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

65. 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.

66. 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

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

68. 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 Viatris' misstatements.

69. 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 Viatris which had become materially false or misleading.

70. 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 Viatris 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 Viatris 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 Viatris' common stock.

71. 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 Viatris 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.

72. By reason of the above conduct, the Individual Defendants and/or Viatris 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: April 4, 2025