

Alan M. HARRIS, Yitzchok Wolpin, Fausto Pombar, Plaintiffs-Appellants,

v.

IVAX CORPORATION, Phillip Frost, Michael W. Fipps, Defendants-Appellees.

No. 98-4818.

United States Court of Appeals,

Eleventh Circuit.

July 27, 1999.

Appeal from the United States District Court for the Southern District of Florida. (No. 97-559-CIV-FAM), Federico A. Moreno, Judge.

Before COX and HULL, Circuit Judges, and COHILL\*, Senior District Judge.

COX, Circuit Judge:

This appeal invites application of the safe harbor for forward-looking statements added to the Securities Exchange Act of 1934<sup>1</sup> by the Private Securities Litigation Reform Act of 1995, Pub.L. 104-67, 109 Stat. 737 (1995) (PSLRA). We affirm the district court's dismissal of the complaint under Fed.R.Civ.P. 12(b)(6).

#### I. BACKGROUND

According to the complaint—our only source of the facts—the defendant Ivax Corporation is a manufacturer of generic drugs, a highly volatile business. Ivax was profitable in 1995, but lost money in the second quarter of 1996. On August 2, 1996 Ivax issued a press release that, while acknowledging business problems, also showed some optimism.<sup>2</sup> Ivax stock rose. On September 30, the last day of the quarter, Ivax

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\*Honorable Maurice B. Cohill, Jr., Senior U.S. District Judge for the Western District of Pennsylvania, sitting by designation.

<sup>1</sup>Codified as amended at 15 U.S.C. §§ 77a-78III.

<sup>2</sup>The full text of the release is found in Appendix I to this opinion. Ordinarily, the full text of such a release would not be part of the record under review for a dismissal under Fed.R.Civ.P. 12(b)(6) unless it was attached to the complaint. *See* 5A Charles A. Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1357, at 299 (2d ed.1990). But a document central to the complaint that the defense appends to its motion to dismiss is also properly considered, provided that its contents are not in dispute. *See, e.g., Brooks v. Blue Cross & Blue Shield of Fla., Inc.*, 116 F.3d 1364, 1369 (11th Cir.1997). The PSLRA,

announced in another press release that it anticipated a \$43 million loss.<sup>3</sup> On November 11, Ivax announced a \$179 million loss for the third quarter, \$104 million of which was a reduction in the carrying value of the goodwill ascribed to certain of Ivax's businesses. Neither of the earlier press releases had mentioned the possibility of this goodwill writedown based on third-quarter results. The price of Ivax stock plummeted.

Investors hoping to represent a class of purchasers of Ivax Corporation stock between August 2, 1996 and November 11, 1996 sued Ivax, its chairman and chief executive officer, and its chief financial officer. They claimed that the defendants had committed fraud under the Securities Exchange Act § 10(b), 15 U.S.C. § 78j, and Securities and Exchange Commission Rule 10b-5, 17 C.F.R. § 240.10b-5, as well as common-law negligent misrepresentation. There are two theories of liability: first, that Ivax's economic projections were fraudulent, and second, that Ivax's disclosure of factors affecting its projections misled by omitting the possibility of a goodwill writedown. The defendants moved to dismiss based on the safe-harbor provision<sup>4</sup> and heightened pleading requirements<sup>5</sup> added to the Securities and Exchange Act of 1934 by the PSLRA.

In a thoughtful opinion, the district court dismissed the complaint under Fed.R.Civ.P. 12(b)(6). *See Harris v. IVAX Corp.*, 998 F.Supp. 1449 (S.D.Fla.1998).<sup>6</sup> The plaintiffs appeal and challenge the district court's dismissal on several grounds. We review the dismissal of a complaint under Fed.R.Civ.P. 12(b)(6) de novo. *See Davis v. Monroe County Bd. of Educ.*, 120 F.3d 1390, 1393 (11th Cir.1997) (en banc). In addition, the plaintiffs argue that the district court should have granted them leave to amend the complaint.

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moreover, contains a provision that directs the district court to consider not only "any statement cited in the complaint" but also "any cautionary statement accompanying the forward-looking statement, which are [*sic*] not subject to material dispute, cited by the defendant." PSLRA § 102(b), *codified at* 15 U.S.C. § 78u-5(e). The usual rules for considering 12(b)(6) motions are thus bent to permit consideration of an allegedly fraudulent statement in its context.

<sup>3</sup>Appendix II contains the full text of this release.

<sup>4</sup>15 U.S.C. § 78u-5(c).

<sup>5</sup>15 U.S.C. § 78u-4(b).

<sup>6</sup>Both the defendants' motion to dismiss, which requested complete dismissal of the complaint, and the district court's opinion ignored the state-law negligent misrepresentation claim. The plaintiffs do not, however, argue on appeal that they stated a claim for negligent misrepresentation. We thus take the claim to be abandoned and spill no ink addressing it.

We review the district court's refusal to do so for abuse of discretion, although we review de novo the underlying legal conclusion of whether a particular amendment to the complaint would be futile. *See Motorcity of Jacksonville, Ltd. v. Southeast Bank N.A.*, 83 F.3d 1317, 1323 (11th Cir.1996) (en banc), *summarily vacated and remanded on other grounds sub nom. Hess v. FDIC*, 519 U.S. 1087, 117 S.Ct. 760, 136 L.Ed.2d 708, *reinstated*, 120 F.3d 1140, 1145 (11th Cir.1997).

## II. DISCUSSION

### A. Overview

The PSLRA made two changes to the Securities Exchange Act of 1934 that potentially affect the complaint here. First, the Act provides a safe harbor from liability for certain "forward-looking statements." *See* PSLRA § 102(b), 109 Stat. at 754, *codified at* 15 U.S.C. § 78u-5(c)(1). In that safe harbor, corporations and individual defendants may avoid liability for forward-looking statements that prove false if the statement is "accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement." *Id.*, *codified at* 15 U.S.C. § 78u-5(c)(1)(A)(i). Even if the forward-looking statement has no accompanying cautionary language, the plaintiff must prove that the defendant made the statement with "actual knowledge" that it was "false or misleading." *Id.*, *codified at* 15 U.S.C. 78u-5(c)(1)(B). Second, the Act has introduced a heightened pleading requirement. Now a complaint seeking recovery for securities fraud must allege specific facts that raise a "strong inference" of "the required state of mind" on the part of officers responsible for an allegedly fraudulent statement. *Id.* §§ 101(b), *codified at* 15 U.S.C. § 78u-4(b)(2).

The district court concluded that all of the statements alleged in the complaint to be fraudulent were forward-looking, and that the statements' "cautionary language" was "meaningful." *See Harris v. IVAX Corp.*, 998 F.Supp. 1449, 1453-54 (S.D.Fla.1998). The court thus concluded that Ivax's statements were anchored within the statutory safe harbor, and that the cautionary language shielded Ivax from liability. The court went further to conclude in the alternative that the complaint stumbled on the new pleading standards by failing

to allege adequate facts to support a "strong inference," as the statute requires, that the defendants made the forward-looking statements with actual knowledge of their falsity. *See id.* at 1454-55.

The plaintiffs make two central legal arguments against the district court's holdings. First, they argue that the statements they allege to be fraudulent were either not forward-looking or were unaccompanied by sufficient cautionary language. For this reason, they contend that the district court should not have dismissed the current complaint. Second, they argue that the current amended complaint sufficiently alleges scienter, which they believe to be reckless indifference to the falsity of the statements, not actual knowledge. Even if the current complaint does not adequately allege scienter, the plaintiffs argue in the alternative that the district court should have permitted them to amend their complaint, since their proposed second amended complaint adequately pleads scienter.

For the more detailed reasons that follow, we reject the plaintiffs' arguments. All of the statements that the plaintiffs claim to be false or misleading are forward-looking. They were accompanied, moreover, by "meaningful cautionary language." Because we reach this conclusion, we need not in this case enter the thicket of the PSLRA's new pleading requirements for scienter; if a statement is accompanied by "meaningful cautionary language," the defendants' state of mind is irrelevant. *See* H.R. Conf. Rep. 104-369, at 44 (1995), *reprinted in* 1995 U.S.C.C.A.N. 730, 743 ("The first prong of the safe harbor requires courts to examine only the cautionary statement accompanying the forward-looking statement. Courts should not examine the state of mind of the person making the statement."). We do not address, therefore, the question of what exactly a "strong inference" of the appropriate scienter is, an issue that has vexed the courts since the PSLRA's enactment. *See, e.g., In re Silicon Graphics Secs. Litig.*, No. 97-16204, --- F.3d ---- (9th Cir. July 2, 1999); *In re Advanta Secs. Litig.*, No. 98-1846, --- F.3d ---- (3d Cir. June 17, 1999); *In re Physicians Corp. Securities Litig.*, --- F.Supp.2d ---- (S.D.Fla. Feb. 18, 1999); *In re Aetna Inc. Securities Litig.*, 34 F.Supp.2d 935, 951 (E.D.Pa.1999).

*B. Were the August 2 and September 30 Statements in the Safe Harbor for Forward Looking Statements?*

Settling on a level of specificity for the forward-looking analysis is the first problem here. In the argument section of their brief, the plaintiffs have specifically mentioned only one of the fraudulent statements alleged in the complaint. From that, we gather that they urge us to treat the August 2 and September 30 press releases with a broad brush, in effect concluding that the releases as a whole were either forward-looking or not. Such an approach would not, however, comport with the Act's demand of articulate pleading: The PSLRA closes the universe of supposedly false statements under scrutiny to those "specif[ied]" in the complaint. PSLRA § 101(b), *codified at* 15 U.S.C. § 78u-4(b)(1). While the legislative history does not explain this particular pleading requirement, it implies piecemeal examination of the statements found in a company communication.

The complaint quotes, with added emphasis apparently meant to indicate the misleading statements, seven passages from these two press releases. Two of those passages are, however, outside the sphere of the plaintiffs' allegations of falsehood. First, there is a statement in the August 2, 1996 press release that "we have taken a hard look at our generic drug business," and that "[w]e have instituted actions to enhance the profitability of our U.S. generics business." (R.2-36 ¶ 37.) (The press release goes on to describe restructuring meant to increase efficiency.) Second, there is a statement in the September 30, 1996 press release that "we have scrutinized our generic drug business" and that "we created a task force ... to rapidly identify and implement strategies to reduce costs and improve efficiencies in our U.S. generic drug business." (*Id.* ¶ 49.) As far as we can tell from the complaint, the plaintiffs believe it to be true that Ivax management reevaluated its generic drug business, and the plaintiffs do not allege that Ivax failed in fact to plan to restructure the business to improve efficiency. The plaintiffs' core theories appear rather to be two: first, that Ivax's hopeful outlooks concealed an intent to write down goodwill by \$104 million in the third quarter of 1996, and second, that a limited list of clouds on the horizon deliberately omitted the risk of a goodwill writedown. In judging whether the statements on which alleged liability rests are forward-looking, our focus is accordingly on the remaining five excerpts from the press releases, discussed below, that contain those outlooks and that list.

1. *Improving reorders.*

The August 2, 1996 press release contained the following sentence: "Reorders are expected to improve as customer inventories are depleted." (R.2-36 ¶ 35.) This statement falls squarely in the middle of one of the categories of "forward-looking statements," as Congress has defined them: it is "a statement of the assumptions underlying" "a statement of future economic performance." 15 U.S.C. § 78u-5(i)(1)(D), (C).<sup>7</sup> The text that follows in the press release (which we discuss below) is a general outlook for the third quarter. The arrangement of the text makes clear that an expected increase in reorders was one of the bases of the optimism. This was therefore a forward-looking statement within the statutory safe harbor.

2. *The "unique challenges."*

The August 2, 1996 press release also announced optimistically that "the challenges unique to this period in our history are now behind us." (R.2-36 ¶ 36.) Taken in context, this statement is forward-looking. The two paragraphs of the press release preceding this statement describe two problems that contributed to a loss in the second quarter: excessive customer inventories, which reduced new orders, and a technical

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<sup>7</sup>The complete definition of "forward-looking statement" is

(A) a statement containing a projection of revenues, income (including income loss), earnings (including earnings loss) per share, capital expenditures, dividends, capital structure, or other financial items;

(B) a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer;

(C) a statement of future economic performance, including any such statement contained in a discussion and analysis of financial condition by the management or in the results of operations included pursuant to the rules and regulations of the Commission;

(D) any statement of the assumptions underlying or relating to any statement described in subparagraph (A), (B), or (C);

(E) any report issued by an outside reviewer retained by an issuer, to the extent that the report assesses a forward-looking statement made by the issuer; or

(F) a statement containing a projection or estimate of such other items as may be specified by rule or regulation of the Commission.

default in a revolving credit facility. Both problems, the statement said, were being resolved; inventories were becoming depleted, and the bank syndicate was expected to waive the default. Thus, the chairman and CEO announced that things were looking up.

"Forward-looking statement[s]" include "statements of future economic performance." 15 U.S.C. § 78u-5(i)(1)(C). The chairman and CEO's hopeful conclusion that conditions are better because of two anticipated improvements in business conditions is a prediction of economic performance, however couched. The plaintiffs' purely grammatical argument to the contrary—that a present-tense statement cannot predict the future—is unpersuasive; a statement about the state of a company whose truth or falsity is discernible only after it is made necessarily refers only to future performance. Whether the worst of Ivax's challenges were behind it was a matter verifiable only after the chairman so declared. This statement was thus forward-looking and in the safe harbor.

3. *Intact strategies.*

The August 2, 1996 press release continued with another hopeful outlook from Ivax's chairman and CEO, Phillip Frost, that "[o]ur fundamental business and its underlying strategies remain intact.... Only a limited number of companies are positioned to meaningfully participate in this rapidly growing market and, among them, IVAX is certainly very well positioned." (R.2-36 ¶ 38.) Like the previous statement, this one is a prediction "of future economic performance." 15 U.S.C. § 78u-5(i)(1)(C). While it is true that the *state* of Ivax's "fundamental business" and "underlying strategies" is a question of present condition, whether they are intact is a fact only verifiable by seeing how they hold up in the future. Likewise, whether Ivax is "well positioned" is a statement whose truth can only be known after seeing how Ivax's future plays out. That puts this statement in the safe harbor, as well.

4. *The laundry list.*

The September 30, 1996 press release, which predicted third quarter results, contained a list of factors "relating to [Ivax's] generic drug business [that] will influence [Ivax's] third quarter results." (R.2-36 ¶ 47.) Those five factors included high customer inventory levels and low orders; declining prices; "shelf

stock adjustments" for existing customers<sup>8</sup>; higher reserves for returns; and the bankruptcy of a major customer who owed Ivax \$16 million. The list is a mixed bag, with some sentences that are forward-looking and some that are not. The statement's choice of language suggests that three of the factors had already been observed: "customer re-orders remain depressed"; "prices have continued to decline"; and "a wholesaler customer who owed us approximately \$16 million filed a Chapter 11 bankruptcy petition." (*Id.*) Observed facts of this kind are not "assumptions,"<sup>9</sup> and they are not any kind of prediction, either, that would put them within the definition of a forwardlooking statement. These sentences are not, therefore, forward-looking. Two other factors, however, are worded as assumptions about future events: "we expect reserves for returns and inventory writeoffs to be well above typical quarters" and "lower prices ... will increase shelf stock adjustments." (*Id.*) As "assumptions underlying" the predictions elsewhere in the press release, these sentences are forward-looking. 15 U.S.C. § 78u-5(i)(1)(D).

The mixed nature of this statement raises the question whether the safe harbor benefits the entire statement or only parts of it. Of course, if any of the individual sentences describing known facts (such as the customer's bankruptcy) were allegedly false, we could easily conclude that that smaller, non-forward-looking statement falls outside the safe harbor. But the allegation here is that the list *as a whole* misleads anyone reading it for an explanation of Ivax's projections, because the list omits the expectation of a goodwill writedown. If the allegation is that the whole list is misleading, then it makes no sense to slice the list into separate sentences. Rather, the list becomes a "statement" in the statutory sense, and a basis of liability, as a unit. It must therefore be either forward-looking or not forward-looking in its entirety. The next issue is what the character of the list is as a whole—forward-looking or not.

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<sup>8</sup>Ivax had a policy of reimbursing customers who had inventories of Ivax products the difference between the price of the products when the customers bought them and the current, lower price. This policy encouraged customers to buy larger amounts at once because the customers did not need to worry about losing the benefit of subsequent price declines.

<sup>9</sup>An "assumption" is "the act of taking for granted or supposing that a thing is true." Webster's Third New International Dictionary 133 (1981).



We conclude that the entire list is due forward-looking treatment. To begin with, there is no question under the statute that a material and misleading omission can fall within the forward-looking safe harbor. *See* 15 U.S.C. § 78u-5(c)(1) ("[I]n any private action arising under this chapter that is based on an untrue statement of material fact *or omission of a material fact necessary to make the statement not misleading*, a person referred to in subsection (a) of this section shall not be liable ....") (emphasis added). And while the statute does not tell us exactly what to do with a mixed statement, extrinsic sources of congressional intent point strongly toward treating the entire list as forward-looking. Congress enacted the safe-harbor provision in order to loosen the "muzzling effect" of potential liability for forward-looking statements, which often kept investors in the dark about what management foresaw for the company. *See* H.R. Conf. Rep. 104-369, at 42 (1995), *reprinted in* 1995 U.S.C.C.A.N. 730, 741. Forward-looking conclusions often rest both on historical observations and assumptions about future events. Thus, were we to banish from the safe harbor lists that contain both factual and forward-looking factors, we would inhibit corporate officers from fully explaining their outlooks. Indeed, liability-conscious officers would be relegated to citing only the factors that could individually be called forward-looking. That would hamper the communication that Congress sought to foster.

Treating mixed lists as forward-looking may open a loophole for misleading omissions, but there are two circumstances that should put investors on guard, anyway. First, a list or explanation will only qualify for this treatment if it contains assumptions underlying a forward-looking statement. Investors should know, under the current statutory scheme, that relying on assumptions is dangerous; there will often be no legal recourse even if the assumption is false. Second, a defendant can fully benefit from the safe harbor's shelter only when it has disclosed risk factors in a warning accompanying the forward-looking statement. This disclosure as well should warn investors against blind reliance on mixed lists.

For these reasons, we hold that when the factors underlying a projection or economic forecast include both assumptions and statements of known fact, and a plaintiff alleges that a material factor is missing, the entire list of factors is treated as a forward-looking statement. This list is therefore in the safe harbor.

C. *Cautionary Language*

The district court was correct that adequate cautionary language accompanies the forward-looking statements here. The italicized warning that Ivax appended to both press releases is detailed and informative; it tells the reader in detail what kind of misfortunes could befall the company and what the effect could be. *See* Appendix I; Appendix II. We can reject out of hand, therefore, the plaintiffs' arguments that the cautionary statements are "mere boilerplate." That leaves, however, another question: the plaintiffs here allege fraud by material omission. Neither of the statements mentions the possibility of a large goodwill writedown. To be "meaningful," 15 U.S.C. § 78u-5(c)(1)(A)(i), must the cautionary language explicitly mention *the* factor that ultimately belies a forward-looking statement?

We think not. The statute requires the warning only to mention "important factors that could cause actual results to differ materially from those in the forward-looking statement." 15 U.S.C. § 78u-5(c)(1)(A)(i). It does not require a listing of *all* factors. The conference report, moreover, that accompanied the PSLRA specified that "[f]ailure to include the particular factor that ultimately causes the forward-looking statement not to come true will not mean that the statement is not protected by the safe harbor." H.R. Conf. Rep. 104-369, at 44 (1995), *reprinted at* 1995 U.S.C.C.A.N. 730, 743. In short, when an investor has been warned of risks of a significance similar to that actually realized, she is sufficiently on notice of the danger of the investment to make an intelligent decision about it according to her own preferences for risk and reward. This statement satisfies Ivax's burden to warn under the statute, and it excuses Ivax from liability.

D. *Should the Plaintiffs Have Been Given Leave to Amend Their Complaint?*

The plaintiffs, stung by the district court's conclusion that they did not plead scienter with the precision the statute demands, requested leave to amend their complaint, which the court denied. While the plaintiffs argue that the proposed amended complaint properly alleges scienter, they do not contend that it blows Ivax out of the safe harbor. Nor could they, since the only significant additions are references to public filings that purportedly show that the defendants knew in September 1996 that a goodwill writedown would

be needed.<sup>10</sup> We therefore agree with the district court that the amendment would be futile and affirm the denial of leave to amend.

### III. CONCLUSION

For the foregoing reasons, we affirm the district court's dismissal of the complaint.

AFFIRMED.

#### APPENDIX I (AUGUST 2, 1996 PRESS RELEASE)

##### *FOR IMMEDIATE RELEASE*

#### IVAX ANNOUNCES 1996 SECOND QUARTER RESULTS

Miami, Florida—August 2, 1996—IVAX Corporation (AMEX:IVX) today announced a net loss for the 1996 second quarter of \$16.0 million, or \$.13 per common share, compared to a net income of \$28.1 million, or \$.24 per common share, for the second quarter of 1995. IVAX' results for the three months ended June 30, 1996 are significantly below the \$.04 to \$.06 cents per share (\$.06 to \$.08 per share before extraordinary items) forecast by IVAX in a June 27, 1996 news release, primarily due to higher than anticipated levels of customer inventory credits and the establishment of additional reserves for customer inventory returns. Included in IVAX' earnings for the second quarter and first half of 1996 is a one-time tax benefit of \$.06 per share, and an extraordinary charge of \$.02 per share.

Net revenues for the 1996 second quarter were \$273.9 million, compared to \$306.7 million for the 1995 second quarter. Gross profit for the second quarter of 1996 was \$82.8 million, compared to \$129.8 million for the second quarter of 1995. Loss before income taxes, minority interest and extraordinary items in the 1996 second quarter was \$31.7 million, compared to income before income taxes, minority interest and extraordinary items of \$37.8 million for the 1995 second quarter.

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<sup>10</sup>The plaintiffs do make a wholly unpersuasive argument that the defendants' knowledge of the need to reduce goodwill robs the projections of their forward-looking status. The statutory definition of "forward-looking statement" does not refer at all to the defendants' knowledge of the truth or falsity of the statement, however; such knowledge is relevant only to liability in the safe harbor, and even there only when there is inadequate cautionary language. *See* 15 U.S.C. § 78u-5(c), (i).

Primary net earnings per share for the first half of 1996 were \$.16, compared to \$.44 for the first half of 1995. Fully diluted net earnings per share for the first six months of 1996 were \$.16, compared to \$.43 for the first six months of 1995. Net income for the first six months of 1996 was \$19.9 million, compared to \$51.5 million for the same period in 1995.

Net revenues for the first half of 1996 were \$607.9 million, compared to \$587.8 million reported for the first half of 1995. Gross profit for the first six months was \$227.3 million, compared to \$249.6 million for the same period in 1995. Income before taxes, minority interest and extraordinary items was \$12.5 million in the first half of 1996, compared to \$70.3 million for the same period in 1995.

IVAX' consolidated 1996 second quarter tax benefit reflects the recognition of a deferred tax asset of \$7.1 million by McGraw following an adjustment resulting from an Internal Revenue Service examination.

IVAX' second quarter results include an extraordinary charge of \$2.1 million (net of tax) relating to the redemption of McGraw's 10-3/8% Senior Notes, which increased the second quarter net loss per share by \$.02.

In its June news release, IVAX stated that significant customer inventories of important U.S. generic drugs, price declines for certain generic drugs, and related credits provided to customers would adversely affect its second quarter financial results. Since its June forecast, IVAX identified significantly higher than estimated inventory levels for certain customers, largely relating to the introduction of an unusually large number of U.S. generic drugs in 1995 and 1996. Accordingly, inventory credits and reserves for returns were higher than originally estimated. In total, inventory credits, return reserves, and other allowances relating to the U.S. generic drug business were approximately \$43.6 million higher than the average levels IVAX has experienced in recent prior quarters.

During the 1996 second quarter, price declines in the U.S. generic drug business reduced margins, and significant customer inventories resulted in lower reorders from certain key accounts. Although IVAX operates in a highly competitive environment and price declines were significant during the second quarter,

prices for IVAX' important generic products, in general, have not materially declined since IVAX' June 27 forecast. Reorders are expected to improve as customer inventories are depleted.

IVAX is a party to a revolving credit facility with a syndicate of banks. As a result of IVAX' second quarter results, IVAX is presently out of compliance with the facility's fixed charge ratio covenant, which constitutes a technical default under the facility. Accordingly, the \$281.8 million outstanding under the facility as of June 30, 1996, ordinarily classified as long term debt on IVAX' balance sheet, has been classified as short term debt. IVAX is seeking a waiver of this default, and is hopeful that a waiver will be granted shortly. IVAX believes that it has a strong balance sheet, with a debt to total capital ratio of less than 32% and, if the waiver is granted and the amounts outstanding under the facility are reclassified as long term debt, a current ratio of 3.7.

Phillip Frost, M.D., IVAX' Chairman and Chief Executive Officer, said "Clearly, we have experienced a very disappointing quarter. We believe, however, that the challenges unique to this period in our history are now behind us. The broader challenges of the generic drug industry as a whole, and its tremendous opportunities, remain. We will meet these challenges with strategies honed and improved as a result of this most difficult quarter. More significantly, we will continue to exploit the industry's opportunities with a science team that has led the industry in U.S. generic drug approvals, and with a distribution network that is among the most extensive in the industry."

"In evaluating our strategies, we have taken a hard look at our U.S. generic drug business. We have determined that, although we will not be blind to opportunities outside our organization to improve shareholder value, we must focus our resources on improving value from within. We have instituted actions to enhance the profitability of our U.S. generics business. We will also be expanding our management team and consolidating manufacturing facilities."

"In addition, we have begun to moderate those selling initiatives in our U.S. generics business which can create high levels of inventory in the distributions channels, and to develop a base on long term customer

contracts and arrangements. We believe this will permit us to distribute sales more evenly over the quarter and, accordingly, reduce heavy end-of-quarter selling."

Dr. Frost concluded "Our fundamental business and its underlying strategies remain intact: the U.S. market for generic drugs doubled over the last three years to more than \$6 billion, and industry experts generally expect it to double yet again over the next three to five years. Only a limited number of companies are positioned to meaningfully participate in this rapidly growing market and, among them, IVAX is certainly very well positioned."

IVAX Corporation, headquartered in Miami, Florida, is a holding company with subsidiaries engaged primarily in the research, development, manufacture and marketing of health care products, including generic and branded pharmaceuticals, intravenous solutions and related products, and in vitro diagnostics.

*Statements made in this press release, including those relating to expectations of increased reorders, receipt of a credit facility waiver, earnings distribution, and the generic drug industry, are forward looking and are made pursuant to the safe harbor provisions of the Securities Litigation Reform Act of 1995. Such statements involve risks and uncertainties which may cause results to differ materially from those set forth in these statements. Among other things, additional competition from existing and new competitors will impact reorders; the credit facility waiver is subject to the discretion of the bank syndicate; and IVAX' ability to distribute earnings more evenly over future quarters is subject to industry practices and purchasing decisions by existing and potential customers. In addition, the U.S. generic drug industry is highly price competitive, with pricing determined by many factors, including the number and timing of product introductions. Although the price of a generic product generally declines over time as competitors introduce additional versions of the product, the actual degree and timing of price competition is not predictable. In addition to the factors set forth elsewhere in this release, the economic, competitive, governmental, technological and other factors identified in IVAX' filing with the Securities and Exchange Commission, could affect the forward looking statements contained in this press release.*

\* \* \* \* \*

CONTACTS:

Michael W. Fipps  
Senior Vice President-Finance  
and Chief Financial Officer  
305-575-6123

-or-

Joseph C. Jones  
Vice President-  
Investor Relations  
305-575-604209

APPENDIX II (SEPTEMBER 30, 1996 PRESS RELEASE)

*FOR IMMEDIATE RELEASE*

IVAX ANNOUNCES RESTRUCTURING; OFFERS THIRD QUARTER OUTLOOK

Expects Annualized Cost Savings

Forecasts Loss for 1996 Third Quarter

Receives FDA Approval for Proprietary Drug Elmiron®

Miami, Florida, September 30, 1996 --- IVAX Corporation (AMEX:IVX) announced today that it is restructuring its U.S. generic pharmaceutical business to enhance operating efficiencies and reduce costs. The restructuring includes work force reductions, facility consolidations and other cost saving measures. When fully implemented, IVAX expects the restructuring ultimately to reduce costs on an annualized basis by approximately \$13 million pre-tax charge to be recorded in the 1996 third quarter.

"As we indicated in our 1996 second quarter earnings release, we have scrutinized our generic drug business and, with today's announcement, we take the first steps of an ongoing, company-wide commitment to improve our competitive edge through cost reductions and improved efficiencies," said Phillip Frost, M.D., IVAX' Chairman and Chief Executive Officer. "In August, we created a task force comprised of IVAX' senior management to rapidly identify and implement strategies to reduce costs and improve efficiencies in

our U.S. generic drug business without compromising product quality, customer satisfaction or future growth prospects. The task force's initial emphasis is on facility consolidation and work force reductions."

"A linchpin of our plan to consolidate manufacturing facilities will take place shortly. In August 1996, we agreed to acquire from Glaxo Wellcome Inc. a highly-efficient, 275,000 square foot facility located in Kirkland, Canada. The acquisition is scheduled to close in the first quarter of 1997. The Kirkland facility has the capacity to manufacture a wide range of pharmaceutical products, including injectable pharmaceuticals, which is an important manufacturing capability that we do not presently possess. The facility comes staffed with approximately 165 highly-trained employees and is fully equipped. Following the acquisition, we will manufacture certain products for Glaxo Wellcome, and expect to contract manufacture products for other third parties on an ongoing basis. The facility's advanced, efficient equipment and design should ultimately lower the overall manufacturing costs of our products to be manufactured there."

"IVAX' Shreveport, Louisiana facility, which manufactures a variety of generic and branded pharmaceuticals, is expect to be closed by year-end 1996. IVAX' Syosset, New York facility, which manufactures topical pharmaceutical products, and a related R & D facility, are expected to be closed by the end of the 1997 first quarter. Production from these facilities will be transferred to the Kirkland facility."

"We also expect to close our facility located in Fort Lauderdale, Florida. Administrative and related functions presently located there will be transferred to our facilities in Miami late this year or in early 1997. Product packaging operations presently located in Fort Lauderdale will be transferred to the Kirkland facility during the 1997 first quarter."

"Our generic drug distribution facility in Northvale, New Jersey is expected to be closed during the 1996 fourth quarter. Our Mason, Ohio generic drug distribution facility, and McGaw's distribution operations in Fairfield, Ohio, will be closed early in the 1997 second quarter. Distribution from those facilities ultimately will be transferred to an advanced, strategically-centralized distribution center to be leased in Kenton County, Kentucky. The Kentucky facility is being built by the owner to our specifications."



"In addition to workforce reductions associated with these facility closings and consolidations, other workforce reductions are underway. We will continue the process of substantially streamlining our generic pharmaceutical selling, marketing, manufacturing, administrative and product development teams located at our two Miami facilities, at our St. Croix, Virgin Islands facility, and elsewhere. Not including employee positions arising from the Kirkland acquisition, the restructuring ultimately will result in the elimination of approximately 450 employee positions, which is over a quarter of the present employee positions at Zenith Goldline."

"Many of the foregoing initiatives will begin to offer cost saving in the fourth quarter of 1996, and substantially all of them will be fully implemented and offering cost savings by early in the 1997 second quarter. Once the restructuring is fully implemented, we should see annualized cost savings of approximately \$20 million before taxes, or \$12 million after taxes."

Dr. Frost commented on future initiatives: "Today's restructuring marks just the beginning of our commitment to improve shareholder value through improved efficiencies and cost reductions. We are targeting a number of other areas in our generic drug and other businesses for additional savings. For example, we are conducting an extensive evaluation of our U.S. pharmaceutical manufacturing operations to better utilize our remaining facilities. To assist us, we have retained a consulting firm that is well-recognized in strategic planning and engineering for the pharmaceutical industry."

"Along similar lines, after receiving FDA approval to do so, we will transfer production of our verapamil HCI ER product from Miami to Ireland. The transfer will permit us to close one of our Miami facilities and to better utilize our Irish facility, and will lower our effective tax rate by subjecting a portion of our verapamil profits to Ireland's favorable tax rates. Looking outside our U.S. generic drug business, as previously indicated, we are examining non-core businesses for opportunities to improve shareholder value."

Dr. Frost provided a preliminary outlook for IVAX' 1996 third quarter results: "The restructuring is estimated to result in a 1996 third quarter charge of approximately \$13 million before taxes, or about \$8 million after taxes. As part of our ongoing efforts to streamline our operations, we may incur additional

charges. In addition to the restructuring charge, several factors relating to our U.S. generic drug business will influence our third quarter results. First, our customer inventory levels continue to be high, so customer re-orders remain depressed. Second, prices have continued to decline for generic drug products. Third, lower prices at a time of elevated inventories will increase shelf stock adjustments paid to customers to levels well above more typical quarters as well. Lastly, a wholesaler customer who owed us approximately \$16 million filed a Chapter 11 bankruptcy petition during the third quarter. Accordingly, in the 1996 third quarter, we supplemented our existing second quarter reserve of approximately \$6 million relating to this account with additional reserves of approximately \$17 million."

"As a result, I regret to say that we forecast a loss of approximately \$35 million for the 1996 third quarter, before taking into account the restructuring charge. Because certain of the factors affecting the quarter are subject to estimation and cannot be precisely quantified at this time, the actual loss for the quarter ultimately may be greater or less than our forecasted loss by as much as several million dollars. We continue to work through our present challenges, and expect to see substantial improvement in our consolidated operating results for the 1996 fourth quarter."

IVAX expects to issue a new release reporting its definitive 1996 third quarter earnings in late October or early November. The estimated restructuring charge, combined with the anticipated loss for the third quarter, is expected to result in IVAX being out of compliance with the provisions of its revolving line of credit agreement. IVAX is working with the participating banks to obtain a waiver of any default and to amend the credit agreement.

"U.S. generic drug sales are poised to double over the next three to five years," said Dr. Frost. "With today's initiatives, we are committed to building a leaner, stronger generic drug business to capture a greater share of this market. At the same time, we are increasing our commitment to our proprietary drug development programs, for therein lies the key to sustained future growth."

"Affirming our resolve in this regard, we were pleased to announce today that we received clearance from the FDA to begin marketing our patented prescription medication Elmiron®. Elmiron® is our

medication for the pain or discomfort associated with *interstitial cystitis* (IC), a chronic, progressive and debilitating urinary bladder disease afflicting primarily women. IC is a disease characterized by severe bladder and pelvic pain, and urinary frequency. Other than Elmiron®, there is no effective orally-administered treatment for the symptoms of this incapacitating disease. We continue to study Elmiron® for other indications as well, and have entered into a Collaborative Research and Development Agreement with the National Institutes of Health to study Elmiron®'s activity in the reversal of certain forms of advanced kidney disease."

"Elmiron® is IVAX' first innovative new drug approved by the FDA for marketing in the U.S. In addition to being important news for IC sufferers across the country, our Elmiron® approval is a major step towards our goal of offsetting the inherent volatility of earnings derived from our generic drug business with a range of proprietary new drugs to provide for more balanced future growth."

"Other innovative drug projects in our portfolio include Cervene® for the mitigation of central nervous system damage following ischemic stroke, and Paxene™ for the treatment of breast, ovarian and other cancers. Both projects are in Phase III Clinical Trials, and New Drug Applications for these compounds are expected to be submitted to the FDA during 1997. IVAX is also developing innovative products for the treatment of asthma, including products which feature our patented breath-activated metered dose inhaler called Easi-Breathe™. These innovative products, if approved, will be of tremendous therapeutic and commercial significance, and should combine with our greater efficiencies to significantly enhance IVAX' growth prospects in the intermediate and long term."

*Statements made in this press release, including those relating to the estimated cost reductions, the amount of the restructuring charge expected in the third quarter, the purchase of the Kirkland facility, the time frames for closing and consolidating facilities and eliminating employee positions, the expected manufacturing costs of products made at the Kirkland facility, the expected transfer of verapamil production from Miami to Ireland, the amount of the write-off expected in the third quarter relating to the wholesaler customer's receivable, the expected loss for the third quarter, expectations for the fourth quarter, the prospects of the generic drug industry, and the expected submissions of NDAs for Cervene® and Paxene™*

*are forward looking and are made pursuant to the safe harbor provisions of the Securities Litigation Reform Act of 1995. Such statements involve risks and uncertainties which may cause results to differ materially from those set forth in these statements. Among other things, the cost reductions are estimated based on preliminary information as well as certain assumptions which management believes to be reasonable at this time and are subject to the successful completion of the actions described in this press release; the expected restructuring charge is an estimate based on certain assumptions which management believes to be reasonable at this time; the purchase of the Kirkland facility is subject to a number of contractual conditions, including governmental approvals; the timing of the closing and consolidating of facilities and the elimination of employee positions are subject to the acquisition of the Kirkland facility, the construction and leasing of the Kentucky distribution center, and FDA approval to transfer manufacturing of certain products; the amount of the write-off of the wholesaler customer's receivable is subject to developments in the related reorganization which could impact the value of the receivable; the transfer of verapamil production is subject to FDA approval; and the expected submissions of NDAs for Cervene® and Paxene™ are subject to the successful completion of clinical trials and the development of additional data required for the NDAs. The waiver of, and amendment to, the credit agreement is subject to the discretion of the participating banks. Expectations concerning financial results for the 1996 third and fourth quarters are not actual results and are based on preliminary estimates as well as certain assumptions which management believes to be reasonable at this time, including estimates and assumptions concerning the price and number of competitors for IVAX' generic drugs, the volume and product mix of sales, and the levels of required reserves for returns, shelf stock adjustments, and other items. The U.S. generic drug industry is extremely competitive, with pricing determined by many factors, including the number and timing of products introductions. Although the price of a generic drug product generally declines over time as competitors introduce additional versions of the product, the actual degree and timing of price competition is not predictable. In addition to the factors set forth elsewhere in this release, the economic, competitive, governmental, technological and other factors identified in IVAX' filings with the Securities and Exchange Commission could affect the forward looking statements contained in this press release.*

CONTACT:

Joseph C. Jones

Vice President—

Investor Relations

IVAX Corporation

305-575-6042