

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(MARK ONE)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 1998

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934

For the transition period from _____ to _____
Commission file number 0-19125

ISIS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

33-0336973

(State or other jurisdiction of
incorporation or organization)

(I.R.S. Employer Identification No.)

2292 Faraday Avenue, Carlsbad, CA 92008

(Address of principal executive offices, including zip code)

(760) 931-9200

(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year,
if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports
required to be filed by Section 13 or 15(d) of the Securities Exchange Act of
1934 during the preceding 12 months (or for such shorter period that the
registrant was required to file such reports), and (2) has been subject to such
filing requirements for the past 90 days.

(1) Yes No (2) Yes No
--- --- --- ---

Indicate the number of shares outstanding of each of the issuer's classes of
common stock, as of the latest practicable date.

Common stock \$.001 par value

27,001,969 shares

(Class)

(Outstanding at October 30, 1998)

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ISIS PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS
(in thousands, except share data)

ASSETS

| | September 30, 1998 ----- (Unaudited) | December 31, 1997 ----- (Note) |
|---|---|---|
| Current assets: | | |
| Cash and cash equivalents | \$ 38,002 | \$ 38,102 |
| Short-term investments | 35,046 | 48,684 |
| Prepaid expenses and other current assets | 2,527 | 2,364 |
| | ----- | ----- |
| Total current assets | 75,575 | 89,150 |
| Property, plant and equipment, net | 20,347 | 18,785 |
| Patent costs, net | 8,579 | 7,485 |
| Deposits and other assets | 2,261 | 2,461 |
| | ----- | ----- |
| | \$ 106,762 | \$ 117,881 |
| | ===== | ===== |

LIABILITIES AND STOCKHOLDERS' EQUITY

| | | |
|---|------------|------------|
| Current liabilities: | | |
| Accounts payable | \$ 2,787 | \$ 2,843 |
| Accrued payroll and related expenses | 1,751 | 2,242 |
| Accrued liabilities | 3,946 | 4,347 |
| Deferred contract revenues | 10,269 | 14,893 |
| Current portion of long term debt and capital lease obligations | 2,234 | 2,252 |
| | ----- | ----- |
| Total current liabilities | 20,987 | 26,577 |
| Long-term debt and capital lease obligations, less current portion | 73,923 | 56,452 |
| Stockholders' equity: | | |
| Common stock, \$.001 par value; 50,000,000 shares authorized, 26,879,000 shares and 26,655,000 shares issued and outstanding at September 30, 1998 and December 31, 1997, respectively | 27 | 27 |
| Additional paid-in capital | 191,976 | 188,793 |
| Unrealized gain on investments | 312 | 165 |
| Accumulated deficit | (180,463) | (154,133) |
| | ----- | ----- |
| Total stockholders' equity | 11,852 | 34,852 |
| | ----- | ----- |
| | \$ 106,762 | \$ 117,881 |
| | ===== | ===== |

Note: The balance sheet at December 31, 1997 has been derived from the audited financial statements at that date.

See accompanying notes.

ISIS PHARMACEUTICALS, INC.
 CONDENSED STATEMENTS OF OPERATIONS
 (in thousands, except for per share amounts)
 (UNAUDITED)

| | Three months ended September 30, | | Nine months ended September 30, | |
|--|-------------------------------------|------------|------------------------------------|-------------|
| | 1998 | 1997 | 1998 | 1997 |
| | ----- | ----- | ----- | ----- |
| Revenues: | | | | |
| Research and development revenue under collaborative agreements | \$ 19,279 | \$ 12,641 | \$ 30,951 | \$ 23,060 |
| Product revenue | 560 | -- | 560 | -- |
| Interest income | 1,038 | 1,133 | 3,309 | 2,846 |
| | ----- | ----- | ----- | ----- |
| | 20,877 | 13,774 | 34,820 | 25,906 |
| Expenses: | | | | |
| Research and development | 16,540 | 13,368 | 47,931 | 38,528 |
| General and administrative | 2,310 | 1,805 | 6,430 | 5,566 |
| Interest expense | 2,983 | 791 | 6,789 | 1,982 |
| | ----- | ----- | ----- | ----- |
| | 21,833 | 15,964 | 61,150 | 46,076 |
| | ----- | ----- | ----- | ----- |
| Net loss | \$ (956) | \$ (2,190) | \$ (26,330) | \$ (20,170) |
| | ===== | ===== | ===== | ===== |
| Basic and diluted net loss per share | \$ (0.04) | \$ (0.08) | \$ (0.98) | \$ (0.76) |
| | ===== | ===== | ===== | ===== |
| Shares used in computing basic and diluted net loss per share | 26,868 | 26,519 | 26,815 | 26,393 |
| | ===== | ===== | ===== | ===== |

See accompanying notes.

ISIS PHARMACEUTICALS, INC.
 CONDENSED STATEMENTS OF CASH FLOWS
 (in thousands)
 (UNAUDITED)

| | Nine months ended September 30, | |
|---|------------------------------------|-------------|
| | 1998 | 1997 |
| | ----- | ----- |
| Cash used in operations: | \$ (24,649) | \$ (14,366) |
| Investing activities: | | |
| Short-term investments | 13,638 | 885 |
| Property and equipment | (2,827) | (3,713) |
| Other assets | (1,095) | (2,088) |
| | ----- | ----- |
| Net cash provided from (used in) investing activities | 9,716 | (4,916) |
| | ----- | ----- |
| Financing activities: | | |
| Net proceeds from issuance of common stock | 3,183 | 3,153 |
| Proceeds from long-term borrowings | 13,354 | 11,386 |

| | | |
|---|-----------|-----------|
| Principal payments on debt and capital lease obligations | (1,704) | (3,479) |
| | ----- | ----- |
| Net cash provided from financing activities | 14,833 | 11,060 |
| | ----- | ----- |
| Net decrease in cash and cash equivalents | (100) | (8,222) |
| Cash and cash equivalents at beginning of period | 38,102 | 37,082 |
| | ----- | ----- |
| Cash and cash equivalents at end of period | \$ 38,002 | \$ 28,860 |
| | ===== | ===== |
| SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION: | | |
| Interest paid | \$ 1,940 | \$ 1,480 |
| SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES | | |
| Additions to long-term debt obligations for acquisitions of property, plant and equipment, and accrued interest | \$ 1,472 | \$ 1,585 |

See accompanying notes.

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ISIS PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS

1. BASIS OF PRESENTATION

The unaudited interim financial statements for the three and nine month periods ended September 30, 1998 and 1997 have been prepared on the same basis as the Company's audited financial statements for the year ended December 31, 1997. The financial statements include all adjustments (consisting only of normal recurring adjustments) which the Company considers necessary for a fair presentation of the financial position at such dates and the operating results and cash flows for those periods. Results for the interim periods are not necessarily indicative of the results for the entire year. For more complete financial information, these financial statements, and notes thereto, should be read in conjunction with the audited financial statements for the year ended December 31, 1997 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission.

2. COMPREHENSIVE INCOME

As of January 1, 1998, the Company adopted Statement of Financial Accounting Standards No. 130, Reporting Comprehensive Income ("SFAS 130"). This statement requires the Company to report in the financial statements, in addition to net income, comprehensive income and its components including foreign currency translation adjustments and unrealized gains and losses on its available-for-sale securities. SFAS 130 also requires the Company to reclassify financial statements for earlier periods provided for comparative purposes. For the three and nine month periods ended September 30, 1998 and 1997 comprehensive income was not materially different than net income.

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

In addition to historical information contained in this Report, this Report contains forward-looking statements regarding the Company's business and products and their projected prospects and qualities, the Company's relationships with its corporate partners, and the impact of the Year 2000 Problem on the Company's operations. Such statements are subject to certain risks and uncertainties, particularly those inherent in both the process of discovering, developing and commercializing safe and effective drugs, and the endeavor of building a business around such potential products. Actual results could differ materially from those projected in this Form 10-Q. As a result, the

reader is cautioned not to place undue reliance on these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in Isis' Annual Report on Form 10-K for the year ended December 31, 1997 which is on file with the U.S. Securities and Exchange Commission, a copy of which is available from the Company.

Since its inception in January 1989, almost all of the Company's resources have been devoted to its research, drug discovery and drug development programs. The Company is not yet profitable and expects to continue to have operating losses for the next several years. Isis' revenue comes from collaborative research and development agreements with pharmaceutical companies, research grants and interest income. The revenue from the collaboration increases the amount of research and development activity that the Company is able to fund and offsets a portion of its research and development costs. During the quarter ended September 30, 1998, Isis received approval from the U.S. Food and Drug Administration ("FDA") to begin marketing its first product, Vitravene(TM), a drug used to treat CMV retinitis.

RESULTS OF OPERATIONS

The Company's revenue from collaborative research and development agreements was \$19.3 million for the third quarter and \$31.0 million for the nine month period ended September 30, 1998, compared with \$12.6 million and \$23.1 million, respectively, for the same periods in 1997. The revenue increase was primarily due to \$7.5 million in milestone payments earned during the quarter when the FDA approved Vitravene(TM). Isis delivered its first commercial shipment of Vitravene(TM) to CIBA Vision Corporation ("CIBA") during the quarter ended September 30, 1998, realizing product revenues of \$0.6 million. An additional \$4.0 million of revenue was recognized when the Company agreed to exclusively license its issued patents covering immune stimulation by phosphorothioate oligonucleotides to CpG ImmunoPharmaceuticals, Inc. The Company also had interest income totaling \$1.0 million for the quarter and \$3.3 million for the nine month period compared with \$1.1 million and \$2.8 million for the same periods in 1997.

Research and development expenses increased to \$16.5 million for the three months and \$47.9 million for the nine months ended September 30, 1998 from \$13.4 million and \$38.5 million for the same periods in 1997. This increase was attributable to an increase in preclinical and clinical development activities including compounds advancing into more expensive stages of clinical development. We expect that research and development expenses will continue to increase as compounds continue to advance in clinical development.

General and administrative expenses increased to \$2.3 million for the quarter and \$6.4 million for the nine months ended September 30, 1998, from \$1.8 million and \$5.6 million for the same periods in 1997. This increase in general and administrative expense is related to additional staffing in general and administrative functions required to support the growth in research and development. We expect that general and administrative expenses will continue to increase in the future to support our growing research and development efforts.

Interest expense increased to \$3.0 million for the third quarter and \$6.8 million for the nine month period ended September 30, 1998, compared with \$0.8 million and \$2.0 million for the same periods in 1997. This increase in interest expense is due to borrowing \$25 million in a private debt financing completed in the fourth quarter of 1997 with an additional \$15 million follow-on private debt financing in the second quarter of 1998. Under the terms of these financing arrangements payment of both principal and interest is deferred for the first five years. Therefore, of the \$3.0 million of interest expense recognized in the third quarter, \$2.1 million was

accrued under the long-term debt agreements and will not require current cash payment. Similarly, of the \$6.8 million interest expense for the nine month period ended September 30, 1998, \$4.3 million was accrued under the long-term debt agreements and will not require current cash payment.

During the quarter ended September 30, 1998, the Company recorded a net loss of \$1.0 million, or \$0.04 per share, compared with \$2.2 million, or \$0.08 per share, for the same period in 1997. During the nine month period ended

September 30, 1998, the Company's net loss amounted to \$26.3 million, or \$0.98 per share, compared to \$20.2 million, or \$0.76 per share for the same period in 1997. We expect that operating losses will continue for several more years as the Company supports the discovery and development of potentially commercializable drugs. Operating losses may fluctuate from quarter to quarter because of differences in the timing of revenue and expense recognition.

The Company believes that inflation and changing prices have not had a material effect on its ongoing operations to date.

LIQUIDITY AND CAPITAL RESOURCES

Isis has financed its operations with revenue from contract research and development through the sale of equity securities and the issuance of long-term debt. From its inception through September 30, 1998, Isis has earned approximately \$136 million in revenue from contract research and development. The Company has also raised net proceeds of approximately \$190 million from the sale of equity securities since it was founded. Since 1996, Isis has borrowed approximately \$67 million under long-term debt arrangements to finance a portion of its operations.

As of September 30, 1998, the Company had cash, cash equivalents and short-term investments totaling \$73.0 million and working capital of \$54.6 million. In comparison, the Company had cash, cash equivalents and short-term investments of \$86.8 million and working capital of \$62.6 million as of December 31, 1997. The decreases in cash and working capital resulted from the funding of operating losses, investments in capital equipment and principal payments on debt and capital lease obligations, offset in part, by an additional \$15 million private debt financing.

The Company's collaborative agreement with Boehringer Ingelheim provides Isis with a \$40 million line of credit. This line of credit is available under certain circumstances and is to be used to support the collaboration cell adhesion programs. As of September 30, 1998, the outstanding balance under this line of credit was \$22.6 million.

In October 1997, Isis borrowed \$25 million in a private transaction. The loan bears interest at 14% per annum and must be repaid on November 1, 2007. No payments of either principal or interest are required during the first five years of the loan. After the first five years, interest must be paid quarterly. No principal payments are required until November 1, 2007. In conjunction with this transaction, Isis issued warrants to purchase 500,000 shares of common stock at a price of \$25 per share. On May 1, 1998, the Company completed a follow-on \$15 million private debt financing. This financing was a follow-on to the Company's October 1997 \$25 million private debt financing and bears the same terms and conditions. Because interest is deferred during the first five years, the combined principal balance of both borrowings will accrue to a total of \$78 million on November 1, 2002. In conjunction with this follow-on transaction, Isis issued warrants to purchase 300,000 shares of common stock at a price of \$25 per share. The warrants issued in connection with both of these financings expire on November 1, 2004. The debt under these arrangements is carried on the balance sheet net of the amortized amount allocated to the warrants and including accrued interest. The combined carrying amount of these notes at September 30, 1998 was \$39.6 million.

The Company had long-term debt and capital lease obligations at September 30, 1998 totaling \$73.9 million, versus \$56.5 million at December 31, 1997. This increase was due to the additional follow-on debt financing and the accrual of interest on the ten-year notes described above, partially offset by principal repayments on existing obligations. We expect that capital lease obligations will increase over time to fund capital equipment acquisitions required for the Company's growing business. We will continue to use lease financing as long as the terms remain commercially attractive. We believe that the Company's existing cash, cash equivalents

and short-term investments, combined with interest income and contract revenue will be sufficient to meet its anticipated requirements for approximately two years.

YEAR 2000 COMPUTER ISSUES

Until recently many computer programs were written to store only 2 digits of date-related information. Thus, the programs were unable to distinguish between the year 1900 and the year 2000. As a result, many computer experts have significant concerns regarding how those programs will function after December 31, 1999. This is frequently referred to as the "Year 2000 Problem." The Company is in the process of reviewing its computer systems and other equipment that utilize embedded microprocessors to assess the potential exposure to this problem. Because Isis was founded in 1989 and all of its computer systems and equipment have been purchased or upgraded since that time, we believe the risk of material disruption to the Company's operations as a result of the presence of this defect in its own computer systems and equipment is minimal.

The Company has also initiated discussions with its significant suppliers, corporate partners and financial institutions to ensure that those parties have appropriate plans to address Year 2000 issues where their systems could impact Isis' operations. The Company is assessing the extent to which its operations are vulnerable should those organizations fail to properly modify their computer systems.

A team of Isis employees is conducting the Company's Year 2000 evaluation and preparation. The team's activities are designed to ensure that there is no adverse effect on the Company's core business operations and that transactions with customers, suppliers, corporate partners and financial institutions are fully supported. We estimate that the evaluation of these risks will be completed by the end of 1998, and that any required remediation and validation will be completed by mid-1999. While the Company believes its planning and preparations will be adequate to address its Year 2000 concerns, the Company cannot guarantee that the systems of other companies on which the Company's systems and operations rely will be converted on a timely basis and will not have a material effect on the Company. The Company does not yet have a formal contingency plan. A contingency plan will be finalized as the risk assessment is completed. Based on the information obtained to date, the cost of identifying and remediating exposures to the Year 2000 Problem is not expected to be material to the Company's results of operations or financial position.

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PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The Company is not a party to any material legal proceedings.

ITEM 2. CHANGES IN SECURITIES

Not applicable.

ITEM 3. DEFAULT UPON SENIOR SECURITIES

Not applicable.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Not applicable.

ITEM 5. OTHER INFORMATION

Pursuant to the Company's bylaws, stockholders who wish to bring matters or propose nominees for director at the Company's 1999 annual meeting of stockholders must provide specified information to the Company by December 14, 1998 (unless such matters are included in the Company's proxy statement pursuant to Rule 14a-8 under the Securities Exchange Act of 1934, as amended).

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

a. Exhibits

The following documents are exhibits to this Form 10-Q:

- 10.1 Amendment No. 2 to the Agreement between the Company and CIBA Vision Corporation, dated September 14, 1998 (with certain confidential information deleted).
- 27.1 Financial Data Schedule

b. Reports on Form 8-K

The Company filed no reports on Form 8-K during the quarter ended September 30, 1998.

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ISIS PHARMACEUTICALS, INC.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ISIS PHARMACEUTICALS, INC.
(Registrant)

Date: November 16, 1998

By: /S/ STANLEY T. CROOKE

Stanley T. Crooke, M.D., Ph.D.
Chairman of the Board and Chief
Executive Officer
(Principal Executive Officer)

Date: November 16, 1998

By: /S/ B. LYNNE PARSHALL

B. Lynne Parshall
Executive Vice President and Chief
Financial Officer
(Principal Financial Officer)

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CONFIDENTIAL TREATMENT REQUESTED
 UNDER 17 C.F.R. SECTIONS 200.80(b)(4), 200.83
 AND 240.24b-2. * INDICATES OMITTED
 MATERIAL THAT IS THE SUBJECT OF A
 CONFIDENTIAL TREATMENT REQUEST THAT IS
 FILED SEPARATELY WITH THE COMMISSION.

AMENDMENT NO. 2

THIS AMENDMENT made effective the 14th day of September, 1998 to the Agreement by and between ISIS Pharmaceuticals, Inc., a Delaware corporation having its principal offices at 2292 Faraday Avenue, Carlsbad, California 92008 ("ISIS") and CIBA Vision Corporation, a Delaware corporation having its principal offices at 11460 Johns Creek Parkway, Duluth, Georgia 30097 ("CV") as previously amended by letter dated June 19, 1998 (the "Agreement").

WHEREAS the parties to the Agreement desire to further amend the Agreement as set forth herein, the parties agree to the following revisions:

1. The third and fourth sentences of Section 3.5 shall be deleted and the following shall be added: "CV will provide launch promotion materials to ISIS for review and comments at least five days prior to submission of such materials to the FDA."
2. A new Section 3.7 shall be added and shall read as follows: "3.7 ISIS will conduct and bear the expense of, [*] to ISIS dated [*] in accordance with Section 3.1 hereof."

* CONFIDENTIAL TREATMENT REQUESTED

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3. Section 4.1(c) shall be revised to read: [*] upon FDA approval of the NDA, to be paid as follows: [*].
4. Section 4.1(d) shall be revised to read: [*]. The foregoing is subject to Section 4.2(b) hereof."
5. Section 4.2(a) shall be deleted in its entirety.
6. The first sentence of Section 4.2(b) shall be revised to read: "If European Approval [*] is not obtained by [*], then CV may, at its option, terminate the Agreement with respect to Europe by giving written notice to ISIS no later than [*]."
7. Section 4.2(c) shall be revised to delete the first sentence thereof.
8. The third and fourth sentences of Section 7.3 shall be deleted in their entirety and shall be replaced with the following: "In any rolling twelve-month period in which orders total [*] will be placed no more than [*] times in such period. In any rolling twelve-month period in which orders total [*] vials or less will be placed no more than [*] during such period. Orders of [*] will be placed no more than [*] in any rolling twelve (12) month period."

* CONFIDENTIAL TREATMENT REQUESTED

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9. Sections 8.1 and 8.2 shall be deleted in their entirety and replaced with the following:

8. ISIS' Supply Price to CV

8.1 Definitions As used in this Section:

- (a) "Supply Price" shall mean ISIS' price to CV for the Product, except for Non-Commercial Product, [*]. The Supply Price for a particular order will be [*].
- (b) "Launch" shall mean the date on which CV makes its first shipment of Product to a third party customer in the U.S.

8.2 Supply Price

- (a) The Supply Price shall be as set forth in Section 8.2(b) below, except that, [*]. Thereafter, the Supply Price shall be determined in accordance with the provisions of Section 8.2(b).
- (b) For the [*], provided that, [*]. For the twelve calendar months after the expiration of the initial [*], the Supply Price will be [*]. Thereafter, the Supply Price will be [*].

10. Sections 8.3 shall be deleted in its entirety and Sections 8.4, 8.5 and 8.6 are renumbered to be sections 8.3, 8.4 and 8.5 respectively.

* CONFIDENTIAL TREATMENT REQUESTED

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11. The first sentence of Section 11.1 shall be revised to read as follows: "CV will supply ISIS with the artwork for the initial labeling and packaging of the Product for review and comment three business days prior to its submission to the FDA by CV." The second sentence of Section 11.1 shall be deleted.

12. All other terms and conditions of the Agreement, as previously amended, shall remain in full force and effect.

IN WITNESS WHEREOF, the parties have caused this Amendment No. Two to be executed by their duly authorized representatives as of the day and the year first written above.

CIBA VISION CORPORATION

ISIS PHARMACEUTICALS, INC.

By: Stephen M. Martin
Title: President

By: B. Lynne Parshall
Title: Executive Vice President

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<ARTICLE> 5

<LEGEND>

This schedule contains summary financial information derived from the Company's Condensed Balance Sheet as of September 30, 1998 (Unaudited) and Condensed Statements of Operations for the Three Months Ended September 30, 1998 (Unaudited) and is qualified in its entirety by reference to such financial statements.

</LEGEND>

<MULTIPLIER> 1,000

| | | |
|------------------------------|-------|-------------|
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