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HOLLIS EDEN PHARMACEUTICALS INC /DE/
Form 10-Q
August 03, 2001

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark one)

X Quarterly Report Under Section 13 or 15 (d)
Of the Securities Exchange Act of 1934

For Quarterly Period Ended June 30, 2001

Transition Report Pursuant to Section 13 or 15(d)
of the Securities Exchange Act 1934 for the period
from ___ to ___.

HOLLIS-EDEN PHARMACEUTICALS, INC
(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction of incorporation)

000-24672
(Commission File No.)

13-3697002
(I.R.S. Employer Identification No.)

9333 Genesee Ave., Suite 200
SAN DIEGO, CALIFORNIA 92121
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (858) 587-9333

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.

YES X NO

As of August 3, 2001 there were 11,615,803 shares of registrant's Common Stock, \$.01 par value, outstanding.

HOLLIS-EDEN PHARMACEUTICALS, INC.
Form 10-Q
FOR THE QUARTER ENDED JUNE 30, 2001

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Part I. Financial Information

Item I. Financial Statements

Hollis-Eden Pharmaceuticals, Inc.
(A Development Stage Company)
Balance Sheets
(Unaudited)

| All numbers in thousands | June 30, 2001 | Dec. 31, 2000 |
|--|------------------|------------------|
| | ----- | ----- |
| ASSETS: | | |
| Current assets: | | |
| Cash and cash equivalents..... | \$ 27,465 | \$ 34,298 |
| Prepaid expenses..... | 224 | 96 |
| Deposits..... | 27 | 27 |
| | ----- | ----- |
| Total current assets..... | 27,716 | 34,421 |
| Property and equipment, net of accumulated depreciation of \$267 and \$204..... | 468 | 422 |
| Other receivables..... | 35 | - |
| Other receivable from related party..... | 279 | 256 |
| | ----- | ----- |

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| | | |
|---|-----------|-----------|
| Total assets..... | \$ 28,498 | \$ 35,099 |
| | ===== | ===== |
| LIABILITIES AND STOCKHOLDERS' EQUITY: | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses..... | \$ 3,279 | \$ 2,636 |
| | ----- | ----- |
| Total liabilities..... | 3,279 | 2,636 |
| | ----- | ----- |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, \$.01 par value, 10,000 shares authorized; no shares outstanding..... | - | - |
| Common stock, \$.01 par value, 30,000 shares authorized; 11,616 and 11,590 shares issued and outstanding..... | 116 | 116 |
| Paid-in capital..... | 80,669 | 80,503 |
| Deficit accumulated during development stage..... | (55,566) | (48,156) |
| | ----- | ----- |
| Total stockholders' equity..... | 25,219 | 32,463 |
| | ----- | ----- |
| Total liabilities and stockholders' equity..... | \$ 28,498 | \$ 35,099 |
| | ===== | ===== |

The accompanying notes are an integral part of these financial statements.

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Hollis-Eden Pharmaceuticals, Inc.
(A Development Stage Company)
Statements of Operations
(Unaudited)

All numbers in thousands, except per share amounts

| | 3 months ended June 30, | | 6 months end |
|---|-------------------------|----------|--------------|
| | 2001 | 2000 | 2001 |
| | ----- | ----- | ----- |
| Operating expenses: | | | |
| Research and development: | | | |
| R&D operating expenses..... | \$ 2,942 | \$ 2,617 | \$ 5,659 |
| R&D costs related to common stock, option, & warrant grants for collaborations..... | 24 | 24 | 48 |
| General and administrative: | | | |
| G&A operating expenses..... | 1,242 | 1,025 | 2,507 |
| G&A costs related to common stock, option, & warrant grants..... | - | - | - |
| | ----- | ----- | ----- |

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| | | | |
|--|------------|------------|------------|
| Total operating expenses..... | 4,208 | 3,666 | 8,214 |
| Other income (expense): | | | |
| Interest income..... | 330 | 673 | 804 |
| Interest expense..... | - | - | - |
| | ----- | ----- | ----- |
| Total other income..... | 330 | 673 | 804 |
| | ----- | ----- | ----- |
| Net loss..... | \$ (3,878) | \$ (2,993) | \$ (7,410) |
| | ===== | ===== | ===== |
| Net loss per share-basic and diluted..... | (0.33) | (0.27) | (0.64) |
| Weighted average number of common shares outstanding-basic and diluted..... | 11,616 | 11,233 | 11,609 |

The accompanying notes are an integral part of these financial statements.

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Hollis-Eden Pharmaceuticals, Inc.
(A Development Stage Company)
Statements of Cash Flows
(Unaudited)

All numbers in thousands

| | 6 months ended June | 2001 | 2002 |
|---|---------------------|---------|-------------|
| | ----- | ----- | ----- |
| Cash flows from operating activities: | | | |
| Net loss..... | \$ | (7,410) | \$ (10,000) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation..... | | 63 | |
| Common stock issued for the company 401k/401m plan..... | | 95 | |
| Common stock issued as consideration for amendments/ termination of agreements..... | | - | |
| Expense related to common stock issued for the purchase of technology..... | | - | 1,000 |
| Common stock and options issued as consideration for license fees and services..... | | 48 | |
| Common stock issued as consideration for In Process R&D..... | | - | |
| Expense related to warrants issued as consideration to consultants..... | | - | |
| Expense related to warrants issued to a director for successful closure of merger..... | | - | |
| Expense related to stock options issued..... | | - | |
| Deferred compensation expense related to options issued..... | | - | |
| Changes in assets and liabilities: | | | |
| Prepaid expenses..... | | (128) | |

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| | | |
|---|-----------|--------|
| Deposits..... | - | |
| Other receivables..... | (35) | |
| Loan receivable from related party..... | (23) | |
| Accounts payable and accrued expenses..... | 1,224 | |
| Wages Payable..... | (581) | |
| Disposal of assets..... | - | |
| | ----- | ----- |
| Net cash used in operating activities..... | (6,747) | (7, |
| Cash flows provided by investing activities: | | |
| Purchase of property and equipment..... | (109) | |
| | ----- | ----- |
| Net cash used in investing activities..... | (109) | |
| Cash flows from financing activities: | | |
| Contributions from stockholder..... | - | |
| Net proceeds from sale of preferred stock..... | - | |
| Net proceeds from sale of common stock..... | - | |
| Proceeds from issuance of debt..... | - | |
| Net proceeds from recapitalization..... | - | |
| Net proceeds from warrants and options exercised..... | 23 | |
| | ----- | ----- |
| Net cash from financing activities..... | 23 | |
| Net increase in cash..... | (6,833) | (6, |
| Cash and equivalents at beginning of period..... | 34,298 | 47, |
| | ----- | ----- |
| Cash and equivalents at end of period..... | \$ 27,465 | \$ 41, |
| | ===== | ===== |

The accompanying notes are an integral part of these financial statements.

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HOLLIS-EDEN PHARMACEUTICALS, INC.
(A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS

(UNAUDITED)

1. Basis of Presentation

The information at June 30, 2001, and for the three-month and six-month periods ended June 30, 2001 and 2000, is unaudited. In the opinion of management, these financial statements include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of the results for the interim periods presented. Interim results are not necessarily indicative of results for a full year. These financial statements should be read in conjunction with the Hollis-Eden Pharmaceuticals, Inc. ("Hollis-Eden" or the "Company") Annual Report on Form 10-K for the year ended December 31, 2000, which was filed with the United States Securities and Exchange Commission on March 30, 2001.

While management believes that the discussion and analysis in this report is adequate for a fair presentation of the information, management recommends that this discussion and analysis be read in conjunction with Management's Discussion and Analysis of Results of Operations and Financial Condition included in the Company's Annual Report on Form 10-K for the year ended December

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31, 2000.

2. Technology Acquisition - Commitments and Contingencies

Pursuant to a Technology Assignment Agreement dated January 20, 2000, Patrick Prendergast and Colthurst Limited assigned to Hollis-Eden ownership of all patents, patent applications and current or future improvements of the technology previously licensed to Hollis-Eden under the Colthurst License Agreement dated May 18, 1994 (as amended), including HE2000, Hollis-Eden's lead clinical compound. In exchange for certain covenants made by Mr. Prendergast and Colthurst regarding their future activities (the "Covenants") as well as for the consideration described above, Hollis-Eden agreed to issue to Colthurst 660,000 shares of Common Stock and a warrant to purchase an aggregate of 400,000 shares of Common Stock at \$25 per share, of which only 132,000 shares were to be issued in 2000, with the remaining 528,000 shares to be issued over the next four years conditioned on continued compliance with the Covenants. The shares underlying the warrant were to vest over four years and were likewise conditioned on continued compliance with the Covenants.

In accordance with Emerging Issues Task Force No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services, certain future events could not be determined at the date of the agreements (January 2000). Accordingly, the shares and warrants were to be accounted for as they vest or were issued. During 2000, we recorded a research and development charge for \$1.9 million representing the fair value of the 132,000 shares issued under the agreement.

Because Mr. Prendergast and Colthurst failed to comply with the Covenants, Hollis-Eden has not issued any additional shares to Colthurst and believes it has no obligation to issue to Colthurst any additional shares. While Hollis-Eden is confident in its analysis, if any dispute should arise in this matter, Hollis-Eden cannot guarantee that, subject to the resolution of any such dispute, it will not be required to issue additional equity to Mr. Prendergast and Colthurst or that it will

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not incur additional accounting charges or other adverse accounting reporting as a result of any such resolution.

Item 2. Management's Discussion and Analysis of Results of Operations and Financial Condition

The forward-looking comments contained in the following discussion involve risks and uncertainties. Our actual results may differ materially from those discussed here. Factors that could cause or contribute to such differences can be found in the following discussion, as well as in the Company's Annual Report on Form 10-K for the year ended December 31, 2000.

General

Hollis-Eden Pharmaceuticals, Inc., a development-stage pharmaceutical company, is presently engaged in the discovery and development of products for the treatment of infectious diseases and immune system disorders, including HIV/AIDS, hepatitis B and C, and malaria.

We are focusing our initial development efforts on a potent series of immune regulating hormones and hormone analogs. We are currently developing three clinical stage compounds with potentially broad therapeutic applications: HE2000, HE2200 and, through our relationship with Aeson Therapeutics, HE2500.

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Our lead compound, HE2000, is currently in Phase II clinical studies. By altering cytokine production, HE2000 appears from early clinical studies to help reestablish immune system balance in situations such as HIV, where the immune system is dysregulated. In the case of HIV, we believe that by reestablishing this balance the immune system may be able to better control virus levels and potentially delay or prevent the progression to AIDS. In addition, based on the mechanism of action, we believe these compounds will have an attractive safety profile and will avoid issues of resistance that plague many existing antiviral drugs.

We have been unprofitable since our inception and we expect to incur substantial additional operating losses for at least the next few years as we increase expenditures on research and development and begin to allocate significant and increasing resources to clinical testing and other activities. In addition, during the next few years, we may have to meet the substantial new challenge of developing the capability to market products. Accordingly, our activities to date are not as broad in depth or scope as the activities we may undertake in the future, and our historical operations and financial information may not be indicative of our future operating results or financial condition or our ability to operate profitably as a commercial enterprise when and if we succeed in bringing any drug candidates to market.

On March 26, 1997, Hollis-Eden, Inc., a Delaware corporation, was merged with and into us, then known as Initial Acquisition Corp. ("IAC"), a Delaware corporation. Upon consummation of the merger of Hollis-Eden, Inc. with IAC (the "Merger"), Hollis-Eden, Inc. ceased to exist, and IAC changed its name to Hollis-Eden Pharmaceuticals, Inc.

Results of Operations

We have not generated any revenues for the period from August 15, 1994 (inception of Hollis-Eden) through June 30, 2001. We have devoted substantially all of our resources to the payment of licensing fees and research and development expenses plus expenses related to the startup of our business. From inception until June 30, 2001, we have incurred expenses of approximately \$37.5 million in research and development (\$5.2 million are non-cash expenses) and \$25.0 million in general and administrative expenses (\$9.5 million are non-cash expenses), which have been partially offset by \$6.9 million in net interest income resulting in a loss of \$55.6 million for the period.

Research and development expenses were \$3.0 million and \$5.7 million for the three- and six-month periods ended June 30, 2001 and \$2.6 million and \$9.3 million for the same periods in 2000. The research and

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development expenses relate primarily to the ongoing development, preclinical testing, and clinical trials for our first drug candidate, HE2000. Included in the six-month period ended June 30, 2000 was \$2.2 million related to collaborations and \$2.5 million in non-cash charges related to the acquisition of technology and in-process R&D. There were no such expenses in the six-month period ended June 30, 2001. The increase in research and development expenses (net of collaborations and technology acquisitions) for the three- and six-month periods ended June 30, 2001, compared to the same period in 2000, was due to increased staffing and clinical trial activities.

General and administrative operating expenses were \$1.2 million and \$2.5 million for the three- and six-month periods ended June 30, 2001, compared to \$1.0 million and \$2.1 million for the same period in 2000. The general and administrative expenses relate to staffing, facilities, supplies, benefits, recruiting, legal, investor relations and travel. The increase in general and

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administrative operating expenses was mainly due to expenses associated with investor relations and the growth of the Company's operations.

Net interest income was \$330,000 and \$804,000 for the three- and six-month periods ended June 30, 2001, compared to \$673,000 and \$1,316,000 for the same periods in 2000. The decline in interest income is due to lower interest rates and lower average balances of cash and cash equivalents as a result of ongoing operating losses.

Liquidity and Capital Resources

We have financed our operations since inception through the sale of equity. During the year ended December 31, 1995, we received cash proceeds of \$250,000 from the sale of securities. In May 1996, we completed a private placement of shares of Common Stock, from which we received aggregate gross proceeds of \$1.3 million. In March 1997, the Merger of IAC and Hollis-Eden, Inc. provided us with \$6.5 million in cash and other receivables. In May 1998, we completed a private placement of shares and warrants, from which we received gross proceeds of \$20 million. During January 1999, we completed two private placements raising approximately \$25 million. In addition, since inception Hollis-Eden has received a total of \$13 million from the exercise of warrants and stock options.

Our operations to date have consumed substantial capital without generating any revenues, and we will continue to require substantial and increasing amounts of funds to conduct necessary research and development and preclinical and clinical testing of our drug candidates, and to market any drug candidates that receive regulatory approval. We do not expect to generate revenue from operations for the foreseeable future, and our ability to meet our cash obligations as they become due and payable is expected to depend for at least the next several years on our ability to sell securities, borrow funds or some combination thereof. Based upon our current plans, we believe that our existing capital resources, together with interest thereon, will be sufficient to meet our operating expenses and capital requirements well into 2002. However, changes in our research and development plans or other events affecting our operating expenses may result in the expenditure of such cash before that time. We may not be successful in raising necessary funds. Our future capital requirements will depend upon many factors, including progress with preclinical testing and clinical trials, the number and breadth of our programs, the time and costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other proprietary rights, the time and costs involved in obtaining regulatory approvals, competing technological and market developments, and our ability to establish collaborative arrangements, effective commercialization, marketing activities and other arrangements. We expect to continue to incur increasing negative cash flows and net losses for the foreseeable future.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

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PART II Other Information

Item 1. Legal Proceedings

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. As of the date of this Quarterly Report on Form 10-Q, we are not engaged in any legal proceedings that are expected, individually or in the aggregate, to have a

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material adverse effect on our business, financial condition or operating results.

Item 2. Changes in Securities

In May 2001, the Company entered into a financial advisory and investment banking agreement with H.C. Wainwright & Co., Inc. As an initial retainer fee, the Company agreed to issue to H.C. Wainwright & Co. Inc, \$25,000 and a warrant to purchase up to 25,000 shares of Common Stock at an exercise price of \$3.09 per share.

The sale and issuance of securities in the transaction described in the foregoing paragraph was deemed to be exempt from registration under the Securities Act of 1933, as amended, by virtue of Section 4(2) and/or Regulation D promulgated under such Act. The recipient represented their intention to acquire the securities for investment only and not with a view to the distribution thereof. Appropriate legends are affixed to the securities issued in such transaction. All recipients either received adequate information about the Company or had access, through employment or other relationships, to such information.

Item 3. Defaults upon Senior Securities

None

Item 4. Submission of Matters to a Vote of Securities Holders

The Annual Meeting of Stockholders of Hollis-Eden Pharmaceuticals was held on June 29, 2001. At this meeting, the Company solicited the vote of the stockholders on the proposals set forth below and received for each proposal the votes indicated below:

- (1) To elect three Class I directors to hold office until the 2004 Annual Meeting of Stockholders. Elected to serve as Class I directors were Paul Bagley, William H. Tilley and Salvatore J. Zizza. For each elected director the results of voting were: 9,974,219 for, 542,099 withheld, and 0 abstained. The continuing directors are Thomas Charles Merigan, Jr., M.D., Brendan R. McDonnell, Richard B. Hollis and Leonard Makowka M.D., Ph.D., FRCS(C), FACS.
- (2) To approve the Company's 1997 Incentive Stock Option Plan, as amended, to increase the aggregate number of shares of Common Stock authorized for issuance under such plan by 500,000 shares to a total of 3,250,000 shares. The 1997 Incentive Stock Option Plan, as amended, was approved with the following votes: 9,799,259 for, 655,081 against, and 61,978 abstained.
- (3) To approve the Company's Restated Certificate of Incorporation, as amended, to increase the authorized number of shares of Common Stock to 50,000,000. The Company's Restated Certificate of Incorporation, as amended, was approved with the following votes: 10,289,416 for, 202,861 against, and 24,041 abstained.
- (4) To ratify the selection of BDO Seidman, LLP as independent auditors of the Company for its fiscal year ending December 31, 2001. The selection of BDO Seidman, LLP as independent auditors of the Company for its fiscal year ending December 31, 2001 was ratified with the following votes: 10,489,259 for, 8,256 against, and 18,803 abstained.

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Item 5. Other Information

None

Item 6. Exhibits and Reports on Form 8-K

(a) The following exhibits are included as part of this report:

| Exhibit Number | Description |
|----------------|---|
| ----- | ----- |
| 3.4 | Certificate of Amendment to Certificate of Incorporation |

(b) Reports on Form 8-K: None

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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 hereunto duly authorized.

HOLLIS-EDEN PHARMACEUTICALS, INC.

Dated: August 3, 2001

By: /s/ Daniel D. Burgess

Daniel D. Burgess
Chief Operating Officer/
Chief Financial Officer
(Principal Financial Officer)

By: /s/ Robert W. Weber

Robert W. Weber
Vice President-Controller/
Chief Accounting Officer
(Principal Accounting Officer)

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