
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
WASHINGTON, D.C. 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, 2001
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE EXCHANGE ACT**

For the transition period from ____ to ____

Commission file number 0-22613

AVI BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

Oregon

(State or other jurisdiction of incorporation or organization)

93-0797222

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

One SW Columbia Street, Suite 1105, Portland, Oregon

(Address of principal executive offices)

97258

(Zip Code)

Issuer's telephone number, including area code: **503-227-0554**

Check whether the issuer (1) 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 ☒ 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 with \$.0001 par value
(Class)

23,158,309
(Outstanding at October 31, 2001)

AVI BIOPHARMA, INC.
FORM 10-Q
INDEX

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

[Balance Sheets – September 30, 2001 and December 31, 2000](#)

[Statements of Operations – Three and Nine Months Ended September 30, 2001 and 2000 and from July 22, 1980 \(Inception\) to September 30, 2001](#)

[Statements of Cash Flows – Nine Months Ended September 30, 2001 and 2000 and from July 22, 1980 \(Inception\) to September 30, 2001](#)

[Notes to Financial Statements](#)

[Item 2. Management's Discussion and Analysis](#)

[PART II – OTHER INFORMATION](#)

[Item 6. Exhibits and Reports on Form 8-K](#)

[Signatures](#)

AVI BIOPHARMA, INC.
(A Development Stage Company)
BALANCE SHEETS

	September 30, 2001	December 31, 2000
Assets		
Current Assets:		
Cash and cash equivalents	\$ 24,612,518	\$ 25,898,513
Short-term securities--available-for-sale	3,157,173	6,213,586
Other current assets	1,048,590	1,019,166
Total Current Assets	28,818,281	33,131,265
Property and Equipment, net of accumulated depreciation and amortization of \$2,846,628 and \$2,658,549		
	3,177,334	1,036,749
Patent Costs, net of accumulated amortization of \$645,185 and \$541,185	1,114,738	890,532
Other Assets	29,847	29,847
Total Assets	<u>\$ 33,140,200</u>	<u>\$ 35,088,393</u>
Liabilities and Shareholders' Equity		
Current Liabilities:		
Accounts payable	\$ 1,149,919	\$ 1,290,804
Accrued employee compensation	431,711	431,988
Total Current Liabilities	1,581,630	1,722,792
Shareholders' Equity:		
Preferred stock, \$.0001 par value, 2,000,000 shares authorized; none issued and outstanding	-	-
Common stock, \$.0001 par value, 50,000,000 shares authorized; 23,157,559 and 21,508,148 issued and outstanding	2,316	2,151
Additional paid-in capital	116,387,745	105,340,697
Accumulated other comprehensive loss	(2,216,739)	(11,683,414)
Deficit accumulated during the development stage	(82,614,752)	(60,293,833)
Total Shareholders' Equity	31,558,570	33,365,601
Total Liabilities and Shareholders' Equity	<u>\$ 33,140,200</u>	<u>\$ 35,088,393</u>

The accompanying notes are an integral part of these balance sheets.

AVI BIOPHARMA, INC
(A Development Stage Company)
STATEMENTS OF OPERATIONS

	Three months ended September 30,		Nine months ended September 30,		July 22, 1980 (Inception) to September 30, 2001
	2001	2000	2001	2000	
Revenues, from license fees, grants and research contracts	\$ 307,549	\$ 122,215	\$ 410,793	\$ 1,272,338	\$ 2,549,348
Operating expenses:					
Research and development	2,774,979	2,155,538	8,530,261	6,575,953	42,526,224
General and administrative	877,615	557,911	2,551,273	1,484,159	14,020,243
Acquired in-process research and development	-	-	-	-	19,545,028
	<u>3,652,594</u>	<u>2,713,449</u>	<u>11,081,534</u>	<u>8,060,112</u>	<u>76,091,495</u>
Other Income (Loss):					
Interest income, net	271,939	339,130	872,910	555,375	3,353,733
Realized gain on sale of short-term securities	-	-	-	-	96,750
Write-down of short-term securities- -available-for-sale	(12,523,088)	-	(12,523,088)	-	(12,523,088)
	<u>(12,251,149)</u>	<u>339,130</u>	<u>(11,650,178)</u>	<u>555,375</u>	<u>(9,072,605)</u>
Net loss	<u>\$ (15,596,194)</u>	<u>\$ (2,252,104)</u>	<u>\$ (22,320,919)</u>	<u>\$ (6,232,399)</u>	<u>\$ (82,614,752)</u>
Net loss per share - basic and diluted	<u>\$ (0.67)</u>	<u>\$ (0.11)</u>	<u>\$ (1.01)</u>	<u>\$ (0.35)</u>	
Weighted average number of common shares outstanding for computing basic and diluted loss per share	<u>23,122,839</u>	<u>20,303,112</u>	<u>22,151,720</u>	<u>17,800,160</u>	

The accompanying notes are an integral part of these balance sheets.

AVI BIOPHARMA, INC.
(A Development Stage Company)
STATEMENTS OF CASH FLOWS

	Nine months ended September 30,		For the Period July 22, 1980 (Inception to) September 30, 2001
	2001	2000	
Cash flows from operating activities:			
Net loss	\$ (22,320,919)	\$ (6,232,399)	\$ (82,614,752)
Adjustments to reconcile net loss to net cash flows used in operating activities:			
Depreciation and amortization	319,926	235,170	3,789,954
Realized gain on sale of short-term investments - available for sale	-	-	(96,750)
Write-down of short-term securities--available for sale	12,523,088	-	12,523,088
Compensation expense on issuance of common stock and partnership units	-	-	251,992
Compensation expense on issuance of options and warrants to purchase common stock or partnership units	-	-	562,353
Conversion of interest accrued to common stock	-	-	7,860
Acquired in-process research and development	-	-	19,545,028
(Increase) decrease in:			
Other current assets	340,576	(90,314)	(678,590)
Other assets	-	-	(29,847)
Net increase (decrease) in accounts payable and accrued employee compensation	(21,162)	276,171	1,701,630
Net cash used in operating activities	(9,158,491)	(5,811,372)	(45,038,034)
Cash flows from investing activities:			
Proceeds from sale or redemption of short-term investments	-	-	247,750
Purchase of property and equipment	(2,356,511)	(532,842)	(6,151,584)
Patent costs	(328,206)	(169,990)	(1,930,442)
Acquisition costs	-	-	(2,377,616)
Net cash used in investing activities	(2,684,717)	(702,832)	(10,211,892)
Cash flows from financing activities:			
Proceeds from sale of common stock, warrants, and partnership units, net of offering costs, and exercise of options and warrants	10,557,213	27,385,974	80,247,881
Buyback of common stock pursuant to rescission offering	-	-	(288,795)
Withdrawal of partnership net assets	-	-	(176,642)
Issuance of convertible debt	-	-	80,000
Net cash provided by financing activities	10,557,213	27,385,974	79,862,444
Increase (decrease) in cash and cash equivalents	(1,285,995)	20,871,770	24,612,518
Cash and cash equivalents:			
Beginning of period	25,898,513	8,683,005	-
End of period	<u>\$ 24,612,518</u>	<u>\$ 29,554,775</u>	<u>\$ 24,612,518</u>
SUPPLEMENTAL SCHEDULE OF NONCASH INVESTING ACTIVITIES AND FINANCING ACTIVITIES:			
Short-term securities--available-for-sale received in connection with the private offering, related party	\$ -	\$ 15,000,000	\$ 17,897,000
Change in unrealized gain (loss) on short-term securities--available-for-sale	\$ 9,466,675	\$ (9,344,614)	\$ (2,216,739)
Issuance of common stock and warrants for services	490,000	-	490,000

The accompanying notes are an integral part of these balance sheets.

AVI BIOPHARMA, INC.
NOTES TO FINANCIAL STATEMENTS
(Unaudited)

Note 1. Basis of Presentation

The financial information included herein for the three and nine-month periods ended September 30, 2001 and 2000 and the financial information as of September 30, 2001 is unaudited; however, such information reflects all adjustments consisting only of normal recurring adjustments which are, in the opinion of management, necessary for a fair presentation of the financial position, results of operations and cash flows for the interim periods. The financial information as of December 31, 2000 is derived from AVI BioPharma, Inc.'s (the Company's) Form 10-K. The interim financial statements should be read in conjunction with the financial statements and the notes thereto included in the Company's Form 10-K. The results of operations for the interim periods presented are not necessarily indicative of the results to be expected for the full year.

Note 2. Earnings Per Share

Basic EPS is calculated using the weighted average number of common shares outstanding for the period and diluted EPS is computed using the weighted average number of common shares and dilutive common equivalent shares outstanding. Given that the Company is in a loss position, there is no difference between basic EPS and diluted EPS since the common stock equivalents would be antidilutive.

Three Months Ended September 30,	2001	2000
Net loss	\$ (15,596,194)	\$ (2,252,104)
Weighted average number of shares of common stock and common stock equivalents outstanding:		
Weighted average number of common shares outstanding for computing basic earnings per share	23,122,839	20,303,112
Dilutive effect of warrants and stock options after application of the treasury stock method	*	*
Weighted average number of common shares outstanding for computing diluted earnings per share	23,122,839	20,303,112
Net loss per share - basic and diluted	\$ (0.67)	\$ (0.11)
 Nine Months Ended September 30,	 2001	 2000
Net loss	\$ (22,320,919)	\$ (6,232,399)
Weighted average number of shares of common stock and common stock equivalents outstanding:		
Weighted average number of common shares outstanding for computing basic earnings per share	22,151,720	17,800,160
Dilutive effect of warrants and stock options after application of the treasury stock method	*	*
Weighted average number of common shares outstanding for computing diluted earnings per share	22,151,720	17,800,160
Net loss per share - basic and diluted	\$ (1.01)	\$ (0.35)

* The following common stock equivalents are excluded from earnings per share calculation as their effect would have been antidilutive:

Three Months Ended September 30,	2001	2000
Warrants and stock options	13,147,589	10,298,111
 Nine Months Ended September 30,	 2001	 2000
Warrants and stock options	13,147,589	10,298,111

Note 3. Comprehensive Income

The Statement of Financial Accounting Standards No. 130 (SFAS 130), "Reporting Comprehensive Income," establishes standards for reporting and display of comprehensive income. Comprehensive income includes charges or credits to equity that did not result from transactions with shareholders. SFAS No. 130 became effective during 1998. The Company's only component of "other comprehensive income (loss)" is unrealized gain (loss) on short-term securities—available-for-sale. The Company accounts for its short-term securities in accordance with Statement of Financial Accounting Standards No. 115, "Accounting for Certain Investments in Debt and Equity Securities" (SFAS 115). In the third quarter of 2001, the Company recorded a one time, non-cash write-down of \$12,523,088 on these short-term securities—available-for-sale that had an other than temporary impairment as defined by SEC accounting rules. This write-down had the effect of writing the investment down to \$12 per share, the approximate recent monthly trading average for this security. The Company continues to classify its investment securities as available-for-sale and, accordingly, such investment securities are stated on the balance sheet at their fair market value, which was below cost by \$2,216,739 at September 30, 2001. The unrealized difference between the cost and the fair market value of these securities has been reflected as a separate component of shareholders' equity. These short-term securities represent common stock of SuperGen, Inc. with a fair value of \$3,157,173 at September 30, 2001.

Item 2. Management's Discussion and Analysis

Forward-Looking Information

The Financial Statements and Notes thereto should be read in conjunction with the following discussion. The discussion in this Form 10-Q contains certain forward-looking statements that involve risks and uncertainties, including, but not limited to, the results of research and development efforts, the results of pre-clinical and clinical testing, the effect of regulation by FDA and other agencies, the impact of competitive products, product development, commercialization and technological difficulties, and other risks detailed in the Company's Securities and Exchange Commission filings.

Overview

From its inception in July 1980, the Company has devoted its resources primarily to fund its research and development efforts. The Company has been unprofitable since inception and, other than limited interest, license fees and grants, has had no material revenues from the sale of products or other sources, and does not expect material revenues for at least the next 12 months. The Company expects to continue to incur losses for the foreseeable future as it expands its research and development efforts. As of September 30, 2001, the Company's accumulated deficit was \$82,614,752.

Results of Operations

Revenues, from license fees, grants and research contracts, increased to \$307,549 in the third quarter of 2001 from \$122,215 in the third quarter of 2000. Revenues, from license fees, grants and research contracts, decreased to \$410,793 for the nine months ended September 30, 2001 from \$1,272,338 for the comparable period of 2000, primarily due to the receipt of a \$1,000,000 fee for expansion of a license for diagnostic applications during the first quarter of 2000.

Operating expenses increased to \$3,652,594 in the third quarter of 2001 from \$2,713,449 in the third quarter of 2000 and to \$11,081,534 for the nine months ended September 30, 2001 from \$8,060,112 for the comparable period of 2000 due to increases in research and development and regulatory affairs staffing and increased expenses associated with outside collaborations and pre-clinical and clinical testing of the Company's technologies. Additionally, increased general and administrative costs were incurred to support the research expansion, and to continue to broaden the Company's investor and public relations efforts. Net interest income decreased to \$271,939 in the third quarter of 2001 from \$339,130 in the third quarter of 2000 due to reductions in market interest rates, which were slightly offset by earnings on increased cash balances. Net interest income increased to \$872,910 for the nine months ended September 30, 2001 from \$555,375 for the comparable period in 2000 due to earnings on increased cash balances, which were offset slightly by reductions in market interest rates. In the third quarter of 2001, the Company recorded a one time, non-cash write-down of \$12,523,088 on short-term securities—available-for-sale that had an other than temporary impairment as defined by SEC accounting rules.

Liquidity and Capital Resources

The Company's cash and cash equivalents were \$24,612,518 at September 30, 2001, compared with \$25,898,513 at December 31, 2000. The decrease of \$1,285,995 was primarily due to \$9,158,491 used in operations and \$2,684,717 used for investing activities which consist primarily of purchases of property and equipment and patent related costs, offset by net proceeds of \$9,954,234 from the stock purchase agreement with Medtronic, Inc. and \$602,979 from the exercise of options and warrants. In addition the Company's short-term securities—available-for-sale decreased by \$3,056,413 to \$3,157,173 at September 30, 2001 due to a reduction in the value of these securities. In the third quarter of 2001, the Company recorded a one time, non-cash write-down of \$12,523,088 on these short-term securities—available-for-sale that had an other than temporary impairment as defined by SEC accounting rules. These short-term securities represent common stock of SuperGen, Inc., related party.

The Company's future expenditures and capital requirements will depend on numerous factors, including without limitation, the progress of its research and development programs, the progress of its pre-clinical and clinical trials, the time and costs involved in obtaining regulatory approvals, the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, competing technological and market developments, the ability of the Company to establish collaborative arrangements and the terms of any such arrangements, and the costs associated with commercialization of its products. The Company's cash requirements are expected to remain the same or increase somewhat each year as it expands its activities and operations, including funding its research and other obligations under existing contractual agreements and joint venture relationships. Those contractual obligations do not require any material cash payments by the Company to third parties. There can be no assurance, however, that the Company will ever be able to generate product revenues or achieve or sustain profitability.

The Company expects that its cash requirements for approximately twenty-four months will be satisfied by existing cash resources. Absent significant new product revenues or partnering arrangements in the next twelve months, the Company may consider raising additional capital through private or public offerings of its securities. The Company, at this time, can not predict whether such a financing would be dilutive to existing investors.

Facilities

The Company has substantially completed its GMP manufacturing facility and is commencing testing and validation of the facility, which could extend into the first part of next year. The Company expects to undertake manufacturing compounds for clinical trials in mid 2002, after the validation and required governmental approvals are obtained.

PART II – OTHER INFORMATION

Item 6. Exhibits and Reports on Form 8-K

(a) The exhibit filed as a part of this report is listed below and this list constitutes the exhibit index.

The Company did not file any Exhibits during the quarter ended September 30, 2001.

(b) Reports on Form 8-K

The Company did not file any Reports on Form 8-K during the quarter ended September 30, 2001.

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.

Date: November 12, 2001

AVI BIOPHARMA, INC.

By: /s/ DENIS R. BURGER, Ph.D.

Denis R. Burger, Ph.D.

Chief Executive Officer

and Chairman (of the Board of Directors)

(Principal Executive Officer)

By: /s/ MARK M. WEBBER

Mark M. Webber

Chief Financial Officer

(Principal Financial and Accounting Officer)