DOR BIOPHARMA INC
Form 10QSB
August 14, 2002

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SEC SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-QSB

ý **QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**

For the Quarterly Period Ended June 30, 2002

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

For the transition period from _____ to _____

Commission File No. 1-14778

DOR BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	**41-1505029**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
28101 BALLARD DRIVE, SUITE F, LAKE FOREST, IL	**60045**
(Address of principal executive offices)	(Zip Code)

Issuer's telephone number, including area code **(847) 573-8990**

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

Check whether the issuer: (1) filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act during the past 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 ý No o

At August 12, 2002, 21,520,812 shares of the registrant's common stock (par value, $.001 per share) were outstanding.

Transitional Small Business Disclosure Format (check one): Yes o No ý

PART I. FINANCIAL INFORMATION

ITEM 1 FINANCIAL STATEMENTS

DOR BIOPHARMA, INC.

(A DEVELOPMENT STAGE ENTERPRISE)

CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

	June 30, 2002	December 31, 2001
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,437,887	$ 9,942,053
Receivable from related party	34,985	44,447
Prepaid expenses	90,072	49,941
Total current assets	5,562,944	10,036,441
Leasehold improvements and equipment, net of accumulated amortization of $1,067,000 and $975,860	357,872	365,219
Patent issuance costs, net of accumulated amortization of $21,542 and $15,091	406,826	284,419
Intangible assets, net of accumulated amortization of $60,277 and $8,611	303,874	355,540
TOTAL ASSETS	$ 6,631,516	$ 11,041,619
LIABILITIES AND STOCKHOLDERS' EQUITY/(DEFICIT)		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,096,128	$ 856,187
Accrued compensation	461,796	205,969
Due to joint ventures		2,042,833
Current portion of note payable	231,897	
Current portion of line of credit	198,656	164,748
Total current liabilities	1,988,477	3,269,737
Long-term liabilities:		
Long-term portion of note payable	347,845	
Long-term portion of line of credit	52,290	52,098
Total long-term liabilities	400,135	52,098
Total Liabilities	2,388,612	3,321,835
Series C exchangeable convertible preferred stock, $.05 par value. Authorized 200,000 shares; 104,435 issued and outstanding at liquidation value		10,348,733
Stockholders' equity/(deficit):		

	June 30, 2002	December 31, 2001
Preferred stock, $.001 par value. Authorized 4,600,000 shares; none issued and outstanding		
Series B convertible preferred stock, $.05 par value. Authorized 200,000 shares; 112,745 issued & outstanding at liquidation value	11,274,486	10,844,280
Series C exchangeable convertible preferred stock, $.05 par value. Authorized 200,000 shares; 108,060 issued and outstanding at liquidation value	10,711,252	
Common stock, $.001 par value. Authorized 50,000,000 shares; 21,639,454 issued, and 21,520,822 outstanding	21,639	20,945
Additional paid-in capital	49,058,779	48,983,361
Common stock held in escrow, 654,930 and 1,350,000 shares	818,663	1,687,500
Deficit accumulated during the development stage	(67,198,165)	(63,721,285)
	4,686,654	(2,185,199)
Less:		
Treasury stock, at cost, 118,642 shares	(443,750)	(443,750)
Total Stockholders' Equity/(Deficit)	4,242,904	(2,628,949)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY/(DEFICIT)	$ 6,631,516	$ 11,041,619

See accompanying condensed notes to financial statements.

DOR BIOPHARMA, INC.

(A DEVELOPMENT STAGE ENTERPRISE)

CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	Six Months Ended June 30,		Cumulative from February 15, 1985 (date of inception) to June 30, 2002
	2002	2001	
Revenue:			
SBIR contract revenue	$	$	$ 100,000
Expenses:			
SBIR contract research and development			86,168
Proprietary research and development	2,243,989	1,171,494	19,547,795
General and administrative	2,058,646	908,269	17,104,145
Write-off of acquired in-process research and development			10,181,000
Total operating expenses	4,302,635	2,079,763	46,919,108
Loss from operations	(4,302,635)	(2,079,763)	(46,819,108)
Equity gains/(losses)in joint ventures	767,234	(577,661)	(22,280,716)
Other income		(1,577)	262,890

	Six Months Ended June 30,		Cumulative from February 15, 1985 (date of inception) to June 30, 2002
Interest income	66,344	294,686	2,531,964
Interest expense	(7,823)	(27,320)	(356,973)
Net loss	(3,476,880)	(2,391,635)	(65,661,943)
Preferred stock dividends	(792,725)	(737,142)	(5,660,026)
Net loss applicable to common stockholders	$ (4,269,605)	$ (3,128,777)	$ (71,321,969)
Basic and diluted net loss per share available to common stockholders	$ (0.20)	$ (0.25)	
Basic and diluted weighted average common shares outstanding	21,179,037	12,741,858	

See accompanying condensed notes to financial statements.

DOR BIOPHARMA, INC.

(A DEVELOPMENT STAGE ENTERPRISE)

CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	Three Months Ended June 30,	
	2002	2001
Revenue:		
SBIR contract revenue	$	$
Expenses:		
SBIR contract research and development		
Proprietary research and development	1,105,188	585,642
General and administrative	1,301,493	439,515
Write-off of acquired in-process research and development		
Total operating expenses	2,406,681	1,025,157
Loss from operations	(2,406,681)	(1,025,157)
Equity gains/(losses) in joint ventures	854,177	(260,603)
Other income		
Interest income	28,176	120,317
Interest expense	(925)	(16,728)
Net loss	(1,525,253)	(1,182,171)
Preferred stock dividends	(398,552)	(370,608)
Net loss applicable to common stockholders	$ (1,923,806)	$ (1,552,779)
Basic and diluted net loss per share available to common stockholders	$ (0.09)	$ (0.12)

	Three Months Ended June 30,	
Basic and diluted weighted average common shares outstanding	21,520,812	12,741,858

See accompanying condensed notes to financial statements.

DOR BIOPHARMA, INC.

(A DEVELOPMENT STAGE ENTERPRISE)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	Six Months Ended June 30,		Cumulative Period February 15, 1985 (Inception) to June 30, 2002
	2002	2001	
OPERATING ACTIVITIES:			
Net Loss:	$ (3,476,880)	$ (2,391,635)	$ (65,661,943)
Adjustments to reconcile net loss in cash used in operating activities:			
Depreciation and amortization	149,257	89,310	1,712,363
Gain on the sale of mkt securities		(5)	(110,244)
Non-cash stock compensation		3,691	786,178
Equity (gains)/losses in joint ventures	(767,234)	577,661	22,280,716
Amortization of fair value of warrants			3,307,546
Gain on sale of assets		1,575	(4,530)
Write off patent issuance costs			439,725
Write off of acquired research and development			10,181,000
Changes in operating assets and liabilities:			
Receivable from third party	9,462	99,793	(34,985)
Prepaid expenses	(40,131)	5,873	(86,050)
Accounts payable and accrued expenses	239,941	31,879	1,041,172
Accrued compensation	255,827	27,411	461,796
Due to joint ventures	(695,857)	275,118	(1,737,091)
Net cash used in operating activities	(4,325,615)	(1,279,329)	(27,424,347)
INVESTING ACTIVITIES:			
Cash received in acquisition of CTD, net			1,392,108
Patent issuance cost	(128,858)	(30,201)	(922,918)
Investment in joint ventures		(577,661)	(19,963,883)
Organizational costs incurred			(135)
Purchases of leasehold improvements and equipment	(83,793)	(94,991)	(1,870,902)
Proceeds from assets sold			4,790
Purchases of marketable securities		(3,973,724)	(11,004,080)
Proceeds from sale of marketable securities		5,988,709	11,114,324
Prepaid acquisition costs		(1,004,608)	
Net cash provided by (used in) investing activities	(212,651)	307,524	(21,250,696)
FINANCING ACTIVITIES:			
Net proceeds from issuance (costs incurred related to issuance) common stock			37,777,399
Net proceeds from issuance of preferred stock			16,325,712

	Six Months Ended June 30,		Cumulative Period February 15, 1985 (Inception) to June 30, 2002
Proceeds from exercise of options			417,092
Proceeds from borrowings under line of credit	52,290		1,203,205
Repayment of amounts under line of credit	(18,190)	(50,785)	(1,015,073)
Proceeds from refinancing of due to joint venture payable			
Repayment of long-term note receivable			50,315
Repayment of note payable issued in exchange for legal service			(71,968)
Purchase and retirement of common stock			(130,000)
Purchase of common stock for treasury stock			(443,750)
Net cash provided by (used in) financing activities	34,100	(50,785)	54,112,930
Net increase (decrease) in cash and Cash equivalents	(4,504,166)	(1,022,590)	5,437,887
Cash and cash equivalents at beginning of period	9,942,053	10,831,266	
Cash and cash equivalents at end of period	$ 5,437,887	$ 9,808,676	$ 5,437,887
SUPPLEMENTAL DISCLOSURE OF CASH FLOW:			
Cash paid for interest	$ 7,823	$ 27,321	
NON-CASH TRANSACTIONS			
Issuance of preferred stock dividends in kind	$ 792,725	$ 737,142	
Issuance of note payable to settle joint venture liabilities	$ 579,742		

The accompanying notes are an integral part of the consolidated financial statements

DOR BIOPHARMA, INC.

(A DEVELOPMENT STAGE ENTERPRISE)

CONDENSED NOTES TO FINANCIAL STATEMENTS

These unaudited interim consolidated financial statements were prepared under the rules and regulations for reporting on Form 10-QSB. Accordingly, we omitted some information and footnote disclosures normally accompanying the annual financial statements. You should read these interim financial statements and notes in conjunction with our audited consolidated financial statements and their notes included in our latest annual report on Form 10-KSB, for the year ending December 31, 2001, as amended. It is our opinion that the consolidated financial statements include all adjustments necessary for a fair statement of the results of operations, financial position and cash flows for the interim periods. All adjustments were of a normal recurring nature. The results of operations for interim periods are not necessarily indicative of the results for the full fiscal year.

NET LOSS PER SHARE

Net loss per share is presented on the Consolidated Statements of Operations in accordance with SFAS No. 128 for the current and prior periods. DOR BioPharma had a net loss for all periods being presented, which resulted in diluted and basic earnings per share being the same for all periods presented. The potential impact of warrants and stock options outstanding was not included in the calculation because their inclusion would have been anti-dilutive.

DISSOLUTION OF THE ELAN JOINT VENTURES

On June 29, 2002 DOR BioPharma Inc and Elan Pharmaceutical Plc signed a definitive agreement for the dissolution of both of their joint ventures; InnoVaccines Corporation ("InnoVaccines") and Endorex Newco, Ltd. ("Newco"). The terms of this settlement call for the termination of Elan's right to exchange the $10,711,252 of Series C Preferred stock into Newco common stock, previously recorded by DOR outside of the equity section of the balance sheet. Additionally, the $2,042,833 due to joint ventures current liability was restructured into payments totaling

$1,104,242; $524,500 payable in cash and the remaining $579,742 payable under a note with scheduled payments of $231,897 (June 30, 2003) $231,897 (June 30, 2004) and $115,948 (December 30, 2003), respectively.

The accounting for this transaction is reflected in the second quarter financial statements; the $10,711,252 of Series C preferred has been reclassified to equity, the $524,500 payable has been recorded as part of "accrued expenses" and the note payable has been classified into its current and long-term portions. The resulting gain of $938,591 on the refinancing of the Company's payable has been reflected as a gain to "equity gains/(losses) in joint ventures".

SEVERANCE COSTS

In June 2002, the Board of Directors authorized management to restructure the Company's operations and implement a cost reduction program in order to reduce future operating costs, preserve existing working capital and avoid the need for additional financing in the near future. The company has reduced its headcount from 22 to 3 employees. The Company communicated all severance benefits to employees before June 30, 2002.

Severance charges recorded in the statement of operations during the six months ended June 30, 2002 totaled approximately $630,000, which was based on management's estimate of probable costs to be incurred under severance agreements with the terminated employees. During June 2002, payments of approximately $170,000 were made and approximately $460,000 was recorded as accrued compensation.

ITEM 2 MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

The following discussion and analysis provides information to explain the results of operations and financial condition of DOR BioPharma, Inc. ("DOR BioPharma," "DOR," or the "Company"). You should also read the Company's unaudited consolidated interim financial statements and their notes, included in this Form 10-QSB, and the Company's audited consolidated financial statements and their notes and other information included in the Company's Annual Report on Form 10-KSB for the year ended December 31, 2001. This report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended which are subject to the safe-harbor created by that section. The forward-looking statements within this Form 10-QSB are identified by words such as "believes," "anticipates," "expects," "intends," "may," "will" "plans" and other similar expressions. However, these words are not the exclusive means of identifying such statements. In addition, any statements that refer to expectations, projections, or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are subject to significant risks, uncertainties and other factors, including those identified in Exhibit 99 "Risk Factors" of this Form 10-QSB, which may cause actual results to differ materially from those expressed in, or implied by, these forward-looking statements. The Company undertakes no obligation to publicly update or revise any forward-looking statements to reflect events or circumstances occurring subsequent to the filing of this Form 10-QSB with the SEC. You should carefully review and consider the various disclosures the Company makes in this report and the Company's other reports filed with the SEC that attempt to advise interested parties of the risks, uncertainties and other factors that may affect the Company's business.

The Company is a development stage enterprise involved in oral and mucosal drug delivery of drugs which may not currently exist in such formulations, but have been already approved by the FDA and are marketed. The Company has not generated any material revenues from operating activities. It believes, however, that its product portfolio which includes a phase III drug will be attractive to potential pharmaceutical partners.

Plan of Operation

As the Company enters the third quarter of 2002, DOR plans to continue focusing it's resources on the orBec , and LPM-Leuprolide technologies. orBec is currently the subject of a pivotal, multi-center phase III clinical trial for the treatment of intestinal-graft-versus-host disease ("IGVHD"). orBec is also in a phase II clinical trials for the treatment of Crohn's disease in the U.S. LPM -Leuprolide has completed pre-clinical animal testing.

The Company plans to continue its clinical and pre-clinical development activities in the most cost effective manner possible; through the out-sourcing of management and development responsibilities to third party vendors.

Significant events during the second quarter of 2002 include:

On June 14th, the Company amicably resolved a dissident stockholder's written consent solicitation by reconstituting the board of directors with three new independent members;

On June 30th, the Company regained technical compliance with the continued listing standards of the American Stock Exchange ("AMEX") by increasing stockholders' equity by over $10 million;

In June, the Company reduced its headcount from 22 employees to 3 resulting in a net savings of approximately $2.6 million per year in employee compensation alone;

In June, the Company notified its external service providers of the Company's overall cost reduction program and new policies seeking to carefully manage these costs;

On June 30th, the Company executed a settlement agreement with Elan reducing the Company's current payables from $2.4 million by approximately $900,000, resulting in a recognized gain of approximately the same amount for the quarter, and negotiated a 30 month installment note to Elan for the remaining $1.5 million;

On June 30th, as part of the settlement agreement executed with Elan, the Company and Elan have agreed to seek to dissolve the Company's two joint venture subsidiaries, InnoVaccines Corporation ("Innovaccines") and Endorex Newco, Ltd., and thereby reduce or eliminate the ongoing expenses associated with maintaining these joint ventures. The agreement excepts the licensed oral vaccine intellectual property of Innovaccines relating to U.S. patents 5,811,128, 5,820,883, 5,853,763, 5,942,252 and 6,024,983, European patents 0266,119 and 0333,353 and their worldwide counterparts, which DOR and Elan will to continue to share on a 50/50 basis, through InnoVaccines;

In June, the Company formed a new subsidiary, Oradel Systems, Inc. ("Oradel"), assigning intellectual property rights to the Company's LPM and LPE oral drug delivery platforms and LPM-Leuprolide and LPE-Paclitaxel preclinical programs to Oradel for the purpose of exploiting strategic alternatives for these technologies and programs;

During the second quarter, the Company continued enrollment and initiated efforts to cost effectively increase recruitment for the Company's ongoing pivotal Phase III of orBec® for the treatment of intestinal graft-vs.-host disease ("IGVHD");

During the second quarter, the Company continued stability testing on Oraprine , an oral suspension formulation of Azathioprine, a commonly prescribed immunosuppressant.

Material Changes in Results of Operations

In comparing the Company's second quarter and first six months of results of operations and financial condition for 2002 with results for the same period in 2001, the reader should note that the 2001 results do not include the impact of the merger between the Company and Corporate Technology Development, Inc. ("CTD"), which was completed on November 29, 2001. As a result, expenditures connected with the clinical trials for orBec and Oraprine , products acquired through this merger, are not included in the 2001 consolidated results for DOR BioPharma.

For the three-month period ended June 30, 2002, the Company had a net loss applicable to common stockholders which increased $343,082 or 29%, to $1,525,253 as compared to a net loss applicable to common stockholders of $1,182,171 for the three months ended June 30, 2001. After giving effect to dividends on preferred stock, which are paid-in-kind in shares of preferred stock, net loss available to common stockholders increased $371,027, or 24%, to $1,923,806, or $0.09 per share, compared with $1,552,779, or $0.12 per share, for the prior year period.

Research and development expenditures for the three months ended June 30, 2002, increased $519,546, or 89%, to $1,105,188, compared with $585,642 for the corresponding period ended June 30, 2001. This increase reflects the cost of the phase III clinical trials for orBec Intestinal

Graft-Versus-Host-Disease ("IGVHD") and phase II clinical trials for Crohn's disease. Second quarter 2002 also includes the one-time effect of severance costs associated with the recent cost containment initiative.

General and administrative expenses for the second quarter 2002 increased $861,978, or 196%, to $1,301,493 as compared to $439,515 for the three months ended June 30, 2001, due to one-time severance costs, increased insurance costs and the amortization of the acquired intangible assets of CTD.

During the second quarter of 2002, equity gains/(losses) from joint venture activities was a gain of $854,177 a decrease of $1,114,780, or 428%, from the loss of $260,603 for the same period in 2001. This change resulted the settlement of the Elan joint ventures as described in the notes to the June 30, 2002 financial statement.

Interest income for the three months ending June 30, 2002 was $28,176, a decrease of $92,141, or 77%, compared to $120,317 for the same period in 2001, due to the continued decrease in interest rates on investment instruments versus the prior year as well as a lower cash balance in 2002.

For the six months ended June 30, 2002, the Company had a net loss applicable to common stockholders which increased $1,085,245 or 45%, to $3,476,880 as compared to a net loss applicable to common stockholders of $2,391,635 for the six months ended June 30, 2001. After giving effect to dividends on preferred stock, which are paid-in-kind in shares of preferred stock, net loss available to common stockholders increased $1,140,828, or 36%, to $4,269,605, or $0.20 per share, compared with $3,128,777, or $0.25 per share, for the prior period.

Year to date 2002 research and development expenditures increased $1,072,495, or 92%, to $2,243,989, compared with $1,171,494 for the corresponding period ended June 30, 2001. This increase reflects the cost of the phase III clinical trials for orBec Intestinal Graft-Versus-Host-Disease ("IGVHD") and phase II clinical trials for Crohn's disease as well as the one-time effect of the severance initiated by the Company's cost cutting measures.

General and administrative expenses for the six months ended June 30, 2002, increased $1,150,377, or 127%, to $2,058,646 as compared to $908,269 for the six months ended June 30, 2001, severance costs, which were recorded in the second quarter of 2002, due to increased insurance costs and the amortization of the acquired intangible assets of CTD.

Year to date 2002 equity gains/(losses) from joint venture activities reflected a gain of $767,234 a decrease of 233% or $1,344,895 compared to the loss of $577,661 for the same period in 2001. This change resulted from the settlement of the Elan joint ventures as described in the notes to the June 30, 2002 financial statements.

Interest income for the first six months of 2002 decreased to $66,344, a decrease of $228,342, or 77%, compared to $294,686 for the first six months of 2001, due to the decline in interest rates on investment instruments versus the prior year as well as a lower cash balance in 2002.

FINANCIAL CONDITION

On June 30, 2002 and December 31, 2001, DOR BioPharma had cash, cash equivalents, and marketable securities of $5,437,887 and $9,942,053, respectively. The level of working capital (current assets less current liabilities) was $3,574,467 for June 30, 2002 compared with $6,766,704, for December 31, 2001. Given the Company's current liquidity position, the current market recession and tightening up of the capital markets, and given the Company's commitment to preserving shareholder value, DOR BioPharma has focused its activities into working capital preservation and reducing the monthly cash "burn rate".

The Company has settled its joint venture payable with Elan, resulting in an approximately $900,000 gain being recorded and a reclassification of approximately $10,700,000 back into equity, bringing DOR's stockholders' equity to over $4 million as of June 30, 2002.

Headcount has been drastically reduced and costs have been pared down to preserve the Company's working capital. The Company continues to look for further reductions in its cash expenditures including, but not necessarily limited to, further reductions in expenditures relating to outside service providers and the reduction or elimination of expenses associated with non-core programs. The Company believes that the cost reductions implemented to date will result in a current burn rate which, if maintained, will preserve cash resources sufficient to support operations for the next 18 months. See Exhibit 99 "Risk Factors."

PART II. OTHER INFORMATION

ITEM 6 EXHIBITS AND REPORTS ON FORM 8-K

(a) 99.1 Risk Factors

99.2 Certification of Interim President, pursuant to the Sarbanes-Oxley Act of 2002.

99.3 Certification of Principal Financial Officer, pursuant to the Sarbanes-Oxley Act of 2002.

(b) Reports on Form 8-K:

Item 5. *Other events.* On June 14, 2002, DOR BioPharma, Inc. (the "Company") filed a current report, on Form 8-k announcing the appointment of new directors, the resignation of senior management and the initiation of a significant cost reduction program.

SIGNATURES

In accordance with 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.

DOR BIOPHARMA, INC.

August 14, 2002 /s/ STEVE KANZER

Steve H. Kanzer
Interim President

August 14, 2002 /s/ STEVE KOULOGEORGE

Steve Koulogeorge
Controller
(principal financial and accounting officer)