DOR BIOPHARMA INC
Form 10QSB
May 15, 2002

QuickLinks -- Click here to rapidly navigate through this document

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 March 31, 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 May 1, 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)

	March 31, 2002	December 31, 2001
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,610,044	$ 9,942,053
Receivable from related party	61,391	44,447
Prepaid expenses	92,706	49,941
Total current assets	7,764,141	10,036,441
Leasehold improvements and equipment, net of accumulated amortization of $1,020,452 and $975,860	333,957	365,219
Patent issuance costs, net of accumulated amortization of $16,121 and $15,091	300,043	284,419
Intangible assets, net of accumulated amortization of $34,444 and $8,611	329,707	355,540
TOTAL ASSETS	$ 8,727,848	$ 11,041,619
LIABILITIES AND STOCKHOLDERS' EQUITY/(DEFICIT)		
Current liabilities:		
Accounts payable and accrued expenses	$ 633,987	$ 856,187
Accrued compensation	98,865	205,969
Due to joint ventures	2,042,833	2,042,833
Current portion of capital lease obligations	145,826	164,748
Total current liabilities	2,921,511	3,269,737
Long-term liabilities:		
Long-term portion of capital lease obligation	38,180	52,098
Total long-term liabilities	38,180	52,098
Total Liabilities	2,959,691	3,321,835
Series C exchangeable convertible preferred stock, $.05 par value. Authorized 200,000 shares; 104,435 issued and outstanding at liquidation value	10,528,991	10,348,733
Stockholders' equity/(deficit):		
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; 108,443 issued & outstanding at liquidation value	11,058,194	10,844,280
Common stock, $.001 par value. Authorized 50,000,000 shares; 21,639,464 issued, and 21,639,454 outstanding	21,619	20,945
Additional paid-in capital	49,457,352	48,983,361
Common stock held in escrow, 654,930 and 1,350,000 shares	818,663	1,687,500

	March 31, 2002	December 31, 2001
Deficit accumulated during the development stage	(65,672,912)	(63,721,285)
	(4,317,084)	(2,185,199)
Less:		
Treasury stock, at cost, 118,642 shares	(443,750)	(443,750)
Total Stockholders' Equity/(Deficit)	(4,760,834)	(2,628,949)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY/(DEFICIT)	$ 8,727,848	$ 11,041,619

See accompanying condensed notes to financial statements.

DOR BIOPHARMA, INC.

(A DEVELOPMENT STAGE ENTERPRISE)

CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	Three Months Ended March 31,		Cumulative from February 15, 1985 (date of inception) to March 31, 2002
	2002	2001	
Revenue:			
SBIR contract revenue	$	$	$ 100,000
Expenses:			
SBIR contract research and development			86,168
Proprietary research and development	1,138,801	585,852	18,442,607
General and administrative	757,153	468,754	15,802,652
Write-off of acquired in-process research and development			10,181,000
Total operating expenses	1,895,954	1,054,606	44,512,427
Loss from operations	(1,895,954)	(1,054,606)	(44,412,427)
Equity losses in joint ventures	(86,943)	(317,058)	(23,134,893)
Other income		(1,577)	262,890
Interest income	38,168	174,369	3,503,788
Interest expense	(6,898)	(10,592)	(356,048)
Net loss	(1,951,627)	(1,209,464)	(64,136,690)
Preferred stock dividends	(394,172)	(366,534)	(5,261,473)
Net loss applicable to common stockholders	$ (2,345,799)	$ (1,575,998)	$ (69,398,163)

	Three Months Ended March 31,	
Basic and diluted net loss per share available to common stockholders	$ (0.11)	$ (0.12)
Basic and diluted weighted average common shares outstanding	20,833,350	12,741,858

See accompanying condensed notes to financial statements.

DOR BIOPHARMA, INC.

(A DEVELOPMENT STAGE ENTERPRISE)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	Three Months Ended March 31,		Cumulative from February 15, 1985 (date of inception) to March 31, 2002
	2002	2001	
OPERATING ACTIVITIES:			
Net Loss:	(1,951,627)	(1,209,463)	(64,136,690)
Adjustments to reconcile net loss in cash used in operating activities:			
Depreciation and amortization	71,455	43,027	1,634,561
Gain on the sale of mkt securities		200	(110,244)
Noncash stock compensation		18,097	786,178
Equity in losses in joint ventures		317,058	23,047,950
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	(16,944)	95,205	(61,391)
Prepaid expenses	(42,765)	(359,606)	(88,684)
Accounts payable and accrued expenses	(222,200)	(39,178)	579,031
Accrued Compensation	(107,104)	(65,058)	98,865
Due to joint ventures		137,171	(1,041,234)
Net cash used in operating activities	(2,269,185)	(1,060,972)	(25,367,917)
INVESTING ACTIVITIES:			
Cash received in acquisition of CTD, net			1,392,108
Patent issuance cost	(16,654)	(7,801)	(810,714)
Investment in joint ventures		(317,058)	(19,963,883)
Organizational costs incurred		(135)	
Purchases of leasehold improvements and equipment	(13,330)	(71,177)	(1,800,439)
Proceeds from assets sold			4,790
Purchases of marketable securities		(3,477,806)	(11,004,080)
Proceeds from sale of marketable securities		4,487,487	11,114,324
Net cash provided by (used in) investing activities	(29,984)	613,645	(21,068,029)
FINANCING ACTIVITIES:			

	Three Months Ended March 31,		
Net proceeds from issuance (costs incurred related to issuance)common stock		(20,365)	37,777,399
Net proceeds from issuance of preferred stock			16,325,712
Proceeds from exercise of options			417,092
Proceeds from borrowings under line of credit		17,195	1,150,913
Repayment of amounts due under line of credit and capital lease obligations	(32,840)	(29,174)	(1,029,723)
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	(32,840)	(32,344)	54,045,990
Net increase (decrease) in cash and Cash equivalents	(2,332,009)	(479,671)	7,610,044
Cash and cash equivalents at beginning of period	9,942,053	10,831,266	
Cash and cash equivalents at end of period	$ 7,610,044	$ 10,351,595	$ 7,610,044
SUPPLEMENTAL DISCLOSURE OF CASH FLOW:			
Cash paid for interest	$ 6,273	$ 10,592	
NON-CASH TRANSACTIONS			
Issuance of preferred stock dividends in kind	$		
Issuance of common stock, options and warrants in acquisition			
Capital lease acquisitions			

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 the consolidated financial statements and their notes included in our latest annual report on Form 10-KSB, 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.

JOINT VENTURE ESTIMATES

The preparation of the quarterly consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts related to the activities of InnoVaccines Corporation ("InnoVaccines") and Endorex Newco, Ltd. ("Newco"), our joint ventures with Elan Corporation, plc ("Elan"), including the reported net liabilities related to the joint ventures and the reported amounts of equity

in losses from joint ventures. Actual results could differ from those estimates.

UNAUDITED CONDENSED FINANCIAL STATEMENTS FOR UNCONSOLIDATED JOINT VENTURES

Condensed, unaudited financial statement information of the joint ventures is stated below. The joint ventures had no revenues. Net expenses equaled the net loss for all periods.

	For the three months ended March 31,	
	2002	**2001**
InnoVaccines, net of DOR mark up on billings to InnoVaccines	$	$ (390,553)
Newco, net of DOR mark up on billings to Newco		(84,088)
Total net loss	$	$ (474,641)
Reconciliation to equity in losses from joint ventures:		
Total joint venture net losses	$	$ (474,641)
Less: Elan minority interest		157,583
InnoVaccines costs incurred by DOR, outside of Joint venture	(86,943)	
Equity in losses from joint ventures	$ (86,943)	$ (317,058)

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 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 and is 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. Although the Company has not generated any material revenues from operating activities, it believes that its product portfolio which includes a phase III drug will be attractive to potential pharmaceutical partners. The Company has initiated preliminary marketing activities for its products. The intensity of the Company's marketing efforts, in particular for orBec , will increase during the second and third quarter of 2002 coincident with the approaching of the completion of enrollment of the pivotal phase III orBec trial.

Plan of Operation

The orBec phase III pivotal multi-center clinical trial continues to progress in terms of patient enrollment and number of clinical sites established in the United States. Evaluation of potential clinical sites in Europe and Canada is under way. The Company received orphan drug designation for orBec for the treatment of IGVHD from the European regulatory agency, EMEA. Additionally, the orBec phase II trial for

Crohn's disease enrolled its first patients and has added additional clinical sites. DOR is completing reformulation work on Oraprine which is presently undergoing stability testing following which a decision will be made on further clinical testing.

The Company continues to make progress in the pre-clinical development of its oral delivery systems LPM , LPE and LPP . LPM Leuprolide, an oral formulation of the leading hormonal therapy for the treatment of prostate cancer and endometriosis has initiated dog studies during the first quarter, demonstrating comparable bioavailability (amount of the drug in blood or plasma) results as those seen in rodent models. Final confirmatory and proof of principal studies have commenced in dogs. LPE and LPM paclitaxel, an oral version of the world's leading anti-cancer agent, has shown promising bioavailability results in rat studies. Upon completion of these studies, a decision will be made on further activities towards clinical development.

The two joint ventures with Elan, InnoVaccines and Endorex Newco (MEDIPAD®) have terminated all development activities. In March 2002, the Endorex Newco joint venture completed an agreement to terminate their license agreement with Schein Pharmaceutical (Bermuda) Ltd., a subsidiary of Watson Pharmaceuticals, Inc. Endorex Newco received a $300,000 final settlement for

reimbursement of joint venture expenditures incurred by Endorex Newco and DOR is currently negotiating the dissolution of the JV with Elan. Negotiations are in progress for the dissolution of both joint ventures. The terms and conditions of the dissolution have not as yet been settled. Until final resolution of this matter the Company continues to carry the approximately $2.0 million of funding obligation as a liability.

Material Changes in Results of Operations

In comparing the first quarter 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 March 31, 2002, the Company had a net loss applicable to common stockholders which increased $742,163 or 61%, to $1,951,627 as compared to a net loss applicable to common stockholders of $1,209,464 for the three months ended March 31, 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 $769,801, or 49%, to $2,345,799, or $0.11 per share, compared with $1,575,998, or $0.12 per share, for the prior year period.

Research and development expenditures for the three months ended March 31, 2002, increased $552,949, or 94%, to $1,138,801, compared with $585,852 for the corresponding period ended March 31, 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.

General and administrative expenses for the three months ended March 31, 2002, increased $288,399, or 62%, to $757,153 as compared to $468,754 for the three months ended March 31, 2001, due to the amortization of the acquired intangible assets of CTD, the costs of new marketing materials related to the company name change, and the timing on hiring staff during 2001.

During the first quarter of 2002, equity in losses from joint venture activities decreased by $230,115, or 73%, to $86,943 compared to $317,058 for the same period in 2001. This decrease represents the refocus of the Company's activities on the proprietary portfolio. The costs incurred in 2002 are legal costs associated with maintaining the Southern Research Institute ("SRI") patents associated with the InnoVaccines joint venture.

Interest income for the first quarter of 2002 decreased to $38,168, a decrease of $136,201, or 78%, compared to $174,369 for the first quarter in 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 March 31, 2002 and December 31, 2001, DOR BioPharma had cash, cash equivalents, and marketable securities of $7,610,044 and $9,942,053, respectively. The net cash burn for the quarter included approximately $290,000 in 2001 expenditures, the majority of which were clinical expenses for orBec which were paid in the first quarter of 2002. The level of working capital of $4,842,630 for March 31, 2002 and $6,766,704, for December 31, 2001 reflects balances include the disputed liability of approximately $2.0 million for the Elan joint ventures.

With the integration of CTD, the Company has begun a program of cost integration and reduction. DOR has already consolidated and eliminated a number of duplicate expenditures and is diligently working to internalize a number of clinical and regulatory expenditures which were formerly outsourced. The hiring of Dr. Franco Quagliata, M.D. as medical director is a significant and positive step in this process. Commencing April 1, 2002, total cash expenditures have been reduced to

approximately $425,000 per month. The Company, on an on-going basis, will look to further reduce its cash expenditures including, but necessarily limited to, the reduction of operational personnel and non-core programs. Contingent on the settlement with Elan, the Company believes that the current cash resources should be sufficient to support planned operations for at least the next 16 months.

It is the intention of DOR BioPharma to focus on its existing products and technologies and continuance of its clinical program for orBec . In order to fund such activity, and to in-license other products and technologies, the Company may also seek to obtain funds from possible future public or private sales of our securities or other sources. See Exhibit 99 "Risk Factors."

PART II. OTHER INFORMATION

ITEM 6 EXHIBITS AND REPORTS ON FORM 8-K

(a)

99.1 Risk Factors

(b)

Reports on Form 8-K: The Company did not file any current reports on Form 8-K during the first quarter of 2002.

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.

May 15, 2002 /s/ COLIN BIER

Colin Bier
Chairman and Chief Executive Officer

May 15, 2002 /s/ STEVE KOULOGEORGE

Steve Koulogeorge
Controller
(principal financial and accounting officer)

QuickLinks