

**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 June 30, 2001

or

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

Commission file number: 0-19311

IDEC PHARMACEUTICALS CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

33-0112644

(IRS Employer Identification No.)

3030 Callan Road, San Diego, CA
(Address of principal executive offices)

92121
(Zip code)

(858) 431-8500

(Registrant's telephone number, including area code)

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 No

As of July 31, 2001 the Registrant had 151,908,204 shares of its common stock, \$.0005 par value, issued and outstanding.

IDEC PHARMACEUTICALS CORPORATION

**FORM 10-Q—QUARTERLY REPORT
FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2001**

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

IDEC PHARMACEUTICALS CORPORATION AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

(unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2001	2000	2001	2000
	Restated		Restated	
Revenues:				
Revenues from unconsolidated joint business	\$ 58,072	\$ 31,302	\$ 106,630	\$ 53,195
Contract revenues	2,152	6,088	3,507	9,592
License fees	4,625	1,625	11,250	3,250
Total revenues	64,849	39,015	121,387	66,037
Operating costs and expenses:				
Manufacturing costs	—	—	—	2,134
Research and development	21,691	17,038	43,161	31,760
Selling, general and administrative	11,430	6,600	23,134	12,677
Total operating costs and expense	33,121	23,638	66,295	46,571
Income from operations	31,728	15,377	55,092	19,466
Interest income, net	8,257	2,389	17,980	4,265
Income before income tax provision	39,985	17,766	73,072	23,731
Income tax provision	(14,832)	(3,091)	(27,112)	(4,109)
Income before cumulative effect of accounting change	25,153	14,675	45,960	19,622
Cumulative effect of accounting change, net of income tax benefit of \$487	—	—	—	(9,263)
Net income	\$ 25,153	\$ 14,675	\$ 45,960	\$ 10,359
Basic earnings per share:				
Before cumulative effect of accounting change	\$ 0.17	\$ 0.11	\$ 0.31	\$ 0.15
Cumulative effect of accounting change	—	—	—	(0.07)
Basic earnings per share	\$ 0.17	\$ 0.11	\$ 0.31	\$ 0.08
Diluted earnings per share:				
Before cumulative effect of accounting change	\$ 0.15	\$ 0.09	\$ 0.27	\$ 0.13
Cumulative effect of accounting change	—	—	—	(0.06)
Diluted earnings per share	\$ 0.15	\$ 0.09	\$ 0.27	\$ 0.07
Shares used in calculation of earnings per share:				
Basic	150,477	133,524	149,167	131,937
Diluted	167,417	156,126	167,297	156,903

IDEC PHARMACEUTICALS CORPORATION AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except par value)
(unaudited)

	June 30, 2001	December 31, 2000
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 453,906	\$ 401,052
Securities available-for-sale	158,613	180,286
Contract revenue receivables, net	2,680	1,697
Due from related parties, net	54,735	41,753
Prepaid expenses and other current assets	6,963	6,470
Total current assets	676,897	631,258
Long-term securities available-for-sale	209,030	169,188
Property and equipment, net	57,807	47,514
Investment and other assets	9,206	8,446
	<u>\$ 952,940</u>	<u>\$ 856,406</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current portion of notes payable	\$ 145	\$ 743
Accounts payable	1,547	1,737
Accrued expenses	18,412	16,071
Deferred revenue	1,440	4,494
Total current liabilities	21,544	23,045
Notes payable, less current portion	132,409	128,888
Deferred rent	2,822	2,752
Deferred taxes and other long-term liabilities	7,500	7,102
Commitments		
Stockholders' equity:		
Convertible preferred stock, \$.001 par value	—	—
Common stock, \$.0005 par value	76	73
Additional paid-in capital	728,374	680,602
Accumulated other comprehensive income—net unrealized gains on securities available-for-sale, net of taxes	828	517
Retained earnings	59,387	13,427
Total stockholders' equity	788,665	694,619
	<u>\$ 952,940</u>	<u>\$ 856,406</u>

See accompanying notes to condensed consolidated financial statements.

IDEC PHARMACEUTICALS CORPORATION AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(unaudited)
**Six months ended
June 30,**
2001
2000

Cash flows from operating activities:		
Net cash provided by operating activities	\$ 66,622	\$ 21,367
Cash flows from investing activities:		
Purchase of property and equipment	(13,116)	(6,832)
Purchase of securities available-for-sale	(326,454)	(81,219)
Sales and maturities of securities available-for-sale	305,661	105,716
Net cash provided by (used in) investing activities	(33,909)	17,665
Cash flows from financing activities:		
Payments on notes payable	(597)	(823)
Proceeds from issuance of common stock	20,738	12,370
Net cash provided by financing activities	20,141	11,547
Net increase in cash and cash equivalents	52,854	50,579
Cash and cash equivalents, beginning of period	401,052	61,404
Cash and cash equivalents, end of period	\$ 453,906	\$ 111,983

See accompanying notes to condensed consolidated financial statements.

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IDEC PHARMACEUTICALS CORPORATION AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

Note 1. Summary of Significant Accounting Policies

Basis of Presentation: The information at June 30, 2001, and for the three and six months ended June 30, 2001 and 2000, is unaudited. In the opinion of management, these condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of results for the interim periods presented. Interim results are not necessarily indicative of results for a full year or for any subsequent interim period. These condensed consolidated financial statements should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2000.

Revenues from Unconsolidated Joint Business: Revenues from unconsolidated joint business consist of our share of the pretax copromotion profits generated from our copromotion arrangement with Genentech Inc., revenue from bulk Rituxan® sales to Genentech through March 2000, reimbursement from Genentech of our Rituxan-related sales force and development expenses and royalty revenue from F. Hoffmann-La Roche Ltd. on sales of Rituximab outside the United States. Revenue from bulk Rituxan sales was recognized when Genentech accepted the bulk Rituxan. Upon acceptance of bulk Rituxan by Genentech the right to return no longer existed and there were no further performance obligations related to bulk Rituxan. We record our royalty revenue from Roche with a one-quarter lag. Rituxan is the trade name in the United States and Japan for the compound Rituximab. Outside the United States and Japan, Rituximab is marketed as MabThera. In our notes to the condensed consolidated financial statements, we refer to Rituximab, Rituxan and MabThera collectively as Rituxan, except where otherwise indicated. Under the copromotion arrangement we share responsibility with Genentech for selling and continued development of Rituxan in the United States. Continued development of Rituxan includes conducting supportive research on Rituxan, post-approval clinical studies and obtaining potential approval of Rituxan for additional indications. Genentech provides the support functions for the commercialization of Rituxan in the United States including marketing, customer service, order entry, distribution, shipping and billing and, as of September 1999, all worldwide manufacturing responsibilities. Under the copromotion arrangement, all U.S. sales of Rituxan and associated costs and expenses are recognized by Genentech and we record our share of the pretax copromotion profits on a quarterly basis, as defined in our collaborative agreement with Genentech. Pretax copromotion profits under the copromotion arrangement are derived by taking the U.S. net sales of Rituxan to third-party customers less cost of sales, third-party royalty expenses, distribution, selling and marketing expenses and joint development expenses incurred by Genentech and us. Our profit-sharing formula with Genentech has two tiers; we earn a higher percentage of the pretax copromotion profits at the upper tier once a fixed pretax copromotion profit level is met. The profit-sharing formula resets annually at the beginning of each year to the lower tier. We began recording our profit share at the higher percentage during the first quarter of 2001 compared to the beginning of the second quarter of 2000.

Cumulative Effect of Accounting Change (Restatement): In the fourth quarter of 2000, we implemented the Securities and Exchange Commission's Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements," or SAB No. 101, effective as of January 1, 2000. SAB No. 101 established new guidelines in applying generally accepted accounting principles to revenue recognition in financial statements. SAB No. 101 provides that nonrefundable up-front fees received under collaborative agreements be recorded as deferred revenue upon receipt and recognized as revenue over future periods. Prior to the implementation of SAB No. 101, we recognized certain nonrefundable

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up-front fees upon receipt as license fee revenue. The cumulative effect of this accounting change on years prior to 2000 resulted in a charge of \$9,263,000 (net of a \$487,000 income tax effect), of which \$3,250,000 was recorded as deferred revenue as of December 31, 2000. For the three and six months ended June 30, 2001, we recognized \$1,625,000 and \$3,250,000, respectively, of the related deferred revenue. The results for the three and six months ended June 30, 2000 have been restated to reflect the adoption of SAB No. 101 as of January 1, 2000 which resulted in \$1,625,000 and \$3,250,000 being recognized as license fee revenue for the three and six months ended June 30, 2000, respectively. This accounting change is directly related to the \$13,000,000 up-front license fee received from Schering Aktiengesellschaft and recognized as license fee revenue in 1999.

Earnings Per Share: Earnings per share are calculated in accordance with Statement of Financial Accounting Standards No. 128 "Earnings per Share." Basic earnings per share excludes the dilutive effects of options and other convertible securities compared to diluted earnings per share which reflects the potential dilution of options and other convertible securities that could share in our earnings. Calculations of basic and diluted earnings per share use the weighted average number of shares outstanding during the period. Diluted earnings per share for the three and six months ended June 30, 2001 includes the dilutive effect of 16,940,000 shares and 18,130,000 shares, respectively, of common stock from options and convertible preferred stock and excludes 13,939,000 shares of common stock from the assumed conversion of our 20-year zero coupon subordinated convertible notes, or convertible promissory notes, and excludes 2,420,000 shares and 2,117,000 shares, respectively, of common stock from options because their effect is antidilutive. Diluted earnings per share for the three and six months ended June 30, 2000 includes the dilutive effect of 22,603,000 shares and 24,967,000 shares, respectively, of common stock from options and convertible preferred stock and excludes 13,939,000 shares of common stock from the assumed conversion of our convertible promissory notes and excludes 2,393,000 shares and 2,035,000 shares, respectively, of common stock from options because their effect is antidilutive. All share and earnings per share amounts for the three and six months ended June 30, 2000 have been restated to reflect our three-for-one stock split effected in January 2001.

Note 2. Related Party Arrangements

In March 1995, we entered into a collaborative agreement with Genentech for the clinical development and commercialization of our anti-CD20 monoclonal antibody, Rituxan, for the treatment of certain B-cell non-Hodgkin's lymphomas. Concurrent with the collaborative agreement we also entered into an expression technology license agreement with Genentech for a proprietary gene expression technology developed by us and a preferred stock purchase agreement providing for certain equity investments in us by Genentech. Under the terms of these agreements, we have received payments totaling \$58,500,000 for the attainment of product development objectives, product license rights and equity investments in us. Additionally, we may be reimbursed by Genentech for other development and regulatory approval expenses under the terms of the collaborative agreement. Genentech may terminate this agreement for any reason, which would result in a loss of Genentech's Rituxan product rights.

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We copromote Rituxan in the United States with Genentech under a joint business arrangement whereby we receive a share of the pretax copromotion profits. In September 1999, we transferred all worldwide manufacturing responsibilities for bulk Rituxan to Genentech.

Revenues from unconsolidated joint business for the three and six months ended June 30, 2001 and 2000 consist of the following (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2001	2000	2001	2000
Copromotion profits	\$ 52,388	\$ 26,670	\$ 96,198	\$ 42,218
Bulk Rituxan sales	—	—	—	2,078
Reimbursement of selling and development expenses	2,372	2,590	4,500	5,019
Royalty income on sales of Rituximab outside the U.S.	3,312	2,042	5,932	3,880
Total revenues from unconsolidated joint business	\$ 58,072	\$ 31,302	\$ 106,630	\$ 53,195

Amounts due from related parties, net at June 30, 2001 and December 31, 2000 consist of the following (in thousands):

	2001	2000
Due from Genentech, copromotion profits	\$ 52,282	\$ 37,459
Due from Genentech, bulk Rituxan sales	—	2,047
Due from Genentech, selling and development expenses	2,426	2,221
Due from Roche	27	26
Total due from related parties, net	\$ 54,735	\$ 41,753

During the first quarter of 2000, we recognized the remaining revenues and related manufacturing costs from bulk Rituxan sales to Genentech. Under the terms of separate agreements with Genentech, commercialization of Rituxan outside the United States is the responsibility of Roche, except in Japan where Zenyaku Kogyo Co. Ltd. is responsible for product development, marketing and sales. We receive royalties on Rituxan sales outside the United States.

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

OVERVIEW

We are primarily engaged in the commercialization, research and development of targeted therapies for the treatment of cancer and autoimmune and inflammatory diseases.

In December 2000, the Food and Drug Administration, or FDA, accepted our filing of a Biological License Application, or BLA, seeking marketing approval for ZEVALIN™ (Ibritumomab Tiuxetan) radioimmunotherapy for the treatment of low grade, follicular, CD20-positive transformed, relapsed or refractory, B-cell non-Hodgkin's lymphoma, or NHL. In May 2001 we received a Complete Review Letter from the FDA regarding our ZEVALIN BLA. In the Complete Review Letter the FDA outlined additional information and analysis we were required to submit as a result of their review. The information requested related to two areas: Clinical and Chemistry, Manufacturing and Controls, or CMC. The FDA also requested imaging with indium-111 as a part of the ZEVALIN commercial protocol. If approved, we now expect to market ZEVALIN as one product which will be comprised of two kits, an imaging kit for use with indium-111 and a therapeutic kit for use with yttrium-90. The FDA's request from their CMC review includes, among other items, establishing an independent schedule for pre-approval inspections of our ZEVALIN radioisotope supplier and fill/finish provider. On July 9, 2001, we submitted documentation and analysis to the FDA in response to the May 2001 Complete Review Letter.

In July 2001, we received notice from the FDA that ZEVALIN will be reviewed by the Oncologic Drugs Advisory Committee (ODAC) on September 11, 2001. ODAC may issue a recommendation to the FDA regarding the commercialization of ZEVALIN. The recommendation of ODAC will not be binding on the FDA. In August 2001, the FDA acknowledged receipt of our July 2001 resubmission and characterized the resubmission as complete. The FDA noted that the resubmission of our license application was a Class II response to our Complete Review Letter of May 2001. As a Class II response under FDA guidelines, the FDA may approve, not approve, or raise additional questions regarding the BLA at any time within six months from the resubmission date.

We have retained all U.S. marketing and distribution rights for ZEVALIN and have granted marketing and distribution rights for ZEVALIN outside the U.S. to Schering AG. We are currently responsible for worldwide manufacturing of the ZEVALIN antibody and kits. In January 2001, Schering AG had its Marketing Authorization Application, or MAA, for ZEVALIN accepted for review by the European Medicines Evaluation Agency.

In November 1997, we received FDA approval to market our first product, Rituxan, in the United States. In May 2001, we announced that the FDA approved a supplemental BLA, or sBLA, for Rituxan. The new product labeling includes:

- retreatment with Rituxan after a prior course of Rituxan therapy;
- initial treatment with eight weekly infusions of Rituxan, compared to the prior approved labeling of four weekly infusions; and
- treatment of NHL patients with bulky disease (tumors greater than 10 centimeters).

The sBLA also amended our package insert to update safety information. In addition, a Dear Healthcare Provider letter was sent to physicians to enhance their understanding of adverse events that may be associated with Rituxan use.

In June 1998, Roche, our European marketing partner for Rituxan, was granted marketing authorization for Rituximab in all European Union countries. In May 2001, Roche submitted an application with the European Medicines Evaluation Agency, for use of Rituximab in combination with standard chemotherapy, or CHOP, to treat patients with aggressive NHL. In June 2001, Zenyaku, our

Japanese marketing partner for Rituxan, was granted marketing authorization for Rituxan in Japan. Rituxan is the trade name in the United States and Japan for the compound Rituximab. Outside the United States and Japan, Rituximab is marketed as MabThera. In this quarterly report, we refer to Rituximab, Rituxan and MabThera collectively as Rituxan, except where we have otherwise indicated.

Rituxan is being copromoted in the United States under a joint business arrangement with Genentech, where we receive a share of the pretax copromotion profits. Under the copromotion arrangement we share responsibility with Genentech for the sale and continued development of Rituxan in the United States. Continued development of Rituxan includes conducting supportive research on Rituxan, post-approval clinical studies and obtaining approval of Rituxan for potential additional indications. Genentech provides the support functions for the commercialization of Rituxan in the United States including marketing, customer service, order entry, distribution, shipping and billing. Since September 1999, Genentech has been responsible for all worldwide manufacturing. Under the terms of separate agreements with Genentech, Roche is responsible for the commercialization of Rituxan outside the United States, except in Japan where Zenyaku is responsible for product development, marketing and sales. We receive royalties on Rituxan sales outside the United States.

Our revenues include revenues from unconsolidated joint business, contract revenues and license fees. Until the commercialization of Rituxan, a substantial portion of our revenues had been derived from contract revenues and license fees. However, since the commercialization of Rituxan in November 1997, our revenues have depended primarily upon the sale of Rituxan.

Revenues from unconsolidated joint business include our share of the pretax copromotion profits generated from our copromotion arrangement with Genentech, revenue from bulk Rituxan sales to Genentech through March 2000, reimbursement from Genentech of our Rituxan-related sales force and development expenses and royalty revenue from Roche on sales of Rituximab outside the United States. Revenue from bulk Rituxan sales was recognized when Genentech accepted the bulk Rituxan. We record our royalty revenue from Roche with a one-quarter lag. Under the copromotion arrangement, all U.S. sales of Rituxan and associated costs and expenses are recognized by Genentech and we record our share of the pretax copromotion profits on a quarterly basis, as defined in our collaborative agreement with Genentech. Pretax copromotion profits under the copromotion arrangement are derived by taking U.S. net sales of Rituxan to third-party customers less cost of sales, third-party royalty expenses, distribution, selling and marketing expenses and joint development expenses incurred by Genentech and us. Our profit-sharing formula with Genentech has two tiers; we earn a higher percentage of the pretax copromotion profits at the upper tier once a fixed pretax copromotion profit level is met. The profit-sharing formula resets annually at the beginning of each year to the lower tier. We began recording our profit share at the higher percentage during the first quarter of 2001 compared to the beginning of the second quarter of 2000.

Contract revenues include nonrefundable research and development funding under collaborative agreements with our strategic partners and other funding under contractual arrangements with other parties. Contract research and development funding generally compensates us for discovery, preclinical and clinical expenses related to our collaborative development programs for our products and is recognized at the time research and development activities are performed under the terms of the collaborative agreements.

License fees include nonrefundable fees from product development milestone payments and nonrefundable fees from the sale of product rights under collaborative development and license agreements with our strategic partners. Nonrefundable up-front fees from the sale of product rights are recorded as

deferred revenue upon receipt and recognized as revenue over future periods as required by SAB No. 101. Included in license fees are nonrefundable product development milestone payments which are recognized upon the achievement of product development milestone objectives as stipulated in agreements with our strategic partners. Product development milestone objectives vary in each of our

agreements. The achievement of product development milestone objectives that may lead to the recognition of license fee revenues include:

- the achievement of preclinical research and development objectives;
- the initiation of various phases of clinical trials;
- the filing of a BLA, an Investigational New Drug application, or IND, or a New Drug Application, or NDA;
- the filing of drug license applications in foreign territories; and
- obtaining United States or foreign regulatory product approvals.

Contract revenues and license fees may vary from period to period and are in part dependent upon achievement of research and development objectives or the consummation of new corporate alliances. The magnitude and timing of contract revenues and license fees may influence our achievement and level of profitability.

The cost of bulk Rituxan sold to Genentech was recorded as manufacturing costs in our condensed consolidated statements of operations. In September 1999, we transferred all worldwide manufacturing responsibilities for bulk Rituxan to Genentech. Since the transfer of bulk Rituxan manufacturing to Genentech in September 1999, we have been using our manufacturing capacity for production of specification-setting lots and pre-commercial inventory of ZEVALIN antibodies and production of other proteins for clinical trials.

We have incurred increasing annual operating expenses and, with the commercialization of Rituxan and preparation for potential commercialization of ZEVALIN, we expect such trends to continue. Since our inception in 1985, through 1997, we incurred annual operating losses. Our ongoing profitability will be dependent upon the continued commercial success of Rituxan, product development, revenues from the achievement of product development objectives and licensing transactions. As of June 30, 2001, we had retained earnings of \$59.4 million.

Results of Operations

Revenues from unconsolidated joint business for the three and six months ended June 30, 2001 and 2000, consist of the following (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2001	2000	2001	2000
Copromotion profits	\$ 52,388	\$ 26,670	\$ 96,198	\$ 42,218
Bulk Rituxan sales	—	—	—	2,078
Reimbursement of selling and development expenses	2,372	2,590	4,500	5,019
Royalty income on sales of Rituximab outside the U.S.	3,312	2,042	5,932	3,880
Total revenues from unconsolidated joint business	\$ 58,072	\$ 31,302	\$ 106,630	\$ 53,195

Under our agreement with Genentech, our pretax copromotion profit-sharing formula has two tiers. We earn a higher percentage of the pretax copromotion profits at the upper tier once a fixed pretax copromotion profit level is met. The profit-sharing formula resets annually at the beginning of each year to the lower tier. We began recording our profit share at the higher percentage during the first quarter of 2001 compared to the beginning of the second quarter of 2000.

Rituxan net sales to third-party customers in the United States recorded by Genentech for the three and six months ended June 30, 2001 amounted to \$180.0 million and \$348.0 million, respectively, compared to \$96.7 million and \$174.7 million for the comparable periods in 2000. This increase was primarily due to increased market penetration in treatments of B-cell non-Hodgkin's lymphoma.

Our royalty revenue on sales of Rituximab outside the U.S. is based on Roche's end-user sales and is recorded with a one-quarter lag.

Contract revenues for the three and six months ended June 30, 2001 totaled \$2.2 million and \$3.5 million, respectively, compared to \$6.1 million and \$9.6 million for the comparable periods in 2000. The decrease in contract research revenues for the three and six months ended June 30, 2001 is primarily the result of decreased funding under our collaboration and license agreements with Schering AG and Taisho Pharmaceuticals Co. Ltd. of Tokyo.

License fees for the three and six months ended June 30, 2001 totaled \$4.6 million and \$11.3 million, respectively, compared to \$1.6 million and \$3.3 million for the comparable periods in 2000. The increase in license fees for the three months ended June 30, 2001 is due to payments received from Eisai Co. Ltd. and Schering AG. for the achievement of product development milestone objectives. The increase in license fee revenue for the six months ended June 30, 2001 resulted from the aforementioned items and the receipt of a \$5.0 million milestone payment from Schering AG when the European Medicines Evaluation Agency

accepted for filing the submission of a Marketing Authorization Application, or MAA, for approval of ZEVALIN in Europe. Also included in license fees for the three and six months ended June 30, 2001 and 2000 is \$1.6 million and \$3.3 million, respectively, recognized as a result of our adoption of SAB No. 101. The results for the three and six months ended June 30, 2000 have been restated to reflect the adoption of SAB No. 101 as of January 1, 2000. This accounting change is directly related to the \$13.0 million up-front license fee received from Schering AG and recognized as license fee revenue in 1999.

Contract revenues and license fees may vary from period to period and are, in part, dependent upon achievement of certain research and development objectives. The magnitude and timing of contract revenues and license fees may influence our achievement and level of profitability. We continue to pursue other collaborative and license arrangements, however, no assurance can be given that any such arrangements will be realized.

There were no manufacturing costs recorded for the six months ended June 30, 2001 compared to \$2.1 million for the comparable period in 2000. Our manufacturing costs recorded in 2000 relate to production of bulk Rituxan sold to Genentech and were recognized when Genentech accepted the bulk Rituxan inventory. The decrease in manufacturing costs from 2000 is due to the transfer of all worldwide manufacturing responsibilities for bulk Rituxan to Genentech in September 1999. The final lots of bulk Rituxan manufactured by us during the third quarter of 1999 were accepted by Genentech during the first quarter of 2000. Since the transfer of all worldwide manufacturing responsibilities for bulk Rituxan to Genentech, we have been using our manufacturing capacity for production of specification setting lots and pre-commercial inventory of ZEVALIN antibodies and production of other proteins for clinical trials. Those manufacturing expenses have been recorded as research and development expenses.

Research and development expenses totaled \$21.7 million and \$43.2 million for the three and six months ended June 30, 2001, respectively, compared to \$17.0 million and \$31.8 million for the

comparable periods in 2000. The increase in research and development expenses in 2001 is primarily due to increased clinical testing of our various products under development, development costs for ZEVALIN, personnel expenses and expansion of our facilities. We expect to continue incurring substantial manufacturing-related expenses as we have begun using our manufacturing capacity for production of pre-commercial inventory of ZEVALIN antibodies and production of other proteins for clinical trials. In the future we expect to continue incurring substantial additional research and development expenses due to:

- completion of our primary development program for ZEVALIN;
- the expansion or addition of research and development programs;
- technology in-licensing;
- regulatory-related expenses;
- the expansion of clinical manufacturing capabilities;
- facilities expansion; and
- preclinical and clinical testing of our various products under development.

Selling, general and administrative expenses totaled \$11.4 million and \$23.1 million for the three and six months ended June 30, 2001, respectively, compared to \$6.6 million and \$12.7 million for the comparable periods in 2000. Selling, general and administrative expenses increased in 2001 primarily due to increased marketing and administrative expenses related to the potential commercialization of ZEVALIN, sales expenses to support Rituxan and general increases in general and administrative expenses to support overall organizational growth. Selling, general and administrative expenses are expected to increase in the foreseeable future to support the following:

- expanded growth of our sales force;
- marketing and administration related to the potential commercialization of ZEVALIN;
- manufacturing capacity;
- clinical trials; and
- research and development.

Interest income totaled \$10.1 million and \$21.6 million for the three and six months ended June 30, 2001, respectively, compared to \$4.2 million and \$7.8 million for the comparable periods in 2000. The increase in interest income in 2001 is primarily due to higher average balances in cash, cash equivalents and securities available-for-sale resulting from the sale of 7.8 million shares of common stock in November 2000 and cash provided by operations. Interest rate fluctuations can substantially effect the returns on our investments. The average interest rates earned on our investments for the three and six months ended June 30, 2001 decreased from the average interest rates earned on our investments for the comparable periods in 2000 as a result of declining market interest rates.

Interest expense totaled \$1.8 million and \$3.6 million for the three and six months ended June 30, 2001, respectively, compared to \$1.8 million and \$3.5 million for the comparable periods in 2000. Interest expense in 2001 is primarily due to noncash interest charges relating to the convertible promissory notes offering in February 1999.

Our effective tax rate for the three and six months ended June 30, 2001 was approximately 37% compared to seventeen percent in 2000. Our effective tax rate for the three and six months ended June 30, 2001 increased primarily due to the utilization in prior years of net operating loss carryforwards for financial reporting purposes. Our effective tax rate for 2000 results from the utilization of net operating loss carryforwards and the reduction of the valuation allowance against the

related deferred tax assets. Our net operating loss carryforwards available to offset future taxable income at December 31, 2000 were approximately \$211.0 million for federal income tax purposes and begin to expire in 2006. The utilization of our net operating loss carryforwards and tax credits may be subject to an annual limitation under the Internal Revenue Code due to a cumulative change of ownership of more than 50% in prior years. However, we anticipate this annual limitation to result only in a slight deferral in the utilization of our net operating loss carryforwards and tax credits. We expect that our effective tax rate in the future will continue to be closer to the maximum statutory tax rate.

Liquidity and Capital Resources

We have financed our operating and capital expenditures since inception principally through sales of equity securities, sales of Rituxan, license fees, contract revenues, lease financing transactions, debt financing transactions and interest income. We expect to finance our current and planned operating requirements principally through cash on hand, anticipated funds from our copromotion arrangement with Genentech and with funds from existing collaborative agreements and contracts. We believe that these funds will be sufficient to meet our operating requirements for the foreseeable future. Existing collaborative research agreements and contracts, however, could be canceled by the contracting parties. In addition, we may, from time to time seek additional funding through a combination of new collaborative agreements, strategic alliances and additional equity and debt financings or from other sources. Additional funds may not be obtainable through these sources on acceptable terms. If adequate funds are not available from the copromotion arrangement, operations or additional sources of financing, our business could be harmed. Our working capital and capital requirements will depend upon numerous factors, including:

- the continued commercial success of Rituxan;
- financing alternatives available for the construction of our large-scale manufacturing facility;
- the progress of our preclinical and clinical testing;
- fluctuating or increasing manufacturing requirements and research and development programs;
- timing and expense of obtaining regulatory approvals;
- levels of resources that we devote to the development of manufacturing, sales and marketing capabilities, including resources devoted to the potential commercial launch of ZEVALIN;
- technological advances;
- status of competitors; and
- our ability to establish collaborative arrangements with other organizations.

Until required for operations, we invest our cash reserves in bank deposits, certificates of deposit, commercial paper, corporate notes, United States government instruments and other readily marketable debt instruments in accordance with our investment policy.

At June 30, 2001, we had \$821.5 million in cash, cash equivalents and securities available-for-sale compared to \$750.5 million at December 31, 2000. Sources of cash, cash equivalents and securities available-for-sale during the six months ended June 30, 2001, included \$66.6 million from operations and \$20.7 million from the issuance of common stock under employee stock option and purchase plans. Uses of cash, cash equivalents and securities available-for-sale during the six months ended June 30, 2001, included \$13.1 million used to purchase capital equipment.

In September 2000, we purchased a 60-acre site in Oceanside for approximately \$18.9 million in cash. We plan to build a large-scale manufacturing facility at the location, which we anticipate using to commercialize our products currently in clinical trials if they are approved by the FDA. Additional

costs we expect to incur in connection with this facility include design, development, construction, validation and start-up costs, as well as the purchase and installation of equipment and furnishings for the facility. We estimate these costs at \$300 to \$400 million over a four-year period. We expect to pay for these costs in part from our working capital and we presently intend to finance the remaining costs for this facility through an off balance sheet lease arrangement that will likely involve using cash on hand as collateral. We cannot assure you that lease financing for this facility will be obtained on acceptable terms, if at all. In the first quarter of 2001, we began preliminary site engineering preparations for the first phase of development, which is anticipated to be approximately 300,000 square

feet. The new facility in Oceanside is anticipated to be completed in early 2004. We expect the facility to be operating by the end of 2005. This expansion will allow us to better control the manufacture of our products, reducing our reliance on contract manufacturers, as well as to reduce commercial risk.

In February 1999, we raised through the sale of convertible promissory notes approximately \$112.7 million, net of underwriting commissions and expenses of \$3.9 million. The convertible promissory notes are zero coupon and were priced with a yield to maturity of 5.5 percent annually. Upon maturity, the convertible promissory notes will have an aggregate principal face value of \$345.0 million. Each \$1,000 aggregate principal face value convertible promissory note is convertible at the holders' option at any time through maturity into 40.404 shares of our common stock at an initial conversion price of \$8.36. We are required under the terms of the convertible promissory notes, as of 35 business days after a change in control occurring on or before February 16, 2004, to purchase any convertible promissory note at the option of its holder at a price equal to the issue price plus accrued original issue discount to the date of purchase. Additionally, the holders of the convertible promissory notes may require us to purchase the convertible promissory notes on February 16, 2004, 2009 or 2014 at a price equal to the issue price plus accrued original issue discount to the date of purchase with us having the option to repay the convertible promissory notes plus accrued original issue discount in cash, our common stock or a combination thereof. We have the right to redeem the convertible promissory notes on or after February 16, 2004.

In September 1997, we entered into a development and license agreement with Cytokine Pharmasciences, Inc. under which we may make payments to them totaling up to \$10.5 million plus a share of future royalty and development milestone payments received by us from third parties, subject to attainment of product development milestone objectives, of which \$3.5 million has been paid through June 30, 2001.

FORWARD-LOOKING INFORMATION AND RISK FACTORS THAT MAY AFFECT FUTURE RESULTS

This Form 10-Q contains forward-looking statements based on our current expectations. You should be aware that these statements are projections or estimates as to future events, and actual results may differ materially.

In addition to the other information contained in this Form 10-Q, you should consider the following risk factors which could affect our actual future results and could harm our business, financial condition and results of operations. The risks and uncertainties described below are not the only risks facing us and additional risks and uncertainties may also harm our business.

Our Revenues Rely Significantly on Rituxan Sales

Our revenues currently depend largely upon continued sales of a single commercialized product, Rituxan. For the three and six months ended June 30, 2001, 90% and 88%, respectively, of our revenues were derived from our Rituxan copromotion arrangement with Genentech. We cannot be certain that Rituxan will continue to be accepted in the United States or in any foreign markets or that Rituxan sales will continue to increase. A number of factors may affect the rate and level of market acceptance of Rituxan, including:

- the perception by physicians and other members of the healthcare community of its safety and efficacy or that of competing products, if any;
- the effectiveness of our and Genentech's sales and marketing efforts in the United States and the effectiveness of Roche's sales and marketing efforts outside the United States and Japan;
- unfavorable publicity concerning Rituxan or similar drugs;
- its price relative to other drugs or competing treatments;
- the availability and level of third-party reimbursement; and
- regulatory developments related to the manufacture or continued use of Rituxan.

We incurred annual operating losses from our inception in 1985 through fiscal 1997. Given our current reliance on Rituxan as the principal source of our revenue, any material adverse developments with respect to the commercialization of Rituxan may cause us to incur losses in the future.

Our Operating Results Are Subject to Significant Fluctuations

Our quarterly revenues, expenses and operating results have fluctuated in the past and are likely to fluctuate significantly in the future. Fluctuation may result from a variety of factors, including:

- our achievement of product development objectives and milestones;
- demand and pricing for Rituxan;
- timing and nature of contract manufacturing and contract research and development payments and receipts;
- hospital and pharmacy buying decisions;
- clinical trial enrollment and expenses;
- research and development and manufacturing expenses;
- physician acceptance of our products;
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- government or private healthcare reimbursement policies;

- our manufacturing performance and capacity and that of our partners;

- the amount and timing of sales orders of Rituxan by Genentech for customers in the United States and by Roche for customers outside the United States and Japan;

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- rate and success of product approvals;

- timing of FDA approval, if any, of competitive products and the rate of market penetration of competing products;

- collaboration obligations and copromotion payments we make or receive;

- interest rate fluctuations;

- foreign currency exchange rates; and

- overall economic conditions.

Our operating results during any one quarter do not necessarily suggest the anticipated results of future quarters. These results fluctuate periodically because our revenues are driven by the occurrence of events, for example, the achievement of product development milestones and the applicable profit-sharing allocation between us and Genentech, based upon our copromotion arrangement.

We Face Uncertain Results of Clinical Trials of Our Potential Products

Our future success depends in large part upon the results of clinical trials designed to assess the safety and efficacy of our potential products. We cannot be certain that patients enrolled in our clinical trials will respond to our products, that any product will be safe and effective or that data derived from the trials will be suitable for submission to the FDA, satisfactorily support a BLA, sBLA, or NDA or be sufficient for approval.

The completion rate of clinical trials depends significantly upon the rate of patient enrollment. Factors that affect patient enrollment include:

- size of patient population for the targeted disease;

- eligibility criteria;

- proximity of eligible patients to clinical sites;

- clinical trial protocols; and

- the existence of competing protocols, including competitive financial incentives for patients and clinicians, and existing approved drugs, including Rituxan.

Our inability to enroll patients on a timely basis could result in increased expenses and product development delays, which could harm our business. Even if a trial is fully enrolled, significant uncertainties remain as to whether it will prove successful.

In addition, the length of time necessary to complete clinical trials and submit an application for marketing and manufacturing approvals varies significantly and may be difficult to predict. Failure to comply with extensive FDA regulations may result in delay, suspension or cancellation of a trial or the FDA's refusal to accept test results. The FDA may also suspend our clinical trials at any time if it concludes that the participants are being exposed to unacceptable risks. Consequently, we cannot ensure that Phase I, Phase II, Phase III or Phase IV post-marketing testing will be completed timely or successfully, if at all, for any of our potential or existing products. Furthermore, success in preclinical and early clinical trials does not ensure that later phase or large scale trials will be successful.

We May be Unable to Develop and Commercialize New Products

Our future results of operations will depend to a large extent upon our ability to successfully commercialize new products in a timely and competitive manner. As a result, we must continue to develop, test and manufacture new products and must meet regulatory standards and obtain regulatory approvals for any new products. Our products currently in development may not receive the regulatory approvals necessary for marketing in a timely manner, if at all. We submitted a BLA for ZEVALIN on November 1, 2000. Additionally, a supplemental filing has been submitted by our third-party radioisotope supplier. In May 2001, we received a Complete Review Letter from the FDA regarding

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our ZEVALIN BLA. In the Complete Review Letter the FDA outlined additional information and analysis we must submit as a result of their review. On July 9, 2001, we submitted documentation and analysis to the FDA in response to the Complete Review Letter. We have been invited to the September 2001 meeting of ODAC. If ODAC's recommendation regarding the commercialization of ZEVALIN is not positive, such recommendation could influence the FDA's regulatory review of ZEVALIN.

The FDA may request additional information and analysis of previously submitted information prior to final approval of ZEVALIN. Moreover, the FDA must approve the labeling and package insert for ZEVALIN prior to commercialization, which could further delay commercialization. The FDA may not approve our application in a timely manner, if at all, which would delay us in or preclude us from commercializing ZEVALIN in the United States. In addition, as part of the

FDA Complete Review Letter received for ZEVALIN in May 2001, the FDA indicated it will establish an independent schedule for pre-approval inspection of our ZEVALIN radioisotope supplier and fill/finish provider. Our failure or the failure of our radioisotope supplier or fill/finish provider to meet FDA requirements would further delay or preclude us from selling ZEVALIN, which would harm our business.

The development and commercialization process is time-consuming and costly, and we cannot be certain that any of our products, if and when developed and approved, will be successfully commercialized or competitive in the marketplace. Delays or unanticipated costs in any part of the process, our inability to obtain regulatory approval for or effectively commercialize our products, especially ZEVALIN, or our inability to maintain manufacturing facilities in compliance with all applicable regulatory requirements could harm our business.

We Have Limited Manufacturing Experience and Rely Heavily On Contract Manufacturers

We rely heavily upon third-party manufacturers to manufacture significant portions of our products and product candidates. Our current manufacturing capacity is limited. Our manufacturing experience to date has been limited to the production of preclinical and clinical quantities of product candidates and to approximately three years of commercial production of bulk Rituxan. We have no fill/finish experience or capacity, and we do not have experience manufacturing in the field of chelates or radioisotopes, which are required for our production of ZEVALIN. Therefore, we rely entirely upon third parties for fill/finish services as well as the manufacture of product components. Consequently, we cannot ensure that either our manufacturing facilities or our ability to sustain ongoing production of our products will be able to meet our expectations. Nor can we be certain that we will be able to enter into satisfactory agreements with third-party manufacturers or service providers. Our failure to enter into agreements with such manufacturers or fill/finish service providers on reasonable terms, if at all, or poor performance or coordination on our part or that of our third-party manufacturers or fill/finish service providers could harm our business.

In September 1999, we transferred all manufacturing of bulk Rituxan to Genentech. We rely upon Genentech for all Rituxan manufacturing to meet worldwide requirements. We cannot ensure that Genentech will manufacture and fill/finish Rituxan in sufficient quantities and on a timely and cost-effective basis or that Genentech will obtain and maintain all required manufacturing approvals. Genentech's failure to manufacture and fill/finish Rituxan or obtain and maintain required manufacturing approvals could harm our business.

Since the completion in September 1999 of our obligation to manufacture bulk Rituxan, we have commenced conversion of our current manufacturing facility to a multi-product facility. From this facility, we have manufactured and will continue to manufacture our own commercial requirements of the antibody for ZEVALIN upon the receipt of approval, if any, from the FDA to manufacture and market the antibody. We cannot be certain that our manufacturing performance will meet our expectations. Also, we may not receive all necessary regulatory approvals for a multi-product facility, or, even if we do receive these approvals, they may not be obtained within our budgeted time and expense.

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estimations. Our inability to receive FDA approval of our manufacturing facility for ZEVALIN would harm our ability to timely produce commercial supplies of the ZEVALIN antibody. To the extent we cannot produce our own biologics, we will need to rely on third-party manufacturers, of which there are only a limited number capable of manufacturing biologics products as contract suppliers. We cannot be certain that we could reach agreement on reasonable terms, if at all, with those manufacturers.

ZEVALIN has multiple components that require successful coordination among several third-party contract manufacturers and suppliers. We may not be able to reach agreement on reasonable terms, if at all, with our contract manufacturers and we may not be able to integrate and coordinate successfully our contract manufacturers and suppliers. In addition our contract manufacturers and suppliers are required to maintain compliance with cGMP. Their inability to receive and maintain FDA approval of their facilities could delay or preclude commercialization of ZEVALIN and impact our ability to meet our worldwide supply obligations.

We Rely Heavily on a Limited Number of Suppliers

Some materials used in our products and potential products, including Rituxan and ZEVALIN, are currently available only from a single supplier or a limited number of suppliers. Some of these suppliers are subject to ongoing FDA approvals or other governmental regulations. Any interruption or delay in our supply of materials required to sell our products could harm our business if we were unable to obtain an alternative supplier for these materials in a cost-effective and timely manner. Additional factors that could cause interruptions or delays in our source of materials include limitations on the availability of raw materials or manufacturing performance experienced by our suppliers and a breakdown in our commercial relations with one or more suppliers. These factors may be completely out of our control.

In addition, we have entered into an agreement with MDS Nordion Inc., the commercial supplier of the radioisotope for our product ZEVALIN. Prior to the commercialization of ZEVALIN, this supplier will be required to obtain FDA approvals. We rely upon this supplier to meet our clinical and commercial requirements. If this supplier were unable to obtain and maintain FDA approvals, or if we were unable to receive the supply of this radioisotope for any other reason, including those described above, we would be unable to commercialize ZEVALIN unless we were to obtain a new supplier. We are aware of other entities that can provide the radioisotope that we need for the commercialization of ZEVALIN and we believe that these suppliers would be required to apply for additional governmental approvals to provide this radioisotope to us. The process of establishing a relationship with another supplier and the process of obtaining the required governmental approvals would be time-consuming and uncertain. There is no guarantee that we could reach an agreement with another supplier in a timely manner and, on commercially reasonable terms, or at all. As a result of these concerns, if we were to lose our supply or were unable to receive sufficient quantities of the radioisotope from our sole supplier, our ability to sell ZEVALIN could be harmed which, in turn, could significantly harm our business.

We Have Limited Sales and Marketing Experience

We have limited experience with commercial sales and marketing, based entirely upon our launch and subsequent sales of Rituxan. Outside the United States, our strategy is to pursue and to rely solely upon collaborations with established pharmaceutical companies for marketing, distribution and sale of our products. We currently have no plans to directly market outside the United States. Given that we currently rely upon our copromotional partner to market Rituxan in the United States and rely exclusively on a third party outside the United States, we cannot be certain that our products will be marketed and distributed in accordance with our expectations or that our market research or sales forecasts will be accurate. We also cannot be certain that we will ever be able to develop our own sales and marketing capabilities to an extent that we would not need to rely on third-party efforts, or that we will be able to maintain satisfactory arrangements with the third parties on whom we rely.

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ZEVALIN, if approved, will be our first product to be marketed exclusively by us in the United States. We have no marketing support service experience and, therefore, we will be dependent on outside contractors to meet those needs. We are currently negotiating with a third-party logistics distributor to provide customer service, order entry, shipping, billing, customer reimbursement assistance and managed care sales support. We cannot be certain that we will reach agreement on reasonable terms, if at all, with our third-party logistics distributor or that the integration of these marketing support services can be successfully coordinated.

Our Industry is Intensely Competitive

The biotechnology industry is intensely competitive and we may not be able to produce or acquire rights to new products with commercial potential. We compete with biotechnology and pharmaceutical companies that have been established longer than we have, have a greater number of products on the market, have greater financial and other resources and have other technological or competitive advantages. We also compete in the development of technologies and processes and in acquiring personnel and technology from academic institutions, government agencies, and other private and public research organizations. We cannot be certain that one or more of our competitors will not receive patent protection that dominates, blocks or adversely affects our product development or business; will benefit from significantly greater sales and marketing capabilities; or will not develop products that are accepted more widely than ours. We are aware that a competitor, Corixa Corporation, formerly Coulter Pharmaceuticals, Inc., filed a BLA in 2000, for Bexxar, (tositumomab, Iodine I 131 tositumomab) a radiolabeled murine antibody product for the treatment of non-Hodgkin's lymphomas, which may compete with Rituxan and ZEVALIN, if approved. We are also aware of other potentially competitive biologic therapies for non-Hodgkin's lymphomas in development.

We May be Unable to Adequately Protect or Enforce Our Intellectual Property Rights or Secure Rights to Third-Party Patents

Our ability and the abilities of our partners to obtain and maintain patent and other protection for our products will affect our success. We are assigned, have rights to, or have exclusive licenses to a number of U.S. and foreign patents and patent applications. However, these patent applications may not be approved and, even if approved, our patent rights may not be upheld in a court of law if challenged. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. Our patent rights may not provide competitive advantages for our products and may be challenged, infringed upon or circumvented by our competitors.

Because of the large number of patent filings in the biopharmaceutical field, our competitors may have filed applications or been issued patents and may obtain additional patents and proprietary rights relating to products or processes competitive with or similar to ours. We cannot be certain that U.S. or foreign patents do not exist or will not issue that would harm our ability to commercialize our products and product candidates.

In September 1999, an interference to determine priority of inventorship was declared and is ongoing in the United States Patent and Trademark Office between Dartmouth University's patent application, which has been exclusively licensed to us, and Columbia University's patent, which we believe has been exclusively licensed to Biogen, Inc., relating to anti-CD40L antibodies. We, along with other companies, have filed oppositions to a Japanese patent assigned to Immunex Corporation relating to anti-CD40L antibodies. We are also aware that oppositions have been filed in the European Patent Office to granted European applications that have been licensed to us. Each of these applications contain claims relating to the use of anti-CD40L antibodies as a therapeutic. Also, we are aware of an opposition that was filed to a granted European patent application which names us as the applicant and which relates to PROVAX and therapeutic use thereof. If the outcome of the interference or any

of the oppositions is adverse, in whole or in part, it could result in the scope of some or all of the granted claims being limited, some or all of the granted claims being lost, the granted patent application not proceeding to a patent or, our competitors having patent claims that may be asserted against us.

We are aware of several third-party patents and patent applications, to the extent they issue as patents, that if successfully asserted against us, may adversely affect our ability to make, use, offer to sell, sell and import our products. These third-party patents and patent applications may include:

- three U.S. patents assigned to Glaxo SmithKline plc, or Glaxo, and foreign counterparts relating to therapeutic uses of CHO-glycosylated human chimeric, CDR-grafted or bi-specific antibodies;
- two U.S. patents assigned to Glaxo and foreign counterparts relating to chelator-stabilized antibody preparations;
- two U.S. patents assigned to Glaxo and foreign counterparts directed to methods of growing CHO cells in media that is free from components obtained directly from an animal source;
- three U.S. patents assigned to Corixa Corporation (formerly Coulter Pharmaceutical, Inc.) and the Regents of the University of Michigan; one that relates to compositions comprising radiolabeled antibodies directed to CD20 antigen which are administered at nonmyelosuppressive doses; a second which relates to methods of treating lymphoma with anti-CD20 antibodies in combination with an anti-CD20 radiolabeled antibody, an apoptosis-inducing agent, external beam radiation, or a chemotherapeutic agent; and a third directed to methods of treating lymphoma comprising imaging the distribution of a radiolabeled anti-CD20 antibody followed by the administration of radiolabeled antibodies directed to the CD20 antigen in non myelo suppressive doses.
- a U.S. patent and foreign counterparts filed by Bristol-Myers Squibb Company that relate to ligands to a B7.1 antigen;
- two U.S. patents assigned to Columbia University and a Japanese patent assigned to Immunex, which we believe have been exclusively licensed to Biogen, related to monoclonal antibodies to the 5C8 antigen found on T cells and methods of their use. We believe the 5C8 antigen and CD40L, the target for our IDEC-131 antibody, are both expressed on the surface of activated T cells; and
- a number of issued U.S. and foreign patents that relate to various aspects of radioimmunotherapy of cancer and to methods of treating patients with anti-CD4 antibodies.

The owners, or licensees of the owners of these patents, or any foreign patents, and patent applications, to the extent they issue as patents, may assert that one or more of our products infringe one or more claims of these patents. If legal action is commenced against us or our partners to enforce any of these patents and patent applications, to the extent they issue as patents, and the plaintiff in such action prevails, we could be prevented from practicing the subject matter claimed in such patents.

On May 28, 1999, Glaxo filed a patent infringement lawsuit against Genentech. On September 14, 2000, Glaxo filed a second patent infringement lawsuit against Genentech. These suits assert that the manufacture, use, and sale of Rituxan infringes U.S. patents owned by Glaxo. The trial for the first of these suits concluded on May 4, 2001 with the jury unanimously finding that Rituxan does not infringe patents held by Glaxo. The jury also unanimously found that all of the patent claims that Glaxo asserted against Genentech were invalid. Glaxo has appealed this ruling. The judge has rescheduled the trial for the second suit to begin June 2002. To date we have not been named in either of these suits.

If Glaxo were to prevail in the second suit or on appeal of the first suit, it could be awarded a variety of remedies, including damages for past sales, requiring Genentech to obtain a license from Glaxo or obtaining an injunction against the sale of Rituxan. Because we rely on sales of Rituxan for

substantially all of our revenue, an injunction would significantly harm our business. Further, if Genentech were required to obtain a license from Glaxo, our operating results in a particular quarter could be harmed as a result of any payment required for past royalties. Additionally, our long-term profitability could be harmed by reduced profit sharing under our collaboration agreement with our partner Genentech as a result of future royalties and other payments to Glaxo.

Glaxo has also sued Roche in Germany asserting that Rituxan infringes Glaxo's patents. On October 26, 2000, a German court handling the infringement phase of the suit issued a decision holding that the manufacture, use and sale of Rituxan infringes patents held by Glaxo. Roche has appealed the decision and the appeal is pending before the Court of Appeal. If Glaxo elects to enforce the decision, it must post a \$6.4 million bond. A second German court considering the validity of the Glaxo patents has to date not issued a decision. Additionally, Roche has filed oppositions in the European Patent Office to several of the Glaxo patents. Although we were not named in the suit, if Glaxo obtains an injunction precluding further sale of Rituxan in Europe, our business could be harmed.

In addition to patents, we rely on trade secrets and proprietary know-how that we seek to protect, in part, through confidentiality agreements with our partners, employees and consultants. These parties may breach our agreements and courts may not enforce the agreements, leaving us without adequate remedies. Further, our trade secrets may become known or be independently developed or patented by our competitors.

If it were ultimately determined that our claimed intellectual property rights are unenforceable, or that our use of our products infringes on the rights of others, we may be required or may desire to obtain licenses to patents and other intellectual property held by third parties to develop, manufacture and market our products. We may not be able to obtain these licenses on commercially reasonable terms, if at all, and any licensed patents or intellectual property that we may obtain may not be valid or enforceable. In addition, the scope of intellectual property protection is subject to scrutiny and change by courts and other governmental bodies. Litigation and other proceedings concerning patents and proprietary technologies can be protracted, expensive and distracting to management and companies may sue competitors as a way of delaying the introduction of competitors' products. Any litigation, including any interference proceeding to determine priority of inventions, oppositions to patents in foreign countries or litigation against our partners, may be costly and time-consuming and could harm our business.

Failure to Obtain Product Approvals or Comply with Government Regulations Could Harm Our Business

As pharmaceutical manufacturers, we as well as our partners, contract manufacturers and suppliers are subject to extensive, complex, costly and evolving governmental rules, regulations and restrictions administered by the FDA, by other federal and state agencies, and by governmental authorities in other countries. In the United States, our products cannot be marketed until they are approved by the FDA. Rituxan is our only product that has received FDA approval, and we cannot be certain that ZEVALIN or any of our product candidates will be approved either in the United States or in other countries in a timely fashion, if at all.

Obtaining FDA approval involves the submission, among other information, of the results of preclinical and clinical studies on the product, and requires substantial time, effort and financial resources. Before approval of an NDA or BLA, the FDA will also perform prelicensing inspections of our facility and our contract manufacturers, suppliers and fill/finish providers facilities to determine compliance with cGMP. For example, as part of the FDA Complete Review Letter received for ZEVALIN in May 2001, the FDA indicated that it will establish an independent schedule for pre-approval inspection of our ZEVALIN radioisotope supplier and fill/finish provider. Our failure or the failure of our partners, contract manufacturers or suppliers, in particular our radioisotope supplier

or fill/finish provider, to meet FDA requirements would delay or preclude our ability to sell ZEVALIN which would harm our business.

Even assuming FDA approval, we, as well as our partners, contract manufacturers and suppliers, are subject to numerous FDA requirements covering, among other things, testing, manufacturing, quality control, labeling and continuing promotion of drugs, and to government inspection at all times. Failure to meet or comply with any rules, regulations or restrictions of the FDA or other agencies could result in:

- fines;
- unanticipated expenditures;
- product delays;
- non-approval or recall;
- interruption of production; and
- criminal prosecution.

Although we have instituted internal compliance programs and continue to address compliance issues raised from time to time by the FDA, we may not be able to meet regulatory agency standards and any lack of compliance may harm our business.

We May be Unable to Maintain Third-Party Research and Development Relationships

Funding of research and development efforts depends largely upon various arrangements with strategic partners and others who provide us with funding and who perform research and development with respect to our products. These strategic partners may generally terminate their arrangements with us at any time. These parties may develop products that compete with ours, and we cannot be certain that they will perform their contractual obligations or that any revenues will be derived from such arrangements. If one or more of our strategic partners fail to achieve product development objectives, this failure could harm our ability to fund related programs and develop products.

Our Business Exposes Us to Product Liability Claims

Our design, testing, development, manufacture and marketing of products involve an inherent risk of exposure to product liability claims and related adverse publicity. Insurance coverage is expensive and difficult to obtain, and we may be unable to obtain coverage in the future on acceptable terms, if at all. Although we currently maintain product liability insurance for our products in the amounts we believe to be commercially reasonable, we cannot be certain that the coverage limits of our insurance policies or those of our strategic partners will be adequate. If we are unable to obtain sufficient insurance at an acceptable cost or if a successful product liability claim is made against us, whether fully covered by insurance or not, our business could be harmed.

Future Transactions May Harm Our Business or the Market Price of Our Securities

We regularly review potential transactions related to technologies, products or product rights and businesses complementary to our business. These transactions could include:

- mergers;
- acquisitions;
- strategic alliances;
- off-balance sheet financings;
- licensing agreements; and

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- copromotion agreements.

We may choose to enter into one or more of these transactions at any time, which may cause substantial fluctuations to the market price of securities that we have issued. Moreover, depending upon the nature of any transaction, we may experience a charge to earnings, which could also harm the market price of securities that we have issued.

We May Not be Able to Successfully Develop and Commence Operations of Our New Manufacturing Facility

We have recently purchased a 60-acre parcel of land on which we intend to develop a manufacturing facility. We have limited experience in developing manufacturing facilities and may not be able to successfully develop or commence operations at this facility. We may encounter difficulties in designing, constructing and initiating our manufacturing facility, including:

- governmental regulation of our manufacturing facility, specifically, FDA approvals required for the commercial manufacture of our products currently in clinical trials;
- public opinion regarding the impact of the facility on nearby communities;
- construction delays, including obtaining necessary governmental approvals and permits;
- cost overruns;
- delays in design, shipment and installation of equipment for our facility;
- other unforeseeable factors inherent in the construction process; and
- obtaining financing we may need to complete the facility.

Even if we are able to successfully develop this manufacturing facility, we may not be able to do so in a cost-effective manner or in a time frame that is consistent with our expected future manufacturing needs.

Volatility of Our Stock Price

The market prices for our common stock and for securities of other companies engaged primarily in biotechnology and pharmaceutical development, manufacture and distribution are highly volatile. For example, the market price of our common stock fluctuated between \$32.63 per share and \$75.00 per share during the six months ended July 31, 2001. The market price of our common stock will likely continue to fluctuate due to a variety of factors, including:

- material public announcements;
- the announcement and timing of new product introductions by us or others;
-

- technical innovations or product development by us or our competitors;
- regulatory approvals or regulatory issues;
- developments relating to patents, proprietary rights and orphan drug status;
- actual or potential clinical results with respect to our products under development or those of our competitors;
- political developments or proposed legislation in the pharmaceutical or healthcare industry;
- economic and other external factors, disaster or crisis;
- hedge and/or arbitrage activities by holders of our convertible promissory notes;
- period-to-period fluctuations in our financial results or results which do not meet or exceed analyst expectations; and

- market trends relating to or affecting stock prices throughout our industry, whether or not related to results or news regarding us or our competitors.

We are Subject to Uncertainties Regarding Healthcare Reimbursement and Reform

Our ability to commercialize products depends in part on the extent to which patients are reimbursed by governmental agencies, private health insurers and other organizations, such as health maintenance organizations, for the cost of such products and related treatments. Our business could be harmed if healthcare payers and providers implement cost-containment measures and governmental agencies implement healthcare reform.

Our Business Involves Environmental Risks

Our business and the business of several of our strategic partners, including Genentech, involve the controlled use of hazardous materials, chemicals, biologics and radioactive compounds. Biologics manufacture is extremely susceptible to product loss due to microbial or viral contamination, material equipment failure, or vendor or operator error. Although we believe that our safety procedures for handling and disposing of such materials complies with state and federal standards, there will always be the risk of accidental contamination or injury. In addition, microbial or viral contamination may cause the closure of the respective manufacturing facility for an extended period of time. By law, radioactive materials may only be disposed of at state-approved facilities. We currently store our radioactive materials on-site because the approval of a disposal site in California for all California-based companies has been delayed indefinitely. If and when a disposal site is approved, we may incur substantial costs related to the disposal of these materials. If we were to become liable for an accident, or if we were to suffer an extended facility shutdown, we could incur significant costs, damages and penalties that could harm our business.

We Face Increased Energy Costs and May Face Power Outages as a Result of the Energy Crisis Currently Being Experienced in California

In late 2000, and continuing into 2001, the State of California has been subject to a deterioration in the ability of major utilities to provide energy for the State's needs. Throughout California, the crisis has resulted in "rolling blackouts" where certain areas are not provided with any electricity for periods of up to two hours. To date the most immediate impact has been the significant increase in power rates for most users, including us. In addition, the loss of electrical power or "blackouts" for any significant periods could harm our ability to manufacture the clinical and commercial requirements of our products, including the ZEVALIN antibody, and could result in significantly higher manufacturing costs.

We Rely upon Key Personnel

Our success will depend, to a great extent, upon the experience, abilities and continued services of our executive officers and key scientific personnel. If we lose the services of any of these officers or key scientific personnel, our business could be harmed. Our success also will depend upon our ability to attract and retain other highly qualified scientific, managerial, sales and manufacturing personnel and our ability to develop and maintain relationships with qualified clinical researchers. Competition for these personnel and relationships is intense and we compete with numerous pharmaceutical and biotechnology companies as well as with universities and non-profit research organizations. We may not be able to continue to attract and retain qualified personnel or develop and maintain relationships with clinical researchers.

We May Be Unable to Raise Additional Capital or to Repurchase Our Convertible Promissory Notes

We expend and will likely continue to expend substantial funds to complete the research, development, manufacturing and marketing of our potential future products. Consequently, we may seek to raise capital through collaborative arrangements, strategic alliances or equity and debt financings or from other sources. We may need to raise additional funds or borrow funds to complete the construction of our planned Oceanside facility. We may be unable to raise additional capital on commercially acceptable terms, if at all, and if we raise capital through equity financing, existing stockholders may have their ownership interests diluted. Our failure to be able to generate adequate funds from operations or from additional sources would harm our business.

If we undergo events constituting a change of control prior to February 16, 2004, we will be obligated to repurchase all our outstanding convertible promissory notes at the option of the holder. We may not have sufficient funds at that time or may not be able to raise sufficient funds to make these repurchases.

Our Convertible Promissory Notes Leverage Us Considerably

As a result of issuing our convertible promissory notes in February 1999, we raised approximately \$112.7 million, net of underwriting commissions and expenses of \$3.9 million, by incurring indebtedness of \$345.0 million at maturity in 2019. As a result of this indebtedness, our principal and interest obligations increased substantially. The degree to which we are leveraged could harm our ability to obtain future financing and could make us more vulnerable to industry

downturns and competitive pressures. Our ability to meet our debt obligations will be dependent upon our future performance, which will be subject to financial, business and other factors affecting our operations, many of which are beyond our control. The holders of the convertible promissory notes may require us to purchase the convertible promissory notes on February 16, 2004, 2009, and 2014 at a price equal to the issue price plus accrued original issue discount to the date of purchase. We have the option to repay our convertible promissory notes plus accrued original issue discount in cash, our common stock or a combination thereof. We have the right to redeem the convertible promissory notes on or after February 16, 2004.

In addition, in the event of our insolvency, bankruptcy, liquidation, reorganization, or dissolution or upon our default in payment with respect to any indebtedness or an event of default with respect to such indebtedness resulting in the acceleration thereof, our assets will be available to pay the amounts due on our convertible promissory notes only after all our senior indebtedness has been paid in full. Moreover, holders of common stock would only receive the assets remaining after payment of all indebtedness and preferred stock, if any.

We Have Adopted Several Anti-takeover Measures and Our Convertible Promissory Notes May Have A Further Anti-takeover Effect

We have taken a number of actions that could discourage a takeover attempt that might be beneficial to stockholders who wish to receive a premium for their shares from a potential bidder. For example, we reincorporated into Delaware, which subjects us to Section 203 of the Delaware General Corporation Law, providing that we may not enter into a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in the manner prescribed in the code section. In addition, we have adopted a stockholder rights plan that was amended and restated as of July 26, 2001 that would cause substantial dilution to a person who attempts to acquire us on terms not approved by our board of directors. In addition, our board of directors has the authority to issue, without vote or action of stockholders, up to 8,000,000 shares of preferred stock and to fix the price, rights, preferences and privileges of those shares. Any series of preferred stock could contain dividend

rights, conversion rights, voting rights, terms of redemption, redemption prices, liquidation preferences or other rights superior to the rights of holders of common stock. Although we currently have 48,014 shares of non-voting convertible preferred stock outstanding, which were convertible into 2,880,842 shares of common stock as of June 30, 2001, the board of directors has no present intention of issuing any additional shares of preferred stock. However, the board of directors may issue additional series of preferred stock in the future. In addition, our copromotion arrangement with Genentech provides Genentech with the option to buy the rights to Rituxan in the event that we undergo a change of control, which may limit our attractiveness to potential acquirers.

We are required by the terms of our convertible promissory notes, as of 35 business days after a change in control occurring on or before February 16, 2004, to purchase any convertible promissory note at the option of its holder and at a price equal to the issue price plus accrued original issue discount to the date of repurchase. This feature of our convertible promissory notes may have an anti-takeover effect.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to a variety of risks, including changes in interest rates affecting the return on our investments and the cost of our debt.

At June 30, 2001, we maintained a portion of our cash and cash equivalents in financial instruments with original maturities of three months or less. We also maintained an investment portfolio containing financial instruments in which the majority have original maturities of greater than three months but less than twenty-four months. These financial instruments, principally comprised of corporate obligations and to a lesser extent foreign and U.S. government obligations, are subject to interest rate risk and will decline in value if interest rates increase. A hypothetical ten percent change in interest rates during the six months ended June 30, 2001, would have resulted in approximately a \$2.1 million change in pretax income. We have not used derivative financial instruments in our investment portfolio.

Our long-term debt totaled \$132.4 million at June 30, 2001 and was comprised solely of the convertible promissory notes. Our long-term debt obligation bears interest at a weighed average interest rate of 5.5%. Due to the fixed rate nature of the convertible promissory notes, an immediate ten percent change in interest rates would not have a material effect on our financial condition or results of operations.

Underlying market risk exists related to an increase in our stock price or an increase in interest rates which may make conversion of the convertible promissory notes to common stock beneficial to the convertible promissory notes holder. Conversion of the convertible promissory notes would have a dilutive effect on our earnings per share and book value per common share.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

- (a) We are involved in certain legal proceedings generally incidental to our normal business activities. While the outcome of any such proceedings cannot be accurately predicted, we do not believe the ultimate resolution of any such existing matters would have a material adverse effect on our business or financial condition.
- (b) No material legal proceedings were terminated in the second quarter of 2001.

Item 2. Changes in Securities.

Effective July 26, 2001, the Company's Board of Directors amended and restated the terms of the Company's stockholder rights plan, originally adopted by the Board in 1997. Under the plan, the Company declared a dividend distribution of one "Right" for each outstanding share of Common Stock of the Company to stockholders of record at the close of business on August 11, 1997. Since that time, the Company has issued one Right with each newly issued share of Common

Stock. As amended, each Right, when exercisable, entitles the holder to purchase from the Company one one-thousandth of a share of the Company's Series X Junior Participating Preferred Stock at a purchase price of \$500.00 (the "Purchase Price").

In general, under the amended and restated plan, if a person or group (an "Acquiring Person") acquires beneficial ownership of 15% or more of the outstanding shares of Common Stock, then each Right (other than those held by an Acquiring Person) will entitle the holder to receive, upon exercise, shares of Common Stock (or, under certain circumstances, a combination of securities or other assets) having a value of twice the Purchase Price. In addition, if following the announcement of the existence of an Acquiring Person the Company is involved in a business combination or sale of 50% or more of its assets or earning power, each Right (other than those held by an Acquiring Person) will entitle the holder to receive, upon exercise, shares of common stock of the acquiring entity having a value of twice the Purchase Price. When the foregoing rights arise, any Rights owned by an Acquiring Person will immediately become void. The Board of Directors will also have the right, after there is an Acquiring Person, to cause each Right (except those that have become void) to be exchanged for Common Stock or substitute consideration.

The Company may redeem the Rights at a price of \$0.001 per Right before the existence of an Acquiring Person is announced. The Rights expire on July 26, 2011.

This summary description of the Rights does not purport to be complete and is qualified in its entirety by reference to the Amended and Restated Rights Agreement, which was filed as an exhibit to the Company's Amendment to Registration Statement on Form 8-A filed on July 27, 2001.

Item 3. Defaults upon Senior Securities.

None

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

On May 18, 2001, we held our Annual Meeting of Stockholders at which the stockholders approved all of the proposals listed below:

- (1) The election of Kazuhiro Hashimoto, Franklin P. Johnson, Jr., and Bruce R. Ross to the Board of Directors to serve for a three-year term ending in the year 2004, or until their successors shall have been duly elected or appointed or until their earlier death, resignation or removal.
- (2) The amendment to our 1988 Stock Option Plan to increase the total number of common shares authorized for issuance thereunder from 47,940,000 shares to a total of 53,580,000 shares.
- (3) The amendment to our Certificate of Incorporation to increase the total number of common shares authorized for issuance thereunder from 200,000,000 shares to a total of 500,000,000 shares.
- (4) The selection of KPMG LLP as our independent public accountants for the fiscal year ending December 31, 2001.

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The following directors received the number of votes set opposite their respective names:

	For Election	Withheld
Kazuhiro Hashimoto	115,434,454	479,375
Franklin P. Johnson, Jr.	115,424,157	489,672
Bruce R. Ross	115,432,639	481,190

The proposal to amend the 1988 Stock Option Plan received 69,223,384 affirmative votes (for the amendment), 46,537,728 negative votes (against the amendment) and 152,717 votes abstained. The proposal did not receive any broker nonvotes.

The proposal to amend our Certificate of Incorporation received 110,153,568 affirmative votes (for the amendment), 5,659,900 negative votes (against the amendment) and 100,361 votes abstained. This proposal did not receive any broker nonvotes.

The proposal to select KPMG LLP as our independent public accountants received 115,523,348 affirmative votes (for the selection), 280,035 negative votes (against the selection), and 110,446 votes abstained. This proposal did not receive any broker nonvotes.

Item 5. Other Information.

None

Item 6. Exhibits and Reports on Form 8-K.

- (a) Exhibits referenced

- 3.1 (3) Amended and Restated Certificate of Incorporation of IDEC Pharmaceuticals Corporation.
- 3.2 Certificate of Amendment of Amended and Restated Certificate of Incorporation of IDEC Pharmaceuticals Corporation.
- 4.1 (2) Amended and Restated Rights Agreement dated as of July 26, 2001 between IDEC Pharmaceuticals Corporation and Mellon Investor Services LLC.
- 10.10 (1) Amended and Restated 1988 Stock Option Plan (Amended and restated on January 16, 2001).

- (1) Incorporated by reference to exhibit 99.1 to our Registration Statement on Form S-8, File No. 333-65494.
- (2) Incorporated by reference to exhibit 4.1 filed with our Registration Statement on Form 8-A, File No. 333-37128 dated July 27, 2001.
- (3) Incorporated by reference to exhibit filed with our Proxy Statement filed on November 4, 1999.
- (b) Reports on Form 8-K. On July 26, 2001, we filed a current report of Form 8-K reporting that we had amended our Rights Agreement, dated as of July 22, 1997, between us and Chase Mellon Shareholder Services LLC, to amend various terms of the rights granted under that plan.

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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 thereunto duly authorized.

IDEC PHARMACEUTICALS CORPORATION

Date: August 10, 2001

By: /s/ WILLIAM H. RASTETTER

William H. Rastetter
Chairman of the Board, President and
Chief Executive Officer
(Principal Executive Officer)

Date: August 10, 2001

By: /s/ PHILLIP M. SCHNEIDER

Phillip M. Schneider
Senior Vice President and
Chief Financial Officer
(Principal Financial and Accounting Officer)

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**CERTIFICATE OF AMENDMENT OF
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
IDEC PHARMACEUTICALS CORPORATION**

IDEC Pharmaceuticals Corporation, a corporation organized and existing under the laws of the State of Delaware, hereby certifies as follows:

FIRST: That the Board of Directors of said corporation, at a meeting duly held, adopted a resolution proposing and declaring advisable the following amendment to the Amended and Restated Certificate of Incorporation:

RESOLVED, that the Amended and Restated Certificate of Incorporation of this corporation be amended by changing Section A of Article IV thereof so that, as amended, said Section A of Article IV shall be and read as follows:

"(A) Classes of Stock. This corporation is authorized to issue two classes of stock to be designated, respectively, "**Common Stock**" and "**Preferred Stock**." The total number of shares which the corporation is authorized to issue is Five Hundred Eight Million (508,000,000) shares. Five Hundred Million (500,000,000) shares shall be Common Stock, par value \$0.0005 per share, and Eight Million (8,000,000) shares shall be Preferred Stock, par value \$0.001 per share."

SECOND: That thereafter, pursuant to resolution of the Board of Directors, the annual meeting of the stockholders of said corporation was duly called and held, upon notice in accordance with Section 222 of the General Corporation Law of the State of Delaware.

THIRD: That said amendment was duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

FOURTH: That the capital of said corporation shall not be reduced under or by reason of said amendment.

IN WITNESS WHEREOF, said IDEC Pharmaceuticals Corporation has caused this certificate to be signed by its President and Chief Executive Officer, William H. Rastetter, this day of May, 2001.

\s\ William H. Rastetter

William H. Rastetter
President and Chief Executive Officer

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[Exhibit 3.2](#)

[CERTIFICATE OF AMENDMENT OF AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF IDEC PHARMACEUTICALS CORPORATION](#)