

BIOMARIN PHARMACEUTICAL INC
Form 10-Q
April 29, 2019

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 March 31, 2019

Or

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

For the transition period from _____ to _____ .

Commission File Number: 000-26727

BioMarin Pharmaceutical Inc.

(Exact name of registrant as specified in its charter)

Delaware 68-0397820
(State or other jurisdiction of (I.R.S. Employer
incorporation or organization) Identification No.)

770 Lindero Street, San Rafael, California 94901
(Address of principal executive offices) (Zip Code)

(415) 506-6700

(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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.) Yes No

Applicable only to corporate issuers:

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 179,071,353 shares of common stock, par value \$0.001, outstanding as of April 15, 2019.

BIOMARIN PHARMACEUTICAL INC.

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Unless the context suggests otherwise, references in this Quarterly Report on Form 10-Q to "BioMarin," the "Company," "we," "us," and "our" refer to BioMarin Pharmaceutical Inc. and, where appropriate, its wholly owned subsidiaries.

BioMarin[®], Brineura[®], Firdapse[®], Kuvan[®], Naglazyme[®], Palynziq[®] and Vimizim[®] are our registered trademarks. Aldurazyme[®] is a registered trademark of BioMarin/Genzyme LLC. All other brand names and service marks, trademarks and other trade names appearing in this report are the property of their respective owners.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" as defined under securities laws. Many of these statements can be identified by the use of terminology such as "believes," "expects," "intends," "anticipates," "plans," "may," "will," "could," "would," "projects," "continues," "estimates," "potential," "opportunity" or the negative versions of these terms and other similar expressions. Our actual results or experience could differ significantly from the forward-looking statements. Factors that could cause or contribute to these differences include those discussed in "Risk Factors," in Part II, Item 1A of this Quarterly Report on Form 10-Q as well as information provided elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2018, which was filed with the Securities and Exchange Commission (the SEC) on February 28, 2019. You should carefully consider that information before you make an investment decision.

You should not place undue reliance on these types of forward-looking statements, which speak only as of the date that they were made. These forward-looking statements are based on the beliefs and assumptions of the Company's management based on information currently available to management and should be considered in connection with any written or oral forward-looking statements that the Company may issue in the future as well as other cautionary statements the Company has made and may make. Except as required by law, the Company does not undertake any obligation to release publicly any revisions to these forward-looking statements after completion of the filing of this Quarterly Report on Form 10-Q to reflect later events or circumstances or the occurrence of unanticipated events.

The discussion of the Company's financial condition and results of operations should be read in conjunction with the Company's Condensed Consolidated Financial Statements and the related Notes thereto included in this Quarterly Report on Form 10-Q.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

BIOMARIN PHARMACEUTICAL INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

March 31, 2019 and December 31, 2018

(In thousands, except share and per share amounts)

	March 31, 2019	December 31, 2018(1)
ASSETS	(unaudited)	
Current assets:		
Cash and cash equivalents	\$364,369	\$493,982
Short-term investments	530,485	590,326
Accounts receivable, net	393,429	342,633
Inventory	534,696	530,871
Other current assets	93,876	98,403
Total current assets	1,916,855	2,056,215
Noncurrent assets:		
Long-term investments	320,000	235,864
Property, plant and equipment, net	951,890	948,682
Intangible assets, net	485,981	491,808
Goodwill	197,039	197,039
Deferred tax assets	467,333	460,952
Other assets	96,300	36,568
Total assets	\$4,435,398	\$4,427,128
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$412,830	\$437,290
Short-term contingent consideration	88,156	85,951
Total current liabilities	500,986	523,241
Noncurrent liabilities:		
Long-term convertible debt, net	834,766	830,417
Long-term contingent consideration	48,461	46,883
Other long-term liabilities	114,558	58,647
Total liabilities	1,498,771	1,459,188
Stockholders' equity:		
Common stock, \$0.001 par value: 500,000,000 shares authorized;	179	178

179,033,104 and 178,252,954 shares issued and outstanding, respectively.		
Additional paid-in capital	4,682,900	4,669,926
Company common stock held by Nonqualified Deferred Compensation Plan		
(the NQDC)	(12,912)	(13,301)
Accumulated other comprehensive income	19,794	5,271
Accumulated deficit	(1,753,334)	(1,694,134)
Total stockholders' equity	2,936,627	2,967,940
Total liabilities and stockholders' equity	\$4,435,398	\$4,427,128

(1) December 31, 2018 balances were derived from the audited Consolidated Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on February 28, 2019.

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements.

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BIOMARIN PHARMACEUTICAL INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

Three Months Ended March 31, 2019 and 2018

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended March 31,	
	2019	2018
REVENUES:		
Net product revenues	\$394,483	\$369,099
Royalty and other revenues	6,262	4,348
Total revenues	400,745	373,447
OPERATING EXPENSES:		
Cost of sales	89,182	82,333
Research and development	183,591	183,948
Selling, general and administrative	162,158	138,336
Intangible asset amortization and contingent consideration	19,765	13,202
Total operating expenses	454,696	417,819
LOSS FROM OPERATIONS	(53,951)	(44,372)
Equity in the income (loss) of BioMarin/Genzyme LLC	(185)	68
Interest income	6,298	5,234
Interest expense	(6,727)	(11,562)
Other income (expense), net	1,608	(172)
LOSS BEFORE INCOME TAXES	(52,957)	(50,804)
Provision for (benefit from) income taxes	3,516	(6,655)
NET LOSS	\$(56,473)	\$(44,149)
NET LOSS PER SHARE, BASIC	\$(0.32)	\$(0.25)
NET LOSS PER SHARE, DILUTED	\$(0.32)	\$(0.26)
Weighted average common shares outstanding, basic	178,271	175,932
Weighted average common shares outstanding, diluted	178,271	176,150
COMPREHENSIVE LOSS	\$(41,950)	\$(49,147)

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements.

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BIOMARIN PHARMACEUTICAL INC.

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

Three Months Ended March 31, 2019 and 2018

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2019	2018
Shares of Common Stock		
Beginning balance (at December 31, 2018 and December 31, 2017, respectively) ⁽¹⁾	178,253	175,844
Issuances under equity incentive plans	780	809
Ending balance	179,033	176,653
Stockholders' equity, beginning balances (at December 31, 2018 and December 31, 2017, respectively)		
	\$2,967,940	\$2,808,663
Common stock:		
Beginning balance ⁽¹⁾	178	176
Issuances under equity incentive plans, net of tax	1	1
Ending balance	179	177
Additional paid-in capital:		
Beginning balance ⁽¹⁾	4,669,926	4,483,220
Issuances under equity incentive plans, net of tax	(28,732)	(9,766)
Stock-based compensation	41,706	36,997
Beginning balance ⁽¹⁾	4,682,900	4,510,451
Company common stock held by the NQDC:		
Beginning balance	(13,301)	(14,224)
Common stock held by the NQDC	389	207
Ending balance	(12,912)	(14,017)
Accumulated other comprehensive income (loss):		
Beginning balance ⁽¹⁾	5,271	(22,961)
Impact of changes in accounting principle	—	(586)
Other comprehensive income (loss)	14,523	(4,998)
Ending balance	19,794	(28,545)
Accumulated Deficit:		
Beginning balance ⁽¹⁾	(1,694,134)	(1,637,548)
Impact of changes in accounting principles	(2,727)	20,634
Net loss	(56,473)	(44,149)
Ending balance	(1,753,334)	(1,661,063)
Total stockholders' equity, ending balances (at March 31, 2019 and	\$2,936,627	\$2,807,003

March 31, 2018, respectively)

- (1) The beginning balances were derived from the audited Consolidated Financial Statements included in Company's Annual Report on Form 10-K for the year ended December 31, 2018 and 2017, respectively, filed with the SEC on February 28, 2019 and February 26, 2018, respectively.

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements.

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BIOMARIN PHARMACEUTICAL INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

Three Months Ended March 31, 2019 and 2018

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$(56,473)	\$(44,149)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	22,427	23,633
Non-cash interest expense	4,409	8,601
Accretion of discount on investments	(891)	761
Stock-based compensation	42,761	36,608
Deferred income taxes	(704)	(13,988)
Unrealized foreign exchange (gain) loss	(419)	5,616
Non-cash changes in the fair value of contingent consideration	12,260	5,631
Other	(19)	662
Changes in operating assets and liabilities:		
Accounts receivable, net	(51,690)	(26,257)
Inventory	1,735	10,843
Other current assets	10,112	2,924
Other assets	2,220	(1,099)
Accounts payable and accrued liabilities	(42,070)	(51,887)
Other long-term liabilities	1,474	(408)
Net cash used in operating activities	(54,868)	(42,509)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property, plant and equipment	(28,756)	(30,164)
Maturities and sales of investments	219,894	104,462
Purchases of available-for-sale securities	(239,843)	(145,933)
Other	(1,774)	(99)
Net cash used in investing activities	(50,479)	(71,734)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercises of awards under equity incentive plans	5,798	13,134
Taxes paid related to net share settlement of equity awards	(30,105)	(22,899)
Other	(674)	—
Net cash used in financing activities	(24,981)	(9,765)
Effect of exchange rate changes on cash	715	(40)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(129,613)	(124,048)
Cash and cash equivalents:		
Beginning of period	\$493,982	\$598,028

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End of period	\$364,369	\$473,980
SUPPLEMENTAL CASH FLOW DISCLOSURES:		
Cash paid for income taxes	\$906	\$11,731
Cash paid for interest	1,483	1,528
SUPPLEMENTAL CASH FLOW DISCLOSURES FOR NON CASH INVESTING AND FINANCING ACTIVITIES:		
Decrease in accounts payable and accrued liabilities related to fixed assets	\$(3,502)	\$(11,367)

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements.

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BIOMARIN PHARMACEUTICAL INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(In thousands of U.S. Dollars, except per share amounts or as otherwise disclosed)

(1) NATURE OF OPERATIONS

BioMarin Pharmaceutical Inc. (the Company) is a global biotechnology company that develops and commercializes innovative therapies for people with serious and life-threatening rare diseases and medical conditions. The Company selects product candidates for diseases and conditions that represent a significant unmet medical need, have well-understood biology and provide an opportunity to be first-to-market or offer a significant benefit over existing products. The Company's portfolio consists of several commercial therapies and multiple clinical and pre-clinical product candidates.

The Company expects to continue to finance future cash needs that exceed its operating activities primarily through its current cash, cash equivalents and investments and through proceeds from debt or equity offerings, commercial borrowing, or through collaborative agreements with corporate partners. If the Company elects to increase its spending on development programs significantly above current long-term plans or enters into potential licenses and other acquisitions of complementary technologies, products or companies, the Company may need additional capital.

(2) BASIS OF PRESENTATION

The accompanying Condensed Consolidated Financial Statements have been prepared pursuant to United States (U.S.) generally accepted accounting principles (U.S. GAAP) and the rules and regulations of the SEC for Quarterly Reports on Form 10-Q and do not include all of the information and note disclosures required by U.S. GAAP for complete financial statements, although the Company believes that the disclosures herein are adequate to ensure that the information presented is not misleading. The Condensed Consolidated Financial Statements should therefore be read in conjunction with the Consolidated Financial Statements and Notes thereto for the fiscal year ended December 31, 2018 included in the Company's Annual Report on Form 10-K. The results of operations for the three months ended March 31, 2019 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2019 or any other period.

On January 1, 2019, the Company adopted Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 842, Leases (ASC Topic 842) using the modified retrospective method for all lease arrangements at the beginning of the period of adoption. Results for reporting periods beginning January 1, 2019 are presented under ASC Topic 842, while prior period amounts were not adjusted and continue to be presented in accordance with the Company's historical accounting under ASC Topic 840, Leases. ASC Topic 842 had a material impact on the Company's Condensed Consolidated Balance Sheet but did not have a significant impact on the Company's consolidated net loss. The Company elected to use the practical expedient allowing the use-of-hindsight and reassessed the lease term for all unexpired leases that commenced before the effective date of ASC Topic 842. For leases that commenced and expired before the effective date of ASC Topic 842, the Company elected not to reassess the expired leases. The Company also elected not to include leases with initial terms of twelve months or less in the recognized right-of-use (ROU) assets and lease liabilities.

As a result of the cumulative impact of adopting ASC Topic 842, the Company recorded lease ROU assets of \$55.9 million and lease liabilities of \$59.0 million as of January 1, 2019, primarily related to real estate and equipment,

based on the present value of future lease payments on the date of adoption. The difference between the ROU assets and lease liabilities was recorded as an adjustment to Accumulated Deficit. Refer to Note 11 for additional disclosures required by ASC Topic 842.

On January 1, 2019, the Company adopted Accounting Standards Update No. 2017-12, Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities (ASU 2017-12), using the modified retrospective method. This ASU provides new guidance about income statement classification and eliminates the requirement to separately measure and report hedge ineffectiveness. Results for reporting periods beginning January 1, 2019 are presented under ASU 2017-12, while prior period amounts were not adjusted and continue to be presented in accordance with the Company's historical accounting. The adoption of this ASU did not have a significant impact on the Company's Condensed Consolidated Financial Statements. See Note 10 for additional disclosures required by ASU 2017-12.

U.S. GAAP requires management to make estimates and assumptions that affect amounts reported in the Condensed Consolidated Financial Statements and accompanying disclosures. Although these estimates are based on management's best knowledge of current events and actions that the Company may undertake in the future, actual results may be different from those estimates. The Condensed Consolidated Financial Statements reflect all adjustments of a normal, recurring nature that are, in the opinion of management, necessary for a fair presentation of results for these interim periods.

Management performed an evaluation of the Company's activities through the date of filing of this Quarterly Report on Form 10-Q, and has concluded that there were no subsequent events or transactions that occurred subsequent to the balance sheet date prior to filing this Quarterly Report on Form 10-Q that would require recognition or disclosure in the Condensed Consolidated Financial Statements.

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BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

(In thousands of U.S. Dollars, except per share amounts or as otherwise disclosed)

(3) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Except as detailed below, there have been no material changes to the Company's significant accounting policies during the three months ended March 31, 2019, as compared to the significant accounting policies disclosed in Note 3 – Significant Accounting Policies included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

Leases

The Company determines if an arrangement is a lease at inception. For leases where the Company is the lessee, ROU assets represent the Company's right to use the underlying asset for the term of the lease and the lease liabilities represent an obligation to make lease payments arising from the lease. ROU assets and lease liabilities are recognized at the lease commencement date based on the present value of the future lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at the commencement date of the underlying lease arrangement to determine the present value of lease payments. The ROU asset also includes any prepaid lease payments and any lease incentives received. The lease term to calculate the ROU asset and related lease liability includes options to extend or terminate the lease when it is reasonably certain that the Company will exercise the option. The Company's lease agreements generally do not contain any material variable lease payments, residual value guarantees or restrictive covenants.

Lease expense for operating leases is recognized on a straight-line basis over the lease term as an operating expense while expense for financing leases is recognized as depreciation expense and interest expense using the accelerated interest method of recognition. When an arrangement requires payments for lease and non-lease components, the Company has elected to account for lease and non-lease components separately. Lease expense for leases with a term of twelve months or less is recognized on a straight-line basis.

Derivatives and Hedging Activities

The Company accounts for its derivative instruments as either assets or liabilities on the balance sheet and measures them at fair value, which is estimated using current exchange rates and interest rates, and takes into consideration the current creditworthiness of the counterparties or the Company, as applicable. For derivatives designated as hedging instruments, the entire change in the fair value of qualifying derivative instruments is recorded in Accumulated Other Comprehensive Income (AOCI) and amounts deferred in AOCI will be reclassified to earnings in the same line item in which the earnings effect of the hedged item is reported. Derivatives not designated as hedging instruments are adjusted to fair value through earnings in Operating Expenses in the Consolidated Statements of Comprehensive Loss.

(4) RECENT ACCOUNTING PRONOUNCEMENTS

Except as described in Note 2 – Basis of Presentation, there have been no new accounting pronouncements adopted by the Company or new accounting pronouncements issued by the FASB during the three months ended March 31, 2019, as compared to the recent accounting pronouncements described in Note 4 of the Company’s Annual Report on Form 10-K for the year ended December 31, 2018, that the Company believes are of significance or potential significance to the Company.

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BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

(In thousands of U.S. Dollars, except per share amounts or as otherwise disclosed)

(5) FINANCIAL INSTRUMENTS

All marketable securities were classified as available-for-sale at March 31, 2019 and December 31, 2018.

The following tables show the Company's cash, cash equivalents and available-for-sale securities by significant investment category as of March 31, 2019 and December 31, 2018, respectively:

	Amortized Cost	Gross Gains	Gross Losses	Aggregate Fair Value	Cash and Cash Equivalents	Short-term Marketable Securities (1)	Long-term Marketable Securities (2)
Level 1:							
Cash	\$ 220,980	\$ —	\$ —	\$ 220,980	\$ 220,980	\$ —	\$ —
Level 2:							
Money market instruments	122,400	—	—	122,400	122,400	—	—
Corporate debt securities	563,691	1,535	(765)	564,461	—	309,721	254,740
Commercial paper	84,584	—	—	84,584	20,989	63,595	—
U.S. government agency securities	222,183	430	(369)	222,244	—	157,169	65,075
Foreign and other	50	136	(1)	185	—	—	185
Subtotal	992,908	2,101	(1,135)	993,874	143,389	530,485	320,000
Total	\$ 1,213,888	\$ 2,101	\$ (1,135)	\$ 1,214,854	\$ 364,369	\$ 530,485	\$ 320,000

	Amortized Cost	Gross Gains	Gross Losses	Aggregate Fair Value	Cash and Cash Equivalents	Short-term Marketable Securities (1)	Long-term Marketable Securities (2)
Level 1:							
Cash	\$ 228,809	\$ —	\$ —	\$ 228,809	\$ 228,809	\$ —	\$ —
Level 2:							
Money market instruments	205,736	—	—	205,736	205,736	—	—
Corporate debt securities	564,852	214	(2,288)	562,778	2,000	376,545	184,233
Commercial paper	77,702	—	—	77,702	21,964	55,738	—

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U.S. government agency securities	240,436	144	(697)	239,883	31,474	156,967	51,442
Foreign and other	5,126	139	(1)	5,264	3999	1,076	189
Subtotal	1,093,852	497	(2,986)	1,091,363	265,173	590,326	235,864
Total	\$1,322,661	\$ 497	\$ (2,986)	\$1,320,172	\$ 493,982	\$ 590,326	\$ 235,864

(1)The Company's short-term marketable securities mature in one year or less.

(2) The Company's long-term marketable securities mature between one and five years.

As of March 31, 2019, the Company's investments in an unrealized loss position were not significant, and since the Company has the ability and intent to hold all investments that have been in a continuous loss position until maturity or recovery, no other-than-temporary impairment was deemed to have occurred.

(6) INTANGIBLE ASSETS

Intangible assets consisted of the following:

	March 31, 2019	December 31, 2018
Intangible assets:		
Finite-lived intangible assets	\$ 309,702	\$ 307,995
Indefinite-lived intangible assets	326,359	326,359
Gross intangible assets:	636,061	634,354
Less: Accumulated amortization	(150,080)	(142,546)
Net carrying value	\$485,981	\$ 491,808

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BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (continued)

(In thousands of U.S. Dollars, except per share amounts or as otherwise disclosed)

(7) PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment, net consisted of the following:

	March 31, 2019	December 31, 2018
Building and improvements	\$ 698,231	\$ 694,447
Manufacturing and laboratory equipment	349,967	345,947
Computer hardware and software	161,063	157,787
Leasehold improvements	42,201	41,188