

TEVA PHARMACEUTICAL INDUSTRIES LTD

Form 6-K

May 11, 2005

Table of Contents

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

Report of Foreign Private Issuer

Pursuant to Rule 13a-16 or 15d-16

under the Securities Exchange Act of 1934

For the month of May 2005

Commission File Number 0-16174

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

(Translation of registrant's name into English)

5 Basel Street, P.O. Box 3190

Petach Tikva 49131 Israel

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F Form 40-F

Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also hereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes No

If is marked, indicate below the file number assigned to the registrant in connection with Rule 12g(3)-2(b): 82-

Table of Contents

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

(An Israeli Corporation)

INDEX

	Page
<u>Condensed Consolidated Statements of Income (Loss)</u>	1
<u>Condensed Consolidated Balance Sheets</u>	2
<u>Condensed Consolidated Statements of Cash Flows</u>	3
<u>Notes to Condensed Consolidated Financial Statements</u>	5
<u>Operating and Financial Review and Prospects</u>	12
<u>Quantitative and Qualitative Disclosure About Market Risk</u>	20
<u>Legal Proceedings</u>	21

Table of Contents**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

CONDENSED CONSOLIDATED STATEMENTS OF INCOME (LOSS)

(U.S. dollars in millions, except earnings (loss) per ADR)

(Unaudited)

	Three months ended	
	March 31,	
	2005	2004
Net sales	\$ 1,304.9	\$ 1,052.4
Cost of sales	701.2	572.0
Gross profit	603.7	480.4
Research and development expenses:		
Total expenses	90.8	72.0
Less - participations and grants	2.6	3.9
	88.2	68.1
Selling, general and administrative expenses	184.6	158.1
	330.9	254.2
Acquisition of research and development in process		596.6
Impairment of product rights		30.0
Operating income (loss)	330.9	(372.4)
Financial expenses - net	0.4	1.3
Income (loss) before income taxes	330.5	(373.7)
Income taxes	71.1	54.0
	259.4	(427.7)
Share in profits of associated companies - net	0.1	0.5
Minority interests in profits of subsidiaries - net	0.4	0.8
Net income (loss)	\$ 259.1	\$ (428.0)
Earnings (loss) per ADR:		
Basic	\$ 0.42	\$ (0.72)
Diluted	\$ 0.38	\$ (0.72)
Weighted average number of ADRs (in millions):		
Basic	620.4	595.8
Diluted	683.8	595.8



The accompanying notes are an integral part of the condensed financial statements.

Table of Contents**TEVA PHARMACEUTICAL INDUSTRIES LIMITED****CONDENSED CONSOLIDATED BALANCE SHEETS**

(U.S. dollars in millions)

	March 31, 2005	December 31, 2004
	Unaudited	Audited
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 701.6	\$ 784.1
Short-term investments	346.6	256.8
Accounts receivable:		
Trade	1,622.2	1,475.9
Other	365.0	398.4
Inventories	1,210.1	1,286.3
Total current assets	4,245.5	4,201.5
Investments and other assets	723.7	843.6
Property, plant and equipment, net	1,292.5	1,278.2
Intangible assets and debt issuance costs, net	714.5	736.3
Goodwill	2,539.5	2,572.4
Total assets	\$ 9,515.7	\$ 9,632.0
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Short-term credit	\$ 502.6	\$ 560.4
Accounts payable and accruals	1,684.6	1,643.5
Total current liabilities	2,187.2	2,203.9
Long-term liabilities:		
Deferred income taxes	204.9	212.3
Employee related obligations	91.1	87.6
Loans and other liabilities	211.3	215.0
Convertible Senior Debentures	1,513.4	1,513.4
Total long-term liabilities	2,020.7	2,028.3
Total liabilities	4,207.9	4,232.2
Minority interests	10.0	10.9
Shareholders equity:		
Ordinary shares of NIS 0.10 par value: March 31, 2005 and December 31, 2004: authorized - 999.6 million; issued and outstanding - 629.6 million and 626.8 million, respectively	42.2	42.1
Additional paid-in capital	3,068.6	3,035.0
Deferred compensation	*	*
Retained earnings	2,387.8	2,171.4
Accumulated other comprehensive income	287.9	377.8

Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

Cost of company shares held by subsidiaries - March 31, 2005 and December 31, 2004 - 24.2 million ordinary shares and 15.4 million ordinary shares, respectively	(488.7)	(237.4)
Total shareholders' equity	5,297.8	5,388.9
Total liabilities and shareholders' equity	\$ 9,515.7	\$ 9,632.0

* Represents an amount of less than \$ 0.1 million.

The accompanying notes are an integral part of the condensed financial statements.

Table of Contents**TEVA PHARMACEUTICAL INDUSTRIES LIMITED****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(U.S. dollars in millions)

(Unaudited)

	Three months ended	
	March 31,	
	2005	2004
Cash flows from operating activities:		
Net Income (loss)	\$ 259.1	\$ (428.0)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Income and expenses not involving cash flows*	49.8	653.5
Changes in certain assets and liabilities*	(6.2)	(1.8)
Net cash provided by operating activities	302.7	223.7
Cash flows from investing activities:		
Purchase of property, plant and equipment	(77.3)	(64.1)
Acquisition of subsidiary		(1,851.2)
Acquisition of intangible assets	(7.0)	(4.6)
Proceeds from sale of property, plant and equipment	0.6	0.9
Acquisition of long-term investments and other assets	(51.7)	(44.0)
Proceeds from sale of long term investments	119.2	101.8
Purchase of minority interest	(2.9)	
Net decrease (increase) in short-term investments	(45.2)	205.6
Net cash used in investing activities	(64.3)	(1,655.6)
Cash flows from financing activities:		
Proceeds from exercise of options by employees	26.7	21.2
Cost of acquisition of Company shares, net of proceeds from sale	(251.3)	0.9
Proceeds from issuance of Convertible Senior Debentures, net of issuance costs		1,076.1
Long-term loans received	0.2	5.7
Discharge of long-term loans and other long-term liabilities	(2.0)	(1.1)
Net increase (decrease) in short-term credit	(40.6)	14.1
Dividends paid	(42.7)	(29.8)
Net cash provided by (used in) financing activities	(309.7)	1,087.1
Translation differences on cash balances of certain subsidiaries	(11.2)	(2.5)
Net decrease in cash and cash equivalents	(82.5)	(347.3)
Balance of cash and cash equivalents at beginning of period	784.1	1,057.3
Balance of cash and cash equivalents at end of period	\$ 701.6	\$ 710.0

Supplemental disclosure of non-cash investing and financing activities:

On January 22, 2004, the Company completed the acquisition of Sicor Inc., for a total consideration of \$ 3.46 billion. Teva shares, stock options and warrants with an aggregate value of \$ 1.4 billion were issued as part of the consideration for the acquisition.

* See details on page 4

The accompanying notes are an integral part of the condensed financial statements.

Table of Contents**TEVA PHARMACEUTICAL INDUSTRIES LIMITED****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(U.S. dollars in millions)

(Unaudited)

	Three months ended	
	March 31,	
	2005	2004
Adjustments to reconcile net income to net cash provided by operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	\$ 55.5	\$ 46.7
Deferred income taxes - net	(8.4)	(26.1)
Increase in employee related obligations	2.4	3.8
Capital gains - net	(0.6)	(0.6)
Share in profits of associated companies - net	(0.1)	(0.5)
Minority interests in profits of subsidiaries - net	0.4	0.8
Acquisition of research and development in process		596.6
Impairment of product rights		30.0
Other items - net	0.6	2.8
	<u>\$ 49.8</u>	<u>\$ 653.5</u>
Changes in certain assets and liabilities:		
Increase in accounts receivables	(154.5)	(41.4)
Decrease (increase) in inventories	48.0	(132.3)
Increase in accounts payable and accruals	100.3	171.9
	<u>\$ (6.2)</u>	<u>\$ (1.8)</u>

The accompanying notes are an integral part of the condensed financial statements.

Table of Contents

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. dollars in millions)

(Unaudited)

NOTE 1 Basis of Presentation:

The accompanying unaudited condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the financial condition and results of operations of Teva Pharmaceutical Industries Limited ("Teva" or "Company"). These consolidated financial statements and notes thereto are unaudited and should be read in conjunction with the Company's audited financial statements included in the Company's report on Form 20-F for the year ended December 31, 2004, as filed with the Securities and Exchange Commission. The results of operations for the three months ended March 31, 2005 are not necessarily indicative of results that could be expected for the entire fiscal year.

NOTE 2 Earnings (loss) per American Depository Receipt (ADR):

Basic earnings (loss) per ADR are computed by dividing net income (loss) by the weighted average number of ADRs/ordinary shares (including special shares exchangeable into ordinary shares), outstanding during the period, net of Company shares held by subsidiaries.

In computing diluted earnings per ADR for the three months period ended March 31, 2005, basic earnings per ADR was adjusted to take into account the potential dilution that could occur upon: (1) the conversion of all Convertible Senior Debentures using the if-converted method, by adding to net income interest expense on these debentures and amortization of issuance costs, net of tax benefits, and by adding the weighted average number of shares issuable upon assumed conversion of all debentures; and (2) the exercise of options granted under employee stock option plans, using the treasury stock method.

In computing diluted loss per ADR for the three months period ended March 31, 2004, no account was taken of the potential dilution that could occur upon the conversion of all Convertible Senior Debentures, and the exercise of options granted under employee stock options plans, since such debentures and options have an antidilutive effect on the loss per ADR.

NOTE 3 Stock based compensation:

The Company accounts for its employee stock option plans using the intrinsic value based method of accounting prescribed by APB 25 and related interpretations. The following table illustrates the effect on net income (loss) and earning (loss) per ADR, assuming the Company had applied the fair value recognition provisions of FAS 123 (as amended by FAS 148) to its stock-based employee compensation:

	Three Months Ended	
	March 31,	
	2005	2004
	In millions, except earnings per ADR	
Net income (loss), as reported	\$ 259.1	\$ (428.0)
Add: amortization of deferred compensation related to employee stock option plans, included in condensed consolidated statements of income (loss), net of related tax effect	*	*
Deduct: amortization of deferred compensation, at fair value, net of related tax effect	10.9	11.4
Pro forma net income (loss)	\$ 248.2	\$ (439.4)
Earnings (loss) per ADR		
Basic - as reported	\$ 0.42	\$ (0.72)
Basic - pro forma	\$ 0.40	\$ (0.74)
Diluted - as reported	\$ 0.38	\$ (0.72)
Diluted - pro forma	\$ 0.37	\$ (0.74)

* Represents an amount of less than \$ 0.1 million

Table of Contents**TEVA PHARMACEUTICAL INDUSTRIES LIMITED****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

(U.S. dollars in millions)

(Unaudited)

In December 2004, the FASB issued FAS 123R, *Share-Based Payment*, which addresses the accounting for share-based payment transactions in which the Company obtains employee services in exchange for (a) equity instruments of the Company or (b) liabilities that are based on the fair value of the Company's equity instruments or that may be settled by the issuance of such equity instruments. This Statement requires that employee equity awards be accounted for using the grant-date fair value based method.

As applicable to Teva, the Statement was to be effective in the third quarter of 2005. On April 15, 2005, the Securities and Exchange Commission approved a new rule, under which FAS 123R is effective for public companies at the beginning of their next fiscal year that begins after June 15, 2005, and in the case of Teva, the first quarter of 2006.

The Company expects that the effect of applying this statement on the Company's results of operations in 2006 as it relates to existing option plans would not be materially different from the FAS 123 pro forma effect previously reported.

NOTE 4 Inventories:

Inventories consisted of the following:

	March 31,	December 31,
	2005	2004
	Unaudited	Audited
Raw and packaging materials	\$ 297.9	\$ 326.3
Products in process	170.9	169.1
Finished products	576.7	619.6
Purchased products	125.0	133.4
	1,170.5	1,248.4
Materials in transit and payments on account	39.6	37.9
	\$ 1,210.1	\$ 1,286.3

NOTE 5 Revenue recognition:

Revenue is recognized when title and risk of loss for the products is transferred to the customer. Provisions for estimated chargebacks, returns, customer volume rebates, discounts, shelf stock adjustments and other allowances are established concurrently with the recognition of revenue, and are deducted from net sales. The reserve balances related to these provisions are included under Accounts payable and accruals.

NOTE 6 Accounts payable and accruals:

	March 31,	December 31,
	2005	2004
	Unaudited	Audited
Sales reserves and allowances	\$ 654.5	\$ 590.9

NOTE 7 Comprehensive income (loss):

Comprehensive income (loss) for the Company is as follows:

	Three Months Ended	
	March 31,	
	2005	2004
Net income (loss)	\$ 259.1	\$ (428.0)
Other comprehensive income (loss), net of tax:		
Unrealized gain (loss) from available-for-sale securities-net	(6.0)	22.3
Minimum liability with respect to defined benefit plans	(1.6)	
Translation of non-dollar-currency financial statements of subsidiaries and associated companies	(82.3)	(0.6)
	\$ 169.2	\$ (406.3)

Table of Contents**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. dollars in millions)

(Unaudited)

NOTE 8 Certain details relating to defined benefit plans:

- a. The consolidated components of net periodic benefit costs are as follows:

	Three Months Ended March 31,	
	2005	2004
Service cost	\$ 1.2	\$ 1.3
Interest cost	1.2	1.1
Expected return on plan assets	(1.1)	(0.8)
Recognized net actuarial loss	0.3	0.3
Prior service cost	(0.1)	(0.1)
Employers' pension cost	<u>\$ 1.5</u>	<u>\$ 1.8</u>

- b. Teva has made contributions of \$ 9.7 million in the three months ended March 31, 2005 to its pension plans, and presently anticipates contributing an additional \$ 28.7 million in 2005, for a total of \$ 38.4 million.

NOTE 9 Financial information by business segment:

- a. Financial data relating to reportable operating segments:

	<u>Pharmaceutical</u>	<u>API*</u>	<u>Other</u>	<u>Total</u>
Three month period ended March 31, 2005:				
Net sales:				
To unaffiliated customers	\$ 1,181.7	\$ 118.0	\$ 5.2	\$ 1,304.9
Intersegment		136.3	0.6	136.9
Total net sales	<u>\$ 1,181.7</u>	<u>\$ 254.3</u>	<u>\$ 5.8</u>	<u>\$ 1,441.8</u>
Operating income	\$ 263.8	\$ 101.1	\$ 0.2	\$ 365.1

Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

Assets (at end of period)	\$ 3,983.8	\$ 910.6	\$ 32.5	\$ 4,926.9
Goodwill (at end of period)	\$ 2,080.2	\$ 459.3	\$	\$ 2,539.5
Depreciation and amortization	\$ 42.7	\$ 11.5	\$ 0.2	\$ 54.4
Three month period ended March 31, 2004:				
Net sales:				
To unaffiliated customers	\$ 928.3	\$ 119.0	\$ 5.1	\$ 1,052.4
Intersegment		85.8	0.6	86.4
Total net sales	\$ 928.3	\$ 204.8	\$ 5.7	\$ 1,138.8
Operating income (loss)**	\$ (417.9)	\$ 72.4	\$ 0.4	\$ (345.1)

* Active Pharmaceutical Ingredients

** Operating income for the three months ended March 31, 2004 of the pharmaceutical segment, included an amount of \$596.6 million acquisition of research and development in process and impairment expenses in the amount of \$30 million.

Table of Contents**TEVA PHARMACEUTICAL INDUSTRIES LIMITED**

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. dollars in millions)

(Unaudited)

Following is a reconciliation of operating income and assets of the reportable segments to the data included in the condensed consolidated financial statements:

	Three Months Ended	
	March 31,	
	2005	2004
	<u> </u>	<u> </u>
Total operating income (loss) of reportable Segments	\$ 364.9	\$ (345.5)
Other	0.2	0.4
Amounts not allocated to segments:		
Profits not yet realized	(16.5)	(13.5)
General and administration expenses	(17.1)	(12.2)
Other expenses	(0.6)	(1.6)
Financial expenses - net	(0.4)	(1.3)
	<u> </u>	<u> </u>
Consolidated income (loss) before income taxes	\$ 330.5	\$ (373.7)
	<u> </u>	<u> </u>

	March 31,
	2005
	<u> </u>
Assets (at end of period):	
Total assets of reportable segments	\$ 4,894.4
Total goodwill of reportable segments	2,539.5
Other assets	32.5
Elimination of intersegment balances	(23.6)
Elimination of unrealized income	(122.8)
Assets not allocated to segments:	
Current assets	1,413.2
Investments and other assets	723.7
Property, plant and equipment, net	38.7
Debt issuance costs	20.1
	<u> </u>
Consolidated assets (at end of period)	\$ 9,515.7
	<u> </u>

NOTE 10 Commitments and contingencies:

In addition to the matters set out below reference should be made to Note 8(b) - Contingent Liabilities - as detailed in the consolidated financial statements included in Teva's Annual Report on Form 20-F for the year ended December 31, 2004.

Teva and its subsidiaries are from time to time subject to claims arising in the ordinary course of their business, including product liability claims. In addition, as described below, as a result of patent challenge procedures under applicable law, Teva is frequently subject to patent litigation. Teva believes it has meritorious defenses to the actions to which it has been made a party and expects to pursue vigorously the defense of each of the ongoing actions described below. Based upon the status of these cases, the advice of counsel, management's assessment of such cases and potential exposure involved relative to insurance coverage, except as otherwise noted below, no provision has been made in Teva's accounts for any of the matters described below. Teva believes that none of the proceedings described below will have a material adverse effect on its financial condition; however, if one or more of such proceedings were to result in judgments against Teva, such judgments could be material to its results of operations in a given period.

Table of Contents

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. dollars in millions)

(Unaudited)

Teva from time to time seeks to develop generic products for sale prior to patent expiration in various territories. In the United States, to obtain generic approval for a product prior to the expiration of the originator's patent or patents, Teva must challenge the patent or patents under the procedures set forth in the Hatch-Waxman Act of 1984, as amended by the Medicare Prescription Drug Improvement and Modernization Act of 2003. To the extent that it seeks to utilize such patent challenge procedures, Teva is involved and expects to be involved in patent litigation regarding the validity, enforceability or infringement of the originator's patent. Teva may also be involved in patent litigation involving the extent to which alternate manufacturing process techniques may infringe originator or third party process patents. Additionally, depending upon a complex analysis of a variety of legal and commercial factors, Teva may, in certain circumstances, elect to market a generic product even though litigation is still pending. This could be before any court decision is rendered or while an appeal of a lower court decision is pending. To the extent Teva elects to proceed in this manner, it could face substantial liability for patent infringement if the final court decision is adverse to Teva. Although the underlying generic industry legislation is different in Canada, Europe and Israel, from time to time Teva is also involved in similar patent litigation regarding corresponding patents in these jurisdictions. Except as described below, Teva does not have a reasonable basis to estimate the loss, or range of loss, that is reasonably possible with respect to such patent infringement cases. However, if Teva were to be required to pay damages in any such case, courts would generally calculate the amount of any such damages based on a reasonable royalty or lost profits of the patentee. If damages were determined based on lost profits, the amount of the damages would be related to the sales of the patentee's product.

Teva's business inherently exposes it to potential product liability claims. Teva believes that it maintains product liability insurance coverage in amounts and with provisions that are reasonable and prudent in light of its business and related risks. However, Teva sells, and will continue to sell, pharmaceutical products that are not covered by insurance and accordingly may be subject to claims that are not covered by insurance as well as claims that exceed its policy limits. In addition, product liability coverage for pharmaceutical companies is becoming more expensive and increasingly difficult to obtain. As a result, Teva may not be able to obtain the type and amount of coverage it desires.

Product Liability Matters

Teva USA is a manufacturer of Adipex-P brand phentermine hydrochloride, and has been sued in both class actions and individual lawsuits relating to the alleged negative health effect of phentermine and fenfluramine. While neither drug had been indicated or approved for combination use by the FDA, physicians sometimes prescribed the two together in a combination treatment for weight control known as fen-phen. Plaintiffs have filed lawsuits from August 1997 to the present in a variety of state and federal jurisdictions seeking monetary damages in unspecified amounts. The federal actions have been consolidated for pretrial purposes in the United States District Court for the Eastern District of Pennsylvania in a multidistrict litigation proceeding.

On April 5, 2001, a claim was filed against Teva in the Tel Aviv District Court with respect to the use of a pharmaceutical product known as Chorigon Ampoules 5000 Units. The plaintiffs claim that they were administered with allegedly defective ampoules of the product during the course of an in vitro fertilization treatment, resulting in the failure of the treatment and causing financial damages and mental anguish. The plaintiffs have filed a petition to certify the claim as a class action, which has not yet been decided.

Intellectual Property Proceedings

On September 14, 2001, Purdue Pharma L.P. filed an action in the U.S. District Court for the Southern District of New York, alleging that the filing of Teva USA's ANDA for 80 mg oxycodone hydrochloride extended-release tablets infringed three patents for OxyContin®. Subsequently on April 3, 2003, Purdue sued Teva USA on its 10, 20 and 40 mg tablet products. On January 5, 2004, those three patents were held unenforceable in a related case, Purdue Pharma L.P. v. Endo Pharmaceuticals Inc., pending before the same judge as in Teva USA's case. Purdue has appealed that decision and oral argument was heard on November 3, 2004 before the Federal Circuit. On June 25, 2004, Teva USA's motion for summary judgment was granted on the ground that collateral estoppel applied to the inequitable conduct finding in the Endo case. On March 31, 2004, Teva USA commenced sales of its 80 mg tablets based upon the court's decision in the Endo case. The 2003 annual sales of the branded product in the U.S. were estimated to be approximately \$707 million. Were Purdue to be successful on its appeal and if Teva USA does not receive a favorable decision in its own case, Teva USA could ultimately be required to pay damages related to the sales of 80 mg oxycodone hydrochloride extended-release tablets and be enjoined from selling this product.

In August 2002, GlaxoSmithKline filed a complaint against Teva USA in the Pennsylvania Court of Common Pleas. The complaint alleges that Teva USA's amoxiclav products are derived from a strain of streptomyces clavuligerus stolen from GlaxoSmithKline. On April 11, 2005, the parties entered into a settlement agreement whereby GSK will dismiss all claims against Teva with prejudice.

Table of Contents

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. dollars in millions)

(Unaudited)

On September 12, 2002, Teva obtained summary judgment from the U.S. District Court for the Northern District of Illinois regarding a U.S. patent on a combination of hydrocodone bitartrate and ibuprofen. The District Court ruled that the U.S. patent was invalid as obvious. Subsequently, on May 19, 2004, the Court of Appeals for the Federal Circuit reversed, mainly on procedural grounds, the District Court's ruling, remanding the case for further proceedings on the issues of infringement, validity and unenforceability. Trial has been scheduled for November 14, 2005. The patent expired on December 18, 2004. The patent was asserted by Knoll Pharmaceutical Company, now a subsidiary of Abbott Laboratories, which markets the combination as Vicoprofen®. Teva had launched its product, hydrocodone bitartrate and ibuprofen tablets, 7.5mg/200mg, in April 2003. Annual sales in 2002 of the branded product in the U.S. were estimated to be approximately \$108 million. Were Knoll ultimately to be successful on its allegation of patent infringement, Teva USA could be required to pay damages.

In September 2002, Sicor launched an idarubicin hydrochloride injection product. On July 8, 2004, Pharmacia filed a complaint in the U.S. District Court for the District of Delaware against Sicor, alleging that its idarubicin hydrochloride injection product infringes a Pharmacia formulation patent. Trial is scheduled for June 12, 2006. Annual sales of the branded product in the U.S. prior to Sicor's launch were estimated to be \$40 million. Were Pharmacia ultimately to be successful on its allegation of patent infringement, Sicor could be required to pay damages and be enjoined from selling that product.

In May 2003, Teva USA commenced sales of its 7.5 mg and 15 mg moexipril hydrochloride tablets. Teva USA had previously obtained summary judgment of non-infringement as to the one patent at issue, but that decision was later vacated on appeal. Following the filing of Schwarz Pharma's motion for a preliminary injunction, on September 12, 2004, Teva entered into an agreement with Schwarz whereby Teva agreed to suspend all manufacturing and selling of its moexipril hydrochloride tablets pending the outcome of litigation between the two companies in the District Court or a court order. On January 4, 2005, the District Court granted Schwarz Pharma's motion for summary judgment of infringement and also held that the patent was valid and enforceable in light of the trial decision in the related case involving Teva's ANDA for quinapril hydrochloride tablets, Warner-Lambert Company v. Teva Pharmaceuticals USA. On March 31, 2005, the Court granted Teva's motion to stay further proceedings pending Teva's appeal to the U.S. Court of Appeals for the Federal Circuit in Teva's related quinapril hydrochloride case. Teva's appeal was argued on April 8, 2005. Were Schwarz Pharma ultimately to be successful on its allegation of patent infringement, Teva USA could be required to pay damages. An appropriate provision for this matter has been included in the accounts.

In September and November 2004, Teva USA commenced sales of Impax Laboratories' 20 and 10 mg omeprazole delayed release capsules, respectively, which are the AB-rated generic equivalent of Prilosec®, marketed by AstraZeneca. Prilosec® had sales for the 10 mg capsule of \$30 million and 20 mg capsule sales of approximately \$532 million for the twelve months ended June 2004. In addition to Teva, there are several other generic manufacturers currently selling the generic version of this product in the United States. As provided for in a strategic alliance agreement between Impax and Teva, the parties agreed to certain risk-sharing arrangements relating to the omeprazole launch. AstraZeneca previously commenced a patent infringement litigation against Impax relating to its omeprazole capsules and also sued Teva following its launch of the omeprazole capsules. Were AstraZeneca ultimately to be successful on its allegation of patent infringement, Teva could be required to pay damages related to a portion of the sales of Impax's omeprazole capsules and be enjoined from selling that product.

In October 2004, Alpharma and Teva launched their 100 mg, 300 mg and 400 mg gabapentin capsule products and, in December 2004, Alpharma and Teva launched their 600 mg and 800 mg gabapentin tablet products. Gabapentin capsules and tablets are the AB-rated generic version of Pfizer's anticonvulsant Neurontin® capsules and tablets, which had annual sales of approximately \$2.7 billion for the twelve months

Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

ended September 2004. On October 13, 2004, the District Court denied Pfizer's motion for a preliminary injunction against Alpharma, holding that Pfizer failed to meet its burden to prove both a likelihood of success on the merits and irreparable harm. No trial has been scheduled. Were Pfizer ultimately to be successful on its allegation of patent infringement, Teva USA could be required to pay damages and be enjoined from selling that product. Pfizer's launch of generic versions of Neurontin[®] through its Greenstone affiliate and its promotion of the product prior to generic entry, among other factors, may be relevant to the damages estimation. Pursuant to the terms of the agreement with Alpharma, were Pfizer to be successful on its allegation of patent infringement against Alpharma, Teva USA may also be required to pay damages related to a portion of the sales of Alpharma's gabapentin products.

Table of Contents

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. dollars in millions)

(Unaudited)

Commercial Matters

On April 21, 2004, Rhodes Technologies and Napp Technologies (Rhodes/Napp) filed a complaint in Massachusetts Superior Court, seeking an equal share of the value to Teva of the settlement of certain claims between GlaxoSmithKline and Teva relating to Teva's nabumetone products. The allegations are based upon the termination of a nabumetone API supply agreement between Teva and Rhodes/Napp. Teva originally assessed the value of the product rights received in connection with the settlement at \$100 million and subsequently revised the value to \$70 million based on certain impairment factors not related to this action.

Environmental Matters

In May 2004, the Israeli Ministry of the Environment imposed additional conditions on business licenses of certain manufacturing plants operated in Ramat Hovav, Israel, including Teva's API plant. These additional conditions, some of which were effective immediately and some of which will take effect commencing June 2006, deal primarily with the treatment and quality of waste discharged. Teva and other companies that operate chemical and pharmaceutical plants in Ramat Hovav have appealed to the relevant court against the imposition of such additional conditions. On March 3, 2005, the parties agreed to transfer the matter to mediation. In the event that the mediation process does not succeed and such additional conditions are not revoked by the court, Teva may have to incur additional costs or capital expenditures in order to comply with the additional conditions and/or find alternative production sites or third-party sources for certain API chemicals produced at the plant.

Competition, Pricing and Regulatory Matters

Teva USA is a defendant, along with Biovail Corp. and Elan Corporation, plc, in several civil actions currently pending in the federal district court in the District of Columbia. The cases allege generally that arrangements between Biovail and Elan relating to sales of nifedipine cc extended release tablets, in connection with which Teva USA acted as a distributor for Biovail, were unlawful under the federal antitrust laws. The challenged arrangements were previously the subject of a consent decree entered into by the U.S. Federal Trade Commission with Biovail and Elan, to which Teva USA was not a party. The cases seek unspecified monetary damages, attorneys' fees and costs. Four of the cases were brought on behalf of alleged classes of persons who allegedly purchased nifedipine cc extended release tablets made by Elan or Biovail in the United States directly from Teva USA; two of the cases were brought individually by alleged direct purchasers. Teva and Teva USA are also defendants, along with Biovail and Elan in a case pending in state court in San Joaquin County, California that was brought on behalf of an alleged class of persons that indirectly purchased nifedipine cc extended release tablets made by Elan or Biovail and sold in the United States by Teva USA.

On February 25, 2003, two motions requesting permission to institute a class action were filed in the Superior Court for the Province of Quebec against all major Canadian generic drug manufacturers, including Novopharm. The claims seek to proceed with a class action for damages based

Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

on alleged marketing practices of generic drug manufacturers in the Province of Quebec. In Quebec, a class action cannot be instituted without court approval, and Novopharm intends to contest the authorization of both as class actions. An authorization hearing is anticipated sometime after the second quarter of 2005.

Sicor is a defendant in several putative private class action complaints on behalf of Medicare and Medicaid patients nationwide who received oncology drugs as well as several actions filed by state attorneys general and one by the federal government alleging that the respective patients and the state and federal health care programs paid fraudulently inflated Average Wholesale Prices for their medicines. The litigation has been largely consolidated in federal court in Boston. Sicor is one of many defendants in each of these cases including many of the largest generic and brand name drug manufacturers alleging the same claims of fraud. In early 2004, the court dismissed all but one count in the consolidated class action complaint and discovery ensued for all parties. Sicor continues to pursue its defenses vigorously. Teva USA has also been named in some related matters, which are still at a preliminary stage. An appropriate provision for certain of these matters has been included in the accounts.

NOTE 11 Impairment of Purinethol® product rights:

During the first quarter of 2004, a generic competition to the Purinethol® product that was received from GlaxoSmithKline in June 2003 entered the market. In accordance with FAS 144, Accounting for impairment or disposal of long lived assets, an analysis for potential impairment was performed by the Company, resulting in an impairment charge of \$30 million.

Table of Contents

OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The following discussion and analysis should be read in conjunction with the consolidated financial statements, the related notes to the consolidated financial statements and the Operating and Financial Review and Prospects included in Teva's Annual Report on Form 20-F for the fiscal year ended December 31, 2004 and the unaudited interim condensed consolidated financial statements contained in this Report on Form 6-K and the related notes to such unaudited interim condensed consolidated financial statements.

Except for historical information contained in this report, the matters discussed below contain forward-looking statements which express the beliefs and expectations of management. Such statements are based on management's current beliefs and expectations and involve a number of known and unknown risks and uncertainties that could cause our future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include our ability to successfully develop and commercialize additional pharmaceutical products, the introduction of competing generic products, the impact of competition from brand-name companies that sell or license their own brand products under generic trade dress and at generic prices (so-called "authorized generics") or seek to delay the introduction of generic products, regulatory changes that may prevent us from exploiting exclusivity periods, potential liability for sales of generic products prior to a final court decision, including that relating to the generic version of Neurontin®, the effects of competition on Copaxone® sales, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry, the difficulty of predicting U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and other regulatory authority approvals, the regulatory environment and changes in the health policies and structures of various countries, our ability to successfully identify, consummate and integrate acquisitions, our potential exposure to product liability claims, our dependence on patent and other protections for innovative products, the fact that we have significant operations outside the United States that may be adversely affected by terrorism or major hostilities, fluctuations in currency, exchange and interest rates, operating results and other factors that are discussed in our Annual Report on Form 20-F and in our other filings made with the U.S. Securities and Exchange Commission (SEC).

We undertake no obligation to publicly update any forward-looking statements or other information contained in this report, whether as a result of new information, future events or otherwise. You are advised, however, to consult any additional disclosures we make in our reports to the SEC on Form 6-K. Also note that we provide a cautionary discussion of risks and uncertainties under "Risk Factors" on page 8 of our 2004 Annual Report on Form 20-F. These are factors that we think could cause our actual results to differ materially from expected results. Other factors besides those listed could also adversely affect us. This discussion is provided as permitted by the Private Securities Litigation Reform Act of 1995.

Results of Operations

Comparison of Three Months Ended March 31, 2005 to Three Months Ended March 31, 2004

General

Teva's net sales for the first quarter of 2005 exceeded \$1.3 billion and grew by 24% over the comparable quarter. Net income for the first quarter of 2005 reached \$259 million, while in the comparable quarter, which included one-time charges of \$641 million (before tax) mainly related to purchase accounting for the Sicor acquisition, Teva recorded a loss of \$428 million. Teva believes that excluding these one-time charges from first quarter 2004 results represents a better indicator of the underlying trends in its operations. Compared to the first quarter of 2004 adjusted for certain one-time items as described below, net income in the first quarter of 2005 increased by 26%.

The main factors affecting the quarter were:

Sales growth both in the U.S. and Europe was driven by new products that were not sold in the comparable quarter of 2004 and by increased Copaxone[®] sales. The quarter over quarter sales growth was achieved with only a minimal contribution from new products launched in the U.S. during the first quarter of 2005.

Global in-market sales of Copaxone[®] grew by 23% and in the United States Copaxone[®] became the prescription MS market leader in March 2005 for both total and new prescriptions.

Table of Contents

Non-U.S. currencies strengthened quarter over quarter relative to the U.S. Dollar, which accounted for approximately 10% of the increase in net sales in U.S. Dollar terms.

Sales of Sicor's injectable products were included for the entire first quarter of 2005, as compared to the ten-week period in the first quarter of 2004, following its acquisition in January 2004. Sicor's January 2004 sales prior to the acquisition were approximately \$16 million.

The Gross Profit Margin declined slightly from the 2004 adjusted figures, reflecting changes in product mix and the geographic distribution of sales. In particular, the growth in generic sales in Europe exceeded the growth in generic sales in the U.S., and margins in Europe, on average, are lower than margins in the U.S.

The Operating Income Margin was 25.4% and the Net Income Margin was 19.9% in the first quarter of 2005.

One-time Items included in the Comparable Quarter

Teva recorded one-time charges aggregating \$641 million (before taxes) during the first quarter of 2004, principally from an in-process R&D write off recorded in connection with the Sicor acquisition. As a result of these one-time charges, Teva reported a loss for the first quarter of 2004 of \$428 million. Without these various one-time charges, Teva's adjusted net income would have been \$205 million.

The one-time items consisted of:

\$584 million of in process R&D write offs in connection with the Sicor acquisition;

\$13 million of in process R&D write offs relating to two collaboration agreements;

\$14 million in a one-time step up of Sicor's inventory at its acquisition date. This one-time step up was fully absorbed in the first quarter as an increase to costs of goods sold; and

\$30 million charge reflecting the partial impairment of the Purinethol® product rights that were received from GlaxoSmithKline in June 2003.

Teva believes that excluding these one-time items from its results of operations represents a better indicator of the underlying trends in its business. The results, after these exclusions are the primary results used by management and Teva's board of directors to evaluate the operational performance of the Company, to compare against the Company's work plans and budgets, and ultimately to evaluate the performance of management. Accordingly, unless otherwise indicated, the analysis that follows speaks to the adjusted numbers, i.e. those before taking into account these one-time charges. For a detailed reconciliation of net income and EPS to the adjusted numbers, see the table below entitled Reconciliation between reported Income (Loss) and Earnings (Loss) per Share to Adjusted Income and Earnings per Share. (see page 18)

Table of Contents

The following tables set forth certain financial data presented as a percentage of net sales and the percentage change, for the periods indicated.

	Percentage of Sales Three Months Ended		Period to Period Percentage Change
	March 31		
	2005	2004	
Actual (GAAP) Results			
Net Sales	100.0%	100.0%	24.0%
Gross Profit	46.3%	45.6%	25.7%
Research and Development Expenses:			
Total Expenses	7.0%	6.8%	26.1%
Less Participations & Grants	(0.2)%	(0.4)%	(33.3)%
R&D Expenses net	6.8%	6.5%	29.5%
Selling, General and Administrative Expenses	14.1%	15.0%	16.8%
Operating Income (Loss)	25.4%	(35.4)%	
Financial Expenses net	*	0.1%	(69.2)%
Income (Loss) Before Income Taxes	25.3%	(35.5)%	
Net Income (Loss)	19.9%	(40.7)%	

* represents a percentage of less than 0.1%

Adjusted Results

Gross Profit	46.3%	47.0%	22.1%
Operating Income	25.4%	25.5%	23.4%
Income Before Income Taxes	25.3%	25.4%	23.9%
Net Income	19.9%	19.5%	26.5%

Sales General

Consolidated sales for the three months ended March 31, 2005 were \$1,305 million, an increase of 24% over the comparable quarter of 2004. Sales of new products that were not sold in the comparable quarter of 2004 and increased Copaxone® sales were the major contributors to sales growth this quarter over the comparable quarter of 2004. Currency neutral growth accounted for 90% of the increase in sales.

Sales By Geographical Areas

	U.S. Dollars In Millions			2005 % of Total
	First Quarter,			
	2005	2004	% Change	
North America	788.6	666.0	18.4%	60.4%

Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

Europe	367.4	266.2	38.0%	28.2%
Rest of the World	148.9	120.2	23.9%	11.4%
Total	1,304.9	1,052.4	24.0%	100.0%

Table of Contents**Sales By Business Segments**

	U.S. Dollars In Millions			2005 % of Total
	First Quarter,		% Change	
	2005	2004		
Pharmaceuticals	1,181.7	928.3	27.3%	90.6%
A.P.I. *	118.0	119.0	(0.8)%	9.0%
Other	5.2	5.1	2.0%	0.4%
Total	1,304.9	1,052.4	24.0%	100.0%

* Third party sales only.

Pharmaceutical Sales

Teva's consolidated pharmaceutical sales during the three months ended March 31, 2005 were \$1,182 million, comprising approximately 90% of Teva's total revenue and representing an increase of 27% over the first quarter of 2004. The following table shows the geographic breakdown of these sales:

Pharmaceutical Sales

	U.S. Dollars In Millions			2005 % of Total
	First Quarter,		% Change	
	2005	2004		
North America	729.9	594.2	22.8%	61.8%
Europe	326.3	231.4	41.0%	27.6%
Rest of the World *	125.5	102.7	22.2%	10.6%
Total	1,181.7	928.3	27.3%	100.0%

* A majority of which are sales in Israel.

North America

Pharmaceutical sales in North America for the three months ended March 31, 2005 reached \$730 million, an increase of 23% over the comparable quarter of 2004. This increase was primarily attributable to the sale of new products that were not sold in the comparable quarter,

Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

including Gabapentin, Quinapril and Oxycodone, which was launched in the final days of the comparable quarter, as well as increased sales of Copaxone®. The 29 generic products that were not sold in the comparable quarter included Adenosine, Amox Clav (Chewable Tabs), Amox Clav Pos ES, Bisoprolol, Bupropion SR, Cefuroxime Axetil, Carboplatin, Ciprofloxacin, Cilostazol, Ethinyl Estradiol/Norgestimate (Ortho Tri-Cyclen®), Ethinyl Estradiol/Norgestimate (Ortho Cyclen®), Flumazenil, Fluconazole (Inj), Fluconazole (Tabs), Fludarabine Phosphate, Gabapentin (Tabs), Gabapentin (Caps), Glyburide/Metformin, Medroxyprogesterone (Inj Syringe), Medroxyprogesterone (Inj SDV), Mesalamine Rectal, Methylprednisolone, Metformin ER, Omeprazole, Oxycodone, Quinapril, Ribavirin, Sotalol AF and Terbutaline.

At the end of the first quarter of 2005, Teva was enjoined from further sales of the Quinapril product it had been distributing in the U.S. under an agreement with Ranbaxy Laboratories, pursuant to a preliminary injunction that is currently on appeal. Subsequent to the end of the first quarter of 2005, Teva began to encounter competition for Gabapentin, and expects more competition as the exclusivity periods for the tablets and capsules expire during the second quarter. In addition, based upon an announced recently granted ANDA, Teva may begin to experience competition for Propofol. All three of these products were significant contributors to sales in the first quarter of 2005.

Table of Contents

The following is a listing of the ANDA approvals Teva received from the U.S. FDA during the first quarter of 2005 and through May 5, 2005:

Generic Product Name	Approval Date	Innovator Product Brand Name
Fluconazole	01/05	Diflucan®
Levofloxacin (750 mg)	01/05	Levaquin®
Methylprednisolone	02/05	Depo-Medrol®
Amox Clav (chewable and suspension versions)	02/05	Augmentin®
Glyburide/Metformine	02/05	Glucovance®
Octreotide (inj MDV)*	03/05	Sandostatin®
Octreotide (inj SDV)*	03/05	Sandostatin®
Topiramate*	03/05	Topamax®
Olanzapine*	03/05	Zyprexa®
Amlodipine Besylate*	03/05	Norvasc®
Levofloxacin (bags)*	03/05	Levaquin®
Levofloxacin (vials)*	03/05	Levaquin®
Metformin ER (750mg)	04/05	Glucoophage® XR
Clozapine tablets (25 and 100mg)	04/05	Clozaril®

* Tentative approvals

As of May 5, 2005, 140 product applications were awaiting final FDA approval. Collectively, the brand products covered by these 140 applications have annual U.S. sales of approximately \$84 billion. Teva believes it is first to file on 34 of these applications relating to products whose annual U.S. branded sales are over \$23 billion.

Although there are relatively fewer generic product launches throughout the industry anticipated for 2005 than was the case in previous years, Teva's industry leading ANDA pipeline should give rise to significantly greater opportunities for generic product launches in the U.S. market, both in terms of numbers of products and in terms of the size of several of such products, in 2006 and 2007.

In Canada, Novopharm continued to experience improved sales and an increased share of the generic market, with results driven most notably by sales of Gabapentin, Pravastatin, and Fosinopril.

Europe

Teva's pharmaceutical sales in Europe were \$326 million in the quarter ended March 31, 2005, an increase of approximately 41% over the first quarter of 2004. This growth rate in sales was substantially larger than that experienced this quarter in the U.S. In Europe we recorded growth in most of the major markets in which we operate. Teva's European generic sales growth during the first quarter of 2005 was driven by the successful launch of Alendronate in the UK, and by the continued strong sales of Gabapentin in the UK and Italy, Amox Clav in Hungary and France, and Simvastatin in the UK. These are all strategic products, which demonstrate the quality and depth of the generic pipeline, which Teva has been developing in Europe.

Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

Approximately 10% of the quarter over quarter European sales growth reflected the first time contribution of Dorom, the Italian company we acquired from Pfizer at the end of 2004. The integration of Dorom has been completed, making Teva the leading generic company in Italy. We also established four new European subsidiaries in 2004, in Sweden, Portugal, Spain and Slovakia. While these operations represent somewhat of a burden on operating profit, three of them have already contributed modestly to first quarter 2005 sales, while the fourth is expected to begin generating revenue later this year. The continued penetration of Copaxone® in Europe and the Euro revaluation of approximately 5% relative to the U.S. dollar and other European currency appreciation at various rates against the U.S. dollar on a quarterly average base comparison were the other contributors to Europe's sales increase.

Rest of the World

Israeli pharmaceutical sales, which account for the major portion of Teva's Rest of the World sales, accounted for 6% of consolidated pharmaceutical sales this quarter, totaling \$76 million, an increase of 13% compared to the first quarter of 2004. As the revaluation (on a quarterly average base comparison) of the New Israeli Shekel (NIS) relative to the U.S. dollar was only 2%, Israeli pharmaceutical sales in NIS terms were significantly higher compared to the first quarter of 2004 mainly due to strong seasonally related demand for certain medications and hospital supplies.

Table of Contents

Pharmaceutical sales in Teva's other international markets, including those in Latin America, Asia, CIS, and Africa, increased by 36% from the comparable quarter. Teva believes that there are large markets and multiple opportunities to leverage its global core competencies, and it is therefore continuing to increase its activities in these parts of the world in order to capture these opportunities.

Innovative Products

During the first quarter of 2005, global in-market sales of Copaxone[®], Teva's leading drug, totaled \$256 million, an increase of 23% over the comparable quarter of 2004. This growth was driven by increased sales both in Europe and in the United States. The United States accounted for 64% of global Copaxone[®] sales in the first quarter of 2005, compared with 67% in the comparable quarter of 2004. U.S. in-market sales increased 18% to \$163 million, and non U.S. in-market sales increased 34% to \$93 million. The global in-market sales increase represents the highest rate of growth in the global MS market. According to IMS data, in March 2005, Copaxone[®] was the leading MS therapy in the US, in terms of both new and total prescriptions. Furthermore, Copaxone[®] continues to lead the other MS therapies in opportunity share, defined as new to therapy patients and net switch patients. Quarter over quarter, Copaxone[®] opportunity share increased from 31.2% to 37%. U.S. sales also benefited from two price increases during early and late 2004.

The events surrounding the withdrawal of Tysabri[®] from the market during the first quarter of 2005 clearly brought the issue of safety to the foreground. Teva has been carefully monitoring Copaxone[®] since well-before its launch, and has compiled over 340,000 patient years of safety data.

In terms of efficacy, Teva remains committed to extending its most recent follow up study (based on the original pivotal study of Copaxone[®]) to 15 years. One of the most important aspects this data reveals is that Copaxone[®] shows meaningful, and consistently positive, results in those measures of MS that correlate with short and long-term efficacy.

Teva launched its second innovative drug, Agilect[®]/Azilec[®], for the treatment of Parkinson's disease, in the Israeli market in March. Launch preparations are underway in Europe, and we expect to begin introducing the product in some of the larger Parkinson's markets such as the UK and Germany, from mid-year onwards.

In the US, Teva has been working closely with the FDA since we received an approvable letter for Agilect[®] last summer. Initially, the FDA had set a deadline of May 4, 2005 to review Teva's response. However, Teva recently submitted additional clarifying information due to a technical error which occurred in an earlier submission to the FDA. As a result, on May 3, 2005, the FDA advised Teva that it would continue with its review for a period of up to three months.

Sales of Active Pharmaceutical Ingredients (API)

API sales, including internal sales to Teva's pharmaceutical businesses, reached \$254 million, an increase of 24% over the first quarter of 2004. API sales to third parties were similar to those of the first quarter of 2004 and reached \$118 million. Although third party sales were practically flat in the first quarter of 2005, impacted by the limited number of new finished dose product launches in the U.S. market as a whole, we increased sales of API for our vertically integrated generic products. This is the second consecutive quarter in which internal sales exceeded sales to third parties.

Of the 200 products that the API Division is currently offering to the market, about one third are API for finished products that have not yet been launched. Almost half of these are expected to be launched by 2007.

Gross Profit

Gross profit margin was 46.3% in the first quarter of 2005 compared with an adjusted gross profit margin of 47.0% for the first quarter of 2004 (excluding the one-time inventory step-up that increased such quarter's cost of goods). The gross profit margin varies from quarter to quarter due to changes in the product and geographic mix including varying sales volumes under certain cooperation agreements. Relative to the annual gross margin for 2004, the slightly lower margin experienced in the first quarter of 2005 reflects mainly the relatively small number of new launches in the first quarter of 2005 and the relatively faster growth of European generics relative to U.S. generics. European generics gross margins are, on the average, lower than those in the U.S. We continue to expect gross profit margins within the range we have indicated in the past: 45-48%.

Table of Contents

Research and Development (R&D) Expenses

Gross R&D spending for the quarter grew by 26% over the comparable quarter of 2004 and reached \$91 million, reflecting an increase mainly in generic R&D activities. Net R&D (after third party participations) grew at a higher rate of 30% and reached \$88 million (6.8% of net sales), due to a lower rate of participation from our strategic partners and Israel's Chief Scientist. Teva expects its gross R&D expenses to generally increase at a level comparable to its increase in net sales.

Selling, General and Administrative (SG&A) Expenses

SG&A expenses, which represented 14.1% of net sales, amounted to \$185 million in the first quarter of 2005, as compared to 15.0% of net sales and \$158 million in the first quarter of 2004. These expenses grew at a substantially slower pace compared with net sales, continuing a trend evidenced during 2004.

Financial Expenses

Although somewhat lower than the comparable quarter, financial expenses were insignificant during the first quarter of 2005. This is in contrast with the past three sequential quarters in which a substantial financial income was recorded. These variations reflect mainly currency movements, as well as varying yields and cash balances, and as such, change from quarter to quarter.

Tax Rate

The tax rate provided for the first quarter of 2005 was 21.5% as compared to 23% in the first quarter of 2004 and 21.7% for the entire 2004. This reflects both a different mix of income sources and slightly lower rates of tax in certain countries, including Israel. The tax rate provided for the first quarter of 2005 is Teva's best estimate for the annual tax rate of 2005.

Net Income

Net income for the first quarter of 2005 reached \$259 million and \$0.38 per share, while in the comparable quarter, which included one-time charges mainly related to purchase accounting for the Sicor acquisition, Teva recorded a loss of \$428 million. When compared to adjusted net income for the first quarter of 2004 of \$205 million (before the one-time charges) and EPS of \$0.31, net income for the first quarter of 2005 increased by 26% and EPS grew by 23%. Net income as a percentage of sales was 20% in the first quarter of 2005, as compared to 19% in the comparable quarter of 2004. The higher net income margin represents the above mentioned trends. Adjusted diluted EPS (adjusted before one time charges) for the first quarter of 2004 has been restated to reflect (i) the potential dilution of Convertible Senior Debentures, pursuant to the adoption of EITF No. 04-8, which requires that the shares issuable upon conversion of such debentures be included in the computation of diluted EPS, regardless of the contingent features included in the instrument; and (ii) the two-for-one stock split effected in June 2004.

Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

During the quarter, Teva repurchased 8.6 million shares for a total of \$250 million. For the first quarter of 2005, the share count for the fully diluted EPS calculation was 684 million shares and for the market capitalization, 642 million shares.

Reconciliation between reported Income (Loss) and Earnings (Loss) per Share to Adjusted Income and Earnings per Share

	U.S. Dollar in Millions (except per share amounts)	
	Quarter ended March 31	
	2005	2004
Reported Net Income (Loss)	259.1	(428.0)
Purchase accounting adjustment:		
In-process R& D		583.6
Acquired Inventory step-up		13.9
In-process R&D Acquired - other		13.0
Impairment of Product Rights		30.0
Tax applicable to Other in-process R&D and Inventory step-up		(7.7)
	259.1	204.8
Adjusted Net Income	259.1	204.8
Reported Diluted Earnings (loss) per ADR	0.38	(0.72)
Adjusted Diluted Earnings per ADR	0.38	0.31

Table of Contents

Critical Accounting Policies

The preparation of Teva's consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions in certain circumstances that affect the amounts reported in the accompanying consolidated financial statements and related footnotes. Actual results may differ from these estimates. To facilitate the understanding of Teva's business activities, certain Teva accounting policies that are more important to the portrayal of its financial condition and results of operations and that require management's subjective judgments are described in Teva's Annual Report on Form 20-F for the year ended December 31, 2004. Teva bases its judgments on its experience and various assumptions that it believes to be reasonable under the circumstances. The more important estimates that Teva makes on an ongoing basis include those related to revenue recognition and sales reserves and allowances, income taxes, contingencies, inventories and valuation and impairment of goodwill and other intangible assets. Please refer to Note 1 to Teva's consolidated financial statements included in Teva's Annual Report on Form 20-F for the year ended December 31, 2004 for a summary of all of Teva's significant accounting policies.

Impact of Currency Fluctuations and Inflation

Because Teva's results are reported in U.S. Dollars, changes in the rate of exchange between the U.S. Dollar and local currencies—mainly the Euro, New Israeli Shekel (NIS), Canadian Dollar, Pound Sterling and Hungarian Forint—affect Teva's results. During the first quarter of 2005, the Euro was 5% higher against the U.S. Dollar relative to the comparable quarter last year (average compared with average). The Hungarian Forint revalued by approximately 10%, and the Pound Sterling by approximately 3%. In addition, the Canadian Dollar revalued by 7% versus the US Dollar. While the U.S. Dollar value of sales in Europe benefited by the revalued Euro, the impact on net income was mitigated by the fact that costs in Europe increased correspondingly in dollar terms as well as the costs of European raw materials purchased by Teva's non-European businesses.

In Israel, the dollar value of local sales increased by the revaluation of the NIS, by 2% between the comparable quarters. However, as Teva's Israeli production was both for local and foreign markets, its NIS-denominated expenses exceeded its NIS-denominated income. As a result, the net impact of the NIS revaluation on Teva's bottom line was negative.

Exchange rate movements accounted for approximately \$25 million or 10% of the increase in first quarter net sales as compared to the comparative quarter of 2004, with no material effect on net income.

Liquidity and Capital Resources

On March 31, 2005, Teva's working capital was \$2.1 billion, compared to \$2.0 billion as of December 31, 2004. Cash provided by operating activities during the first quarter of 2005 amounted to \$303 million compared with \$224 million in the first quarter of 2004.

Inventories decreased during the quarter by \$76 million and trade receivables increased by \$146 million. The ratio of days sales in inventory was slightly down compared to December 2004 (162 compared with 163 days in December), but significantly lower than the ratio for March 31, 2004 of 181 days. Days Sales Outstanding (receivables) increased from December 2004 to March 2005 from 61 days to 65 days, but decreased compared to March 31, 2004, when the level was 69 days.

Days Sales Outstanding have been calculated after netting out the Sales Reserves and Allowances (SR&A) from the receivables. Although Teva records receivables on a gross basis, and records substantially all of the SR&A as a liability under accounts payable and accruals, in order to facilitate a more meaningful comparison with some of its peers, who record receivables net of these reserves, Teva has used the net figure.

Sales Reserve and Allowances increased during the first quarter of 2005 from \$591 million at year end to \$655 million at March 31, 2005, mainly as a result of increased charge back reserves relating primarily to increased competition in connection with certain new products. Chargeback reserves are estimated based on gross sales in the period to wholesalers compared to estimated contract prices to the Company s indirect and wholesaler contract customers. Historical selling prices are used for the estimates with additional consideration given to current and expected price competition where appropriate. As selling price declines, the liability for chargebacks increases.

Investment in property, plant and equipment in the first quarter of 2005 amounted to \$77 million, compared to \$64 million in the comparable quarter last year. Depreciation and amortization amounted to \$56 million in the first quarter of 2005, as compared to \$47 million in the comparable quarter of 2004.

Table of Contents

Shareholders equity reached \$5.3 billion at March 31, 2005, a decrease of \$91 million from December 31, 2004. This decrease resulted from the combined effect of the share repurchase program, dividends paid and negative balance sheet translation differences recorded in the first quarter of 2005, offset mainly by the net income for the first quarter of 2005.

During the first quarter of 2005, the Company spent \$250 million to repurchase 8.6 million of Teva's shares pursuant to an authorization by Teva's board of directors to repurchase Teva securities in an amount valued at up to an aggregate of \$600 million of Teva's securities.

Teva's principal sources of short-term liquidity are its existing cash and internally generated funds, which Teva believes are sufficient to meet its operating needs and anticipated capital expenditures over the near term. Teva's cash is invested in high rated liquid short and long-term corporate bonds that bear fixed and floating interest rates. Teva continues to constantly review additional opportunities to acquire companies in the generic pharmaceuticals industry and to acquire complementary technologies or product rights. To the extent that any such acquisitions involve cash payments rather than the issuance of shares, they may require Teva to draw upon its credit lines available from Israeli and other banks, or may involve raising additional funds from debt or equity markets.

Share Repurchases

Set forth below is a summary of the shares repurchased by the Company during the quarter and the approximate dollar value of securities that may yet be purchased under the Company's repurchase plan:

Teva Shares/ADRs

	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of publicly announced plans or programs	Approximate dollar value of shares that may yet be purchased under the plans or programs (1)
January 2005	2,896,500	\$ 28.17	9,460,947	\$ 313 million
February 2005	2,742,070	\$ 28.56	12,203,017	\$ 235 million
March 2005	2,964,590	\$ 30.29	15,167,607	\$ 145 million
Total	8,603,160	\$ 29.02		

- (1) Remaining amount available for repurchase under the Company's repurchase authorization that was approved by the Board of Directors in December 2004, after taking into account \$24 million of convertible senior debentures that have been purchased under the plan as well

Material Changes in Contractual Obligations

Edgar Filing: TEVA PHARMACEUTICAL INDUSTRIES LTD - Form 6-K

During the quarter ended March 31, 2005, there were no material changes outside the ordinary course of Teva's business in the specified contractual obligations included in the table of contractual obligations in Teva's annual report on Form 20-F for the year ended December 31, 2004.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Reference is made to the "Quantitative and Qualitative Disclosures About Market Risk" section (Item 11) in Teva's Annual Report on Form 20-F for the year ended December 31, 2004.

Table of Contents

LEGAL PROCEEDINGS

Reference is made to the Commitments and Contingencies Note 10 to Teva's Financial Statements for the quarter ended March 31, 2005. Except as described below, there were no material developments to the Legal Proceedings section in Teva's Annual Report on Form 20-F for the year ended December 31, 2004 during the quarter ended March 31, 2005.

In August 2002, GlaxoSmithKline filed a complaint against Teva USA in the Pennsylvania Court of Common Pleas. The complaint alleges that Teva USA's Amox Clav products are derived from a strain of streptomyces clavuligerus stolen from GlaxoSmithKline. On April 11, 2005, the parties entered into a settlement agreement whereby GSK will dismiss all claims against Teva with prejudice.

In May 2003, Teva USA commenced sales of its 7.5 mg and 15 mg moexipril hydrochloride tablets. Teva USA had previously obtained summary judgment of non-infringement as to the one patent at issue, but that decision was later vacated on appeal. Following the filing of Schwarz Pharma's motion for a preliminary injunction, on September 12, 2004, Teva entered into an agreement with Schwarz whereby Teva agreed to suspend all manufacturing and selling of its moexipril hydrochloride tablets pending the outcome of litigation between the two companies in the District Court or a court order. On January 4, 2005, the District Court granted Schwarz Pharma's motion for summary judgment of infringement and also held that the patent was valid and enforceable in light of the trial decision in the related case involving Teva's ANDA for quinapril hydrochloride tablets, Warner-Lambert Company v. Teva Pharmaceuticals USA. On March 31, 2005, the Court granted Teva's motion to stay further proceedings pending Teva's appeal to the U.S. Court of Appeals for the Federal Circuit in Teva's related quinapril hydrochloride case. Teva's appeal was argued on April 8, 2005. Were Schwarz Pharma ultimately to be successful on its allegation of patent infringement, Teva USA could be required to pay damages. An appropriate provision for this matter has been included in the accounts.

In December 2004, Teva commenced sales of quinapril HCl tablets, 5, 10, 20 and 40 mg, supplied by Ranbaxy Pharmaceuticals Inc. pursuant to a distribution agreement between the companies. In January 2005, Pfizer filed a complaint and request for preliminary injunction against Ranbaxy and Teva for infringement of Pfizer Inc.'s 4,743,450 patent. The preliminary injunction was granted on March 31, 2005 and Teva ceased further sales of the product. Ranbaxy and Teva have appealed the preliminary injunction decision. Quinapril HCl tablets are the AB-rated generic equivalent of Pfizer's antihypertensive agent Accupril Tablets, which had annual sales of approximately \$555 million as of December 2004. Ranbaxy has agreed to fully indemnify Teva for all patent infringement claims related to the Ranbaxy product at issue.

Table of Contents

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.

TEVA PHARMACEUTICAL INDUSTRIES LIMITED
(Registrant)

By: /s/ Dan Suesskind
Name: Dan Suesskind
Title: Chief Financial Officer

Date: May 11, 2005