

# QUESTCOR PHARMACEUTICALS INC

## FORM 8-K (Current report filing)

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

**CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): March 1, 2010**

**QUESTCOR PHARMACEUTICALS, INC.**

(Exact Name of Registrant as Specified in Charter)

**California**  
(State or Other Jurisdiction  
of Incorporation)

**001-14758**  
(Commission File Number)

**33-0476164**  
(I.R.S. Employer  
Identification No.)

**3260 Whipple Road, Union City, California**  
(Address of Principal Executive Offices)

**94587**  
(Zip Code)

Registrant's telephone number, including area code: **(510) 400-0700**

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 2.02. Results of Operations and Financial Condition.**

On March 1, 2010, Questcor Pharmaceuticals, Inc. (the “Company”) announced via press release its results for the quarter and year ended December 31, 2009. A copy of the Company’s press release is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2. of Form 8-K, the information in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 7.01 Regulation FD Disclosure.**

The information disclosed in item 2.02 is incorporated herein by this reference.

**Item 9.01. Financial Statements and Exhibits.**

(c) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Questcor Pharmaceuticals, Inc. press release dated March 1, 2010.

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**SIGNATURE**

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 hereunto duly authorized.

Date: March 1, 2010

QUESTCOR PHARMACEUTICALS, INC.

By: /s/ Gary Sawka

Gary Sawka

Senior Vice President, Finance and Chief  
Financial Officer

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## EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Questcor Pharmaceuticals, Inc. press release dated March 1, 2010.



## QUESTCOR REPORTS SOLID FOURTH QUARTER RESULTS

- Paid commercial Acthar prescriptions for MS up 223% over prior year quarter-*
- Paid commercial IS prescriptions up 56% sequentially-*
- Received initial set of nephrotic syndrome prescriptions-*
- Fourth quarter 2009 net income per share \$0.13 on \$25.9 million in net sales-*
- 2.5 million common shares repurchased during fourth quarter-*
- Conference call today at 5:00 PM ET-*

**UNION CITY, Calif.** — March 1, 2010 — Questcor Pharmaceuticals, Inc. (NASDAQ: QCOR) today reported financial results for the fourth quarter and year ended December 31, 2009. The Company's financial performance in the fourth quarter of 2009 was driven primarily by:

- a 223% increase in the number of new paid Acthar commercial prescriptions for the treatment of multiple sclerosis (MS) exacerbations versus the fourth quarter of 2008,
- a sequential 56% increase in new paid Acthar commercial prescriptions for the treatment of infantile spasms (IS), and
- lower sequential Medicaid usage.

In addition to the financial improvement in the quarter, the Company also received an encouraging initial set of Acthar prescriptions for the treatment of nephrotic syndrome (NS). Also, during the fourth quarter, the FDA accepted for review Questcor's supplemental New Drug Application (sNDA) filing which seeks approval for an indication for Acthar in the treatment of IS.

Net sales totaled \$25.9 million for the quarter ended December 31, 2009 compared to \$13.9 million for the quarter ended September 30, 2009, and \$27.0 million for the fourth quarter of 2008. Net income for the fourth quarter of 2009 was \$8.4 million, or \$0.13 per diluted common share compared to \$1.2 million, or \$0.02 per diluted common share for the third quarter of 2009, and \$16.2 million, or \$0.24 per diluted common share for the fourth quarter of 2008. An additional \$1.2 million in sales reserves was recorded during the fourth quarter of 2009 for retroactive Tricare rebates. Significantly higher sales reserves adjustments reduced net sales and operating income for the third quarter of 2009 by \$4.6 million. Tax benefits resulting from the reversal of a valuation allowance positively affected net income in the fourth quarter of 2008 by \$4.4 million.

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Net sales totaled \$88.3 million for the year ended December 31, 2009, compared with \$95.2 million for 2008. Net income for 2009 was \$26.6 million, or \$0.40 per diluted common share compared with net income applicable to common shareholders of \$35.3 million, or \$0.49 per diluted common share for 2008. The 2008 earnings were impacted by a one-time net tax benefit of \$5.2 million and a deemed dividend of \$5.3 million.

“We are making excellent progress on all of Questcor’s top priorities,” said Don M. Bailey, President and CEO. “Our fourth quarter financial performance improved significantly on a sequential basis. Questcor’s sales in the MS market showed marked growth and there are preliminary indications that Acthar may also begin to be adopted in the NS market, which is much larger than either the IS or MS markets. In addition, IS prescriptions and payer mix both improved during the fourth quarter from a very weak third quarter. To date, we are seeing little or no impact on Acthar sales in the IS market from the September 2009 introduction of Sabril (vigabatrin).”

### **IS, MS, and NS Sales**

During the fourth quarter of 2009, Questcor shipped 1,626 vials of Acthar compared to third quarter 2009 shipments of 1,354 vials and fourth quarter 2008 shipments of 1,510 vials. Because Acthar prescriptions are filled at specialty pharmacies, the Company does not receive complete information regarding either the number of prescriptions or the number of vials by therapeutic area for all of the patients being treated with Acthar. However, Questcor is able to monitor historic trends in payer mix for new Acthar prescriptions based on data it receives from its reimbursement support center. Questcor estimates that approximately 90% of new Acthar prescriptions are processed by this support center, but that very few refill prescriptions are processed at this center. The following tables show the number of prescriptions shipped by payer category for each of three therapeutic areas for those new prescriptions processed by the Questcor support center:

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### Multiple Sclerosis New Prescriptions

	<u>Paid/Commercial</u>	<u>Medicaid</u>	<u>Tricare/VA</u>
Q108	24	5	0
Q208	35	1	0
Q308	50	5	1
Q408	66	3	2
<b>Total 2008</b>	<u>175</u>	<u>14</u>	<u>3</u>
Q109	78	5	3
Q209	125	11	6
Q309	141	14	5
Q409	213	10	5
<b>Total 2009</b>	<u>557</u>	<u>40</u>	<u>19</u>

### Infantile Spasms New Prescriptions

	<u>Paid/Commercial</u>	<u>Medicaid</u>	<u>Tricare/VA</u>
Q108	98	38	2
Q208	114	47	3
Q308	113	67	3
Q408	103	56	3
<b>Total 2008</b>	<u>428</u>	<u>208</u>	<u>11</u>
Q109	104	70	5
Q209	93	63	5
Q309	61	55	3
Q409	95	40	5
<b>Total 2009</b>	<u>353</u>	<u>228</u>	<u>18</u>

### Nephrotic Syndrome New Prescriptions

	<u>Paid/Commercial</u>	<u>Medicaid</u>	<u>Tricare/VA</u>
Q109	1	0	0
Q209	3	0	1
Q309	2	0	0
Q409	14	2	1
<b>Total 2009</b>	<u>20</u>	<u>2</u>	<u>2</u>

*Note: Historical trend information is not necessarily indicative of future results. The total number of vials associated with an individual prescription varies by the condition being treated and by patient.*

“As the above tables illustrate, our efforts in MS continue to show that the use of Acthar is expanding,” commented Steve Cartt, Executive Vice President. “Our initiatives to educate MS specialists about the treatment benefits of Acthar have resulted in a tripling in MS prescriptions year over year.”

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“In addition, spontaneous IS prescriptions during the fourth quarter rebounded to 140 new paid prescriptions from a low level of 119 in the third quarter,” noted Mr. Cartt. “If we are able to receive approval from the FDA to market Acthar for the treatment of IS, we may be able to expand our sales in this therapeutic area.”

“The modest set of prescriptions for NS in the fourth quarter was an unexpected development at this stage in our efforts to generate sales in this market,” added Mr. Cartt. “NS is a devastating kidney disorder which leads to end-stage renal disease (ESRD). NS is an on-label indication for Acthar and we are working to generate more clinical data to further support the effectiveness of Acthar in the treatment of this disease.”

#### **Sales Reserves—Medicaid, Tricare and VA Adjustments**

As required by federal regulations, the Company provides rebates to state Medicaid programs for Acthar dispensed to Medicaid patients. The Medicaid rebate portion of sales reserves for the fourth quarter of 2009 was \$8.4 million or 22% of 2009 fourth quarter gross sales. While total new commercially paid Acthar prescriptions for the treatment of IS processed through the Company’s reimbursement support center increased to 95 in the fourth quarter from 61 in the third quarter, the number of Medicaid-reimbursed IS prescriptions dropped 27% sequentially.

The Department of Defense (DOD) operates a prescription drug program through its Tricare Management Administration (Tricare). As a result of uncertainties in an on-going dispute between the pharmaceutical industry and the DOD over Tricare rebate regulations, Questcor recorded a sales reserve related to a portion of Tricare-claimed rebates during the third quarter of 2009. Due to recent developments in that dispute, Questcor recorded an additional \$1.2 million in sales reserves during the fourth quarter of 2009 for the remaining potential Tricare-claimed rebates. Effective January 1, 2010, Questcor established new prices for Acthar purchased by Tricare and Veterans Administration (VA) medical centers. Additionally, Questcor has removed uncertainty regarding Tricare rebate liabilities going forward. The new agreement with Tricare does not diminish Questcor’s rights in regards to the fully reserved 2008-2009

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liability. Any sales in 2010 to Tricare or the VA will represent an increase from the negligible net sales to these customers in 2009.

### **Regulatory Activity**

Acthar is currently approved in the U.S. for the treatment of MS exacerbations, nephrotic syndrome and many other conditions. Acthar is not approved in the U.S. for the treatment of IS, a potentially life-threatening disorder that typically begins in the first year of life. However, pursuant to guidelines published by the American Academy of Neurology and the Child Neurology Society, many child neurologists use Acthar to treat infants afflicted with IS.

On December 23, 2009 the FDA accepted for review Questcor's supplemental New Drug Application (sNDA) seeking approval to market Acthar for the treatment of infantile spasms. The FDA has notified Questcor that an Advisory Committee Meeting of independent experts will be held to discuss the approval and use of Acthar in infantile spasms. The FDA has also notified Questcor that it has set a PDUFA goal date of June 11, 2010, but there is no assurance that this date will not be delayed. Approval of the IS indication would allow Questcor to promote the use of Acthar in treating IS to child neurologists.

Previously, the FDA granted Orphan Designation to Acthar for the treatment of IS. As a result of this Orphan Designation, if Questcor is successful in obtaining FDA approval for the IS indication, Questcor believes that it will also qualify for a seven-year exclusivity period during which the FDA is prohibited from approving any other adrenocorticotrophic hormone (ACTH) formulation for IS unless the other formulation is demonstrated to be clinically superior to Acthar.

### **Cash, Accounts Receivable and Share Repurchase Program**

At February 26, 2010, Questcor's cash, cash equivalents and short-term investments totaled approximately \$81 million, and accounts receivable totaled approximately \$9 million.

During the fourth quarter, the Company repurchased 2.5 million shares of its common stock at a total cost of \$9.9 million. In the last two years, Questcor has spent \$67.0 million for the repurchase of 14.5 million common and preferred shares.

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As of December 31, 2009, Questcor had 61.7 million common shares outstanding, with 5.1 million shares remaining under its common share repurchase program.

### **Conference Call Details**

The Company will host a conference call today to discuss these results at 5:00 p.m. ET. Don Bailey, President and Chief Executive Officer; Steve Cartt, Executive Vice President and Chief Business Officer; Dr. David Young, Chief Scientific Officer; Dave Medeiros, Senior Vice President, Pharmaceutical Operations; Dr. Jason Zielonka, Senior Vice President and Chief Medical Officer; and Gary Sawka, Senior Vice President, Finance and Chief Financial Officer will host the call.

To participate in the live call by telephone, please dial 877-941-2928 from the U.S. or 480-629-9724 from outside the U.S. Participants are asked to call the above numbers 5-10 minutes prior to the starting time. The call will also be webcast live at [www.questcor.com](http://www.questcor.com). An audio replay of the call will be available for 7 days following the call. This replay can be accessed by dialing 800-406-7325 for domestic callers and 303-590-3030 for international callers, both using passcode 4221516#. An archived webcast will also be available at [www.questcor.com](http://www.questcor.com).

### **About Questcor**

Questcor Pharmaceuticals, Inc. is a pharmaceutical company that markets H.P. Acthar<sup>®</sup> Gel (repository corticotropin injection). H.P. Acthar Gel ("Acthar") is an injectable drug that is approved for the treatment of certain disorders, including the treatment of exacerbations associated with multiple sclerosis ("MS") and to induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that is due to lupus erythamatosus. In addition, Acthar is not indicated for, but is used in treating patients with infantile spasms ("IS"), a rare form of refractory childhood epilepsy, and opsoclonus myoclonus syndrome, a rare autoimmune-related childhood neurological disorder. For more information, please visit [www.questcor.com](http://www.questcor.com).

Note: Except for the historical information contained herein, this press release contains forward-looking statements that have been made pursuant to the Private Securities Litigation Reform Act of 1995. These statements relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "if," "should," "forecasts," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential," or "continue" or the negative of such terms and other comparable terminology. These statements are only predictions. Actual events or results may differ materially. Factors that could cause or contribute to such differences include, but are not limited to, the following:

- Questcor's ability to continue to successfully implement its Acthar-centric business strategy, including its expansion in the MS marketplace;
  - FDA approval of and the market introduction of competitive products and our inability to market Acthar in IS prior to approval of IS as a labeled indication;
  - Questcor's ability to operate within an industry that is highly regulated at both the Federal and state level;
  - Regulatory changes or actions including Federal or State health care reform initiatives;
  - Questcor's ability to accurately forecast the demand for its products;
  - The gross margin achieved from the sale of its products;
  - Questcor's ability to estimate the quantity of Acthar used by government entities and Medicaid-eligible patients;
  - That the actual amount of rebates and chargebacks related to the use of Acthar by government entities, including the Department of Defense Tricare network, and Medicaid-eligible patients may differ materially from Questcor's estimates;
  - Questcor's expenses and other cash needs for upcoming periods;
  - The inventories carried by Questcor's distributors, specialty pharmacies and hospitals;
  - Volatility in Questcor's monthly and quarterly Acthar shipments and end-user demand;
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- Questcor's ability to obtain finished goods from its sole source contract manufacturers on a timely basis if at all;
- Questcor's ability to attract and retain key management personnel;
- Research and development risks, including risks associated with Questcor's sNDA for IS and its preliminary work in the area of nephrotic syndrome;
- Uncertainties regarding Questcor's intellectual property;
- The uncertainty of receiving required regulatory approvals in a timely way, or at all; and,
- Questcor's ability to identify product acquisition candidates and consummate transactions on terms acceptable to the Company.
- Other risks discussed in Questcor's annual report on Form 10-K for the year ended December 31, 2008 and other documents filed with the Securities and Exchange Commission.

The risk factors and other information contained in these documents should be considered in evaluating Questcor's prospects and future financial performance.

Questcor undertakes no obligation to publicly release the result of any revisions to these forward-looking statements, which may be made to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

For more information, please visit [www.questcor.com](http://www.questcor.com) or [www.acthar.com](http://www.acthar.com).

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Questcor Pharmaceuticals, Inc.  
Consolidated Statements of Income  
(In thousands, except per share amounts)

	Three Months Ended December 31,		Years Ended December 31,	
	2009	2008	2009	2008
Net sales	\$25,905	\$27,018	\$88,320	\$95,248
Cost of sales (exclusive of amortization of purchased technology)	1,898	1,858	7,017	7,304
Gross profit	24,007	25,160	81,303	87,944
Gross margin	93%	93%	92%	92%
Operating expenses:				
Selling, general and administrative	7,841	5,075	29,950	19,247
Research and development	2,662	2,511	9,653	10,614
Depreciation and amortization	121	124	480	503
Total operating expenses	10,624	7,710	40,083	30,364
Income from operations	13,383	17,450	41,220	57,580
Other income:				
Interest and other income, net	101	247	686	1,075
Gain on sale of product rights	—	75	225	75
Total other income	101	322	911	1,150
Income before income taxes	13,484	17,772	42,131	58,730
Income tax expense	5,063	1,530	15,502	18,198
Net income	8,421	16,242	26,629	40,532
Deemed dividend on Series A preferred stock	—	—	—	5,267
Net income applicable to common shareholders	<u>\$ 8,421</u>	<u>\$16,242</u>	<u>\$26,629</u>	<u>\$35,265</u>
Net income per share applicable to common shareholders:				
Basic	<u>\$ 0.13</u>	<u>\$ 0.25</u>	<u>\$ 0.41</u>	<u>\$ 0.52</u>
Diluted	<u>\$ 0.13</u>	<u>\$ 0.24</u>	<u>\$ 0.40</u>	<u>\$ 0.49</u>
Shares used in computing net income per share applicable to common shareholders:				
Basic	<u>63,086</u>	<u>65,135</u>	<u>64,196</u>	<u>67,761</u>
Diluted	<u>64,783</u>	<u>68,345</u>	<u>66,257</u>	<u>71,350</u>

Questcor Pharmaceuticals, Inc.  
Consolidated Balance Sheets  
(In thousands, except share amounts)

	December 31,	
	2009	2008
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 45,829	\$ 13,282
Short-term investments	29,878	42,169
Total cash, cash equivalents and short-term investments	75,707	55,451
Accounts receivable, net of allowance for doubtful accounts of \$77 and \$62 at December 31, 2009 and 2008, respectively	14,833	10,418
Inventories, net	3,378	2,459
Prepaid income taxes	—	3,316
Prepaid expenses and other current assets	1,162	1,101
Deferred tax assets	8,180	6,252
Total current assets	103,260	78,997
Property and equipment, net	407	450
Purchased technology, net	3,372	3,669
Goodwill	299	299
Deposits and other assets	710	710
Deferred tax assets	3,392	5,021
Total assets	\$111,440	\$ 89,146
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 12,921	\$ 4,302
Accrued compensation	2,140	1,896
Sales-related reserves	14,922	11,825
Income taxes payable	477	—
Other accrued liabilities	1,751	1,702
Total current liabilities	32,211	19,725
Lease termination and deferred rent liabilities and other non-current liabilities	1,226	1,529
Total liabilities	33,437	21,254
Shareholders' equity:		
Preferred stock, no par value, 7,500,000 shares authorized; none outstanding	—	—
Common stock, no par value, 105,000,000 shares authorized; 61,726,609 and 65,970,653 shares issued and outstanding at December 31, 2009 and 2008, respectively	67,793	84,028
Retained earnings (accumulated deficit)	10,224	(16,405)
Accumulated other comprehensive income (loss)	(14)	269
Total shareholders' equity	78,003	67,892
Total liabilities and shareholders' equity	\$111,440	\$ 89,146

Questcor Pharmaceuticals, Inc.  
Consolidated Statements of Cash Flows  
(In thousands)

	Years Ended December 31,	
	2009	2008
<b>OPERATING ACTIVITIES</b>		
Net income	\$ 26,629	\$ 40,532
Adjustments to reconcile net income to net cash provided by operating activities:		
Share-based compensation expense	3,066	4,119
Deferred income taxes	(290)	4,649
Amortization of investments	181	(456)
Depreciation and amortization	480	503
Gain on sale of product rights	(225)	(75)
Income tax benefit realized from share-based compensation plans	783	4,932
Excess tax benefit from share-based compensation plans	(743)	(4,841)
Changes in operating assets and liabilities:		
Accounts receivable	(4,415)	13,221
Inventories	(919)	(94)
Prepaid income taxes	3,316	(3,316)
Prepaid expenses and other current assets	(61)	(323)
Accounts payable	8,619	2,525
Accrued compensation	244	(49)
Sales-related reserves	3,097	3,649
Income taxes payable	477	(1,330)
Other accrued liabilities	49	210
Other non-current liabilities	(303)	(347)
Net cash flows provided by operating activities	<u>39,985</u>	<u>63,509</u>
<b>INVESTING ACTIVITIES</b>		
Purchase of property and equipment	(140)	(133)
Purchase of short-term investments	(61,557)	(69,613)
Proceeds from the sale and maturities of short-term investments	73,375	42,388
Net proceeds from sale of product rights	225	75
Changes in deposits and other assets	—	34
Net cash flows provided by (used in) investing activities	<u>11,903</u>	<u>(27,249)</u>
<b>FINANCING ACTIVITIES</b>		
Issuance of common stock, net	1,002	2,161
Repurchase of common stock	(21,086)	(35,571)
Repurchase of Series A preferred stock	—	(10,348)
Excess tax benefit from share-based compensation plans	743	4,841
Net cash flows used in financing activities	<u>(19,341)</u>	<u>(38,917)</u>
Increase (decrease) in cash and cash equivalents	32,547	(2,657)
Cash and cash equivalents at beginning of year	13,282	15,939
Cash and cash equivalents at end of year	<u>\$ 45,829</u>	<u>\$ 13,282</u>