

# ASTEX PHARMACEUTICALS, INC

## FORM 8-K (Current report filing)

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Address	4140 DUBLIN BLVD SUITE 200 DUBLIN, CA 94568
Telephone	9255600100
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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 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)  
**April 30, 2012**

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**ASTEX PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of incorporation)

**0-27628**  
(Commission File Number)

**91-1841574**  
(IRS Employer  
Identification No.)

**4140 Dublin Blvd., Suite 200  
Dublin, CA 94568**  
(Address of principal executive offices, including zip code)

**(925) 560-0100**  
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

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 April 30, 2012, Astex Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 31, 2012. The full text of this press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

In accordance with General Instruction B.2. of Form 8-K, the information in this Current Report on Form 8-K and the Exhibit attached hereto is being “furnished” and 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 liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the “Securities Act”) or the Exchange Act, except if the Company specifically states that the information and the Exhibit is to be considered “filed” under the Exchange Act or incorporates it by reference into a filing under the Securities Act or the Exchange Act.

## Item 9.01. Financial Statements and Exhibits.

### (d) Exhibits

Exhibit No.	Description
99.1	Press release dated April 30, 2012, announcing financial results for the quarter ended March 31, 2012 (solely furnished and not filed herewith, pursuant to Item 2.02).

## 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 hereunto duly authorized.

ASTEX PHARMACEUTICALS, INC.

By: /s/ MICHAEL MOLKENTIN

Michael Molkentin  
Chief Financial Officer

Date: April 30, 2012

## EXHIBIT INDEX

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press release dated April 30, 2012, announcing financial results for the quarter ended March 31, 2012 (solely furnished and not filed herewith, pursuant to Item 2.02).



News Release

**Astex Pharmaceuticals Reports 2012 First Quarter Financial Results**

***Reports First Quarter Net Income of \$4.2 Million  
Dacogen Royalty Revenue Increases 21% from Prior Year  
Ends First Quarter with \$126 Million in Cash & Marketable Securities***

**DUBLIN, Calif., April 30, 2012** - Astex Pharmaceuticals, Inc. (NASDAQ: ASTX), today reported financial results for the first quarter ended March 31, 2012. The Company reported net income for the 2012 first quarter of \$4.2 million, or \$0.05 per basic share and \$0.04 per diluted share, compared with \$5.5 million, or \$0.09 per basic and diluted share, for the same prior year period.

“During our 2012 first quarter we maintained a strong financial position and reported another profitable quarter. We advanced further a number of clinical programs and we expect to preview Phase II data on them by year end. Our partnered programs have also progressed and data from both internal and partnered programs should be presented at ASCO and ASH later this year,” said James S.J. Manuso, PhD, chairman and chief executive officer of Astex Pharmaceuticals.

Total revenues for the 2012 first quarter were \$22.0 million compared with \$17.1 million for the same prior year period. Total revenues for the 2012 first quarter includes royalty revenue of \$20.6 million compared with \$17.0 million for the same prior year period. Royalty revenue is earned pursuant to the license agreement entered into with MGI PHARMA (acquired by Eisai Corporation of North America in January 2008) during 2004, which granted MGI PHARMA exclusive rights to the development, manufacture, commercialization and distribution of *Dacogen*. Total revenues for the 2012 first quarter also includes development and license revenue of \$1.4 million compared with \$127,000 for the same prior year period. Resulting from the first quarter transfer to GlaxoSmithKline (GSK) of epigenetic research work and assets generated under the former CLIMB™ collaboration with GSK, the recognition of all remaining deferred development and license revenue has been accelerated.

Total operating expenses for the 2012 first quarter were \$20.6 million, compared with \$11.6 million for the same prior year period. The primary reasons for the increase in total operating expenses for the 2012 first quarter compared with the same prior year period

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are the consolidation of research and development and general and administrative costs related to the acquisition of Astex Therapeutics Limited effective July 20, 2011, increased research and development activities from product development and clinical trial programs associated with SGI-110, AT13387, and amuvatinib, and an expense for the amortization of intangible assets related to the acquisition. The non-cash amortization of intangible assets was \$2.2 million for the 2012 first quarter while there was no similar amortization expense for the same prior year period. Stock-based compensation expense, a non-cash expense that is included in operating expenses, was \$765,000 for the 2012 first quarter, compared with \$712,000 for the same prior year period.

The Company reported net income for the 2012 first quarter of \$4.2 million, or \$0.05 per basic share and \$0.04 per diluted share, compared with net income of \$5.5 million, or \$0.09 per basic and diluted share, for the same prior year period. The net income for the 2012 first quarter includes an income tax benefit of \$2.8 million compared with an income tax provision of \$44,000 for the same prior year period. The income tax benefit for the 2012 first quarter was primarily due to the recognition of a tax benefit associated with the amortization of deferred tax liabilities resulting from the acquisition and foreign research and development tax credits related to the UK subsidiary.

### **Financial Position**

As of March 31, 2012, the Company had \$126.2 million in unrestricted cash, cash equivalents, and current and non-current marketable securities compared to \$128.1 million at December 31, 2011.

### **Operational Highlights**

During January 2012, Astex Pharmaceuticals, Inc. announced that the multi-year collaboration to discover cancer therapeutics based on epigenetic targets entered into by the Company and GSK in November 2009 was terminated, resulting in the transfer to GSK of existing research work and assets generated under the CLIMB epigenetic collaboration. The Company has no further obligation to conduct additional research work on the program. This transfer arose from the review and rationalization of the Company's internal pipeline and drug discovery programs as part of the prior year merger of Astex Therapeutics Limited and SuperGen, Inc. to form Astex Pharmaceuticals, Inc., and discussions with GSK. The Company will continue to be eligible to receive milestones and royalties under the asset transfer agreement. A separate Research and Development Collaboration and License Agreement that includes a multi-target drug discovery collaboration, entered into by the Company's UK subsidiary and GSK in November 2009 will continue.

During March 2012, the Company announced that the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter to partner Eisai for their

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supplemental New Drug Application (sNDA) for *Dacogen* for patients with acute myeloid leukemia (AML) in adults 65 years of age or older who are not considered candidates for induction therapy. The FDA declined to approve the application. A separate Marketing Authorization Application (MAA) was submitted to the European Medicines Agency (EMA) in May 2011 by Janssen-Cilag International NV for *Dacogen* in the treatment of patients with elderly AML. It is expected the EMA will issue a decision on this application later this year.

During April 2012, the Company presented interim Phase I/II clinical data showing that subcutaneous SGI-110, a novel hypomethylating agent and follow on to *Dacogen*, demonstrated a differentiated pharmacokinetic (PK) profile, good tolerability, and preliminary promising complete responses in heavily pretreated AML patients enrolled in the Phase I segment of the trial. The data were presented at an oral session at the American Association for Cancer Research (AACR) 2012 Annual Meeting in Chicago, IL and were featured in a joint AACR-Stand Up To Cancer (SU2C) media forum. SU2C has provided funding for the Epigenetics Dream Team that is collaborating on the scientific and clinical evaluation of SGI-110.

The randomized Phase I/II first-in-human dose escalation study of SGI-110 enrolled 66 patients with previously treated intermediate or high-risk myelodysplastic syndromes (MDS) or AML as of March 28, 2012. Of seven evaluable refractory AML patients who had adequate hypomethylation with no prior resistance to hypomethylating agents (HMAs), two showed complete responses, and one showed a partial response. Additionally, the PK data suggests that subcutaneous SGI-110 achieves higher decitabine exposure and longer half life compared to the intravenous (IV) infusion of *Dacogen*. The pharmacodynamic (PD) data shows potent dose-dependent hypomethylation induction in the daily regimen.

The Company's overall product pipeline continues to advance in the clinic. Four products in or entering Phase II trials are expected to produce data from clinical proof of concept trials in the next 12 months including AT13387, SGI-110, amuvatinib, and AT7519. During the second half of 2012 we plan to initiate new Phase II clinical proof-of-concept trials for AT13387 and SGI-110 in solid tumors.

## **2012 Financial Guidance**

The financial guidance for 2012 remains substantially unchanged from our previous guidance:

- Royalty revenue for *Dacogen* is expected to increase up to 10% from the prior year to a range from \$64 million to \$67 million.
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- Development and license revenue is reported at \$1.4 million. We do not guide to future potential development and license revenue from other partnered programs due to the uncertainty and timing of milestone achievements.
- The last remaining payment of \$700,000 related to the sale of *Nipent*® (pentostatin for injection) to Hospira, Inc. to be classified as gain on sale of products is expected to be received during 2012.
- Research and development expenses are expected to increase from the prior year to a range from \$62 million to \$67 million.
- Amortization of intangible assets, a non-cash charge, has been revised upward from an estimated \$7.6 million to \$8.5 million.
- General and administrative expenses are expected to decrease from the prior year to a range from \$14 million to \$15 million.
- An estimated income tax benefit associated primarily with the amortization of deferred tax liabilities resulting from the acquisition and a foreign research and development tax credit related to the UK subsidiary has been revised upward from our prior guidance and is now anticipated to be in a range from \$5 million to \$6 million for the year.
- A net loss is still forecasted in a range from \$13 million to \$15 million for the year.
- In addition to the amortization of intangible assets included in total operating expenses are other recurring non-cash operating charges such as stock-based compensation expense and depreciation estimated at \$3.5 million for the year.
- Average annual shares outstanding are expected to be approximately 93 million common shares.

### **Conference Call Information**

Astex Pharmaceuticals will host a conference call to discuss the 2012 first quarter financial results today at 1:30 p.m. PT / 4:30 p.m. ET. A live webcast of the conference call is accessible via the investor relations section of the Company's website at <http://www.astx.com>. A webcast replay of the conference call will be available for 30 days.

### **About Astex Pharmaceuticals**

Astex Pharmaceuticals is dedicated to the discovery and development of novel small molecule therapeutics with a focus on oncology. The Company is developing a proprietary pipeline of novel therapies and is creating de-risked products for partnership with leading pharmaceutical companies. Astex Pharmaceuticals developed *Dacogen* and receives significant royalties on global sales.

For more information about Astex Pharmaceuticals, Inc., please visit <http://www.astx.com>.

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## Forward-Looking Statements

This press release contains “forward-looking” statements within the meaning of Section 21A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and is subject to the safe harbor created thereby. Actual results could differ materially from those projected in the forward-looking statements as a result of a number of risks and uncertainties. These forward-looking statements include, but are not limited to, statements regarding expectations regarding the completion of drug candidate optimization and advancement of drug candidates in the clinic; expectations regarding our clinical trials including the production of clinical data from these trials; the continued growth of worldwide sales of *Dacogen*, expectations regarding the ability of the Company to expand and develop our pipeline of products in the years ahead; the Company’s ability to develop the current and future pipeline into commercially viable drugs; the expectations regarding our clinical trials including the timing of clinical proof of concept data from these trials; the progress of our collaborations with strategic partners and other programs added through the acquisition of Astex Therapeutics Limited; the sufficiency of our operating cash to fund our development initiatives this year and thereafter; expectations about increases in royalty revenue; expectations regarding research and development expenses and general and administrative expenses; expectations regarding development and license revenue; estimates of 2012 net losses and anticipated tax benefits; statements about expected losses or profitability; estimates regarding our total expected shares outstanding; and expectations regarding Eisai’s and Janssen’s plans for *Dacogen* including with respect to submissions to the EMA. Important factors that could cause actual results to differ materially from the expectations reflected in the forward-looking statements include, but are not limited to: the ability of Eisai and Janssen to generate global sales of *Dacogen*; the outcomes of the on-going clinical trials; risks and uncertainties related to the achievement of developmental milestones with respect to the compounds in development; the research and development of amuvatinib, AT13387, SGI-110, and other programs added by the acquisition; the decision by certain strategic partners whether or not to license and then develop and commercialize the products that are the subject of our collaboration with them and whether any of those products will be commercially successful; the outcome of Janssen’s examination of *Dacogen* clinical trial data and the outcome of the submission of a European regulatory filing; and the risks and uncertainties associated with the combined Company. In general, our future success is dependent upon numerous factors, including our ability to generate pre-clinical development candidates for selection into clinical testing, obtaining regulatory approval of product development programs, conducting and completing clinical trials, obtaining regulatory approval of our products and product candidates, our ability to successfully partner with leading pharmaceutical companies, and creating opportunities for future commercialization of compounds. Our future revenue and operating and net loss or income could be worse than anticipated if demand for our products is less than expected, if our partnerships and collaborations with other parties are not successful, if our drug

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pipeline does not progress, or if the introductions of new products are delayed, for any reason, including regulatory delay. References made to the discussion of risk factors are detailed in the Company's filings with the Securities and Exchange Commission including reports on its most recently filed Form 10-K and Form 10-Q. These forward-looking statements are made only as of the date hereof, and we disclaim any obligation to update or revise the information contained in any such forward-looking statements, whether as a result of new information, future events or otherwise.

**Contacts:**

**Timothy L. Enns**

Astex Pharmaceuticals, Inc.  
Senior Vice President  
Corporate Communications & Marketing  
Tel: (925) 560-2810  
E-mail: tim.enns@astx.com

**Susanna Chau**

Astex Pharmaceuticals, Inc.  
Manager  
Investor Relations  
Tel: (925) 560-2845  
E-mail: susanna.chau@astx.com

**Alan Roemer**

The Trout Group  
Managing Director  
Tel: (646) 378-2945  
E-mail: aroemer@troutgroup.com

**Melanie Toyne-Sewell (Europe)**

**Rebecca Skye Dietrich (US)**  
College Hill  
Tel: +44 20 7866 7866  
Tel: (857) 241-0795  
E-mail: astex@collegehill.com

*Condensed Consolidated Statements of Operations and Balance Sheets to follow*

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**ASTEX PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(In thousands, except per share amounts)  
(Unaudited)

	Three months ended	
	March 31,	
	2012	2011
<b>Revenues:</b>		
Royalty revenue	\$ 20,594	\$ 16,971
Development and license revenue	1,430	127
Total revenues	<u>22,024</u>	<u>17,098</u>
<b>Operating expenses:</b>		
Research and development	14,065	7,992
General and administrative	4,342	3,621
Amortization of intangibles	2,157	—
Total operating expenses	<u>20,564</u>	<u>11,613</u>
Income from operations	1,460	5,485
Interest income	41	49
Other income (expense)	(44)	—
Income before income taxes	1,457	5,534
Income tax benefit (provision)	2,783	(44)
Net income	<u>\$ 4,240</u>	<u>\$ 5,490</u>
<b>Net income per common share:</b>		
Basic	<u>\$ 0.05</u>	<u>\$ 0.09</u>
Diluted	<u>\$ 0.04</u>	<u>\$ 0.09</u>
<b>Weighted average shares outstanding:</b>		
Basic	<u>93,072</u>	<u>60,364</u>
Diluted	<u>103,988</u>	<u>61,026</u>

**ASTEX PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(In thousands)  
(Unaudited)

	<u>March 31,</u> <u>2012</u>	<u>December 31,</u> <u>2011</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 34,684	\$ 39,788
Marketable securities	87,780	86,444
Accounts receivable	598	5,189
Income tax receivable	4,394	2,963
Prepaid expenses and other current assets	2,129	2,186
Total current assets	129,585	136,570
Marketable securities, non-current	3,688	1,819
Property, plant and equipment, net	7,371	7,013
Goodwill	46,317	44,794
Other intangible assets, net	86,985	86,198
Other assets	554	554
Total assets	\$ 274,500	\$ 276,948
<b>LIABILITIES &amp; STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 6,044	\$ 7,529
Accrued compensation	5,122	5,324
Other accrued liabilities	619	613
Deferred acquisition consideration	10,056	17,353
Deferred tax liability	3,458	3,342
Deferred revenue	—	509
Total current liabilities	25,299	34,670
Warrant liability	188	187
Deferred acquisition consideration, non-current	9,045	11,624
Deferred tax liability, non-current	8,391	9,545
Deferred revenue, non-current	—	921
Total liabilities	42,923	56,947
Total stockholders' equity	231,577	220,001
Total liabilities and stockholders' equity	\$ 274,500	\$ 276,948