



October 30, 2012

Astex Pharmaceuticals Reports 2012 Third Quarter Financial Results

Dacogen Approved in the European Union for the Treatment of Elderly AML

Initiated HSP90 Inhibitor AT13387 Clinical Trials in Prostate & Lung Cancer Patients

Initiated SGI-110 Clinical Trial in Ovarian Cancer

Ended Quarter With Nearly \$130 Million in Cash & Marketable Securities

DUBLIN, Calif., Oct. 30, 2012 (GLOBE NEWSWIRE) -- Astex Pharmaceuticals, Inc. (Nasdaq:ASTX), today reported financial results for the third quarter ended September 30, 2012. The Company reported a net loss for the 2012 third quarter of \$1.8 million, or \$0.02 per basic and diluted share, compared with a net loss of \$1.1 million, or \$0.01 per basic and diluted share, for the same prior year period. The Company reported net income for the nine months ended September 30, 2012 of \$3.7 million, or \$0.04 per basic and diluted share, compared with a net income of \$5.3 million, or \$0.08 per basic and diluted share, for the same prior year period.

Highlights of 2012 Third Quarter:

- *Dacogen*[®] (decitabine) for Injection was approved in the European Union (EU) for the treatment of adult patients (age 65 years and above) with newly diagnosed de novo or secondary Acute Myeloid Leukemia (AML). In October 2012, the Company earned \$5 million upon first commercial sale of *Dacogen* in the EU.
- Royalty revenue increased from \$16.6 million in the prior year third quarter to \$17.0 million in the current year third quarter.
- Ended the 2012 third quarter with nearly \$130 million in cash & marketable securities.
- Revised 2012 financial guidance from a forecasted net loss of \$5 million to net income of \$4 million.
- Initiated two Phase 2 clinical trials of the HSP90 inhibitor AT13387 in castration resistant prostate cancer patients, and in non-small cell lung cancer (NSCLC) patients with anaplastic lymphoma kinase positive (ALK+) or other crizotinib sensitive tumors.
- Initiated Phase 2 clinical trial of SGI-110 in platinum-resistant ovarian cancer patients.
- Initiated new epigenetics drug discovery collaboration with The Institute of Cancer Research and Cancer Research Technology Limited, as well as a five-year strategic drug discovery alliance with the UK's Cancer Research Technology Limited (CRT) and Newcastle University.

"Thanks to Eisai and Janssen, *Dacogen* is now sold and marketed in more than 35 countries around the world. *Dacogen* royalties received in the third quarter helped to drive revenue and increase our cash and cash equivalents position," said James S.J. Manuso, Ph.D., chairman and chief executive officer. "We revised our operating guidance and now project a small profit for 2012. Before year-end, our prioritized products, AT13387 and SGI-110, will be in four Phase 2 proof-of-concept clinical trials."

2012 Third Quarter Financial Results

Total revenues for the 2012 third quarter were \$17.2 million compared with \$16.9 million for the same prior year period. Total revenues for the 2012 third quarter include royalty revenue of \$17.0 million compared with \$16.6 million for the same prior year period. Total revenues for the 2012 third quarter also include development and license revenue of \$199,000 compared with \$308,000 for the same prior year period.

Total operating expenses for the 2012 third quarter were \$26.6 million, compared with \$20.1 million for the same prior year period. The primary reasons for the increase in total operating expenses for the 2012 third quarter compared with the same prior year period 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 initiatives associated with SGI-110 and AT13387, an increase in the amortization of intangible assets related to the acquisition, and an impairment charge associated with the write down of an intangible asset. The non-cash amortization of intangible assets was \$1.9 million for the 2012 third quarter compared with \$1.5 million for the same prior year period. The non-cash impairment charge was \$7.4

million for the 2012 third quarter while there was no similar impairment charge for the same prior year period. Stock-based compensation expense, a non-cash expense that is included in operating expenses, was \$885,000 for the 2012 third quarter, compared with \$858,000 for the same prior year period.

The Company reported a net loss for the 2012 third quarter of \$1.8 million, or \$0.02 per basic and diluted share, compared with a net loss of \$1.1 million, or \$0.01 per basic and diluted share, for the same prior year period. Included in the 2012 third quarter net loss is a \$2.6 million gain on sale of investments related to the disposition of an equity position held in another entity. In addition, the 2012 third quarter net loss also includes an income tax benefit of \$5.5 million compared with an income tax benefit of \$2.4 million for the same prior year period. The income tax benefit for the current and prior year third quarter is primarily due to the recognition of a tax benefit associated with the amortization of deferred tax liabilities resulting from the acquisition, a change in the UK tax rates, and foreign research and development tax credits related to the UK subsidiary.

Financial Position

At September 30, 2012, the Company had \$129.9 million in cash, cash equivalents, and current and non-current marketable securities compared to \$120.8 million at June 30, 2012.

Operational Highlights

The Company announced that Janssen-Cilag International NV was notified that the European Commission approved the marketing authorization for *Dacogen* for the treatment of adult patients (age 65 years and above) with newly diagnosed de novo or secondary AML, according to the World Health Organization classification, who are not candidates for standard induction chemotherapy. *Dacogen* was also granted a 10-year Orphan Drug designation for the treatment of elderly AML. In early October, 2012, the Company announced that a \$5 million milestone was earned from Eisai Inc. for the first commercial sale of *Dacogen* in the EU, which will be reflected as revenue during the Company's 2012 fourth quarter.

The Company announced the initiation of three Phase 2 clinical trials, including a study with HSP90 inhibitor, AT13387, in castration-resistant prostate cancer patients, an AT13387 study in NSCLC patients with ALK+ or other crizotinib sensitive tumors, and a study with the novel hypomethylator SGI-110 in platinum-resistant ovarian cancer patients.

The Company announced that clinical development of amuvatinib (MP-470), a multi-targeted tyrosine kinase inhibitor that inhibits the mutant forms of c-Kit and PDGFR alpha and disrupts DNA repair, was discontinued. Amuvatinib was being investigated in a Phase 2 study for the treatment of SCLC in combination with Platinum Etoposide using a Simon 2-stage design. Response evaluation by RECIST criteria validated two partial responses in the 21 evaluable patients in the stage 1 segment of the Simon 2-stage designed trial (9.5% Response Rate), which fell short of the targeted primary endpoint response rate. No new safety issues were identified, and biological marker studies are ongoing. There were several patients with prolonged stable disease. The results will be presented at a future scientific meeting.

The Company, Cancer Research Technology Limited (CRT) and The Institute of Cancer Research, London UK, initiated a collaboration to discover and develop drug candidates against an undisclosed epigenetic target in a blood cancer with a high unmet medical need. The collaboration combines the Company's world-renowned fragment-based drug discovery platform and epigenetic drug development experience with the expertise in blood cancer biology at The Institute of Cancer Research (ICR) and the proven success in drug discovery at the Cancer Research UK Cancer Therapeutics Unit at the ICR.

2012 (Revised) and 2013 Annual Financial Guidance

The annual financial guidance for 2012 and 2013 is presented in the table below:

	<u>Annual Financial Guidance (In \$000's)</u>	
	<u>2012</u>	<u>2013</u>
Revenues:		
Royalty revenue	\$ 70,000	\$ 60,000
Development & license revenue (a)	<u>12,000</u>	<u>--</u>
	<u>82,000</u>	<u>60,000</u>
Operating expenses (b):		
Research & development	61,000	67,000
Amortization of intangibles and impairment charge	15,500	8,000
General & administrative	15,500	15,000

Gain on disposition of assets and sale of products	(1,300)	--
	<u>90,700</u>	<u>90,000</u>
Loss from operations	(8,700)	(30,000)
Other income (expense), net	2,200	--
Income tax benefit	<u>10,500</u>	<u>8,000</u>
Net income (loss)	<u>\$ 4,000</u>	<u>\$(22,000)</u>
Net income (loss) per average share outstanding	<u>\$ 0.04</u>	<u>\$ (0.23)</u>
Weighted average shares outstanding	<u>93,000</u>	<u>94,000</u>

(a) Though the Company anticipates earning additional development and license revenue from its partnered programs we do not provide guidance to such revenue due to the general uncertainty around, and timing of, milestone achievements and payments.

(b) Includes total non-cash charges of approximately \$20 million and \$12 million for 2012 and 2013, respectively.

Conference Call Information

Astex Pharmaceuticals will host a conference call to discuss the 2012 third 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.

The Astex Pharmaceuticals, Inc. logo is available at <http://www.globenewswire.com/newsroom/prs/?pkgid=12273>

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

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 financial guidance, which include expectations regarding royalty revenue, development and license revenue, research and development expenses and general and administrative expenses, amortization of intangibles and impairment charges, gains on dispositions of assets and sales of products, estimates of net income or loss and anticipated tax benefits and statements about expected losses or profitability; expectations regarding the completion of drug candidate optimization and advancement of drug candidates in the clinic; expectations regarding our clinical trials including the production and timing of clinical data from these trials; expectations regarding the potential 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 sufficiency of our operating cash to fund our development initiatives this year and thereafter; estimates regarding our total expected shares outstanding; and expectations regarding Eisai's and Janssen's plans for *Dacogen* since its approval in Europe. 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: failure to achieve the results included in the financial guidance; 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 SGI-110, AT13387, and other programs; 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. 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 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.

Condensed Consolidated Statements of Operations and Balance Sheets to follow

ASTEX PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(Unaudited)

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2012	2011	2012	2011
Revenues:				
Royalty revenue	\$ 16,995	\$ 16,638	\$ 52,030	\$ 45,148
Development and license revenue	199	308	7,068	562
Total revenues	17,194	16,946	59,098	45,710
Operating expenses:				
Research and development	13,633	13,546	43,092	29,531
General and administrative	4,188	5,095	12,180	12,246
Amortization of intangibles	1,938	1,485	6,036	1,485
Impairment of intangibles	7,402	--	7,402	--
Gains on disposition of assets and sale of products	(576)	--	(1,276)	(700)
Total operating expenses	26,585	20,126	67,434	42,562
Income (loss) from operations	(9,391)	(3,180)	(8,336)	3,148
Interest income	50	48	136	153
Gain on sale of investments and fixed assets	2,591	--	2,583	10
Other than temporary decline in value of investments	(485)	--	(524)	--
Other income (expense)	(4)	(291)	(31)	(291)
Income (loss) before income taxes	(7,239)	(3,423)	(6,172)	3,020
Income tax benefit	5,479	2,352	9,892	2,302
Net income (loss)	\$ (1,760)	\$ (1,071)	\$ 3,720	\$ 5,322
Net income (loss) per common share:				
Basic	\$ (0.02)	\$ (0.01)	\$ 0.04	\$ 0.08
Diluted	\$ (0.02)	\$ (0.01)	\$ 0.04	\$ 0.08
Weighted average shares outstanding:				
Basic	93,316	86,116	93,175	69,054

Diluted	<u>93,316</u>	<u>86,116</u>	<u>102,335</u>	<u>69,809</u>
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ASTEX PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)
(Unaudited)

September 30, December 31,
<u>2012</u> <u>2011</u>

ASSETS

Current assets:

Cash and cash equivalents	\$ 26,772	\$ 39,788
Marketable securities	103,065	86,444
Accounts receivable	880	5,189
Income tax receivable	6,174	2,963
Prepaid expenses and other current assets	<u>2,146</u>	<u>2,186</u>
Total current assets	139,037	136,570

Marketable securities, non-current	31	1,819
Property, plant and equipment, net	5,911	7,013
Goodwill	46,822	44,794
Other intangible assets, net	76,547	86,198
Other assets	<u>1,564</u>	<u>554</u>
Total assets	<u>\$ 269,912</u>	<u>\$ 276,948</u>

LIABILITIES & STOCKHOLDERS' EQUITY

Current liabilities:

Accounts payable	\$ 7,723	\$ 7,529
Accrued compensation	4,213	5,324
Other accrued liabilities	616	613
Deferred acquisition consideration	8,283	17,353
Deferred tax liability	3,496	3,342
Deferred revenue	<u>--</u>	<u>509</u>
Total current liabilities	24,331	34,670

Warrant liability	316	187
Deferred acquisition consideration, non-current	8,628	11,624
Deferred tax liability, non-current	4,152	9,545
Deferred revenue, non-current	<u>--</u>	<u>921</u>
Total liabilities	37,427	56,947

Total stockholders' equity	<u>232,485</u>	<u>220,001</u>
Total liabilities and stockholders' equity	<u>\$ 269,912</u>	<u>\$ 276,948</u>

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