



## *News Release*

### **Astex Pharmaceuticals Reports 2012 Second Quarter Financial Results**

***Dacogen Royalty Revenue Increased 25% from Prior Year  
\$5.4 Million Earned on Phase I Trial Initiation of FGFR Kinase Inhibitor  
Dacogen Receives Positive Regulatory Recommendation in the EU for Treatment of  
Elderly AML***

**DUBLIN, Calif., July 30, 2012** - Astex Pharmaceuticals, Inc. (NASDAQ: ASTX), today reported financial results for the second quarter ended June 30, 2012. The Company reported net income for the 2012 second quarter of \$1.2 million, or \$0.01 per basic and diluted share, compared with \$903,000, or \$0.01 per basic and diluted share, for the same prior year period. The Company reported net income for the six months ended June 30, 2012 of \$5.5 million, or \$0.06 per basic and \$0.05 per diluted share, compared with a net income of \$6.4 million, or \$0.11 per basic and \$0.10 per diluted share, for the same prior year period.

#### **Highlights of 2012 Second Quarter:**

- *Dacogen*<sup>®</sup> (decitabine) for Injection received a positive regulatory recommendation in the European Union (EU) for the treatment of elderly Acute Myeloid Leukemia (AML). If approved, *Dacogen* would receive 10 years of market exclusivity in the EU and the Company would earn a milestone payment of \$5.0 million.
- *Dacogen* second quarter royalty revenue increased 25% from the prior year's second quarter, from \$11.5 million to \$14.4 million.
- Earned \$5.4 million on Phase I trial initiation of a Fibroblast Growth Factor Receptor (FGFR) kinase inhibitor from the collaborative drug discovery program with Janssen Pharmaceutica NV.
- Ended 2012 second quarter with \$121 million in cash & marketable securities.
- Revised 2012 financial guidance from a forecasted net loss of \$15 million to a net loss of \$5 million with the potential to be operationally cash flow positive.

“Astex’s financial position remains strong, and our operating performance for 2012 to date is positive. Pipeline products in development continue to advance in Phase II trials with expected trial result readouts in the near future,” said James S.J. Manuso, PhD,

chairman and chief executive officer of Astex Pharmaceuticals. “We plan to initiate new Phase II clinical proof-of-concept trials for our prioritized products, AT13387 and SGI-110, in solid tumors during the second half of 2012.”

Dr. Manuso continued, “We were pleased to learn that the Committee for Medical Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion recommending approval of *Dacogen* for the treatment of elderly AML. The CHMP's reference to the impact of *Dacogen* on overall survival in elderly AML was gratifying. If *Dacogen* is approved in the EU it would become the first drug ever to be approved for the elderly AML indication.”

### **2012 Second Quarter Financial Results**

Total revenues for the 2012 second quarter were \$19.9 million compared with \$11.7 million for the same prior year period. Total revenues for the 2012 second quarter include royalty revenue of \$14.4 million compared with \$11.5 million for the same prior year period. Total revenues for the 2012 second quarter also include development and license revenue of \$5.4 million compared with \$127,000 for the same prior year period. Development and license revenue for the 2012 second quarter reflects revenue earned from a collaborative drug discovery program with Janssen Pharmaceutica NV and was triggered when the partner received clearance to commence a Phase I clinical trial of a FGFR kinase inhibitor.

Excluding the gain on sale of products, total operating expenses for the 2012 second quarter were \$21.0 million, compared with \$11.5 million for the same prior year period. The primary reasons for the increase in total operating expenses for the 2012 second 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 activities from product development and clinical trial programs associated with SGI-110, AT13387, and amuvatinib, and the amortization of intangible assets related to the acquisition. The non-cash amortization of intangible assets was \$1.9 million for the 2012 second quarter while there was no amortization expense for the same prior year period. Stock-based compensation expense, a non-cash expense that is included in operating expenses, was \$810,000 for the 2012 second quarter, compared with \$744,000 for the same prior year period.

The gain on sale of products for the 2012 second quarter was \$700,000 compared with the same amount for the same prior year period. The gain on sale of products relates to the receipt of the last contractual payment resulting from the 2007 sale of the worldwide rights for Nipent® (pentostatin for injection) to Mayne Pharma (acquired by Hospira, Inc. in February 2007).

The Company reported net income for the 2012 second quarter of \$1.2 million, or \$0.01 per basic and diluted share, compared with net income of \$903,000, or \$0.01 per basic and diluted share, for the same prior year period. The net income for the 2012 second quarter includes an income tax benefit of \$1.6 million compared with an income tax provision of \$6,000 for the same prior year period. The income tax benefit for the 2012 second 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 June 30, 2012, the Company had \$120.8 million in cash, cash equivalents, and current and non-current marketable securities compared to \$126.2 million at March 31, 2012.

### **Operational Highlights**

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 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.

During June 2012, the Company announced it had initiated the Phase II dose expansion segment of the clinical trial of SGI-110 in patients with intermediate-2 or high risk myelodysplastic syndromes (MDS) or elderly AML. Treatment-naïve MDS and AML ( $\geq 65$  years) will be enrolled in the dose expansion. Enrollment in the Phase II segment is currently open, and the first patient has been dosed. The Phase II segment includes expansion to approximately 90 patients treated on the five day subcutaneous dosing schedule to better evaluate both efficacy and safety in MDS and AML patients.

In June 2012, the Company and the National Cancer Institute (NCI) presented data from the two Phase I trials of our HSP90 inhibitor AT13387 at the 2012 American Society of Clinical Oncology (ASCO) Annual Meeting held in Chicago, IL. The trials defined the maximum tolerated dose (MTD) of the drug using different schedules and demonstrated that the drug was well tolerated at the MTD. In study AT13387-01, three of the seven refractory gastrointestinal stromal tumor (GIST) patients recruited into the study achieved Partial Response or Stable Disease for more than 6 months.

Also in June 2012, the Company announced that Janssen Pharmaceutica NV had received clearance to commence a Phase I clinical trial of a FGFR kinase inhibitor from its cancer drug discovery collaboration with Astex. The regulatory approval required to take the compound into Phase I triggered a payment obligation to Astex of £3.5 million (US\$5.4 million). Astex is eligible to receive further milestones during clinical development and royalties on commercialization of products derived from the collaboration. The FGFR inhibitor program originated from a collaboration between Astex, the Cancer Research UK Drug Discovery Group at the Newcastle Cancer Centre (NCC), and the Northern Institute for Cancer Research, Newcastle University, UK. As part of the collaboration, the Company applied its fragment-based drug discovery approach, Pyramid™, to identify lead compounds inhibiting FGFR kinase. The partnership with Janssen was entered into in June 2008. Janssen is responsible for the clinical and regulatory development of all products arising from the collaboration and for their global commercialization.

During July 2012, the Company announced that Janssen-Cilag International NV was notified that the CHMP of the EMA granted a positive opinion recommending approval of *Dacogen* for the treatment of adult patients (age 65 years and above) with newly diagnosed de novo or secondary AML that according to the World Health Organization (WHO) classification are not candidates for standard induction chemotherapy. Janssen is the licensee for *Dacogen* in territories outside of the United States, Canada and Mexico. The CHMP is the committee responsible for the scientific assessment of products seeking centralized marketing authorization throughout the EU. The CHMP's positive opinion is now referred for approval to the European Commission. Janssen anticipates receiving the regulatory decision from the Commission later in the 2012 third quarter. If approved, *Dacogen* will become the first drug to be approved for the elderly AML indication, and clinicians and patients in Europe would have access to this new treatment option. As an Orphan Drug, *Dacogen* would have ten years of market exclusivity for the elderly AML indication in the EU. In addition, Astex would earn a \$5.0 million milestone payment upon first commercialization of the drug in addition to earning future royalty revenue.

### **2012 Revised Financial Guidance**

The revised financial guidance for 2012 is presented in the table below:

**2012 Financial Guidance**  
(In \$000's)

	<u>Prior</u>	<u>Revised</u>
Revenues:		
Royalty revenue	\$ 67,000	\$ 70,000
Development & license revenue	1,400	6,900
	<u>68,400</u>	<u>76,900</u>
Operating expenses: **		
Research & development	67,000	65,000
Amortization of intangibles	8,500	8,500
General & administrative	15,000	15,000
Gain on sale of products	(700)	(700)
	<u>89,800</u>	<u>87,800</u>
Loss from operations	(21,400)	(10,900)
Other income (expense), net	400	(100)
Income tax benefit	6,000	6,000
Net income (loss)	<u>\$ (15,000)</u>	<u>\$ (5,000)</u>
Weighted average shares outstanding	<u>93,000</u>	<u>93,000</u>

\*\* Includes recurring non-cash charges of approximately \$12 million.

### Conference Call Information

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

## 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 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; 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 income or 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 ultimate outcome of the submission of the European regulatory filing; 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; 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.

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*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		Six months ended	
	June 30,		June 30,	
	2012	2011	2012	2011
Revenues:				
Royalty revenue.....	\$ 14,441	\$ 11,539	\$ 35,035	\$ 28,510
Development and license revenue.....	5,439	127	6,868	254
Total revenues .....	19,880	11,666	41,903	28,764
Operating expenses:				
Research and development .....	15,394	7,992	29,458	15,985
General and administrative .....	3,650	3,532	7,992	7,152
Amortization of intangibles.....	1,941	-	4,098	-
Gain on sale of products .....	(700)	(700)	(700)	(700)
Total operating expenses .....	20,285	10,824	40,848	22,437
Income (loss) from operations .....	(405)	842	1,055	6,327
Interest income .....	45	57	87	106
Other income (expense).....	(31)	10	(75)	10
Income (loss) before income taxes.....	(391)	909	1,067	6,443
Income tax benefit (provision).....	1,630	(6)	4,413	(50)
Net income.....	\$ 1,239	\$ 903	\$ 5,480	\$ 6,393
Net income per common share:				
Basic .....	\$ 0.01	\$ 0.01	\$ 0.06	\$ 0.11
Diluted.....	\$ 0.01	\$ 0.01	\$ 0.05	\$ 0.10
Weighted average shares outstanding:				
Basic.....	93,135	60,399	93,103	60,382
Diluted.....	102,722	61,070	103,355	61,044



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

	<b>June 30, 2012</b>	<b>December 31, 2011</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents .....	\$ 26,338	\$ 39,788
Marketable securities .....	92,942	86,444
Accounts receivable .....	6,041	5,189
Income tax receivable.....	4,413	2,963
Prepaid expenses and other current assets .....	2,329	2,186
Total current assets .....	132,063	136,570
Marketable securities, non-current .....	1,518	1,819
Property, plant and equipment, net .....	6,870	7,013
Goodwill .....	45,256	44,794
Other intangible assets, net .....	83,045	86,198
Other assets .....	554	554
Total assets .....	\$ 269,306	\$ 276,948
<b>LIABILITIES &amp; STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable .....	\$ 7,113	\$ 7,529
Accrued compensation.....	3,703	5,324
Other accrued liabilities .....	613	613
Deferred acquisition consideration.....	4,404	17,353
Deferred tax liability.....	3,377	3,342
Deferred revenue .....	-	509
Total current liabilities .....	19,210	34,670
Warrant liability.....	195	187
Deferred acquisition consideration, non-current.....	14,586	11,624
Deferred tax liability, non-current.....	6,915	9,545
Deferred revenue, non-current .....	-	921
Total liabilities .....	40,906	56,947
Total stockholders' equity .....	228,400	220,001
Total liabilities and stockholders' equity .....	\$ 269,306	\$ 276,948