



ANADYS PHARMACEUTICALS REPORTS FOURTH QUARTER AND YEAR-END 2009 FINANCIAL RESULTS AND HIGHLIGHTS

San Diego, February 24, 2010 – Anadys Pharmaceuticals, Inc. (Nasdaq: ANDS), a biopharmaceutical company dedicated to improving patient care by developing novel medicines for the treatment of hepatitis C, today reported its financial results and program highlights for the fourth quarter and year ended December 31, 2009.

“In the past year we’ve significantly advanced the development of ANA598, our wholly owned non-nucleoside polymerase inhibitor in development for the treatment of hepatitis C,” said Steve Worland, Ph.D., President and CEO of Anadys. “The twelve week Phase II results announced today demonstrate the ability of ANA598 to significantly accelerate the rate of patients achieving undetectable levels of virus when added to current treatment. The durability of antiviral response through twelve weeks and a very favorable safety profile to date position ANA598 as one of the most attractive and advanced polymerase inhibitors in the HCV development landscape today, ready for clinical trials exploring the use of ANA598 in combination with other direct antivirals.”

Recent Highlights

Today, Anadys reported preliminary results from an ongoing Phase II study demonstrating that 73% of hepatitis C patients treated with 200 mg ANA598 twice daily in combination with pegylated interferon and ribavirin (SOC) achieved undetectable levels of virus (<15 IU/mL) at week 12, known as complete Early Virological Response or cEVR. No patient experienced viral rebound on ANA598. ANA598 was well tolerated through twelve weeks, with no serious adverse events reported and a profile of adverse events in the ANA598 group comparable to the group receiving SOC alone.

Financial Results

As of December 31, 2009, the Company’s cash, cash equivalents and securities available-for-sale totaled \$20.5 million compared to \$27.9 million as of December 31, 2008. The decrease in cash, cash equivalents and securities available-for-sale is the result of our cash utilization to fund operations during 2009 partially offset by proceeds of approximately \$16.0 million received from a “registered direct” offering of common stock and warrants in early June 2009.

Total operating expenses were \$5.6 million for the fourth quarter of 2009, compared to \$8.9 million for the fourth quarter of 2008. Included as a component of Anadys’ operating expenses were non-cash, share-based expenses of \$0.4 million and \$0.7 million for the fourth quarter of 2009 and 2008, respectively.

Research and development expenses were \$4.0 million for the fourth quarter of 2009, compared to \$6.9 million for the fourth quarter of 2008. The \$2.9 million decrease was primarily attributable to cost savings associated with our strategic restructuring initiated in June 2009 which included a \$1.5 million decrease in ANA773 development costs.

General and administrative expenses were \$1.6 million for the fourth quarter of 2009, compared to \$2.0 million for the fourth quarter of 2008. The \$0.4 million decrease primarily resulted from cost savings associated with our strategic restructuring and the relocation of our corporate headquarters to a smaller facility during July 2009.

The net loss was \$4.3 million for the fourth quarter of 2009, compared to a net loss of \$8.5 million for the fourth quarter of 2008. Included in the net loss for the fourth quarter of 2009 is a \$1.3 million gain resulting from a decrease in the liability associated with our common stock warrants from September 30, 2009 to December 31, 2009. The warrants were issued in connection with our “registered direct” offering in early June 2009. Basic and diluted net loss per common share was \$0.11 in the fourth quarter of 2009, compared to \$0.30 in the fourth quarter of 2008. Non-cash share-based expense resulted in a \$0.01 and \$0.02 increase in basic and diluted net loss per share for the fourth quarter of 2009 and 2008, respectively.

For the twelve months ended December 31, 2009, Anadys reported a net loss of \$27.3 million, compared to \$32.4 million for the same period last year. Basic and diluted net loss per common share was \$0.81 and \$1.13 for the twelve months ended December 31, 2009 and 2008, respectively.

2009 Development Program Highlights

ANA598-non-nucleoside HCV polymerase inhibitor in Phase II development.

- **Reported Positive Phase II Combination Data.** In December 2009, Anadys announced preliminary results from a planned interim analysis of data at four weeks for the first dose cohort, 200 mg given twice daily (bid), in an ongoing Phase II study of ANA598 in combination with pegylated interferon and ribavirin (SOC) in HCV patients. At each week, a greater proportion of patients receiving ANA598 plus SOC achieved undetectable levels of virus compared to patients receiving placebo plus SOC, with 56% of patients in the ANA598 group having undetectable levels of virus at week four. ANA598 was well tolerated through four weeks, with no serious adverse events reported.

In the ongoing Phase II study, treatment-naïve genotype 1 patients are to receive ANA598 or placebo in combination with Pegasys[®] (peginterferon alfa-2a) and Copegus[®] (ribavirin, USP) for 12 weeks at dose levels of 200 mg or 400 mg both given twice daily (bid), each with a loading dose of 800 mg bid on day one. After week 12, patients are to continue receiving SOC. Patients who achieve undetectable levels of virus at weeks 4 and 12 will be randomized to stop all treatment at week 24 or 48. The primary endpoint of the study is the proportion of patients who achieve undetectable levels of virus at week 12 (defined as complete Early Virological Response, or cEVR). Additional endpoints include safety and tolerability as well as the proportion of patients with undetectable levels of virus at week 4 (defined as Rapid Virological Response, or RVR). Patients will be followed for 24 weeks after stopping therapy to determine the rate of Sustained Virological Response, or SVR. Approximately 90 patients were to be and have been enrolled in this study – with approximately 30 patients receiving ANA598 and 15 receiving placebo at each dose level. The study is being managed by the Duke Clinical Research Institute (DCRI) under the leadership of John McHutchison, M.D. and is being conducted at a number of clinical sites in the United States.

- **Reported Potent Antiviral Activity/Good Tolerability at EASL.** In April 2009, Anadys reported data at the 44th Annual Meeting of the European Association of the Study of Liver Disease demonstrating potent antiviral activity and good tolerability of ANA598 as a single agent

at all dose levels in a Phase Ib study, in which ANA598 was dosed for three days in HCV patients. No patient at any dose level showed evidence of viral rebound while on ANA598 and there were no serious adverse events reported.

- **Reported 14-day Healthy Volunteer Study Results.** In April 2009, Anadys reported that ANA598 was generally well-tolerated in all cohorts with no serious adverse events in a 14-day monotherapy study of ANA598 in healthy volunteers. Pharmacokinetic results from this trial confirmed the plasma half-life of ANA598 of approximately 24 hours, and demonstrated that steady-state levels of ANA598 in plasma are reached after six to seven days of dosing.
- **Favorable Toxicology Profile Established.** In October 2009, Anadys completed its long-term, chronic toxicology studies of ANA598 and reported that the No Observed Adverse Effect Level, or NOAEL, is 1000 mg/kg (the highest dose tested) in both species tested. The completed studies confirm the favorable toxicology profile of ANA598 and support dosing durations of as long as one year if desirable in future clinical studies.

ANA773-oral inducer of endogenous interferons that acts via the toll like receptor 7 (TLR7) pathway.

- **Proof of Concept Achieved in Phase I Clinical Trial in HCV.** In August 2009, Anadys announced proof of concept results from a completed Phase I clinical trial of ANA773 in HCV. Patients receiving 2000 mg ANA773 every other day over 10 days experienced a 1.3 log₁₀ mean maximal decline in viral load. Based on these results, Anadys believes that ANA773 continues to hold promise as a potential replacement for injectable interferon products in HCV therapy. As part of the strategic restructuring implemented in mid-2009, Anadys has deferred initiation of any subsequent trials of ANA773 in HCV.
- **Phase I Clinical Trial in Oncology.** In 2009 Anadys completed enrollment through the 800 mg dose cohort in a trial of ANA773 in oncology patients in which patients were to receive ANA773 every other day over 14 days followed by a 14-day period off drug, with repeated cycles permitted in patients whose disease did not progress. ANA773 was well tolerated at all doses tested. ANA773 induced several biomarkers of immunological stimulation at higher doses. Two patients from this trial with stable disease continue to receive ANA773. As part of the strategic restructuring implemented in mid-2009, Anadys elected not to enroll any patients in previously planned higher dose cohorts.

2009 Operational Highlights

- **Closed Registered Direct Financing.** In June 2009, Anadys closed a “registered direct” offering of common stock and warrants in which net proceeds of approximately \$16.0 million were raised. Proceeds from the transaction are being used to further the development of ANA598, as well as for other general corporate purposes.
- **Focused Operations on Development of ANA598.** In June 2009, Anadys effected a strategic restructuring and facilities reduction in order to focus its operations on the continued development of ANA598 in the ongoing Phase II combination study.

Conference Call Webcast and Slides

Anadys will host a conference call at 5:00 pm Eastern Standard Time today to discuss its fourth quarter year-end 2009 financial results and highlights and to present the 12-week results at 200 mg bid in the ongoing ANA598 Phase II study. A live webcast of the call, including accompanying slides, will be available online at www.anadyspharma.com. A telephone replay will also be available approximately one hour after completion of the call. To access the telephone replay, dial 888-286-8010 (domestic) or 617-801-6888 (international), passcode 92658014. The webcast and telephone replay will be available through March 10, 2010.

About Anadys

Anadys Pharmaceuticals, Inc. is a biopharmaceutical company dedicated to improving patient care by developing novel medicines for the treatment of hepatitis C. The Company believes hepatitis C represents a large unmet medical need in which meaningful improvements in treatment outcomes may be attainable with the introduction of new medicines. The Company is developing ANA598, a non-nucleoside polymerase inhibitor for the treatment of hepatitis C. The Company has also investigated the potential of ANA773, an oral, small-molecule inducer of endogenous interferons that acts via the Toll-like receptor 7, or TLR7, pathway in hepatitis C.

Safe Harbor Statement

Statements in this press release that are not strictly historical in nature constitute "forward-looking statements." Such statements include, but are not limited to, references to (i) the belief that the durability of antiviral response through twelve weeks and a very favorable safety profile to date position ANA598 as one of the most attractive and advanced polymerase inhibitors in the HCV development landscape today, ready for clinical trials exploring the use of ANA598 in combination with other direct antivirals; (ii) assessments of the safety and tolerability profile of ANA598 based on the 200 mg bid 12 week results; (iii) the ability for patients to achieve a SVR in the ANA598 Phase II study; and (iv) the belief that ANA773 holds promise as a potential replacement for injectable interferon products in HCV therapy. Such forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause Anadys' actual results to be materially different from historical results or from any results expressed or implied by such forward-looking statements. For example, the results of preclinical and early clinical studies may not be predictive of future results, and Anadys cannot provide any assurances that ANA598 will not have unforeseen safety issues or will continue to have favorable results as the Phase II trial progresses. In addition, Anadys' results may be affected by competition from other biotechnology and pharmaceutical companies, its effectiveness at managing its financial resources, its ability to enter into transactions around its product candidates, its ability to successfully develop and market products, difficulties or delays in its preclinical studies or clinical trials, difficulties or delays in manufacturing its clinical trials materials, the scope and validity of patent protection for its products, regulatory developments and its ability to obtain additional funding to support its operations. Risk factors that may cause actual results to differ are more fully discussed in Anadys' SEC filings, including Anadys' Form 10-K for the year ended December 31, 2008 and Anadys' Form 10-Q for the quarter ended September 30, 2009. All forward-looking statements are qualified in their entirety by this cautionary statement. Anadys is providing this information as of this date and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

Condensed Consolidated Financial Statements

Anadys Pharmaceuticals, Inc. Condensed Consolidated Statements of Operations (In thousands except per share amounts) (Unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	<u>2009</u>	<u>2008</u>	<u>2009</u>	<u>2008</u>
Operating expenses				
Research and development	3,948	6,902	19,494	25,993
General and administrative	1,632	2,005	8,243	8,109
Total operating expenses ⁽¹⁾	5,580	8,907	27,737	34,102
Interest income and other, net	44	390	610	1,700
Gain (loss) from valuation of common stock warrant liability	1,279	—	(151)	—
Total other income, net	1,323	390	459	1,700
Net loss ⁽¹⁾	<u>\$ (4,257)</u>	<u>\$ (8,517)</u>	<u>\$ (27,278)</u>	<u>\$ (32,402)</u>
Net loss per share, basic and diluted ⁽¹⁾	<u>\$ (0.11)</u>	<u>\$ (0.30)</u>	<u>\$ (0.81)</u>	<u>\$ (1.13)</u>
Share used in calculating net loss per share, basic and diluted	<u>37,326</u>	<u>28,797</u>	<u>33,775</u>	<u>28,750</u>

⁽¹⁾ Includes non-cash share-based expenses of \$384 and \$699 or approximately \$0.01 and \$0.02 effect on basic and diluted net loss per common share for the three months ended December 31, 2009 and 2008, respectively. Research and development expense and general and administrative expense includes \$123 and \$261, respectively, of non-cash share-based expenses for the three months ended December 31, 2009. Includes non-cash share-based expenses of \$2,714 and \$2,763 or approximately \$0.08 and \$0.10 effect on basic and diluted net loss per common share for the twelve months ended December 31, 2009 and 2008, respectively. Research and development expense and general and administrative expense includes \$1,354 and \$1,360, respectively, of non-cash share-based expenses for the twelve months ended December 31, 2009.

Anadys Pharmaceuticals, Inc. Condensed Consolidated Balance Sheets (In thousands)

	December 31, 2009	December 31, 2008
	(Unaudited)	(Audited)
Assets		
Cash, cash equivalents and securities available-for-sale	\$ 20,490	\$ 27,936
Other current assets	559	2,202
Noncurrent assets	686	1,536
Total assets	\$ 21,735	\$ 31,674
Liabilities and Stockholders' Equity		
Current liabilities	\$ 3,383	\$ 5,813
Common stock warrant liability	3,897	—

Other long-term liabilities	26	36
Stockholders' equity	<u>14,429</u>	<u>25,825</u>
Total liabilities and stockholders' equity	<u>\$ 21,735</u>	<u>\$ 31,674</u>

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