Progenics Pharmaceuticals Reports Fourth Quarter and Year-End Results and Corporate Update

TARRYTOWN, N.Y., Mar 13, 2009 (BUSINESS WIRE) -- Progenics Pharmaceuticals, Inc. (Nasdaq: PGNX) today announced its results of operations for the fourth quarter and year ended December 31, 2008.

Revenues for the fourth quarter totaled $6.8 million, compared to $15.5 million for the same period of 2007. For the year ended December 31, 2008, the Company reported revenues of $67.7 million compared to $75.6 million for the comparable period of 2007.

Progenics ended the year 2008 with cash, cash equivalents and marketable securities of $141.4 million, compared to $170.4 million at December 31, 2007.

"Progenics had a pivotal year in 2008 - most significantly with the approval of RELISTOR(R), our first commercial product, by the U.S. Food and Drug Administration," said Paul J. Maddon, M.D., Ph.D., Progenics' Founder, Chief Executive Officer and Chief Science Officer. "RELISTOR is now approved in over 30 countries including the U.S., Canada, Australia and all member states of the European Union, and we are receiving royalties on worldwide sales. In addition, we made significant progress in advancing product candidates in our pipeline, completing two phase 2 trials of PRO 140 for the treatment of HIV infection, initiating the first clinical study of our PSMA antibody-drug conjugate for prostate cancer, and selecting PRO 206, a novel viral-entry inhibitor for the treatment of hepatitis C infection, for clinical development."

"Progenics has historically been efficient in managing its capital and has not incurred debt," Dr. Maddon continued. "In these challenging economic times, we will continue controlling expenses while carefully deploying existing cash, government funding and royalty proceeds for product development. We are guided by a conservative fiscal strategy in seeking non-dilutive sources of funding, including alliances to help us support our development programs."

Revenues for the three months and years ended December 31, 2008 and 2007 reflect:

- **Reimbursement from Wyeth Pharmaceuticals,** a division of Wyeth(NYSE: WYE), for development work performed by Progenics under the RELISTOR collaboration, which was recognized in the amounts of $2.9 million and $9.2 million for the fourth quarters of 2008 and 2007, respectively. For the years 2008 and 2007, $24.7 million and $40.1 million was recognized.
- **Amortization of the $60.0 millionupfront payment received from Wyeth** in December 2005, which was recognized in the amounts of $2.1 million and $3.3 million in the fourth quarters of 2008 and 2007, respectively. For the years 2008 and 2007, $10.2 million and $16.4 million was recognized.
- **$25.0 million in additional milestone payments from Wyeth**, whichwere received in 2008 (no payments were received in the fourth quarter). During 2007, Progenics received milestone payments totaling $9.0 million.
- **Royalty income on net sales of subcutaneous RELISTOR**, which was recognized in the amounts of $60,000 for the fourth quarter of 2008 and $146,000 for the year 2008. Cumulative earned royalties of $519,000 were deferred at December 31, 2008 and will be recognized as royalty income over the period of Progenics' development obligations.
- **Funding from government grants and contract** related to the Company's proprietary virology and oncology programs, which totaled $1.8 million and $3.0 million in the fourth quarters of 2008 and 2007, respectively. For the years 2008 and 2007, $7.5 million and $10.1 million was recognized.

Expenses for the fourth quarter of 2008 were $22.6 million, compared to $33.2 million for the fourth quarter of 2007. For the year ended December 31, 2008, expenses totaled $118.6 million, compared to $127.1 million for the same period of 2007.

Research and development expenses, including license fees and royalty expense, decreased $11.0 million, both for the fourth quarter of 2008 and the year ended December 31, 2008, compared to the same periods of 2007. The fourth quarter 2008 decrease in research and development expenses resulted primarily from a decrease in activity related to the RELISTOR, PRO 140 and PSMA clinical programs, partially offset by an increase in license fees. For the year ended December 31, 2008, research and development expenses decreased, primarily from a decrease in activity related to the PSMA clinical program, and to a lesser extent, activity related to the HCV research program, partially offset by increased activity in the PRO 140 clinical program and increased headcount.

General and administrative expenses increased for the three months and for the year ended December 31, 2008, compared to the same periods of 2007. The fourth quarter 2008 increase in general and administrative expenses was primarily due to an

increase in consulting expenses, partially offset by decreases in operating expenses and share-based compensation. For the year ended December 31, 2008, general and administrative expenses increased primarily due to increased headcount, consulting and professional fees, partially offset by decreases in operating expenses and share-based compensation.

Fourth quarter 2008 net loss was $14.6 million, compared to a net loss of $15.3 million for the same period of 2007. Net loss per share was $0.49, basic and diluted, for the fourth quarter of 2008, compared to net loss per share of $0.53, basic and diluted, for the same period of 2007. The net loss for the year ended December 31, 2008 was $44.7 million, compared to a $43.7 million net loss for the same period of 2007. Net loss per share for the year ended December 31, 2008 was $1.51, basic and diluted, compared to net loss per share of $1.60, basic and diluted, for the same period of 2007.

In April 2008, Progenics' Board of Directors approved a share repurchase program to acquire up to $15.0 million of the Company's outstanding common stock, funding for which came from the $15.0 million milestone payment from Wyeth for receipt of U.S. marketing approval for subcutaneous RELISTOR. Progenics repurchased 200,000 shares during the year ended December 31, 2008 for a total purchase price of $2.7 million.

2008 Company Highlights

- Received marketing approval for RELISTORfor the treatment of opioid-induced constipation (OIC) in advanced illness patients from the U.S. Food and Drug Administration (FDA) and the regulatory agencies of Canada, the European Union, Australia and elsewhere, representing approval in over 30 countries.
- Entered an exclusive license agreement with Ono Pharmaceutical Co., Ltd., granting Ono the rights to develop and commercialize subcutaneous RELISTOR in Japan for the treatment of OIC; received a $15.0 million upfront payment from Ono recorded as deferred revenue - current, which is expected to be recognized as revenue during the first quarter of 2009, upon satisfaction of our performance obligations.
- Reported a positive outcome from a phase 3 trial of subcutaneous RELISTOR in patients with OIC who have chronic, non-cancer pain. This clinical study showed statistically significant improvements in the occurrence of bowel movements, and adverse events observed were similar to those seen in prior studies of subcutaneous RELISTOR.
- Selected for further development the subcutaneous dosage form of PRO 140 for the treatment of HIV infection, following completion of two, phase 2 trials using the subcutaneous and intravenous formulations, both of which produced positive results. The subcutaneous dosage form has the potential for convenient, weekly self-administration. To design future pivotal trials for this product candidate, Progenics plans to meet with the FDA and key opinion leaders during 2009 to gather their views and guidance.
- Initiated a phase 1 trial of the Company's prostate-specific membrane antigen antibody-drug conjugate (PSMA ADC) compound in patients with progressive, castration-resistant prostate cancer.
- Selected PRO 206, a targeted, orally available hepatitis C viral entry inhibitor, for clinical development.

RELISTOR Program Developments

- In December, Progenics and Wyeth initiated an FDA-required one-year, open-label safety study of subcutaneous RELISTOR in chronic, non-cancer pain patients with OIC. This study is expected to enroll approximately 800 patients to supplement the already completed 470-patient, double-blind, phase 3 trial conducted in this patient population. Progenics and Wyeth recently conducted a pre-supplemental New Drug Application (sNDA) meeting with FDA. Based on this meeting, Progenics and Wyeth plan to present a consolidated safety database from both of these trials as part of an sNDA, which is now planned for submission by the end of 2010.

- Results from the completed one-month, blinded portion of the 470-patient phase 3 study will be presented at the annual meeting of the American Pain Society, May 7-9, 2009 in San Diego. Results from the two-month, open-label portion of this study are expected to be presented at other scientific conferences throughout the year.
- Wyeth and Progenics announced positive preliminary results evaluating the effects of an oral formulation of RELISTOR for the treatment of OIC in patients with chronic, non-cancer pain. Progenics and Wyeth are evaluating information from clinical optimization studies of a formulation of this product candidate to determine the next stages of development.
- Wyeth and Progenics also have had in development an intravenous formulation of RELISTOR for the management of post-operative ileus, a temporary impairment of gastrointestinal tract function. As previously announced, results from the two, phase 3 clinical trials of this formulation showed that treatment did not achieve primary or secondary endpoints. Recent results from a third phase 3 trial evaluating an intravenous formulation of RELISTOR in patients following abdominal hernia repair have confirmed these earlier findings.

Expected Developments in Proprietary Programs

- Progenics expects to report results from the 12-week portion of a phase 1 study of PSMA ADC in patients with castration-resistant prostate cancer during the second half of 2009.
- Progenics plans to submit an Investigational New Drug Application (IND) for PRO 206 by the end of 2009, and enter the candidate into phase 1 clinical testing in 2010.

About Progenics' Collaboration with Wyeth

In December 2005, Wyeth Pharmaceuticals, a division of Wyeth, and Progenics Pharmaceuticals, Inc. entered into an exclusive, worldwide agreement for the joint development and commercialization of methylnaltrexone for the treatment of opioid-induced side effects.

In January 2009, Wyeth and Pfizer Inc. executed a definitive agreement under which Pfizer is to acquire Wyeth. The proposed acquisition of Wyeth by Pfizer, which is subject to closing conditions, does not trigger any change-of-control provisions in our collaboration with Wyeth, and we believe that if the acquisition occurs, the combined Pfizer/Wyeth organization will continue to have the same rights and responsibilities under the collaboration agreement following the acquisition as Wyeth had before.

About Progenics' Collaboration with Ono

In October 2008, Ono Pharmaceutical Co., Ltd. and Progenics Pharmaceuticals, Inc. entered into an exclusive license agreement under which Ono has acquired the rights to subcutaneous RELISTOR in Japan, where it plans to develop and commercialize the U.S.-approved drug for the treatment of opioid-induced constipation. RELISTOR is being developed and commercialized in the rest of the world by Progenics and Wyeth Pharmaceuticals, a division of Wyeth, and is approved in over 30 countries.

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About the Company

Progenics Pharmaceuticals, Inc., of Tarrytown, NY, is a biopharmaceutical company focusing on the development and commercialization of innovative therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases. Principal programs are directed toward supportive care, virology-including human immunodeficiency virus (HIV) and hepatitis C virus (HCV) infections-and oncology. Progenics, in collaboration with Wyeth, is developing RELISTOR (R) (methylnaltrexone bromide) for the treatment of opioid-induced side effects. Wyeth has worldwide rights to develop and commercialize all forms of RELISTOR, except in Japan where Progenics has granted Ono Pharmaceutical Co., Ltd. an exclusive license to the subcutaneous form of RELISTOR for development and commercialization in that country. RELISTOR is currently approved in over 30 countries, including the U.S., Canada, Australia and all European Union member states. In the U.S., RELISTOR (methylnaltrexone bromide) subcutaneous injection is indicated for the treatment of opioid-induced constipation (OIC) in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. Marketing applications are pending for RELISTOR in other countries. In the area of virology, Progenics is developing the HIV entry inhibitor PRO 140, a humanized monoclonal antibody targeting the entry co-receptor CCR5, which is currently in phase 2 clinical testing. The Company is also developing a novel HCV entry inhibitor, PRO 206. For the treatment of prostate cancer, Progenics is conducting a phase 1 clinical trial of a human monoclonal antibody-drug conjugate (ADC) designed to selectively target prostate-specific membrane antigen (PSMA), a protein found on the surface of prostate cancer cells as well as in blood vessels supplying non-prostatic solid tumors. Progenics is also conducting phase 1 clinical trials with vaccines designed to treat prostate cancer by stimulating an immune response to PSMA.

(Financial Tables Follow)

PROGENICS PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except net loss per share)

	For the Three Months Ended December 31,		For the Year Ended December 31,	
	2008	2007	2008	2007
Revenues:				
Research and development from collaborator	$ 4,989	$ 12,468	$ 59,885	$ 65,455
Royalty income	60	-	146	-
Research grants and contract	1,771	2,999	7,460	10,075
Other revenues	8	67	180	116
Total revenues	6,828	15,534	67,671	75,646
Expenses:				
Research and development	14,099	26,068	82,290	95,234

License fees - research and development	1,042	109	2,830	942
General and administrative	6,304	6,154	28,834	27,901
Royalty expense	6	-	15	-
Depreciation and amortization	1,182	883	4,609	3,027
Total expenses	22,633	33,214	118,578	127,104
Operating loss	(15,805)	(17,680)	(50,907)	(51,458)
Interest income	1,207	2,408	6,235	7,770
Net loss	$(14,598)	$ (15,272)	$(44,672)	$(43,688)
Net loss per share; basic and diluted	$(0.49)	$ (0.53)	$(1.51)	$(1.60)
Weighted average shares outstanding; basic and diluted	29,953	29,570	29,654	27,378

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)

(in thousands)

	December 31, 2008	December 31, 2007
Cash, cash equivalents and marketable securities	$141,374	$170,370
Accounts receivable	1,337	1,995
Fixed assets, net	11,071	13,511
Other assets	4,051	3,663
Total assets	$157,833	$189,539
Liabilities	$38,464	$42,040
Stockholders' equity	119,369	147,499
Total liabilities and stockholders' equity	$157,833	$189,539

DISCLOSURE NOTICE:

This document contains statements that do not relate strictly to historical fact, any of which may be forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. When we use the words "anticipates," "plans," "expects" and similar expressions, we are identifying forward-looking statements. Forward-looking statements involve known and unknown risks and uncertainties which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. While it is impossible to identify or predict all such matters, these differences may result from, among other things, the inherent uncertainty of the timing and success of, and expense associated with, research, development, regulatory approval and commercialization of our products and product candidates, including the risks that clinical trials will not commence or proceed as planned; products appearing promising in early trials will not demonstrate efficacy or safety in larger-scale trials; clinical trial data on our products and product candidates will be unfavorable; our products will not receive marketing approval from regulators or, if approved, do not gain sufficient market acceptance to justify development and commercialization costs; we, our collaborators or others might identify side effects after the product is on the market; or efficacy or safety concerns regarding marketed products, whether or not originating from subsequent testing or other activities by us, governmental regulators, other entities or organizations or otherwise, and whether or not scientifically justified, may lead to product recalls, withdrawals of marketing approval, reformulation of the product, additional pre-clinical testing or clinical trials, changes in labeling of the product, the need for additional marketing applications, declining sales or other adverse events.

We are also subject to risks and uncertainties associated with the actions of our corporate, academic and other collaborators and government regulatory agencies, including risks from market forces and trends, such as those relating to the recently-announced acquisition of our RELISTOR(R) collaborator, Wyeth Pharmaceuticals, by Pfizer, Inc.; potential product liability; intellectual property, litigation, environmental and other risks; the risk that licenses to intellectual property may be terminated for our failure to satisfy performance milestones; the risk of difficulties in, and regulatory compliance relating to, manufacturing products; and the uncertainty of our future profitability.

Risks and uncertainties also include general economic conditions, including interest and currency exchange-rate fluctuations and the availability of capital; changes in generally accepted accounting principles; the impact of legislation and regulatory compliance; the highly regulated nature of our business, including government cost-containment initiatives and restrictions on third-party payments for our products; trade buying patterns; the competitive climate of our industry; and other factors set forth in our Annual Report on Form 10-K and other reports filed with the U.S. Securities and Exchange Commission. In particular, we cannot assure you that RELISTOR will be commercially successful or be approved in the future in other formulations, indications or jurisdictions, or that any of our other programs will result in a commercial product.

We do not have a policy of updating or revising forward-looking statements, and we assume no obligation to update any statements as a result of new information or future events or developments. Thus, it should not be assumed that our silence over time means that actual events are bearing out as expressed or implied in forward-looking statements.

Editors Note:

For more information about Progenics Pharmaceuticals, Inc., please visit www.progenics.com.

SOURCE: Progenics Pharmaceuticals, Inc.

Investors:
Progenics Pharmaceuticals, Inc.
Richard W. Krawiec, Ph.D., 914-789-2814
Vice President, Corporate Affairs
rkrawiec@progenics.com
or
Dory A. Lombardo, 914-789-2818
Associate Director, Corporate Affairs
dlombardo@progenics.com
or
Media:
WeissComm Partners
Aline Schimmel, 312-646-6295
or
Barri Winiarski, 914-584-7468