Progenics Reports Third Quarter 2008 Financial Results and Corporate Updates

TARRYTOWN, N.Y., Nov 10, 2008 (BUSINESS WIRE) -- Progenics Pharmaceuticals, Inc. (Nasdaq: PGNX) today announced its results of operations for the third quarter and nine months ended September 30, 2008.

Revenues for the third quarter totaled $17.5 million, compared to $17.0 million for the same period of 2007. For the nine months ended September 30, 2008, the Company reported revenues of $60.8 million compared to $60.1 million for the comparable period of 2007. Revenues for the three-month and nine-month periods ended September 30, 2008 and 2007 reflect the following:

-- Reimbursement from Wyeth Pharmaceuticals, a division of Wyeth (NYSE: WYE), of development work performed by Progenics under their RELISTOR(R) collaboration: Reimbursement was recognized in the amounts of $3.9 million and $11.3 million for the third quarters of 2008 and 2007, respectively. For the nine months ended September 30, 2008 and 2007, $21.8 million and $30.8 million was recognized, respectively.

-- Amortization of the upfront payment from Wyeth under the RELISTOR collaboration: Of the $60.0 million upfront payment received from Wyeth in December 2005, $2.1 million and $3.2 million was recognized in the third quarters of 2008 and 2007, respectively. For the nine months ended September 30, 2008 and 2007, $8.1 million and $13.1 million was recognized, respectively.

-- Milestone payments from Wyeth: Milestone payments related to the European and U.S. approvals of subcutaneous RELISTOR totaled $10.0 million in the third quarter of 2008 and $25.0 million in the nine months ended September 30, 2008. Milestone payments of $9.0 million were received during the nine months ended September 30, 2007.

-- Royalty income payments from Wyeth: Royalty income based on net sales of subcutaneous RELISTOR was recorded in the amounts of $44,000 for the third quarter of 2008 and $86,000 for the nine months ended September 30, 2008. Cumulative royalties of $352,000 were deferred at September 30, 2008 and are expected to be recognized as royalty income over the period of our development obligations relating to RELISTOR.

-- Funding from government grants and contract: These revenues, related to the Company's proprietary programs in virology and oncology, totaled $1.4 million and $2.5 million in the third quarters of 2008 and 2007, respectively. For the nine months ended September 30, 2008 and 2007, $5.7 million and $7.1 million were earned, respectively.

"We have been able to maintain a healthy balance sheet while advancing our product pipeline because of the continued funding by Wyeth of our lead program, RELISTOR, together with payments for achieving milestones and royalties on commercial sales," said Paul J. Maddon, M.D., Ph.D., Founder, Chief Executive Officer and Chief Science Officer, Progenics Pharmaceuticals, Inc. "This quarter we achieved another development milestone as PSMA ADC, our prostate cancer therapy, entered phase 1 testing. Going forward, we will look to leverage the extensive drug development expertise we have gained from the RELISTOR program to develop our virology and oncology pipeline."

Expenses for the third quarter of 2008 were $31.2 million, compared to $34.4 million for the third quarter of 2007. For the nine months ended September 30, 2008, expenses totaled $95.9 million, compared to $93.9 million for the same period of 2007. Research and development expenses, including license fees and royalty expense, decreased $2.5 million in the third quarter of 2008, compared to the third quarter of 2007, and were at approximately the same levels for the nine months ended September 30, 2008 and 2007. The decrease in the third quarter Research and development expenses resulted primarily from a decrease in RELISTOR clinical trial activity, partially offset by an increase in headcount. General and administrative expenses decreased for the three months but increased for the nine months ended September 30, 2008, compared to the same periods of 2007. The third quarter decrease in General and administrative expenses was primarily due to a decrease in share-based compensation expense while the year-to-date increase was primarily due to an increase in headcount and consulting and professional fees.

Third quarter 2008 net loss was $12.2 million, compared to $15.6 million for the same period of 2007. Net loss per share was ($0.41), basic and diluted, for the third quarter of 2008, compared to a net loss per share of ($0.58), basic and diluted, for the same period of 2007. The net loss for the first nine months of 2008 was $30.1 million, compared to a $28.4 million net loss for the same period of 2007. Net loss per share for the first nine months of 2008 was ($1.02), basic and diluted, compared to a net loss per share of ($1.07), 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 shares, funding for which came from a $15.0 million milestone payment from Wyeth for the receipt of marketing approval of the subcutaneous form of RELISTOR in the U.S. Progenics repurchased 200,000 shares during the three months ended September 30, 2008 for a total purchase price of $2.7 million. The Company has $12.3 million remaining available for purchases under the program. Purchases under the program may be discontinued at any time.

Progenics ended the third quarter of 2008 with cash, cash equivalents and marketable securities of $134.6 million, compared to $170.4 million at December 31, 2007.

Third Quarter 2008 Highlights

-- In September, Progenics' wholly owned subsidiary, PSMA Development Company (PDC), initiated a phase 1 dose-escalation clinical study of its prostate-specific membrane antigen (PSMA) antibody-drug conjugate (ADC). PSMA ADC is an investigational therapy that combines a fully human monoclonal antibody with a derivative of auristatin, a chemotherapeutic agent. Unlike traditional chemotherapy, PSMA ADC is designed to deliver the drug selectively to prostate cancer cells by targeting PSMA, a protein abundantly expressed on the surface of prostate cancer cells as well as on the neovasculature of many types of solid tumors. The study is designed to assess the safety, tolerability and initial clinical activity of PSMA ADC during an initial 12-week treatment period, followed by the option to continue therapy for a total of 12 months.

-- Also in the third quarter, enrollment was completed in a phase 3 clinical study of the subcutaneous form of RELISTOR for the treatment of opioid-induced constipation in patients with chronic pain not related to cancer, such as chronic severe back pain.

Recent Highlights

-- In October, Progenics entered into an exclusive license agreement with Ono Pharmaceutical Co., Ltd., under which Ono acquired the rights to the subcutaneous form of RELISTOR in Japan, where it plans to develop and commercialize this drug for the treatment of opioid-induced constipation. Under the collaboration terms, Progenics is entitled to receive a $15.0 million upfront payment, development and commercialization milestone payments and royalties on net sales.

-- In October, Progenics announced the completion of enrollment in two phase 2 studies of subcutaneous and intravenous PRO 140, an HIV entry inhibitor and humanized monoclonal antibody targeting the entry co-receptor CCR5. Interim data from these two studies showed that both forms of PRO 140 exhibited potent and prolonged activity and were generally well tolerated. Interim data from the study of intravenous PRO 140 were presented in a "late-breaker" session at the 2008 joint meeting of the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) and the Infectious Diseases Society of America (IDSA).

-- In November, Progenics also announced the selection of a proprietary small-molecule drug candidate, designated PRO 206, a novel HCV entry inhibitor for clinical development as a treatment of hepatitis C virus (HCV) infection. Pre-clinical results supporting the development of PRO 206 were presented at the annual meeting of the American Association for the Study of Liver Diseases (AASLD) in San Francisco. PRO 206 is an orally available viral-entry inhibitor designed to prevent HCV from entering and infecting healthy liver cells. PRO 206 represents an innovative approach to HCV therapy as it specifically blocks the hepatitis C virus. HCV currently is treated with interferon in combination with ribavirin, non-specific antiviral agents that are associated with significant side effects and failure rates. Targeted antiviral agents are widely viewed as a promising approach to improving treatment of HCV infection.

-- Also in November, Progenics' wholly owned subsidiary, PDC, plans to initiate a 29-week, phase 1, multi-dose, dose-escalation study of a therapeutic vaccine for prostate cancer, PSMA-VRP. PSMA-VRP is designed to induce both antibodies and killer T-cells that can recognize and potentially eliminate PSMA-positive prostate cancer cells in a vaccinated patient. The phase 1 clinical study will assess the safety, tolerability, initial immunogenicity and clinical activity of PSMA-VRP in patients with progressive, castrated, metastatic prostate cancer. The PSMA-VRP vaccine is based on the platform alphavirus replicon vector technology system (a non-replicating viral vector system), and was developed under license from AlphaVax, Inc., located in Research Triangle Park, NC.

Executive Management Promotions

Progenics also announced five recent executive promotions in Corporate Strategy, Research and Development, Manufacturing, Quality and Regulatory Affairs.

"In recent years, Progenics has benefited from the collective knowledge and experience of its management team, resulting in our first commercial product approved earlier this year," said Dr. Maddon. "Beyond our RELISTOR franchise, these five members of executive management will be instrumental in developing the significant potential in our pipeline."

Mark R. Baker, J.D., Executive Vice President -- Corporate

Mr. Baker joined the Company in 2005 as Senior Vice President, General Counsel and Secretary, and leads the Company's efforts in the areas of business and commercial development, strategy, intellectual property and law. In his expanded role, Mr. Baker plans to build value for the Company through innovative licensing, development and commercialization activities, and enhance shareholder value by in- and/or out-licensing clinical candidates that fit Progenics' strategy of becoming a profitable biopharmaceutical company.

William C. Olson, Ph.D., Senior Vice President, Research and Development

Dr. Olson joined the Company in 1994 as an investigator and oversees research and development, including discovery efforts to identify novel small-molecule and biologic drugs in oncology and infectious diseases. Dr. Olson's team also performs translational research studies, designed to accelerate drug development. Dr. Olson will assume increased responsibility for expanding Progenics' product pipeline with innovative drug candidates that address significant unmet medical needs.

Nitya G. Ray, Ph.D., Senior Vice President, Manufacturing

Dr. Ray joined Progenics in 2001 as a Senior Director, Manufacturing. He is responsible for overseeing drug supply for all clinical efforts related to the Company's HIV and prostate cancer programs. In his new role, Dr. Ray will supervise the advancement of these manufacturing programs toward commercialization. His goals include using advanced technology to increase productivity, and coordinating in-house manufacturing activity with contracted or commercial manufacturing partnerships to supply investigational and commercial drugs cost-effectively.

Benedict Osorio, M.S., M.B.A., Senior Vice President, Quality

Mr. Osorio joined Progenics in 2005 as Vice President, Quality. Mr. Osorio will maintain a quality program that supports the development of products that are compliant with the requirements of worldwide regulatory agencies. As Senior Vice President, Mr. Osorio will expand the quality program to include the Company's development and commercial partners. Quality assurance and quality control/analytical development will continue to play a key role in product evaluation and the continuous improvement of Progenics' facilities, processes and operations, helping to assure the timely availability of drug products for further clinical development.

Ann Marie Assumma, M.S., Vice President, Regulatory Affairs

Ms. Assumma joined Progenics in 2004 as Senior Director, Regulatory Affairs -- Biologics. She provides regulatory leadership, direction, strategic focus and advocacy for ensuring that overall operations of the regulatory affairs group are compliant with federal guidelines and consistent with the Company's business strategy. As Vice President, Ms. Assumma will also guide the transition to electronic records management of regulatory communications and submissions to create a streamlined process that reduces costs, expedites submissions and approval times, and creates greater transparency.

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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 gastroenterology, 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. 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. In Canada, RELISTOR (methylnaltrexone bromide injection) for subcutaneous use is indicated for the treatment of OIC in patients with advanced illness receiving palliative care. In European member states and Iceland, Norway and Liechtenstein, RELISTOR (methylnaltrexone bromide) subcutaneous injection is indicated for the treatment of OIC in patients with advanced illness who are receiving palliative care, when response to the usual laxative therapy has not been sufficient. Marketing applications are pending for RELISTOR in Australia and 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 in phase 2 clinical testing. A novel HCV entry inhibitor, PRO 206, has been selected for clinical development and is currently undergoing IND-enabling studies. In the area of oncology, the Company is conducting a phase 1 clinical trial of a human monoclonal antibody-drug conjugate (ADC) for the treatment of prostate cancer--a selectively targeted cytotoxin-linked antibody directed against prostate-specific membrane antigen (PSMA). PSMA is a protein found on the surface of prostate cancer cells as well as in blood vessels supplying other solid tumors. Progenics is also developing 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 September 30,		For the Nine Months Ended September 30,	
	2008	2007	2008	2007
Revenues:				
Research and development from collaborator	$ 16,015	$ 14,540	$ 54,896	$ 52,987
Royalty income	44	-	86	-
Research grants and contract	1,377	2,471	5,689	7,077
Other revenues	61	7	172	48
Total revenues	17,497	17,018	60,843	60,112
Expenses:				
Research and development	21,478	24,263	68,191	69,166
License fees -- research and development	305	(16)	1,788	833
General and administrative	8,265	9,275	22,530	21,746
Royalty expense	5	-	9	-
Depreciation and amortization	1,166	845	3,427	2,144
Total expenses	31,219	34,367	95,945	93,889
Operating loss	(13,722)	(17,349)	(35,102)	(33,777)
Interest income	1,502	1,749	5,028	5,361
Net loss	$ (12,220)	$ (15,600)	$ (30,074)	$ (28,416)
Net loss per share; basic and diluted	$ (0.41)	$ (0.58)	$ (1.02)	$ (1.07)
Weighted average shares outstanding; basic and diluted	29,820	26,976	29,553	26,639

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands)

	September 30, 2008	December 31, 2007
Cash, cash equivalents and marketable securities	$ 134,594	$ 170,370
Accounts receivable	6,832	1,995
Fixed assets, net	12,104	13,511
Other assets	3,315	3,663
Total assets	$ 156,845	$ 189,539
Liabilities	$ 28,773	$ 42,040
Stockholders' equity	128,072	147,499
Total liabilities and stockholders' equity	$ 156,845	$ 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 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, this 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; 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 our lead product, RELISTOR(R), 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 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.

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