CORRECTING and REPLACING Progenics Announces Third Quarter 2009 Financial Results

TARRYTOWN, N.Y., Nov 09, 2009 (BUSINESS WIRE) -- In the October Highlights section, the third sentence in the second bullet should read xxx Significantly more patients on study drug experienced laxation within two and four hours compared to those on placebo (33% versus 0%, [p<0.05] and 39% versus 7%, [p<0.05], respectively). (sted xxx Significantly more patients on study drug experienced laxation within two and four hours compared to those on placebo (39% versus 7%, [p<0.05] and 33% versus 0%, [p<0.05], respectively)).

The corrected release reads:

PROGENICS ANNOUNCES THIRD QUARTER 2009 FINANCIAL RESULTS

Progenics Pharmaceuticals, Inc. (Nasdaq: PGNX) today announced its results of operations for the third quarter and nine months ended September 30, 2009.

Financial Results

Net loss for the third quarter of 2009 was $13.0 million or $0.41, basic and diluted, per share, compared to $12.2 million or $0.40, basic and diluted, per share in the third quarter of 2008. Net loss for the nine months ended September 30, 2009 was $30.0 million or $0.97, basic and diluted, per share, compared to a net loss of $30.1 million or $1.00, basic and diluted, per share for the first nine months of 2008.

Revenues for the third quarter of 2009 totaled $5.4 million, compared to $17.5 million for the same period of 2008, reflecting a decrease in reimbursement revenue from Wyeth (NYSE: WYE) for RELISTOR(R) research and development under the recently terminated 2005 collaboration between Wyeth and Progenics. For the first nine months of 2009, Progenics reported revenues of $31.8 million compared to $60.8 million for the comparable period of 2008. Revenues for nine months also reflect a decrease in reimbursement and milestone revenue from Wyeth, offset by recognition in the first quarter of a $15.0 million upfront payment received in 2008 from Ono Pharmaceutical Co., Ltd. (OSE-TYO: 4528), Progenics' collaborator for subcutaneous RELISTOR in Japan.

Expenses for the third quarter of 2009 were $18.6 million, compared to $31.2 million for the same period in the previous year. For the nine months ended September 30, 2009, expenses totaled $63.5 million, compared to $95.9 million for the same period of 2008.

Progenics ended the quarter with cash, cash equivalents and marketable securities of $106.8 million, a reduction of $10.7 million from $117.5 million at June 30, 2009.

The decreases in expenses for the third quarter and nine months ended September 30, 2009 compared to 2008 were attributable primarily to decreases of $10.3 million and $29.9 million, respectively, in research and development expenses. The overall decreases, which reflect increases in PSMA-related clinical activities, resulted primarily from:

- Reduced RELISTOR development expenses following completion of Progenics-conducted clinical trials and other development work; and
- Reduced manufacturing activities for PRO 140 clinical trials.

Global net sales of RELISTOR for the third quarter of 2009 were $3.3 million, as compared to $3.2 million in sales for the previous quarter and $0.8 million for the third quarter of 2008 when RELISTOR had only been partially launched by Wyeth. Of the current period's global net sales, U.S. net sales comprised $1.8 million, as compared with $2.0 million in the previous quarter.

"During the third quarter, we worked diligently to regain worldwide rights to RELISTOR, the only approved drug for opioid-induced constipation, and our announcement just after the closing of this quarter was a significant event," said Paul J. Maddon, Founder, Chief Executive Officer and Chief Science Officer of Progenics Pharmaceuticals. "We are excited about the future of the RELISTOR franchise, including our plans to submit an sNDA by early 2011 for approval of subcutaneous RELISTOR for the treatment of opioid-induced constipation in the broader chronic-pain market and to take immediate responsibility for development of oral RELISTOR. We believe that RELISTOR is just beginning to realize its potential in the opioid-induced

constipation marketplace."

Third Quarter Highlights

- Applications for a new RELISTOR pre-filled syringe delivery system were submitted to the U.S. Food and Drug Administration and the European Union European Medicines Agency. Pre-filled syringes are designed to ease preparation and administration for patients and caregivers and, if approved, could be available to advanced-illness patients in the U.S. and Europe as early as the first half of 2010.
- Mark R. Baker, formerly Executive Vice President - Corporate, was appointed President and a member of the Board of Directors. He continues to report to Dr. Maddon. In his new role, Mr. Baker oversees business and commercial development, strategic planning, investor relations, corporate communications, finance and accounting, operations and legal affairs.

October Highlights

- Progenics and Wyeth terminated their 2005 collaboration, and Progenics is regaining all worldwide rights to the RELISTOR franchise. Progenics will assume full control of future development and commercialization of subcutaneous RELISTOR after a transition period, and is taking over clinical and non-clinical development of the oral form of the drug. Wyeth has agreed to pay Progenics a total of $10.0 million in installments through January 2011, and to provide support by continuing manufacturing, marketing, sales, distribution, ongoing clinical studies and regulatory activities for subcutaneous RELISTOR over the transitional period. Wyeth is also committing up to $14.5 million of funding for development of RELISTOR in a multi-dose pen delivery system for the chronic-pain patient population and for pediatric clinical trials. Progenics' out-license of subcutaneous RELISTOR to Ono Pharmaceutical in Japan is not affected by the Wyeth collaboration termination.
- Positive data from a phase 2 study of methylnaltrexone treatment during rehabilitation following orthopedic procedures was presented at the annual meeting of the *American Academy of Physical Medicine and Rehabilitation*. The hypothesis-generating study was conducted by Progenics in 33 patients and served to evaluate methylnaltrexone in a new patient setting. Significantly more patients on study drug experienced laxation within two and four hours compared to those on placebo (33% versus 0%, [p<0.05] and 39% versus 7%, [p<0.05], respectively). In addition, the median time to laxation in the methylnaltrexone group was nearly one day earlier than the placebo group. Incidences of adverse events were comparable between the two treatment groups, and no serious adverse events were reported. Data from this study will support the safety portion of the chronic-pain sNDA planned for FDA submission by early 2011.

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,	
	2009	2008	2009	2008
Revenues:				
Research and development	$ 4,431	$ 16,015	$ 29,206	$ 54,896
Royalty income	509	44	976	86
Research grants and contract	404	1,377	1,421	5,689
Other revenues	75	61	189	172
Total revenues	5,419	17,497	31,792	60,843
Expenses:				
Research and development	11,345	21,478	39,055	68,191
License fees - research and development	136	305	961	1,788
General and administrative	5,844	8,265	19,758	22,530
Royalty expense	51	5	98	9
Depreciation and amortization	1,207	1,166	3,633	3,427
Total expenses	18,583	31,219	63,505	95,945
Operating loss	(13,164)	(13,722)	(31,713)	(35,102)
Other income:				
Interest income	123	1,502	1,457	5,028
Gain on sale of marketable securities	-	-	237	-
Gain on disposal of fixed assets	27	-	46	-
Total other income	150	1,502	1,740	5,028

Net loss	$ (13,014)	$ (12,220)	$ (29,973)	$ (30,074)
Net loss per share; basic and diluted	$ (0.41)	$ (0.40)	$ (0.97)	$ (1.00)
Weighted average shares outstanding; basic and diluted	31,428	30,323	31,060	30,048

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands)

	September 30, 2009	December 31, 2008
Cash, cash equivalents and marketable securities	$ 106,756	$ 141,374
Accounts receivable	697	1,337
Fixed assets, net	8,080	11,071
Other assets	1,513	4,051
Total assets	$ 117,046	$ 157,833
Liabilities	$ 12,547	$ 38,464
Stockholders' equity	104,499	119,369
Total liabilities and stockholders' equity	$ 117,046	$ 157,833

About Subcutaneous RELISTOR

RELISTOR subcutaneous injection is approved in the United States 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. The use of RELISTOR beyond four months has not been studied. The drug is also approved for use in over 30 countries worldwide, including the European Union, Canada, Australia and Brazil. Applications in additional countries are pending.

Important Safety Information for RELISTOR

- RELISTOR is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.
- If severe or persistent diarrhea occurs during treatment, advise patients to discontinue therapy with RELISTOR and consult their physician.
- Use of RELISTOR has not been studied in patients with peritoneal catheters.
- The most common adverse reactions reported with RELISTOR compared with placebo in clinical trials were abdominal pain (28.5% vs. 9.8%), flatulence (13.3% vs. 5.7%), nausea (11.5% vs. 4.9%), dizziness (7.3% vs. 2.4%), diarrhea (5.5% vs. 2.4%), and hyperhidrosis (6.7% vs. 6.5%).
- RELISTOR full Prescribing Information for the U.S. is available at www.relistor.com.

About Subcutaneous RELISTOR for OIC in the Chronic-pain Setting

In May 2009, Progenics and Wyeth reported a positive outcome from a 470-patient, phase 3 efficacy clinical trial in patients with chronic, non-cancer pain. This study showed statistically significant improvements in the occurrence of bowel movements with the use of RELISTOR. Adverse events observed in this study were similar to those seen in prior studies. Enrollment was also recently completed for phase 3 safety study of over 1,000 patients, with results expected by the end of 2010. Results from these two studies are expected to be included in an sNDA submission by early 2011. If FDA approval of the application is granted, Progenics plans to launch subcutaneous RELISTOR in a multi-dose pen for the chronic-pain OIC market thereafter.

(PGNX-F)

About Progenics

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 and oncology. Progenics is developing RELISTOR(R) (methylnaltrexone bromide) for the treatment of opioid-induced side effects. RELISTOR is currently approved in over 30 countries, including the U.S., E.U. member countries, Canada, Australia and Brazil; marketing applications are pending elsewhere throughout the world. Progenics is pursuing strategic alternatives for RELISTOR, including licensing, collaboration, strategic alliances and U.S. commercialization or co-promotion, following termination of its 2005 collaboration with

Wyeth Pharmaceuticals, which is continuing manufacturing, sales, marketing, and certain development and regulatory activities for RELISTOR during the transition. Ono Pharmaceutical Co., Ltd. has an exclusive license from Progenics for development and commercialization of subcutaneous RELISTOR in Japan. In the area of virology, Progenics is developing the viral-entry inhibitor PRO 140, a humanized monoclonal antibody which binds to co-receptor CCR5 to inhibit human immunodeficiency virus (HIV) infection. PRO 140 is currently in phase 2 clinical testing. The Company's hepatitis C virus discovery program seeks to identify novel inhibitors of HCV entry. In 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 chemotherapeutic antibody directed against prostate-specific membrane antigen. 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 conducting phase 1 clinical trials with vaccines designed to treat prostate cancer by stimulating an immune response to PSMA.

PROGENICS 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; competing products currently on the market or in development might reduce the commercial potential of our products; 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; potential product liability; intellectual property, litigation, environmental and other risks; the risk that we may not be able to enter into favorable collaboration or other relationships or that existing or future relationships may not proceed as planned; the risk that current and pending patent protection for our products may be invalid, unenforceable or challenged, or fail to provide adequate market exclusivity, or that our rights to in-licensed 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. 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.

For more information about RELISTOR, please visit www.RELISTOR.com.

SOURCE: Progenics Pharmaceuticals, Inc.

Investors:
Progenics Pharmaceuticals, Inc.
Richard W. Krawiec, Ph.D., 914-789-2814
Vice President, Corporate Affairs
krawiecr@progenics.com
or

Dory A. Kurowski, 914-789-2818
Associate Director, Corporate Affairs
dkurowski@progenics.com
or
Media:
WeissComm Partners
Aline Schimmel, 312-646-6295