Progenics Announces Fourth Quarter and Year-End 2009 Financial Results

TARRYTOWN, N.Y., Mar 15, 2010 (BUSINESS WIRE) -- Progenics Pharmaceuticals, Inc. (Nasdaq: PGNX) today announced its results of operations for the fourth quarter and year ended December 31, 2009.

Financial Results

Net loss for the fourth quarter was $0.6 million or $0.02, basic and diluted, per share, compared to $14.6 million or $0.48, basic and diluted, per share in the fourth quarter of 2008. Net loss for the year was $30.6 million or $0.98, basic and diluted, per share, compared to a net loss of $44.7 million or $1.48, basic and diluted, per share for 2008.

Progenics ended the year with cash, cash equivalents and marketable securities of $96.2 million, reflecting use of cash of $10.6 million in the fourth quarter and $45.2 million for the full year.

Revenues for the fourth quarter of 2009 totaled $17.2 million, compared to $6.8 million for the same period of 2008, reflecting the recognition of the $10.0 million that Wyeth, now a wholly owned subsidiary of Pfizer, Inc. (NYSE: PFE), agreed to pay Progenics in connection with termination of their 2005 collaboration and an increase in amortization of Wyeth's $60.0 million upfront payment in 2005, partially offset by a decrease in reimbursement revenue from Wyeth for RELISTOR(R) research and development. For the full year 2009, Progenics reported revenues of $48.9 million compared to $67.7 million for 2008. Full year 2009 revenues reflect primarily a decrease in reimbursement and milestone revenue from Wyeth, which was offset by recognition in the fourth quarter of the $10.0 million termination payment and in the first quarter of 2009 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 fourth quarter of 2009 were $17.8 million, compared to $22.6 million for the same period in the previous year. For the full year 2009, expenses totaled $81.3 million, compared to $118.6 million for 2008.

The decreases in expenses for the fourth quarter and year ended December 31, 2009 compared to 2008 were attributable primarily to decreases of $4.1 million and $34.0 million, respectively, in research and development expenses. The overall decreases (which were partially offset by 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 of PRO 140.

Global net sales of RELISTOR for the fourth quarter of 2009 were $3.9 million, as compared to $3.3 million in sales for the previous quarter (a 19% increase) and $1.5 million for the fourth quarter of 2008 (a 158% increase). Of the current period's global net sales, U.S. net sales comprised $2.1 million, as compared with $1.8 million in the previous quarter (a 17% increase) and $0.8 million for the fourth quarter of 2008 (a 151% increase). Ex-U.S. RELISTOR net sales totaled $1.8 million in the fourth quarter of 2009, compared to $1.5 million in the previous quarter (a 21% increase) and $0.7 million in the fourth quarter of 2008 (a 165% increase).

Global net sales of RELISTOR, which began in June 2008, were $12.3 million for the year ended December 31, 2009, comprised of $7.1 million of U.S. net sales and $5.2 million of ex-U.S. net sales.

"We have entered 2010 with rights to the RELISTOR franchise and the ability to map out the best path forward to advance this important product," said Paul J. Maddon, Progenics' Founder, Chief Executive Officer and Chief Science Officer. "Our primary objectives this year are to identify a strategic marketing partner for the RELISTOR franchise, to advance development of the oral formulation, and to finalize a supplemental New Drug Application for subcutaneous RELISTOR to treat opioid-induced constipation in the broader chronic-pain patient setting. As we focus on these priorities, we continue to reduce expenditures and increase operating efficiencies throughout the organization. We also look forward to presenting data from the ongoing phase 1 trial of our PSMA ADC candidate for the treatment of metastatic prostate cancer later this year."

Fourth Quarter Highlights

- Progenics and Wyeth terminated their 2005 RELISTOR collaboration, and Progenics regained all worldwide rights to

RELISTOR. Ono Pharmaceutical remains Progenics' exclusive licensee for subcutaneous RELISTOR in Japan. Progenics assumed clinical and non-clinical development responsibilities for the oral form of RELISTOR and will assume full control of development and commercialization of subcutaneous RELISTOR upon conclusion of the transition period. Wyeth agreed to pay Progenics $10.0 million in six quarterly installments, and to provide support by continuing manufacturing, marketing, sales, distribution, ongoing clinical studies and regulatory activities for subcutaneous RELISTOR over the transition period. Wyeth also committed up to $14.5 million of funding for the development of a multi-dose pen for subcutaneous RELISTOR and for pediatric clinical trials. Progenics is considering a range of strategic alternatives for the future development and commercialization of RELISTOR, including licensing, collaboration and/or strategic alliances with world-wide or regional partners.

- Enrollment was completed ahead of schedule in a phase 3 one-year, open-label safety study of subcutaneous RELISTOR in over 1,000 chronic, non-cancer pain patients. The study, initiated in December 2008 by Wyeth, is designed to support planned supplemental regulatory filings by early 2011 in the U.S., Europe and elsewhere for approval of RELISTOR to treat opioid-induced constipation (OIC) in the chronic-pain setting. Progenics expects to present a consolidated safety database from this study and a 470-patient efficacy study in chronic, non-cancer pain patients (results of which were announced in May 2009) as part of the submissions.
- 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 FDA filing.

Recent Highlights and Updates

- Progenics announced data from a clinical trial of an oral tablet form of methylnaltrexone conducted in subjects with chronic, non-cancer pain receiving various opioid treatment regimens with a history of OIC. Subjects were administered a single methylnaltrexone tablet at different dose levels following an overnight fast. Forty-eight percent of subjects receiving one of the doses (n=25) laxated within four hours of treatment.
- The Company announced plans to advance oral methylnaltrexone for the treatment of OIC into late stage clinical development and will commence a phase 2b/3 clinical trial of a methylnaltrexone tablet in chronic-pain patients in the second half of 2010. Wyeth has manufactured the tablets to be used in Progenics' planned phase 2b/3 trial as provided for under the provisions of the termination of the collaboration between the two companies.
- The Company presented data from preclinical studies of novel multiplex phosphoinositide 3-kinase (PI3K) inhibitors at the American Association for Cancer Research's Conference on Protein Translation and Cancer. In laboratory studies, these synthetic, small-molecule compounds identified by Progenics blocked both PI3K, a key regulator of one molecular signaling pathway, and MNK, an oncogenic kinase in the Ras pathway. Progenics believes simultaneously blocking these interlinked cellular pathways with a single agent may provide a strategy to combat some of the most aggressive forms of cancer.

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,	
	2009	2008	2009	2008
Revenues:				
Research and development	$ 15,145	$ 4,989	$ 44,351	$ 59,885
Royalty income	1,396	60	2,372	146
Research grants and contract	547	1,771	1,968	7,460
Other revenues	67	8	256	180
Total revenues	17,155	6,828	48,947	67,671
Expenses:				
Research and development	10,775	14,099	49,798	82,290
License fees - research and development	97	1,042	1,058	2,830
General and administrative	5,362	6,304	25,106	28,834
Royalty expense	139	6	237	15
Depreciation and amortization	1,445	1,182	5,078	4,609

Total expenses	17,818	22,633	81,277	118,578
Operating loss	(663)	(15,805)	(32,330)	(50,907)
Other income:				
Interest income	24	1,207	1,481	6,235
Gain on sale of marketable securities	-	-	237	-
Total other income	24	1,207	1,718	6,235
Net loss	$ (639)	$ (14,598)	$ (30,612)	$ (44,672)
Net loss per share; basic and diluted	$ (0.02)	$ (0.48)	$ (0.98)	$ (1.48)
Weighted average shares outstanding; basic and diluted	31,688	30,438	31,219	30,142

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands)

	December 31, 2009	December 31, 2008
Cash, cash equivalents and marketable securities	$ 96,196	$ 141,374
Accounts receivable	7,522	1,337
Fixed assets, net	6,560	11,071
Other assets	3,335	4,051
Total assets	$ 113,613	$ 157,833
Liabilities	$ 6,006	$ 38,464
Stockholders' equity	107,607	119,369
Total liabilities and stockholders' equity	$ 113,613	$ 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.

Subcutaneous RELISTOR development 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. Subject to FDA approval, 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, oncology and virology. Progenics is developing RELISTOR(R) (methylnaltrexone bromide) for the treatment of opioid-induced side effects. RELISTOR is now approved in over 40 countries, including the U.S., Canada, the European Union, Latin America countries and Australia. 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 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 in immunized subjects. Progenics is also developing novel multiplex PI3-Kinase inhibitors as a potential strategy to combat some of the most aggressive forms of cancer. In 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.

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, please visit www.progenics.com.

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