Progenics Pharmaceuticals Announces First Quarter 2010 Financial Results

TARRYTOWN, N.Y., May 10, 2010 (BUSINESS WIRE) -- Progenics Pharmaceuticals, Inc. (Nasdaq: PGNX) today announced its results of operations for the quarter ended March 31, 2010.

Financial Results

Net loss for the first quarter of 2010 was $18.6 million or $0.58, basic and diluted, per share, compared to $1.8 million or $0.06, basic and diluted, per share in the first quarter of 2009. Progenics ended the quarter with cash, cash equivalents and marketable securities of $84.7 million, reflecting use of cash of $11.5 million in the quarter.

First quarter revenue of $1.5 million reflected a decrease in research and development revenue from Wyeth, now a Pfizer, Inc. (NYSE: PFE) subsidiary, from the same period of 2009, in which the Company also recognized a $15.0 million upfront payment from Ono Pharmaceutical Co., Ltd. (OSE-TYO: 4528), Progenics' collaborator for subcutaneous RELISTOR(R) (methylnaltrexone bromide) in Japan. The decreased research and development revenue resulted from termination of the 2005 Progenics-Wyeth collaboration pursuant to the 2009 transition agreement. Revenue for the 2009 period was $20.9 million.

Expenses for the first quarter of 2010 were $20.1 million compared to $23.5 million for the same period in the previous year. The decrease was attributable primarily to lower compensation expenses resulting from a decrease in average headcount Company-wide, reduced manufacturing expenses for PRO 140, completion of manufacturing for PSMA ADC phase 1 clinical supplies and reduced expenses for PSMA raw material-related research supplies, partially offset by increases in PSMA-related clinical activities and RELISTOR manufacturing expenses for the multi-dose pen.

Global net sales of RELISTOR for the first quarter of 2010 were $4.2 million, a 6% increase over the $3.9 million for the previous quarter and a 123% increase over the $1.9 million for the first quarter of 2009. U.S. net sales were $2.4 million, a 15% increase over the $2.1 million for the previous quarter and a 103% increase over the $1.2 million for the first quarter of 2009. Ex-U.S. RELISTOR net sales were $1.8 million in both the first quarter of 2010 and the previous quarter, an increase of 158% over the $0.7 million for the first quarter of 2009.

"The first quarter has been an active one at Progenics," said Paul J. Maddon, Founder, Chief Executive and Chief Science Officer. "We continue discussions with potential partners for the RELISTOR franchise while we plan for the entry of oral RELISTOR into pivotal clinical testing. We are also assessing the safety and activity of our lead development candidate PSMA ADC in a phase 1 clinical trial and this will allow us to determine a maximum tolerated dose. We will continue to keep shareholders apprised of these initiatives in the coming quarters."

First Quarter 2010 Highlights

- Progenics announced plans to commence a phase 2b/3 clinical trial of oral methylnaltrexone in chronic-pain patients during the second half of 2010 using tablets manufactured by Wyeth under the 2009 transition agreement. This followed an analysis of complete data from the previously reported pilot clinical trial in chronic, non-cancer pain patients, in which 48% of the 25 patients receiving one of the oral methylnaltrexone doses after an overnight fast laxated within four hours of treatment.
- The Company presented data from preclinical studies of novel multiplex PI3-Kinase 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 phosphoinositide 3-kinase, 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 is awaiting FDA and EMEA action for RELISTOR in pre-filled syringes and, if approved, plans to coordinate the launch with a new commercialization partner.

PROGENICS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)
(in thousands, except net loss per share)

	For the Three Months Ended March 31,	
	2010	2009
Revenues:		
Research and development	$ 213	$ 20,144
Royalty income	625	175
Research grants	644	507
Other revenues	41	78
Total revenues	1,523	20,904
Expenses:		
Research and development	11,892	14,830
License fees - research and development	816	630
General and administrative	6,474	6,801
Royalty expense	62	18
Depreciation and amortization	877	1,203
Total expenses	20,121	23,482
Operating loss	(18,598)	(2,578)
Other income:		
Interest income	15	790
Total other income	15	790
Net loss	$ (18,583)	$ (1,788)
Net loss per share; basic and diluted	$ (0.58)	$ (0.06)
Weighted average shares outstanding; basic and diluted	32,103	30,707

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands)

	March 31, 2010	December 31, 2009
Cash, cash equivalents and marketable securities	$ 84,693	$ 96,196
Accounts receivable	7,802	7,522
Fixed assets, net	5,695	6,560
Other assets	2,534	3,335
Total assets	$ 100,724	$ 113,613
Liabilities	$ 7,938	$ 6,006
Stockholders' equity	92,786	107,607
Total liabilities and stockholders' equity	$ 100,724	$ 113,613

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 40 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.

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

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