Progenics Pharmaceuticals Reports Second Quarter 2008 Results

TARRYTOWN, N.Y., Aug 08, 2008 (BUSINESS WIRE) -- Progenics Pharmaceuticals, Inc. (Nasdaq: PGNX) today announced its results of operations for the second quarter and first half of 2008.

Revenues for the second quarter ended June 30, 2008 totaled $28.6 million compared to $25.5 million for the same quarter in 2007. For the first half of 2008, Progenics reported revenues of $43.3 million compared to $43.1 million for the comparable period in 2007. Revenues primarily reflect reimbursement by the Company's collaborator, Wyeth, for development work performed by the Company under its methylnaltrexone collaboration ($9.0 million and $9.0 million for the three months ended June 30, 2008 and 2007, respectively, and $17.8 million and $19.5 million for the six months ended June 30, 2008 and 2007, respectively), and recognition of a portion of the $60.0 million upfront payment received from Wyeth in December 2005 ($2.8 million and $4.9 million for the three months ended June 30, 2008 and 2007, respectively, and $6.0 million and $9.9 million for the six months ended June 30, 2008 and 2007, respectively).

In the second quarter of 2008, Progenics earned a $15.0 million milestone payment for U.S. Food and Drug Administration (FDA) approval of subcutaneous RELISTOR(TM). In May 2007, the Company had earned $9.0 million in milestone payments related to the acceptance for review of applications submitted for marketing approval of a subcutaneous formulation of RELISTOR in the U.S. and European Union (E.U.).

Progenics also earned $321,000 of royalties based on net sales of RELISTOR which commenced June 2008. Of this amount, $42,000 was recognized as royalty income and $279,000 was deferred and will be recognized as royalty income through 2009.

Progenics also earned revenue from the Company's government grants and contract related to its proprietary programs in virology and oncology ($1.7 million for the three months ended June 30, 2008 compared to $2.5 million in the second quarter of 2007). For the six months ended June 30, 2008, government grants and contract totaled $4.3 million compared to $4.6 million in the comparable period in 2007.

Expenses for the second quarter of 2008 were $32.5 million, compared to $29.6 million for the second quarter of 2007. For the six months ended June 30, 2008, expenses totaled $64.7 million, compared to $59.5 million for the same period of 2007. Research and development expenses, including license fees - research and development and royalty expense, increased $1.7 million in the second quarter of 2008 compared to the second quarter of 2007, and increased $2.4 million in the first half of 2008 compared to the first half of 2007. The increases in these expenses resulted primarily from an increase in clinical trials activity related to the Company's proprietary development programs in virology and oncology, and an increase in headcount. General and administrative expenses also increased for the three months and six months ended June 30, 2008, due primarily to an increase in headcount.

The second quarter net loss was $2.4 million, approximately the same as in the second quarter of 2007. Net loss per share was ($0.08) basic and diluted, compared to a net loss per share of ($0.09), basic and diluted, for the same period of 2007. The net loss for the first half of 2008 was $17.9 million, compared to a $12.8 million net loss for the same period in 2007. Net loss per share for the first half of 2008 was ($0.61), basic and diluted, compared to a net loss per share of ($0.48), basic and diluted, for the same period of 2007.

Progenics ended the second quarter with cash, cash equivalents and marketable securities of $150.6 million compared to $170.4 million at December 31, 2007.

"We are especially pleased to report that for the first time in our Company's history we earned royalties of $321,000 on June 2008 sales of our first commercial product, RELISTOR," said Paul J. Maddon, M.D., Ph.D., Founder, Chief Executive Officer and Chief Science Officer, Progenics Pharmaceuticals, Inc. "The 15% royalty on this quarter's RELISTOR sales represents the lowest tier of royalties payable to us under our collaboration agreement with Wyeth. Royalty rates can range up to 30% of U.S. and 25% of foreign net sales at the highest sales levels. Royalty rates will increase on incremental sales as net sales in a calendar year exceed specified levels."

Oral RELISTOR

Oral RELISTOR is an investigational drug being developed for the treatment of opioid-induced constipation (OIC). Two proprietary oral formulations of RELISTOR were tested in separate four-week, double-blind, randomized, placebo-controlled phase 2 trials each consisting of approximately 120 patients with chronic, non-malignant pain who were receiving opioids for pain management.

In comparing the activity and tolerability of these oral formulations of RELISTOR, both were generally well tolerated; however, one formulation was identified as having a more favorable clinical profile, while the other did not demonstrate sufficient clinical activity to warrant its continued study.

As previously announced on May 22, 2008, the formulation with the more favorable clinical profile demonstrated statistically significant results after once daily dosing, as assessed by the occurrence of spontaneous bowel movements and other efficacy measures. Further improvement upon this oral formulation through clinical optimization studies will begin in the coming months, with next steps in the development plan for oral RELISTOR to be decided in early 2009.

Developments / Highlights for the Second Quarter of 2008

-- On April 24th, Wyeth and Progenics received FDA approval of RELISTOR (methylnaltrexone bromide) subcutaneous injection for the treatment of opioid-induced constipation in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. On the same day, the Companies also announced they received a Positive Opinion for RELISTOR (methylnaltrexone bromide) subcutaneous injection from the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMEA). On July 3rd, Wyeth and Progenics announced receipt of marketing approval for RELISTOR (methylnaltrexone bromide) subcutaneous injection from the European Commission. RELISTOR was approved in the 27 E.U. member states as well as Iceland, Norway and Liechtenstein for the treatment of OIC in advanced illness patients who are receiving palliative care when response to usual laxative therapy has not been sufficient. RELISTOR is the first approved treatment for OIC in the E.U.

-- FDA approval of RELISTOR for subcutaneous use triggered a $15.0 million milestone payment from Wyeth to Progenics. Progenics' Board of Directors approved a share repurchase program to acquire up to $15.0 million of its outstanding common shares, funding for which will come from the milestone payment. As of second quarter end, the Company had not repurchased any shares.

-- As previously announced, a Progenics phase 3 study examining the use of an intravenous formulation of RELISTOR for post-operative ileus (POI) in segmental colectomy surgery did not meet its primary or secondary end points, confirming earlier findings from a similar study conducted by Wyeth. Progenics and Wyeth are analyzing the results of both studies to determine whether and how to continue development of this formulation of RELISTOR for this indication.

-- The May 29th edition of the New England Journal of Medicine published results from a pivotal phase 3 trial of RELISTOR (methylnaltrexone bromide) subcutaneous injection. The phase 3 study demonstrated the efficacy of RELISTOR for use in advanced-illness patients with opioid-induced constipation. RELISTOR is now approved for marketing worldwide in over 30 countries.

(PGNX-F)

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 (methylnaltrexone bromide) for the treatment of opioid-induced side effects. 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, 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 has completed phase 1b clinical studies with positive results. PRO 140 is currently in phase 2 clinical testing. Pre-clinical programs for the development of novel HCV entry inhibitors are also underway. In the area of oncology, the Company is developing a human monoclonal antibody-drug conjugate (ADC) for the treatment of prostate cancer --a selectively targeted cytotoxic 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.

PROGENICS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)

(in thousands, except net loss per share)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2008	2007	2008	2007
Revenues:				
Research and development from collaborator	$ 26,771	$ 22,948	$ 38,881	$ 38,447
Royalty income	42	-	42	-
Research grants and contract	1,699	2,486	4,312	4,606
Other revenues	72	23	111	41
Total revenues	28,584	25,457	43,346	43,094
Expenses:				
Research and development	23,923	22,371	46,713	44,792
License fees - research and development	334	210	1,483	960
General and administrative	7,113	6,196	14,265	12,471
Royalty expense	4	-	4	-
Depreciation and amortization	1,147	807	2,261	1,299
Total expenses	32,521	29,584	64,726	59,522
Operating loss	(3,937)	(4,127)	(21,380)	(16,428)
Interest income	1,568	1,744	3,526	3,612
Net loss	$ (2,369)	$ (2,383)	$ (17,854)	$ (12,816)
Net loss per share; basic and diluted	$ (0.08)	$ (0.09)	$ (0.61)	$ (0.48)
Weighted average shares outstanding; basic and diluted	29,526	26,569	29,418	26,468

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands)

	June 30, 2008	December 31, 2007
Cash, cash equivalents and marketable securities	$ 150,565	$ 170,370
Accounts receivable	4,209	1,995
Fixed assets, net	12,840	13,511
Other assets	3,587	3,663
Total assets	$ 171,201	$ 189,539
Liabilities	$ 32,393	$ 42,040
Stockholders' equity	138,808	147,499
Total liabilities and stockholders' equity	$ 171,201	$ 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 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 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.

Editor's Note:

Additional information on Progenics is available at http://www.progenics.com

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