Progenics Pharmaceuticals Announces Second Quarter 2010 Financial Results

TARRYTOWN, N.Y., Aug 09, 2010 (BUSINESS WIRE) -- Progenics Pharmaceuticals, Inc. (Nasdaq: PGNX) today announced its results of operations for the second quarter and six months ended June 30, 2010.

Net loss for the second quarter of 2010 was $15.2 million or $0.47, basic and diluted, per share, compared to $15.2 million or $0.49, basic and diluted, per share in the second quarter of 2009. Net loss for the six months ended June 30th was $33.8 million or $1.05, basic and diluted, per share, compared to $17.0 million or $0.55, basic and diluted, per share for the first half of 2009.

Progenics ended the second quarter of 2010 with cash, cash equivalents and marketable securities of $73.6 million, reflecting use of cash of $11.1 million in the quarter, in line with use of cash for the first quarter of 2010, and $22.6 million for the first six months of 2010.

Second quarter revenue totaled $2.3 million, compared to $5.5 million for the same period of 2009, reflecting a decrease in research and development revenue from Wyeth, now a Pfizer Inc. (NYSE: PFE) subsidiary, resulting from the wind down of the Progenics-Wyeth RELISTOR(R) collaboration. For the first half of 2010, Progenics reported revenues of $3.8 million, compared to $26.4 million for the same period in 2009, reflecting decreased research and development revenue and recognition in the first quarter of 2009 of a $15.0 million upfront payment from Ono Pharmaceutical Co., Ltd. (OSE-TYO: 4528), Progenics' collaborator for subcutaneous RELISTOR(R) (methylnaltrexone bromide) in Japan.

Progenics receives royalties from its former collaborator Pfizer on all global net sales of RELISTOR. For the second quarter of 2010, global net sales of RELISTOR, the Company's drug approved for the treatment of opioid-induced constipation in advanced-illness patients, were $3.8 million compared to $4.2 million for the previous quarter and $3.2 million for the second quarter of 2009. U.S. net sales were $2.3 million compared to $2.4 million for the previous quarter and $2.0 million for the same period last year. Ex-U.S. RELISTOR net sales were $1.5 million compared to $1.8 million for the previous quarter and $1.2 million for the same period last year.

Global net sales of RELISTOR for the first half of 2010 were $8.0 million comprised of U.S. and ex-U.S. net sales of $4.7 million and $3.3 million, respectively.

Expenses for the second quarter of 2010 were $17.6 million, $3.8 million less than the $21.4 million for the same period in 2009. For the first half of 2010, expenses totaled $37.7 million, a decrease of $7.2 million from $44.9 million for the same period last year. These decreases in expenses were attributable primarily to lower compensation expenses resulting from a Company-wide decrease in average headcount, reduced manufacturing expenses for PRO 140 and completion of manufacturing for PSMA ADC phase 1 clinical trials, partially offset by an increase in subcutaneous RELISTOR contract manufacturing expenses for the multi-dose pen.

Progenics continues to pursue a range of strategic alternatives for RELISTOR, including licensing, collaboration and/or strategic alliances with worldwide or regional partners, U.S. commercialization of the currently-approved product on its own or with pharmaceutical detailing and sales organizations and/or co-promotion of the franchise with a partner using its own sales force.

"During the second quarter, we made good progress in our discussions with potential partners for the RELISTOR franchise," said Paul J. Maddon, M.D., Ph.D., Founder, Chief Executive and Chief Science Officer. "We finalized the design prototype for a multi-dose pen, another more convenient means of administering RELISTOR and the next planned presentation of the product in its commercial life cycle. We also remain on track to begin pivotal testing of our oral RELISTOR candidate in the second half of 2010."

Second Quarter Highlights and Recent Updates

- **Europe's CHMP Issues Positive Opinion for RELISTOR in Pre-filled Syringes**

The European Medicines Agency (EMA)'s Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion on marketing approval for RELISTOR in pre-filled syringes. Progenics awaits a final decision from the European Commission as well as FDA action on the related U.S. regulatory application, and expects that pre-filled syringe commercial launches would occur in the United States and European Union in the second quarter of 2011.

- **Recent Company Presentations:**

Preclinical data on novel monoclonal antibodies against toxins produced by the bacterium Clostridium difficile (*C. difficile*) was presented at the 110th General Meeting of the American Society for Microbiology in San Diego.

The design and rationale of an ongoing phase 1 trial of Progenics' prostate-specific membrane antigen antibody drug conjugate (PSMA ADC) therapy was presented in the newly devised 'Trials in Progress' session at the 2010 Annual Meeting of the American Society of Clinical Oncology (ASCO).

- **Corporate Updates:**

Director Peter J. Crowley was elected Chairman of the Board at Progenics' Annual Meeting. Mr. Crowley has over two decades of finance and advisory experience as a senior investment banker in the healthcare and life sciences industry.

Thomas Boyd, Progenics' Senior Vice President of Product Development, has announced his retirement, effective later this month. Dr. Boyd will remain a consultant to the Company, providing support and guidance for key activities. "We are grateful for Tom's long tenure with Progenics, and wish him well in his retirement," said Dr. Maddon. "We are especially pleased that he will be continuing with us as a consultant, and in particular, will continue to provide support for the planned filing of the sNDA for RELISTOR in the non-cancer pain setting."

PROGENICS PHARMACEUTICALS, INC.
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,	
	2010	2009	2010	2009
Revenues:				
Research and development	$ 880	$ 4,631	$ 1,093	$ 24,775
Royalty income	581	292	1,206	467
Research grants	789	510	1,433	1,017
Other revenues	55	36	96	114
Total revenues	2,305	5,469	3,828	26,373
Expenses:				
Research and development	10,659	12,861	22,551	27,691
License fees - research and development	291	195	1,107	825
General and administrative	5,680	7,113	12,154	13,914
Royalty expense	58	29	120	47
Depreciation and amortization	874	1,223	1,751	2,426
Total expenses	17,562	21,421	37,683	44,903
Operating loss	(15,257)	(15,952)	(33,855)	(18,530)
Other income:				
Interest income	16	544	31	1,334
Gain on sale of marketable securities	-	237	-	237
Total other income	16	781	31	1,571
Net loss	$ (15,241)	$ (15,171)	$ (33,824)	$ (16,959)
Net loss per share; basic and diluted	$ (0.47)	$ (0.49)	$ (1.05)	$ (0.55)
Weighted average shares outstanding; basic and diluted	32,396	31,032	32,251	30,871

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands)

	June 30, 2010	December 31, 2009
Cash, cash equivalents and marketable securities	$ 73,576	$ 96,196

Accounts receivable	6,085	7,522
Fixed assets, net	6,093	6,560
Other assets	1,926	3,335
Total assets	$ 87,680	$ 113,613
Liabilities	$ 6,961	$ 6,006
Stockholders' equity	80,719	107,607
Total liabilities and stockholders' equity	$ 87,680	$ 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 50 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
- Rare cases of gastrointestinal (GI) perforation have been reported in advanced illness patients. Use of RELISTOR with caution in patients with known or suspected lesions of the GI tract
- 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%)
- Safety and efficacy of RELISTOR have not been established in pediatric patients

RELISTOR full Prescribing Information for the U.S. is available at www.relistor.com.

RELISTOR 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. Use of RELISTOR beyond 4 months has not been studied.

(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 constipation. RELISTOR is now approved in over 50 countries, including the U.S., E.U., Canada, Australia and Brazil. 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, clinical, 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 PSMA ADC, a human monoclonal antibody-drug conjugate for the treatment of prostate cancer. PSMA is a protein found on the surface of prostate cancer cells as well as in blood vessels supplying other solid tumors. In virology, Progenics is also 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. In early development, Progenics is evaluating novel antibodies to toxins produced by the bacteria *C. difficile*, as well as single-agent multiplex PI3-Kinase inhibitors as a potential strategy to combat some of the most aggressive forms of cancer, and is also seeking 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.

* Wyeth is now part of Pfizer Inc.

Editors Note:

For more information, please visit www.progenics.com.

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

SOURCE: Progenics Pharmaceuticals, Inc.

Investors:
Progenics Pharmaceuticals, Inc.
Dory A. Kurowski, 914-789-2818
Director, Corporate Affairs
dkurowski@progenics.com
or
Media:
Scienta Communications
Aline Schimmel, 312-238-8957
aschimmel@scientapr.com