



August 9, 2017

Progenics Pharmaceuticals Announces Second Quarter 2017 Financial Results and Business Update

- | NDA (New Drug Application) for AZEDRA[®] Expected to be Submitted to U.S. Food and Drug Administration (FDA) in August 2017
- | Results from Phase 2b Study of AZEDRA Accepted for Oral Presentation on September 1st at 2017 International Symposium on Pheochromocytoma and Paraganglioma (ISP)
- | Data Highlighting Potential Utility of Automated Bone Scan Index (aBSI) Presented at 2017 American Society of Clinical Oncology (ASCO) Annual Meeting in June
- | Enrollment Ongoing in Clinical Trials for Prostate Cancer Product Candidates 1404, PyL[™], and 1095
- | Second Quarter 2017 RELISTOR[®] Net Sales of \$17.3 Million

NEW YORK, Aug. 09, 2017 (GLOBE NEWSWIRE) -- Progenics Pharmaceuticals, Inc. (Nasdaq:PGNX) today announced financial results and provided a business update for the second quarter of 2017.

"We are nearing completion of the NDA for AZEDRA and expect to complete the rolling submission to the FDA this month," said Mark Baker, Chief Executive Officer of Progenics. "The application is based on our Phase 2b data, which suggest that AZEDRA could deliver meaningful benefits to malignant and/or recurrent and/or unresectable pheochromocytoma and paraganglioma patients, who do not currently have approved therapies in the U.S. We announced topline data on March 30th and look forward to presenting the results from this trial at the International Symposium of Pheochromocytoma and Paraganglioma meeting on September 1st. Our PSMA-targeted pipeline, including our imaging agents 1404 and PyL and our therapeutic agent, 1095, continues to progress with the strategic goal to Find Fight and Follow[™] — detect, treat and monitor — prostate cancer. I am especially pleased to see the momentum building in Oral RELISTOR prescriptions, which we believe underscores the long-term potential for that franchise," Mr. Baker added.

Second Quarter and Recent Key Business Highlights

AZEDRA, Ultra-orphan radiotherapeutic candidate

- | **AZEDRA NDA Expected to be Submitted August 2017**
Progenics expects to complete the rolling submission of the NDA for AZEDRA in patients with malignant and/or recurrent pheochromocytoma to the FDA in August 2017. The filing will be supported by data from a pivotal Phase 2b trial, which met the primary endpoint evaluating the proportion of patients who achieved a 50% or greater reduction of all antihypertensive medications for at least six months. In addition, favorable data was reported for a key secondary endpoint, the proportion of patients with overall tumor response as measured by Response Evaluation Criteria in Solid Tumors (RECIST) criteria. AZEDRA was also shown to be safe and generally well tolerated.

AZEDRA holds Breakthrough Therapy and Orphan Drug statuses, as well as a Fast Track designation in the U.S. under a Special Protocol Assessment agreement with the FDA.

- | **Additional Data from Phase 2b Trial of AZEDRA to be Presented at ISP 2017**
In September 2017, Progenics will present further results from its Phase 2b study evaluating AZEDRA, for which topline data were announced in March 2017.

PSMA-Targeted Prostate Cancer Pipeline

- | **Data Demonstrating Potential Use of Automated Bone Scan Index Presented at ASCO 2017 Meeting**
In June 2017, two presentations highlighting the utility of aBSI were presented at the American Society of Clinical Oncology's Annual Meeting.
 - In an oral presentation, investigators demonstrated the potential of aBSI to serve as quantitative prognostic biomarker for survival in patients with bone-metastatic castration resistant prostate cancer (CPRC). The large scale Phase 3 study demonstrated that in these patients, aBSI at baseline was prognostic for overall and disease specific survival ($p < 0.0001$), progression free survival ($p = 0.0024$), radiographic progression-free survival (rPFS) ($p = 0.0061$), and symptomatic skeletal related events (SSEs) ($p = 0.0068$).

- An additional poster showed that aBSI could be used to quantitatively assess total tumor burden during the course of disease progression, as called for by Prostate Cancer Working Group criteria. The data presented in the poster was also published in the *Journal of Nuclear Medicine*, and the Progenics researcher, Dr. Aseem Anand, was selected for the Alavi—Mandell Award for that publication.

▮ **Advancing Phase 3 Study of 1404**

Enrollment in the Phase 3 study of 1404, a PSMA-targeted imaging agent, is ongoing. The trial is designed to evaluate the specificity of 1404 in identifying patients without clinically significant prostate cancer, as well as its sensitivity to identify patients with clinically significant disease.

▮ **Advancing Phase 2/3 Study of PyL**

Enrollment is also continuing in the Phase 2/3 study evaluating the diagnostic accuracy of PyL PET/CT imaging in patients with recurrent and/or metastatic prostate cancer. The trial is being conducted in the U.S. and Canada.

▮ **Advancing Phase 1 Trial of 1095**

Dosing and enrollment are ongoing in the Phase 1 open-label dose escalation study of 1095 in patients with metastatic CRPC who have demonstrated tumor avidity to 1095. The study is being conducted at Memorial Sloan Kettering.

RELISTOR, treatment for opioid-induced constipation (partnered with Valeant Pharmaceuticals International, Inc.)

▮ **Second Quarter 2017 RELISTOR Net Sales of \$17.3 Million**

The second quarter 2017 sales, as reported to Progenics by its partner Valeant, translated to \$2.6 million in royalty revenue for Progenics for the quarter. Oral RELISTOR prescriptions increased 68% over the preceding quarter.

Second Quarter 2017 Financial Results

Second quarter revenue totaled \$2.8 million, down from \$8.5 million in the second quarter of 2016. RELISTOR royalty income was \$2.6 million during the second quarter compared to \$2.4 million in the corresponding period of 2016. The prior year period included upfront and milestone revenue of \$5.0 million under the Bayer license agreement.

Second quarter research and development expenses increased by \$3.3 million compared to the corresponding prior year period, resulting primarily from higher clinical trial expenses for PyL and 1404, and costs associated with the preparation of the NDA for AZEDRA. Second quarter general and administrative expenses increased by \$0.7 million compared to the corresponding prior year period, primarily attributable to higher costs associated with building our commercial capabilities in preparation of the AZEDRA launch and higher stock-based compensation expense, partially offset by lower depreciation expense. For the three months ended June 30, 2017, Progenics recognized interest expense (including amortization of the debt discount) of \$1.1 million related to the RELISTOR royalty-backed loan.

Net loss attributable to Progenics for the quarter was \$16.6 million or \$0.24 per diluted share, compared to a net loss of \$5.6 million or \$0.08 per diluted share in the corresponding 2016 period. Progenics ended the quarter with cash and cash equivalents of \$114.0 million, a decrease of \$24.9 million compared to cash and cash equivalents as of December 31, 2016.

Conference Call and Webcast

Progenics will review second quarter financial results in a conference call today at 8:30 a.m. ET. To participate, please dial (877) 250-8889 (domestic) or (720) 545-0001 (international) and reference conference ID 59855960. A live webcast will be available in the Media Center of the Progenics website, www.progenics.com, and a replay will be available for two weeks.

- Financial Tables follow -

PROGENICS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2017	2016	2017	2016
Revenues:		(Unaudited)		
Royalty income	\$ 2,601	\$ 2,380	\$ 4,720	\$ 4,569

License revenue	147	6,073	362	6,315
Other revenues	17	23	30	42
Total revenues	<u>2,765</u>	<u>8,476</u>	<u>5,112</u>	<u>10,926</u>
Operating expenses:				
Research and development	11,292	7,988	21,297	17,137
General and administrative	6,333	5,599	12,028	11,416
Change in contingent consideration liability	700	600	2,600	800
Total operating expenses	<u>18,325</u>	<u>14,187</u>	<u>35,925</u>	<u>29,353</u>
Operating loss	(15,560)	(5,711)	(30,813)	(18,427)
Other (expense) income:				
Interest (expense) income, net	(1,076)	54	(2,183)	97
Total other (expense) income	<u>(1,076)</u>	<u>54</u>	<u>(2,183)</u>	<u>97</u>
Net loss	(16,636)	(5,657)	(32,996)	(18,330)
Net loss attributable to noncontrolling interests	-	(19)	-	(37)
Net loss attributable to Progenics	<u>\$ (16,636)</u>	<u>\$ (5,638)</u>	<u>\$ (32,996)</u>	<u>\$ (18,293)</u>
Net loss per share attributable to Progenics - basic and diluted	<u>\$ (0.24)</u>	<u>\$ (0.08)</u>	<u>\$ (0.47)</u>	<u>\$ (0.26)</u>
Weighted average shares outstanding — basic and diluted	<u>70,202</u>	<u>69,947</u>	<u>70,214</u>	<u>69,947</u>

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)

	<u>June 30, 2017</u>	<u>December 31, 2016</u>
	(unaudited)	(audited)
Cash and cash equivalents	\$ 113,959	\$ 138,909
Accounts receivable, net	2,715	4,864
Property and equipment, net	4,563	4,760
Intangible assets, net and goodwill	43,549	43,655
Other assets	5,741	6,798
Total assets	<u>\$ 170,527</u>	<u>\$ 198,986</u>
Current liabilities	\$ 16,479	\$ 16,357
Acquisition-related contingent consideration liability	16,800	14,200
Long-term debt, deferred tax and other liabilities	62,698	63,667
Total liabilities	<u>95,977</u>	<u>94,224</u>
Total stockholders' equity	<u>74,550</u>	<u>104,762</u>
Total liabilities and stockholders' equity	<u>\$ 170,527</u>	<u>\$ 198,986</u>

About RELISTOR®

Progenics has exclusively licensed development and commercialization rights for its first commercial product, RELISTOR, to Valeant. RELISTOR Tablets (450 mg once daily) are approved in the United States for the treatment of opioid-induced constipation (OIC) in patients with chronic non-cancer pain. RELISTOR Subcutaneous Injection (12 mg and 8 mg) is a treatment for OIC approved in the United States and worldwide for patients with advanced illness and chronic non-cancer pain.

IMPORTANT SAFETY INFORMATION - RELISTOR (methylnaltrexone bromide) tablets, for oral use and RELISTOR (methylnaltrexone bromide) injection, for subcutaneous use

RELISTOR tablets and injection are contraindicated in patients with known or suspected gastrointestinal obstruction and patients at increased risk of recurrent obstruction, due to the potential for gastrointestinal perforation.

Cases of gastrointestinal perforation have been reported in adult patients with opioid-induced constipation and advanced illness with conditions that may be associated with localized or diffuse reduction of structural integrity in the wall of the gastrointestinal tract (e.g., peptic ulcer disease, Ogilvie's syndrome, diverticular disease, infiltrative gastrointestinal tract malignancies or peritoneal metastases). Take into account the overall risk-benefit profile when using RELISTOR in patients with these conditions or other conditions which might result in impaired integrity of the gastrointestinal tract wall (e.g., Crohn's disease). Monitor for the development of severe, persistent, or worsening abdominal pain; discontinue RELISTOR in patients who develop this symptom.

If severe or persistent diarrhea occurs during treatment, advise patients to discontinue therapy with RELISTOR and consult their healthcare provider.

Symptoms consistent with opioid withdrawal, including hyperhidrosis, chills, diarrhea, abdominal pain, anxiety, and yawning have occurred in patients treated with RELISTOR. Patients having disruptions to the blood-brain barrier may be at increased risk for opioid withdrawal and/or reduced analgesia and should be monitored for adequacy of analgesia and symptoms of opioid withdrawal.

Avoid concomitant use of RELISTOR with other opioid antagonists because of the potential for additive effects of opioid receptor antagonism and increased risk of opioid withdrawal.

The use of RELISTOR during pregnancy may precipitate opioid withdrawal in a fetus due to the immature fetal blood brain barrier and should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Because of the potential for serious adverse reactions, including opioid withdrawal, in breastfed infants, advise women that breastfeeding is not recommended during treatment with RELISTOR. In nursing mothers, a decision should be made to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

A dosage reduction of RELISTOR tablets and RELISTOR injection is recommended in patients with moderate and severe renal impairment (creatinine clearance less than 60 mL/minute as estimated by Cockcroft-Gault). No dosage adjustment of RELISTOR tablets or RELISTOR injection is needed in patients with mild renal impairment.

A dosage reduction of RELISTOR tablets is recommended in patients with moderate (Child-Pugh Class B) or severe (Child-Pugh Class C) hepatic impairment. No dosage adjustment of RELISTOR tablets is needed in patients with mild hepatic impairment (Child-Pugh Class A). No dosage adjustment of RELISTOR injection is needed for patients with mild or moderate hepatic impairment. In patients with severe hepatic impairment, monitor for methylnaltrexone-related adverse reactions.

In the clinical studies, the most common adverse reactions were:

OIC in adult patients with chronic non-cancer pain

- ▮ RELISTOR tablets (≥ 2% of RELISTOR patients and at a greater incidence than placebo): abdominal pain (14%), diarrhea (5%), headache (4%), abdominal distention (4%), vomiting (3%), hyperhidrosis (3%), anxiety (2%), muscle spasms (2%), rhinorrhea (2%), and chills (2%).
- ▮ RELISTOR injection (≥ 1% of RELISTOR patients and at a greater incidence than placebo): abdominal pain (21%), nausea (9%), diarrhea (6%), hyperhidrosis (6%), hot flush (3%), tremor (1%), and chills (1%).

OIC in adult patients with advanced illness

- ▮ RELISTOR injection (≥ 5% of RELISTOR patients and at a greater incidence than placebo): abdominal pain (29%) flatulence (13%), nausea (12%), dizziness (7%), and diarrhea (6%).

Please see complete Prescribing Information for RELISTOR at www.valeant.com. For more information about RELISTOR, please visit www.RELISTOR.com.

About Progenics

Progenics develops innovative medicines and other technologies to target and treat cancer. Progenics' pipeline includes: 1) therapeutic agents designed to precisely target cancer (AZEDRA[®] and 1095), 2) PSMA-targeted imaging agents for prostate cancer (1404 and PyL[™]), and 3) imaging analysis tools. Progenics' first commercial product, RELISTOR[®] (methylnaltrexone bromide) for OIC, is partnered with Valeant Pharmaceuticals International, Inc.

This press release may contain projections and other "forward-looking statements" regarding future events. Statements contained in this communication that refer to Progenics' estimated or anticipated future results or other non-historical facts are forward-looking statements that reflect Progenics' current perspective of existing trends and information as of the date of this communication. Forward looking statements generally will be accompanied by words such as "anticipate," "believe," "plan," "could," "should," "estimate," "expect," "forecast," "outlook," "guidance," "intend," "may," "might," "will," "possible," "potential," "predict," "project," or other similar words, phrases or expressions. Such statements are predictions only, and are subject to risks and uncertainties that could cause actual events or results to differ materially. These risks and uncertainties include, among others: the cost, timing and unpredictability of results of clinical trials and other development activities and collaborations, such as the Phase 3 clinical program for 1404; our ability to successfully develop and commercialize the products of EXINI Diagnostics AB; the unpredictability of the duration and results of regulatory review of New Drug Applications and Investigational NDAs; market acceptance for approved products; the effectiveness of the efforts of our partners to market and sell products on which we collaborate and the royalty revenue generated thereby; generic and other competition; the possible impairment of, inability to obtain and costs of obtaining intellectual property rights; possible product safety or efficacy concerns; and general business, financial and accounting matters, litigation and other risks. More information concerning Progenics and such risks and uncertainties is available on our website, and in our press releases and reports we file with the U.S. Securities and Exchange Commission. Progenics is providing the information in this press release only as of its date and, except as expressly required by law, Progenics disclaims any intent or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or circumstances or otherwise.

Additional information concerning Progenics and its business may be available in press releases or other public announcements and public filings made after this release. For more information, please visit www.progenics.com. Please follow us on LinkedIn[®]. Information on or accessed through our website or social media sites is not included in Progenics' SEC filings.

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