UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **March 14, 2019**

Progenics Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**000-23143**	**13-3379479**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

One World Trade Center, 47th Floor, New York, New York 10007
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: **(646) 975-2500**

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On March 14, 2019, Progenics Pharmaceuticals, Inc. ("Progenics") issued a press release announcing its financial results and business update for the fourth quarter and full-year ended December 31, 2018. A copy of the foregoing press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated in this Item 2.02 by reference.

The information in this Item 2.02, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 7.01. Regulation FD Disclosure.

Pursuant to Regulation FD, Progenics is furnishing as Exhibit 99.1 its financial results and business update for the fourth quarter and full-year ended December 31, 2018.

The information contained in Items 2.02 and 7.01, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release announcing Progenics' fourth quarter and full-year ended December 31, 2018 financial results and business update, dated March 14, 2019.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PROGENICS PHARMACEUTICALS, INC.

By: /s/ Patrick Fabbio
Patrick Fabbio
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: March 14, 2019

Exhibit 99.1

Progenics Pharmaceuticals, Inc.
One World Trade Center
47th Floor, Suite J
New York, New York 10007
(646) 975-2500
www.progenics.com

PROGENICS PHARMACEUTICALS ANNOUNCES FOURTH QUARTER AND FULL-YEAR 2018 FINANCIAL RESULTS AND BUSINESS UPDATE

- AZEDRA® (iobenguane I 131) U.S. Commercial Launch – 14 Treatment Requests from Patients Have Been Received and Scheduling for those Patients is Underway; 8 Centers Throughout the U.S. are Ready to Treat Patients
- Advancing Lifecycle Initiatives for AZEDRA in Additional MIBG-Avid Tumor Indications
- Presentation at Upcoming ENDO Meeting to Highlight AZEDRA Safety Profile
- Enrollment of Phase 3 CONDOR Trial of PyL™ for the Detection of Biochemical Recurrence of Prostate Cancer Expected to Complete in the Fourth Quarter of 2019
- Established European Collaboration with Curium for PyL
- Phase 2 Trial of 1095, PSMA-Targeted Therapeutic for Metastatic Prostate Cancer, Expected to Commence in the Second Quarter of 2019
- Data Validating PSMA AI Technology to be Presented at Upcoming Medical Conferences
- Fourth Quarter 2018 RELISTOR® Net Sales Total $21.0 Million
- CytoDyn Expected to File BLA for Leronlimab (PRO 140), an Anti-CCR5 Monoclonal Antibody for the Treatment of HIV Infection, in First Half of 2019; Progenics is Entitled to an Approval Milestone and Royalties
- Company Asserts Ownership of PSMA-617 Intellectual Property, Including Composition of Matter Patent

NEW YORK, NY, March 14, 2019 – Progenics Pharmaceuticals, Inc. (Nasdaq:PGNX) today announced financial results for the fourth quarter and full-year 2018 and provided a business update.

"2018 was an extremely productive year for the advancement of our portfolio of radiopharmaceuticals, highlighted by the FDA's approval of AZEDRA for the treatment of advanced or metastatic pheochromocytoma and paraganglioma. As part of our ongoing U.S. commercial launch efforts, patient scheduling is ongoing at eight activated treatment centers across the country. We recently acquired the launch manufacturing facility for AZEDRA, allowing us to become a fully-integrated operation," said Mark Baker, Chief Executive Officer of Progenics.

Mr. Baker continued, "In parallel with our AZEDRA launch, we have made significant progress across our entire prostate cancer and AI portfolio, including the initiation of patient dosing in our Phase 3 CONDOR trial, which is evaluating the diagnostic potential and clinical impact of PyL in patients with suspected biochemical recurrence of prostate cancer. We have extended the reach of our PSMA-targeted portfolio with our collaboration with Curium for the development and commercialization of PyL in Europe, which validates the potential of our PET/CT imaging agent. We look forward to providing further updates on our PSMA-targeted programs during the year with the initiation of the Phase 2 trial of 1095 planned in the second quarter of 2019 and data presentations of deep convolutional neural network algorithms from our cutting-edge AI technology."

Fourth Quarter and Recent Key Business Highlights

AZEDRA (iobenguane I 131) 555 MBq/mL injection for intravenous use, Ultra-orphan Radiotherapeutic

- **U.S. Launch Progressing with 14 Patient Treatment Requests in Queue at Eight Activated Treatment Centers**
  AZEDRA is the first and only approved therapy in the U.S. for the treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy. The AZEDRA salesforce is in active dialogue with over 30 multidisciplinary treatment centers across the U.S with eight activated for patient treatment. Fourteen patient treatment requests for patients to be treated at these eight centers have been received.

- **Acquisition of Radiopharmaceutical Manufacturing Facility to Support AZEDRA and 1095**
  In February 2019, the Company acquired the manufacturing facility for AZEDRA based in Somerset, New Jersey, for $8.0 million in cash. Progenics also secured the long-term supply of iodine necessary for the production of both AZEDRA and 1095. The acquisition positions the Company to have full internal control of the manufacturing facility, which has the potential to label multiple types of isotopes, including iodine-131, for AZEDRA and 1095.

- **Planned Meeting with FDA to Discuss Regulatory Path for Additional Indications**
  Following a productive advisory board meeting with leading physicians in February 2019, the Company plans to request a life cycle management meeting with the U.S. Food and Drug Administration (FDA) to discuss potential pathways for additional AZEDRA indications. Given the lack of available therapies, the advisory board was supportive of AZEDRA in multiple MIBG-avid tumor indications, including gastroenteropancreatic and other neuroendocrine tumors.

- **Upcoming Presentation at ENDO Highlighting AZEDRA Safety**
  A poster entitled, "Safety Analysis of High-Specific-Activity I-131 MIBG (AZEDRA®) in Patients with Iobenguane Scan Positive Cancers," is expected to be presented on March 24, 2019 at the ENDO 2019 Meeting in New Orleans, Louisiana.

PSMA-Targeted Prostate Cancer Pipeline

- **Initiation of Patient Dosing in Phase 3 Trial of PyL (^{18}F-DCFPyL)**
  In December 2018, the Company announced the first patient was dosed in the Phase 3 CONDOR trial evaluating the diagnostic performance and clinical impact of PyL, the Company's PSMA-targeted small molecule PET/CT imaging agent designed to visualize prostate cancer. The Phase 3 CONDOR trial is a multi-center, open label trial that will enroll approximately 200 male patients with biochemical recurrence of prostate cancer in 14 sites in the United States and Canada. The Company expects to complete enrollment in the fourth quarter of 2019 and report data in early 2020.

- **European Collaboration with Curium for PyL**
  The Company entered into an exclusive license agreement in December 2018 with Curium, the largest global nuclear medicine company formed through the union of Mallinckrodt and IBA Molecular, to develop, manufacture and commercialize PyL in Europe. Under the terms of the collaboration, Curium will be responsible for the development, regulatory approvals and commercialization of PyL in Europe while Progenics is entitled to royalties on net sales. We understand from Curium that Curium plans to meet with European regulators in 2019 to agree upon the regulatory path forward for PyL in the territory.

- **Phase 2 Trial of 1095 Expected to Commence in the Second Quarter of 2019**
  Following discussions with the FDA in 2018, Progenics plans to initiate a Phase 2 trial of 1095 in combination with enzalutamide in chemo-naïve patients with metastatic castration-resistant prostate cancer (mCRPC) who are refractory to novel anti-androgen drugs (NAAD) in the second quarter of 2019. 1095 is a small molecule radiotherapeutic designed to selectively bind to the extracellular domain of prostate specific membrane antigen (PSMA), a protein that is highly expressed on prostate cancer cells.

- **Enrollment of Phase 1 Trial of PSMA-TTC by Bayer Expected in 2019**
  Progenics' partner, Bayer AG (Bayer), initiated a Phase 1 trial of PSMA-Targeted Thorium Conjugate (PSMA-TTC) in patients with mCRPC in 2018. Bayer was previously granted exclusive worldwide rights to develop and commercialize products using Progenics' PSMA antibody technology in combination with Bayer's alpha-emitting radionuclides.

- **Company Asserts Ownership of PSMA-617 Intellectual Property**
  Progenics has filed a lawsuit disputing the ownership of certain worldwide patent filings related to PSMA-617, a PSMA targeted radiopharmaceutical compound under development by Novartis AG for the treatment of prostate cancer. The Company claims that the discovery and development of PSMA-617 was related to work performed under research collaboration sponsored by Molecular Insight Pharmaceuticals (MIP), prior to its acquisition by Progenics in 2013, and that the Company accordingly has worldwide rights to intellectual property resulting from the collaboration.

Digital Technology

- **Statistically Significant Data from PSMA AI Program**
  Progenics recently completed a prospectively planned retrospective analysis using its deep convolutional neural network algorithms (PSMA AI) to automatically assess a set of PSMA images from prior trials. The reads with PSMA AI demonstrated a statistically significant improvement over manual assessment in terms of increased diagnostic accuracy, precision, speed, and reproducibility. The results from this analysis are expected to be presented at upcoming scientific conferences.

RELISTOR, Treatment for Opioid-Induced Constipation (partnered with Bausch Health Companies Inc.)

- **Fourth Quarter 2018 RELISTOR Net Sales of $21.0 Million**
  Full-year 2018 net worldwide sales totaled $99.4 million as reported to Progenics by its partner Bausch Health Companies, Inc. The fourth quarter 2018 net sales of $21.0 million translated to $3.2 million in royalty revenue for Progenics, while the full year net sales resulted in $14.9 million in royalty revenue.

Leronlimab (PRO 140), Monoclonal Antibody for HIV (owned and developed by CytoDyn)

- **CytoDyn Expected to File BLA for Leronlimab (PRO 140), an Anti-CCR5 Monoclonal Antibody for the Treatment of HIV Infection, in First Half of 2019; Progenics is Entitled to an Approval Milestone and Royalties**

  CytoDyn has announced its plan to submit a Biologics License Application (BLA) to the FDA for leronlimab for the treatment of HIV. Leronlimab is a fully-humanized, anti-CCR5 monoclonal antibody that Progenics sold to CytoDyn in 2012. Under the terms of the agreement, Progenics is eligible to receive an additional $5.0 million milestone payment upon U.S. or E.U. approval, as well as 5% royalty on net sales of the approved product.

Fourth Quarter and Full-Year 2018 Financial Results

Fourth quarter 2018 revenue totaled $3.2 million, down from $3.9 million in the fourth quarter of 2017. Revenue for the 2018 period reflects RELISTOR royalty income of $3.2 million compared to $3.7 million in the corresponding period of 2017. The full-year 2018 revenue totaled $15.6 million, up from $11.7 million for the full-year of 2017, resulting primarily from higher royalty income of $14.9 million in 2018 compared to $11.0 million in 2017.

Research and development expenses decreased by $1.3 million and $7.4 million in the fourth quarter and full-year 2018, respectively, compared to the corresponding periods in 2017, resulting primarily from lower external costs associated with the completion of the Phase 2 pivotal trial for AZEDRA and the Phase 3 trial for 1404. Fourth quarter and full-year selling, general and administrative expenses increased by $1.2 million and $4.5 million, respectively, compared to the corresponding periods in 2017, primarily attributable to higher costs associated with the commercial launch of AZEDRA. Progenics also recorded a net non-cash charge of $17.4 million in 2018, resulting from changes in the estimated fair values of intangible assets and contingent consideration liability, primarily related to 1404, following the decision not to invest in additional 1404 clinical trials.

For the three months and full-year ended December 31, 2018, Progenics recognized interest expense of $1.1 million and $4.7 million, respectively, related to the RELISTOR royalty-backed loan, compared to $1.2 million and $4.8 million recognized in the corresponding periods in 2017. For the three months and full-year ended December 31, 2018, Progenics recorded $0.1 million and $1.6 million, respectively, in income tax benefit. The primary driver of this tax benefit is related to the impairment and reclassification of the indefinite-lived intangibles for in process research and development assets. In the fourth quarter of 2017, Progenics recorded $11.7 million income tax benefit, primarily related to the reduction in the federal tax rate and the use of the Company's deferred tax liability related to indefinite-lived intangible assets (naked tax credit) as a source of income to release a portion of its valuation allowance recorded against deferred tax assets.

Net loss attributable to Progenics for the fourth quarter was $14.7 million or $0.17 per diluted share, compared to a net loss of $2.7 million or $0.04 per diluted share in the corresponding 2017 period. Net loss for the full-year 2018 was $67.7 million or $0.87 per diluted share, compared to net loss of $51.0 million or $0.73 per diluted share for the full-year 2017.

Progenics ended the year with cash and cash equivalents of $137.7 million, reflecting a decrease of $11.2 million in the quarter and an increase of $47.0 million from 2017 year-end. During the year ended December 31, 2018, the Company raised net proceeds of $70.0 million in an underwritten public offering and an additional $27.5 million in at-the-market transactions.

Conference Call and Webcast

Progenics will review fourth quarter and year-end financial results in a conference call today at 8:30 a.m. EDT. To participate, please dial (877) 250-8889 (domestic) or (720) 545-0001 (international) and reference conference ID 7764968. A live webcast will be available in the Media Center of the Progenics website, www.progenics.com, and a replay will be available there for two weeks.

-Financial Tables follow -

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

	For the Three Months Ended December 31,		For the Year Ended December 31,	
	2018	**2017**	**2018**	**2017**
	(Unaudited)			
Revenues:				
Royalty income	$ 3,151	$ 3,683	$ 14,908	$ 10,965
Other revenues	87	206	714	733
Total revenues	3,238	3,889	15,622	11,698
Operating expenses:				
Research and development	9,600	10,948	35,147	42,589
Selling, general and administrative	8,090	6,923	29,431	24,909
Intangible impairment charge	-	-	23,200	-
Change in contingent consideration liability	100	(700)	(5,800)	2,600
Total operating expenses	17,790	17,171	81,978	70,098
Operating loss	(14,552)	(13,282)	(66,356)	(58,400)
Other (expense) income:				
Interest (expense) income and other income, net	(235)	(1,055)	(2,933)	(4,285)
Total other (expense) income	(235)	(1,055)	(2,933)	(4,285)
Loss before income tax benefit	(14,787)	(14,337)	(69,289)	(62,685)
Income tax benefit	83	11,672	1,632	11,672
Net loss	**$ (14,704)**	**$ (2,665)**	**$ (67,657)**	**$ (51,013)**
Net loss per share - basic and diluted	**$ (0.17)**	**$ (0.04)**	**$ (0.87)**	**$ (0.73)**
Weighted average shares outstanding – basic and diluted	**84,543**	**70,437**	**77,890**	**70,284**

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)

	December 31, 2018	December 31, 2017
Cash and cash equivalents	$ 137,686	$ 90,642
Accounts receivable, net	3,803	3,972
Property and equipment, net	3,944	4,122
Intangible assets, net and goodwill	19,740	43,443
Other assets	4,324	3,778
Total assets	**$ 169,497**	**$ 145,957**
Current liabilities	$ 23,446	$ 15,359
Contingent consideration liability	3,950	16,800
Long-term debt, deferred tax and other liabilities	41,026	50,345
Total liabilities	68,422	82,504
Total stockholders' equity	101,075	63,453
Total liabilities and stockholders' equity	**$ 169,497**	**$ 145,957**

Indication

AZEDRA® (iobenguane I 131) is indicated for the treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy.

Important Safety Information

Warnings and Precautions:

- **Risk from Radiation Exposure:** AZEDRA contributes to a patient's overall long-term radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk for cancer. These risks of radiation associated with the use of AZEDRA are greater in pediatric patients than in adults. Minimize radiation exposure to patients, medical personnel, and household contacts during and after treatment with AZEDRA consistent with institutional good radiation safety practices and patient management procedures.
- **Myelosuppression:** Among the 88 patients who received a therapeutic dose of AZEDRA, 33% experienced Grade 4 thrombocytopenia, 16% experienced Grade 4 neutropenia, and 7% experienced Grade 4 anemia. Five percent of patients experienced febrile neutropenia. Monitor blood cell counts weekly for up to 12 weeks or until levels return to baseline or the normal range. Withhold and dose reduce AZEDRA as recommended in the prescribing information based on severity of the cytopenia.
- **Secondary myelodysplastic syndrome, leukemia, and other malignancies:** Myelodysplastic syndrome (MDS) and acute leukemias were reported in 6.8% of the 88 patients who received a therapeutic dose of AZEDRA. The time to development of MDS or acute leukemia ranged from 12 months to 7 years. Two of the 88 patients developed a non-hematological malignancy.
- **Hypothyroidism:** Hypothyroidism was reported in 3.4% of the 88 patients who received a therapeutic dose of AZEDRA. Initiate thyroid-blocking medications starting at least 1 day before and continuing for 10 days after each AZEDRA dose to reduce the risk of hypothyroidism or thyroid neoplasia. Evaluate for clinical evidence of hypothyroidism and measure thyroid-stimulating hormone (TSH) levels prior to initiating AZEDRA and annually thereafter.
- **Elevations in blood pressure:** Eleven percent of the 88 patients who received a therapeutic dose of AZEDRA experienced a worsening of pre-existing hypertension defined as an increase in systolic blood pressure to ≥160 mmHg with an increase of 20 mmHg or an increase in diastolic blood pressure to ≥ 100 mmHg with an increase of 10 mmHg. All changes in blood pressure occurred within the first 24 hours post infusion. Monitor blood pressure frequently during the first 24 hours after each therapeutic dose of AZEDRA.
- **Renal toxicity**: Of the 88 patients who received a therapeutic dose of AZEDRA, 9% developed renal failure or acute kidney injury and 22% demonstrated a clinically significant decrease in glomerular filtration rate (GFR) measured at 6 or 12 months. Monitor renal function during and after treatment with AZEDRA. Patients with baseline renal impairment may be at greater risk of toxicity; perform more frequent assessments of renal function in patients with mild or moderate impairment. AZEDRA has not been studied in patients with severe renal impairment.
- **Pneumonitis**: Fatal pneumonitis occurred 9 weeks after a single dose in one patient in the expanded access program. Monitor patients for signs and symptoms of pneumonitis and treat appropriately.
- **Embryo-fetal toxicity:** Based on its mechanism of action, AZEDRA can cause fetal harm. Verify pregnancy status in females of reproductive potential prior to initiating AZEDRA. Advise females and males of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment with AZEDRA and for 7 months after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 4 months after the final dose.

- **Risk of infertility:** Radiation exposure associated with AZEDRA may cause infertility in males and females. Radiation absorbed by testes and ovaries from the recommended cumulative dose of AZEDRA is within the range where temporary or permanent infertility can be expected following external beam radiotherapy.

Adverse Reactions:
The most common severe (Grade 3–4) adverse reactions observed in AZEDRA clinical trials (≥ 10%) were lymphopenia (78%), neutropenia (59%), thrombocytopenia (50%), fatigue (26%), anemia (24%), increased international normalized ratio (18%), nausea (16%), dizziness (13%), hypertension (11%), and vomiting (10%). Twelve percent of patients discontinued treatment due to adverse reactions (thrombocytopenia, anemia, lymphopenia, nausea and vomiting, multiple hematologic adverse reactions).

Drug Interactions:
Based on the mechanism of action of iobenguane, drugs that reduce catecholamine uptake or that deplete catecholamine stores may interfere with iobenguane uptake into cells and therefore interfere with dosimetry calculations or the efficacy of AZEDRA. These drugs were not permitted in clinical trials that assessed the safety and efficacy of AZEDRA. Discontinue the drugs listed in the prescribing information for at least 5 half-lives before administration of either the dosimetry dose or a therapeutic dose of AZEDRA. Do not administer these drugs until at least 7 days after each AZEDRA dose.

For important risk and use information about AZEDRA, please see Full Prescribing Information**.**

To report suspected adverse reactions, contact Progenics Pharmaceuticals, Inc. at 844-668-3950 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Reference:
AZEDRA® prescribing information. New York, NY: Progenics Pharmaceuticals, Inc.; 08 2018 and 07 2018.

About RELISTOR®

Progenics has exclusively licensed development and commercialization rights for its first commercial product, RELISTOR, to Bausch Health Companies, Inc. 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.bauschhealth.com. For more information about RELISTOR, please visit www.RELISTOR.com.

About PROGENICS

Progenics is an oncology company focused on the development and commercialization of innovative targeted medicines and artificial intelligence to find, fight and follow cancer, including: therapeutic agents designed to treat cancer (AZEDRA®, 1095, and PSMA TTC); prostate-specific membrane antigen ("PSMA") targeted imaging agent for prostate cancer (PyL™); and imaging analysis technology (aBSI and PSMA AI). Progenics has two commercial products, AZEDRA, for the treatment of patients with unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma (rare neuroendocrine tumors of neural crest origin) who require systemic anticancer therapy; and RELISTOR® (methylnaltrexone bromide) for the treatment of opioid-induced constipation, which is partnered with Bausch Health Companies Inc.

This press release contains 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, market acceptance for approved products; the risk that the commercial launch of AZEDRA may not meet revenue and income expectations; the cost, timing and unpredictability of results of clinical trials and other development activities and collaborations; the unpredictability of the duration and results of regulatory review of New Drug Applications (NDA) and Investigational NDAs; the inherent uncertainty of outcomes in the intellectual property disputes such as the dispute with the University of Heidelberg regarding PSMA-617; our ability to successfully develop and commercialize products that incorporate licensed intellectual property; 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, general business, financial, regulatory and accounting matters, litigation and other risks. More information concerning Progenics and such risks and uncertainties is available on its website, and in its press releases and reports it files with the U.S. Securities and Exchange Commission, including those risk factors included in its Annual Report on Form 10-K for the year ended December 31, 2018, as updated in its subsequent Quarterly Reports on Form 10-Q.Progenics is providing the information in this press release 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. Information on or accessed through our website or social media sites is not included in the company's SEC filings.

(PGNX-F)

Contact
Melissa Downs
Investor Relations
(646) 975-2533
mdowns@progenics.com

###