JOHNSON & JOHNSON

FORM 8-K
(Current report filing)

Filed 12/21/17 for the Period Ending 12/21/17

Address	ONE JOHNSON & JOHNSON PLZ
	NEW BRUNSWICK, NJ, 08933
Telephone	732-524-2455
CIK	0000200406
Symbol	JNJ
SIC Code	2834 - Pharmaceutical Preparations
Industry	Pharmaceuticals
Sector	Healthcare
Fiscal Year	01/01

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 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): December 21, 2017

(Exact name of registrant as specified in its charter)

New Jersey	I-3215	22-1024240
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933

(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: 732-524-0400

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 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 8.01 Other Events.

Janssen Biotech, Inc. ("Janssen"), a Janssen Pharmaceutical Company of Johnson & Johnson, announced today that it has entered into a worldwide collaboration and license agreement with Legend Biotech USA Inc. and Legend Biotech Ireland Limited ("Legend"), subsidiaries of Genscript Biotech Corporation, to develop, manufacture and commercialize a chimeric antigen receptor (CAR) T-cell drug candidate, LCAR-B38M, which specifically targets the B-cell maturation antigen (BCMA). LCAR-B38M is currently accepted for review by the China Food and Drug Administration (CFDA) and in the planning phase of clinical studies in the United States for multiple myeloma.

LCAR-B38M is the first CAR-T therapy accepted for review by the CFDA. Under terms of the agreement, Legend will grant Janssen a worldwide license to jointly develop and commercialize LCAR-B38M in multiple myeloma with the Legend team of experts. Janssen will record worldwide net trade sales, except for sales made in Greater China. The companies have entered into a 50/50 percent cost-sharing/profit-split arrangement, except in Greater China, where Janssen and Legend have a 30/70 percent cost-sharing/profit-split arrangement. Janssen will make an upfront payment of $350 million that will be recorded in the fourth quarter and additional payments based upon the achievement of certain development, regulatory and sales milestones.

Johnson & Johnson reaffirms its previously announced adjusted earnings guidance for full-year 2017 of $7.25-$7.30 per share.

The press release dated December 21, 2017 is attached as Exhibit 99.1 to this Report.

Item 9.01 . Financial Statements and Exhibits .

(d) *Exhibits .*

Exhibit No.	**Description**
99.1	Press release dated December 21, 2017.

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.

Johnson & Johnson
(Registrant)

Date: December 21, 2017

By: /S/ Thomas J. Spellman III

Thomas J. Spellman III
Assistant General Counsel and
Corporate Secretary

Exhibit 99.1

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Janssen Enters Worldwide Collaboration and License Agreement with

Chinese Company Legend Biotech to Develop Investigational CAR-T Anti-Cancer Therapy

CAR-T BCMA in Development for Patients with Multiple Myeloma

HORSHAM, PA (December 21, 2017) – Janssen Biotech, Inc. (“Janssen”), a Janssen Pharmaceutical Company of Johnson & Johnson, announced today that it has entered into a worldwide collaboration and license agreement with Legend Biotech USA Inc. and Legend Biotech Ireland Limited (“Legend”), subsidiaries of Genscript Biotech Corporation, to develop, manufacture and commercialize a chimeric antigen receptor (CAR) T-cell drug candidate, LCAR-B38M, which specifically targets the B-cell maturation antigen (BCMA). LCAR-B38M is currently accepted for review by the China Food and Drug Administration (CFDA) and in the planning phase of clinical studies in the United States for multiple myeloma.

“Despite significant advances, multiple myeloma remains an incurable disease for most patients, creating the need for additional, highly active options. LCAR-B38M provides an innovative approach with the potential to transform the treatment of myeloma,” said Peter F. Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. “We look forward to collaborating with the pioneering scientific team at Legend and applying our expertise to the development of this cell therapy, with the goal of building regimens aiming for a cure.”

LCAR-B38M is the first CAR-T therapy accepted for review by the CFDA. Under terms of the agreement, Legend will grant Janssen a worldwide license to jointly develop and commercialize LCAR-B38M in

multiple myeloma with the Legend team of experts. Janssen will record worldwide net trade sales, except for sales made in Greater China. The companies have entered into a 50/50 percent cost-sharing/profit-split arrangement, except in Greater China, where Janssen and Legend have a 30/70 percent cost-sharing/profit-split arrangement. Janssen will make an upfront payment of $350 million that will be recorded in the fourth quarter and additional payments based upon the achievement of certain development, regulatory and sales milestones.

Johnson & Johnson reaffirms its previously announced adjusted earnings guidance for full-year 2017 of $7.25-$7.30 per share.

“We are pleased to enter into a partnership with Legend to gain access to their CAR-T platform, an important future therapeutic modality for Janssen,” says Mathai Mammen, M.D., Ph.D., Global Head, Science & Development, Janssen Research & Development, LLC. “Legend is an innovative biotech company that has developed a differentiated CAR-T therapy, which has shown promising results in early-stage multiple myeloma trials conducted in China. We are excited to bring Janssen’s global expertise in drug development to advance this innovation into potential new treatment options for patients around the world.”

About CAR-T and BCMA

CAR T-cells are an innovative approach to eradicate cancer cells by harnessing the power of a patient’s own immune system. BCMA is a protein that is highly expressed on myeloma cells. By targeting BCMA via a CAR-T approach, CAR-T therapies may have the potential to redefine the treatment paradigm for multiple myeloma and potentially advance towards cures for patients with the disease.

About Multiple Myeloma

Multiple myeloma is an incurable blood cancer that occurs when malignant plasma cells grow uncontrollably in the bone marrow. [1,2] While some patients with myeloma have no symptoms at all, most patients are diagnosed due to symptoms, which can include bone fracture or pain, low red blood counts, fatigue, calcium elevation, kidney problems or infections. [3] Despite significant treatment advances in the past 10 years, many myeloma patients relapse after initial or secondary treatment and/or become resistant to therapies. There is a significant unmet medical need for more efficacious treatments that can overcome resistance associated with standard of care based on an immunomodulatory agent and/or a proteasome inhibitor to induce deeper and durable responses. [1,4] Globally, it is estimated that 124,225 people were diagnosed and 87,084 died from multiple myeloma in 2015. [5,6]

Janssen in Oncology

In oncology, our goal is to fundamentally alter the way cancer is understood, diagnosed and managed, reinforcing our commitment to the patients who inspire us. In looking to find innovative ways to address the cancer challenge, our primary efforts focus on several treatment and prevention solutions. These include a focus on hematologic malignancies, prostate cancer and lung cancer; cancer interception with the goal of developing products that interrupt the carcinogenic process; biomarkers that may help guide targeted, individualized use of our therapies; as well as safe and effective identification and treatment of early changes in the tumor microenvironment. Please visit www.janssen.com/oncology.

About the Janssen Pharmaceutical Companies

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenUS and www.twitter.com/JanssenGlobal.

About Johnson & Johnson

Caring for the world, one person at a time, inspires and unites the people of Johnson & Johnson. We embrace research and science - bringing innovative ideas, products and services to advance the health and well-being of people. Our approximately 134,100 employees at more than 250 Johnson & Johnson operating companies work with partners in health care to touch the lives of over a billion people every day, throughout the world.

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Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 related to a new collaboration and product development. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Biotech, Inc. and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: the potential that the expected benefits and opportunities related to the collaboration may not be realized or may take longer to realize than expected; challenges inherent in new product development, including the uncertainty of clinical success and obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; uncertainty of commercial success for new

products; the ability of the company and Legend to successfully execute strategic plans; impact of business combinations and divestitures; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; and global health care reforms and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 1, 2017, including under "Item 1A. Risk Factors," its most recently filed Quarterly Report on Form 10-Q, including under the caption "Cautionary Note Regarding Forward-Looking Statements," and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. The Janssen Pharmaceutical Companies of Johnson & Johnson and Johnson & Johnson do not undertake to update any forward-looking statement as a result of new information or future events or developments.

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[1] Kumar, SK et al. Risk of progression and survival in multiple myeloma relapsing after therapy with IMiDs and bortezomib: a multicenter international myeloma working group study. *Leukemia* . 2012;26(1):149-157. https://www.ncbi.nlm.nih.gov/pubmed/21799510.

[2] American Cancer Society. "Multiple Myeloma Overview." Available at: http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-what-is-multiple-myeloma. Accessed December 2017.

[3] American Cancer Society. "How is Multiple Myeloma Diagnosed?" Available at: http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-diagnosis. Accessed December 2017.

[4] Borrello, I. Can we change the disease biology of multiple myeloma? *Leukemia* Research. 2012;36(0 1):S3-12. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3698609/.

[5] GLOBOCAN 2012: Estimated Cancer Incidence, Mortality and Prevalence Worldwide: Number of New Cancers in 2015. Available at: http://globocan.iarc.fr/old/burden.asp?selection_pop=224900&Text-p=World&selection_cancer=17270&Text-c=Multiple+myeloma&pYear=3&type=0&window=1&submit=%C2%A0Execute. Accessed December 2017.

[6] GLOBOCAN 2012: Estimated Cancer Incidence, Mortality and Prevalence Worldwide: Number of Cancer Deaths in 2015. Available at: http://globocan.iarc.fr/old/burden.asp?selection_pop=224900&Text-p=World&selection_cancer=17270&Text-c=Multiple+myeloma&pYear=3&type=1&window=1&submit=%C2%A0Execute. Accessed December 2017.