
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): **October 31, 2018 (October 25, 2018)**

BAUSCH HEALTH COMPANIES INC.
(Exact name of registrant as specified in its charter)

British Columbia, Canada
(State or other jurisdiction
of incorporation)

001-14956
(Commission
file number)

98-0448205
(IRS Employer
Identification No.)

2150 St. Elzéar Blvd. West, Laval, Québec, Canada H7L 4A8
(Address of principal executive offices) (Zip Code)

(514) 744-6792
(Registrant's telephone number, including area code)

N/A
(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 (§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 1.01 Entry into a Material Definitive Agreement

On October 25, 2018, in connection with (and as consideration for) the settlement and release of certain claims that were the subject of an arbitration proceeding among Bausch Health Companies Inc. (“Bausch Health” or the “Company”) and its subsidiary Salix Pharmaceuticals, Inc. (“Salix”), on the one hand, and Alfasigma S.p.A. (“Alfa”), on the other hand, Alfa, Salix and Salix’s affiliates, Valeant Pharmaceuticals Ireland Limited (“VIRL”) and Valeant Pharmaceuticals Luxembourg s.à r.l. (“VPL” and together with Salix and VIRL, the “Salix Parties”) entered into (i) an Amendment No. 2 to the Amended and Restated License Agreement (the “ARLA Amendment”) and (ii) an Amended and Restated Supply Agreement (the “A&R Supply Agreement”).

The ARLA Amendment

The ARLA Amendment amends that certain Amended and Restated License Agreement between Salix and Alfa dated August 6, 2012, as amended on September 5, 2012 (the “ARLA”), copies of which were incorporated by reference into the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2017 as Exhibits 10.27 and 10.28. Under the terms of the ARLA, Alfa has granted the Salix Parties certain rights in Alfa’s intellectual property with respect to the exploitation of products containing the rifaximin compound in certain territories and for certain fields. The Company’s existing licenses and rights to its Xifaxan[®] products under the ARLA are not amended by the ARLA Amendment, and remain in effect on their current terms.

Under the terms of the ARLA Amendment, the parties have agreed to terminate the Crohn’s EIR Development program and replace it with a new development program, pursuant to which the parties will collaborate on the development of a new formulation for the rifaximin compound, called extended intestinal release (EIR), for the treatment of postoperative Crohn’s disease (the “POCD EIR Product”). Alfa will have primary responsibility to conduct the development work pursuant to this new program, including the preparation and filing of the regulatory documentation to obtain the initial marketing approval for the POCD EIR Product in the United States, in accordance with a development plan to be agreed upon by the parties. The Salix Parties will be responsible for funding third party costs incurred in connection with such development to the extent necessary or required to obtain the initial marketing approval for the POCD EIR Product in the United States, in accordance with such agreed development plan, including as may be amended to address FDA requirements for the POCD EIR Product in the United States. Once approved, the Salix Parties will have the right to commercialize the POCD EIR Product in the United States and Canada. The ARLA Amendment also provides for the establishment and operation of a steering committee to oversee and coordinate the development of the POCD EIR Product.

Under the terms of the ARLA Amendment, until the occurrence of certain specified events, Alfa is prohibited from exploiting products containing the rifaximin compound, in any formulation (including the rifaximin compound that is the subject of the development collaboration described above in specific dosages in the territory licensed by the Salix Parties), in specific dosages in the territory licensed by the Salix Parties, whether inside or outside the licensed field.

Subject to specified notice periods and specified limitations, each of Alfa and the Salix Parties have the right to terminate the ARLA with respect to the POCD EIR Product without cause at any time, as well as certain other customary termination rights. In the case of a termination of the ARLA with respect to the POCD EIR Product (other than by Alfa on a without cause basis), all licenses granted to the Salix Parties relating to the EIR formulation of the rifaximin compound, including as relates to the POCD EIR Product, will terminate and revert to Alfa and, to the extent that the development costs incurred by the Salix Parties at the time of termination are below a specific amount, the Salix Parties will be required to pay Alfa the difference between what the development costs that have then been paid by the Salix Parties and such specific amount.

The foregoing is a summary description of certain terms of the ARLA Amendment, is not complete and is qualified in its entirety by reference to the text of the ARLA Amendment, which the Company expects to file as an exhibit to the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

The A&R Supply Agreement

The A&R Supply Agreement amends and restates the supply agreement between Alfa and Salix dated June 24, 1996, as amended, copies of which agreement and prior amendments thereto were incorporated by reference into the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2017 as Exhibits 10.23, 10.24, 10.25 and 10.26. The A&R Supply Agreement provides for the supply of the rifaximin compound by Alfa to the Salix Parties.

Under the terms of the A&R Supply Agreement, the Salix Parties are required to purchase a specific portion of their annual requirements for the rifaximin compound from Alfa from January 1, 2019. Subject to certain limitations, the Salix Parties have the right to purchase any remaining portion of such annual requirements in excess of such specific portion either from Alfa or from certain other specified manufacturers. There are no minimum purchase quantity obligations under the A&R Supply Agreement. The A&R Supply Agreement also contains provisions regarding payment terms, confidentiality, inspections, representations and warranties and indemnification, as well as other customary provisions.

The initial term of the A&R Supply Agreement expires on December 31, 2023. The Salix Parties have the right, subject to compliance with certain notice requirements, to unilaterally extend the initial term by an additional five years, namely to December 31, 2028, following which the term shall be automatically extended for additional three-year terms. Subject to specified notice periods and specified limitations, either party may terminate the Agreement in the event of (i) uncured material breach by the other party, (ii) the bankruptcy, insolvency, dissolution or winding up of the other party, or (iii) for convenience after a specified period of time.

The foregoing is a summary description of certain terms of the A&R Supply Agreement, is not complete and is qualified in its entirety by reference to the text of the A&R Supply Agreement, which the Company expects to file as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Bausch Health Companies Inc., dated October 29, 2018

SIGNATURES

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

Date: October 31, 2018

BAUSCH HEALTH COMPANIES INC.

By: /s/ Christina Ackermann

Christina Ackermann
Executive Vice President, General Counsel

Exhibit Index

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99.1	Press Release of Bausch Health Companies Inc., dated October 29, 2018

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SALIX AND ALFASIGMA WILL INITIATE LATE-STAGE PROGRAM TO STUDY RIFAXIMIN IN PATIENTS WITH POSTOPERATIVE CROHN'S DISEASE

Companies Announce Resolution of Outstanding Arbitration

BRIDGEWATER, N.J., Oct. 29, 2018 – Salix Pharmaceuticals, Inc. (“Salix”), one of the largest specialty pharmaceutical companies in the world committed to the prevention and treatment of gastrointestinal diseases and a wholly owned subsidiary of Bausch Health Companies Inc. (NYSE/TSX: BHC) (“Bausch Health”), announced it has entered into an amendment to its existing license agreement with Alfasigma S.p.A. (“Alfasigma”) to initiate a late-stage clinical program to study an investigational formulation of rifaximin in patients with postoperative Crohn’s disease, an area of unmet medical need. Additionally, the companies have agreed to resolve the outstanding arbitration regarding another development project for a formulation of rifaximin.

According to the Crohn's & Colitis Foundation, more than 750,000 Americans have Crohn's disease, and of those, up to 75 percent will eventually require surgery. Surgery in Crohn’s disease is not curative, and postoperative recurrence frequently occurs.¹

“Today, there are no approved treatments in the United States for the prevention of postoperative Crohn’s disease recurrence. Based on existing clinical data, we believe rifaximin may be a potential treatment solution to help postoperative patients manage their Crohn’s disease,” said Mark McKenna, president of Salix Pharmaceuticals. “The amended agreement with Alfasigma allows us to start working together on a clinical research program that could lead to a new option in the treatment paradigm for postoperative Crohn’s disease patients.”

The new formulation of rifaximin, called Extended Intestinal Release (EIR), will be used in the late-stage clinical research program. In 2012, a European clinical Phase 2 study in 402 patients with moderately active Crohn’s disease was performed to assess the efficacy and safety of multiple doses of rifaximin-EIR. The Phase 2 trial demonstrated that administration of rifaximin-EIR twice daily for 12 weeks induced remission with few adverse events in patients with moderately active Crohn's disease.²

“I am very happy regarding this agreement with Salix as it re-energizes our long-term partnership, one that has played a critical role in the success of XIFAXAN® (rifaximin) in the United States,” commented Anton Giorgio Failla, executive director of Corporate Development, Alfasigma. “We look forward to dedicating our efforts to develop a new generation of rifaximin that may improve patients’ lives and address a significant unmet medical need.”

Resolution of the Arbitration

The companies have agreed to resolve the outstanding arbitration regarding performance under an Amended and Restated License Agreement between Alfasigma and Salix concerning another development project for a new formulation of rifaximin. As a result of the resolution, all claims related to the arbitration will be released.

About XIFAXAN

XIFAXAN® (rifaximin) 550 mg tablets are indicated for the reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults and for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults.

IMPORTANT SAFETY INFORMATION

- XIFAXAN is contraindicated in patients with a hypersensitivity to rifaximin, rifamycin antimicrobial agents, or any of the components in XIFAXAN. Hypersensitivity reactions have included exfoliative dermatitis, angioneurotic edema, and anaphylaxis.
- Clostridium difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including XIFAXAN, and may range in severity from mild diarrhea to fatal colitis. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued.
- There is an increased systemic exposure in patients with severe (Child-Pugh Class C) hepatic impairment. Caution should be exercised when administering XIFAXAN to these patients.
- Caution should be exercised when concomitant use of XIFAXAN and P-glycoprotein (Pgp) and/or OATPs inhibitors is needed. Concomitant administration of cyclosporine, an inhibitor of P-gp and OATPs, significantly increased the systemic exposure of rifaximin. In patients with hepatic impairment, a potential additive effect of reduced metabolism and concomitant P-gp inhibitors may further increase the systemic exposure to rifaximin.
- In clinical studies, the most common adverse reactions for XIFAXAN were: o HE ($\geq 10\%$): Peripheral edema (15%), nausea (14%), dizziness (13%), fatigue (12%), and ascites(11%) o IBS-D ($\geq 2\%$): Nausea (3%), ALT increased (2%).
- INR changes have been reported in patients receiving rifaximin and warfarin concomitantly. Monitor INR and prothrombin time. Dose adjustment of warfarin may be required. • XIFAXAN may cause fetal harm. Advise pregnant women of the potential risk to a fetus.

To report SUSPECTED ADVERSE REACTIONS, contact Salix Pharmaceuticals at 1-800-321-4576.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please click [here](#) for full Prescribing Information.

About Alfasigma

Alfasigma, is an Italy-based integrated multinational pharmaceutical company with 2017 revenues in excess of €1 billion and 2,800 employees globally. Outside of its core Italian market, Alfasigma has 16 subsidiaries in Europe, Asia, North and Central America and Africa, and has authorised distributors in more than 70 countries. More than 44% of Alfasigma turnover comes from internally developed proprietary products, one of which is XIFAXAN.

About Salix

Salix is one of the largest specialty pharmaceutical companies in the world committed to the prevention and treatment of gastrointestinal diseases. For almost 30 years, Salix has licensed, developed, and marketed innovative products to improve patients' lives and arm health care providers with life-changing solutions for many chronic and debilitating conditions. Salix currently markets its product line to U.S. health care providers through an expanded sales force that focuses on gastroenterology, hepatology, pain specialists, and primary care. Salix is headquartered in Bridgewater, New Jersey.

About Bausch Health

Bausch Health Companies Inc. (NYSE/TSX: BHC) is a global company whose mission is to improve people's lives with our health care products. We develop, manufacture and market a range of pharmaceutical, medical device and over-the-counter products, primarily in the therapeutic areas of eye health, gastroenterology and dermatology. We are delivering on our commitments as we build an innovative company dedicated to advancing global health. More information can be found at www.bauschhealth.com.

Forward-looking Statements

This news release may contain forward-looking statements, which may generally be identified by the use of the words "anticipates," "expects," "intends," "plans," "should," "could," "would," "may," "will," "believes," "estimates," "potential," "target," or "continue" and variations or similar expressions. These statements are based upon the current expectations and beliefs of management and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include, but are not limited to, risks and uncertainties discussed in the Bausch Health's most recent annual or quarterly report and detailed from time to time in Bausch Health's other filings with the Securities and Exchange Commission and the Canadian Securities Administrators, which factors are incorporated herein by reference. In addition, certain material factors and assumptions have been applied in making these forward-looking statements, including that the risks and uncertainties outlined above will not cause actual results or events to differ materially from those described in these forward-looking statements. Bausch Health believes that the material factors and assumptions reflected in these forward-looking statements are reasonable, but readers are cautioned not to place undue reliance on any of these forward-looking statements. These forward-looking statements speak only as of the date hereof. Bausch Health and Salix undertake no obligation to update any of these forward-looking statements to reflect events or circumstances after the date of this news release or to reflect actual outcomes, unless required by law.

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References

1. Crohn's & Colitis Foundation (2014) The Facts About Inflammatory Bowel Diseases. <http://www.crohnscolitisfoundation.org/assets/pdfs/updatedibdfactbook.pdf>. Accessed October 24, 2018.
2. Gastroenterology (2011) Rifaximin-Extended Intestinal Release Induces Remission in Patients With Moderately Active Crohn's Disease. [https://www.gastrojournal.org/article/S0016-5085\(11\)01628-3/fulltext](https://www.gastrojournal.org/article/S0016-5085(11)01628-3/fulltext) Accessed October 24, 2018.

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