Axovant Sciences Ltd.
Form 8-K
June 06, 2018

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): **June 5, 2018**

Axovant Sciences Ltd.

(Exact name of registrant as specified in its charter)

Bermuda	**001-37418**	**98-1333697**
(State or other jurisdiction of incorporation)	(Commission File No.)	(I.R.S. Employer Identification No.)

Suite 1, 3rd Floor

11-12 St. James s Square

London SW1Y 4LB, United Kingdom

(Address of principal executive office)

Registrant s telephone number, including area code: **+44 203 318 9708**

(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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 x

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. x

Item 1.01 **Entry into a Material Definitive Agreement.**

Oxford BioMedica License Agreement

License Agreement

On June 5, 2018, Axovant Sciences Ltd. (the Company), through its wholly owned subsidiary, Axovant Sciences GmbH, entered into a license agreement (the License Agreement) with Oxford BioMedica (UK) Ltd. (BioMedica). Pursuant to the License Agreement, the Company received a worldwide, exclusive, royalty-bearing, sub-licensable license under certain patents and other intellectual property controlled by BioMedica to develop and commercialize OXB-102 (now AXO-Lenti-PD) and related gene therapy products (collectively, the Gene Therapy Products) for all diseases and conditions. The Company s license includes a right of reference to regulatory materials controlled by BioMedica related to the Gene Therapy Products. Under the License Agreement, the Company also received from BioMedica an exclusive option to obtain a worldwide license to other patents and know-how controlled by BioMedica related to certain technology processes. Under the terms of the License Agreement, the Company and BioMedica have each agreed to customary non-compete restrictions limiting their respective abilities to develop certain directly-competing gene therapy products.

Pursuant to the License Agreement, the parties will establish a clinical project team, a process development project team and a scientific advisory board. The clinical project team will oversee the transition of the long-term follow-up study of ProSavin and the AXO-Lenti-PD clinical program. Additionally, BioMedica will provide the Company with the equivalent of up to six full-time employees to assist with the conduct of these clinical programs, and the Company will reimburse BioMedica for costs related to such individuals. The process development project team will oversee certain process development services that BioMedica will perform for the Company with respect to the manufacture of the Gene Therapy Products. The scientific advisory board will enable BioMedica to advise with respect to certain clinical and scientific aspects of the development of the Gene Therapy Products.

The Company is solely responsible, at its expense, for all activities related to the development and commercialization of the Gene Therapy Products. Pursuant to the License Agreement, the Company is required to use commercially reasonable efforts to develop, obtain regulatory approval of, and commercialize a Gene Therapy Product in the United States and at least one major market country in Europe. In addition, the Company is required to meet certain diligence milestones and to include at least one U.S.-based clinical trial site in a pivotal study of a Gene Therapy Product. If the Company fails to meet any of these specified development milestones, it may cure such failure by paying BioMedica certain fees, which range from $0.5 million to $1.0 million.

The License Agreement provides that BioMedica will transfer its existing inventory of AXO-Lenti-PD to the Company, which the Company intends to use to supply its planned Phase 1/2 study. BioMedica will manufacture and supply the Gene Therapy Products to the Company in accordance with separate clinical and commercial supply agreements that will be negotiated by the parties after the effective date of the License Agreement. Pursuant to the License Agreement, such clinical and commercial supply agreements will contain certain key provisions as set forth in the License Agreement, including the pricing structure and the Company s ability to transfer the technology to another manufacturer at any time following the completion of formal process characterization, process validation or BLA submission.

As partial consideration for the license, the Company made an upfront payment to BioMedica of $30.0 million, $5.0 million of which will be applied as a credit against the process development work and clinical supply that BioMedica will provide to the Company. Under the terms of the License Agreement, the Company could be obligated to make payments to BioMedica totaling up to $55.0 million upon the achievement of specified development milestones and $757.5 million upon the achievement of specified regulatory and sales milestones. The Company will also pay BioMedica a tiered royalty from 7% to 10%, based on yearly aggregate net sales of the Gene Therapy Products, subject to specified reductions upon the occurrence of certain events as set forth in the License Agreement. These royalties are required to be paid, on a product-by-product and country-by-country basis, until the latest to occur of the expiration of the last to expire valid claim of a licensed patent covering such product in such country, the expiration of regulatory exclusivity for such product in such country, or 10 years after the first commercial sale of such product in such country.

BioMedica will continue to be responsible for the prosecution, maintenance, and enforcement of the licensed patents that relate to the Gene Therapy Products at their expense, but the Company has the right to take over any prosecution, maintenance, and enforcement of licensed patents that are solely and specifically related to the Gene Therapy Products if BioMedica fails to act.

The License Agreement will expire on a product-by-product and country-by-country basis, on the expiration of the royalty payment term described above for such product in such country. The Company may terminate the License Agreement at any time for any reason with prior written notice to BioMedica. Either party may terminate the License Agreement for the other party s uncured material breach of the Agreement or insolvency. If the License Agreement is terminated in its entirety, all rights and licenses granted to the Company cease and the Company must transfer all regulatory filings and know-how related to the Gene Therapy Products to BioMedica. BioMedica will reimburse the Company for the costs associated with such transfer. Upon termination of the License Agreement, the Company must also grant BioMedica an exclusive license under all patents that cover the Gene Therapy Products and related know-how that the Company or its affiliates or sublicensees control. The Company may sell off any existing inventory of Gene Therapy Products for a specified period after termination.

The foregoing description of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the License Agreement, a copy of which the Company expects to file as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending June 30, 2018.

AXO-Lenti-PD

AXO-Lenti-PD is an *in vivo* lentiviral vector gene therapy investigational product for the treatment of Parkinson s disease. AXO-Lenti-PD delivers a construct of three genes that encode the critical enzymes required for the biochemical synthesis of endogenous dopamine from tyrosine: Tyrosine Hydroxylase (TH, the enzyme that converts tyrosine to L-dopa), Cyclohydrolase 1 (CH1, the rate-limiting enzyme for synthesis of tetrahydrobiopterin (BH4), an essential cofactor for production of L-dopa), and Aromatic L-Amino Acid Decarboxylase (AADC, the enzyme that converts L-dopa to dopamine). AXO-Lenti-PD is delivered by a one-time MRI-guided stereotactic infusion into the putamen.

Patients with Parkinson s disease suffer from progressive motor symptoms, including hypo- and bradykinesia, rigidity, tremor, and postural instability. Oral treatment with the dopamine precursor, L-dopa, is the current standard of care for the treatment of Parkinson s disease and has been shown to be effective in managing motor symptoms in the early stages of the disease. However, as the disease progresses, the efficacy of L-dopa in controlling motor symptoms begins to wear off, eventually resulting in severe on-off motor fluctuations, characterized by unpredictable OFF periods of reduced mobility, and increased rigidity and tremor, as well as debilitating dyskinetic periods of abnormal and involuntary movements. AXO-Lenti-PD s three-gene delivery approach is designed to optimize motor control by enabling continuous, tonic, endogenous dopamine production within the putamen.

The Company believes that the lentiviral vector delivery approach utilized by AXO-Lenti-PD has unique advantages compared to other viral vectors for drug delivery. Lentiviral vectors have a larger viral packaging capacity compared to Adeno-Associated Viral vectors, thereby enabling simultaneous delivery of multiple genes within the same construct. In addition, lentiviral vectors are capable of integrating into the host genome, and consequently, possess a potential for long-term expression.

The Company believes that proof-of-concept has been established based on data previously generated with ProSavin, the predecessor gene therapy construct developed by BioMedica. ProSavin delivers the same three genes as AXO-Lenti-PD (TH, CH1 and AADC), in a different payload configuration. In a Phase 1/2 study of 15 patients with advanced Parkinson s disease conducted by BioMedica, durable motor improvements were observed throughout four years of long-term follow up of patients who received a one-time administration of ProSavin. No serious adverse events related to ProSavin or the surgical procedure were observed in this study.

AXO-Lenti-PD is a second-generation gene therapy investigational product that was designed to modify the payload configuration of ProSavin to further improve endogenous dopamine production. In nonclinical studies, these changes resulted in up to 10-fold increases in dopamine plus L-dopa production as compared to ProSavin.

The Company plans to initiate a Phase 1/2 study of AXO-Lenti-PD in patients with advanced Parkinson s disease by the end of 2018. The study design consists of two parts:

- Part A is a non-randomized dose-escalation of multiple potential dose levels.

- Part B is a double-blind design with patients randomized either to an active group receiving the optimal dose as determined in Part A, or a control group receiving an imitation sham surgical procedure.

The study will evaluate the safety and tolerability of AXO-Lenti-PD, as well as its effects on biomarkers and clinical measures of motor function, including those measured by the unified Parkinson s disease rating scale.

Roivant Financing

On June 5, 2018, the Company entered into a share purchase agreement (the Purchase Agreement) with Roivant Sciences Ltd. (RSL), our majority shareholder, pursuant to which the Company agreed to issue and sell to RSL 14,285,714 common shares at a purchase price of $1.75 per common share in a private placement (the Private Placement), equal to the per share closing price of the Company s common shares on the Nasdaq Global Select Market on June 5, 2018. The Purchase Agreement includes customary representations, warranties and covenants by the Company. Closing of the Private Placement is subject to satisfaction or waiver of customary closing conditions, including the lapse of a 20-day period following the mailing by the Company of an information statement relating to the Private Placement to its shareholders. As of March 31, 2018, RSL held 69.6% of the Company s outstanding common shares.

The aggregate gross proceeds to the Company from the Private Placement are expected to be approximately $25.0 million. The Company intends to use the net proceeds from the Private Placement to support the clinical development of AXO-Lenti-PD as well as additional business development activities, for working capital and other general corporate purposes.

The foregoing description of the Purchase Agreement does not purport to be complete and is qualified in its entirety by reference to such agreement, a copy of which the Company expects to file as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending June 30, 2018.

Amended and Restated Information Sharing and Cooperation Agreement

On June 5, 2018, the Company entered into an amended and restated information sharing and cooperation agreement (the Cooperation Agreement) with RSL, our majority shareholder, which agreement will become effective as of the closing date of the Private Placement. The Cooperation Agreement, among other things: (1) obligates the Company to deliver to RSL periodic financial statements and other information upon reasonable request and to comply with other specified financial reporting requirements; (2) requires the Company to supply certain material information to RSL to assist it in preparing any future Securities and Exchange Commission (SEC) filings; and (3) requires the Company to implement and observe certain policies and procedures related to applicable laws and regulations. The Company agreed to indemnify RSL and its affiliates and their respective officers, employees and directors against all losses arising out of, due to or in connection with RSL s status as a shareholder under the Cooperation Agreement and the operations of or services provided by RSL or its affiliates or their respective officers, employees or directors to the Company or any of its subsidiaries, subject to certain limitations set forth in the Cooperation Agreement.

Subject to specified exceptions, the Cooperation Agreement will terminate at such time as RSL is no longer required (a) under U.S. GAAP to consolidate the Company s results of operations and financial position, (b) under U.S. GAAP to account for its investment in the Company under the equity method of accounting, or (c) otherwise to include separate financial statements of the Company in its filings with the SEC pursuant to any SEC rule. In addition, the Cooperation Agreement may be terminated upon mutual written consent of the parties or upon written notice from RSL to the Company in the event of the Company s bankruptcy, liquidation, dissolution or winding-up.

The foregoing description of the Cooperation Agreement does not purport to be complete and is qualified in its entirety by reference to the Cooperation Agreement, a copy of which the Company expects to file as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending June 30, 2018.

Item 2.02 **Results of Operations and Financial Condition.**

As of March 31, 2018, the Company had $154.3 million of cash, working capital of $111.7 million, and long-term debt of $42.9 million. These amounts are preliminary, unaudited and subject to change upon completion of the Company s audit of its financial statements as of and for the fiscal year ended March 31, 2018. Additional information and disclosures would be required for a more complete understanding of the Company s financial position as of and results of operations for the fiscal year ended March 31, 2018.

The information furnished under this Item 2.02 shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section. The information shall not be deemed incorporated by reference into any other filing with the SEC made by the Company, regardless of any general incorporation language in such filing.

Item 3.02 **Unregistered Sale of Equity Securities.**

The information in Item 1.01 above under the caption Roivant Financing is incorporated by reference into this Item 3.02.

The Private Placement is exempt from the registration requirements of the Securities Act of 1933, as amended (the Securities Act), pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) of the Securities Act and in reliance on similar exemptions under applicable state laws. RSL has represented that it is an accredited investor within the meaning of Rule 501 of Regulation D under the Securities Act, and is acquiring the Company s common shares for investment only and not with a view towards the resale or distribution of such common shares. The Company s common shares have been offered without any general solicitation by the Company or its representatives. Neither the Company nor RSL has engaged any investment advisors with respect to the issuance by the Company of its common shares to RSL in the Private Placement, and no finders fees were paid to any party in connection therewith.

The Company s common shares issued and sold in the Private Placement may not be sold, offered for sale, pledged or hypothecated in the absence of a registration statement in effect with respect to the Company s common shares under the Securities Act or an applicable exemption from the registration requirements. This Current Report on Form 8-K does not constitute an offer to sell, or a solicitation of an offer to buy, any security and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offering would be unlawful.

Item 5.02 **Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

On June 6, 2018, Ilan Oren was appointed to the Board of Directors (the *Board*) of the Company, filling an existing vacancy, with a term expiring at the 2018 Annual General Meeting of Shareholders. Mr. Oren has been appointed to serve as a member of the Nominating and Corporate Governance Committee of the Board. The Board has determined that Mr. Oren, by virtue of his position as a director of RSL, which holds 69.6% of the Company s outstanding common shares, is not independent under applicable SEC and Nasdaq listing rules.

There are no transactions to which the Company or any of its subsidiaries is a party and in which Mr. Oren has a direct or indirect material interest subject to disclosure under Item 404(a) of Regulation S-K. There are no arrangements or understandings between Mr. Oren and any other persons pursuant to which he was appointed to the Board. There are no family relationships between Mr. Oren and any director, executive officer, or any person nominated or chosen by the Company to become a director or executive officer.

Mr. Oren, age 34, previously served as a member of the Board of the Company from March 2015 to December 2017. Since September 2011, Mr. Oren has served as Vice President, Business Development at Dexcel Pharma Technologies Ltd., an international pharmaceutical company involved in the development, manufacture and commercialization of pharmaceuticals. Mr. Oren currently serves as a director of RSL and he previously served as a director of Cynapsus Therapeutics Inc., a specialty pharmaceutical company, until its acquisition in 2016. Mr. Oren received his B.A. in Economics from Harvard College. The Company believes that Mr. Oren s extensive leadership experience and knowledge of the life sciences industry qualify him to serve on the Board.

Mr. Oren has declined to receive any cash or equity compensation for his service as director under the Company s non-employee director program.

The Company expects to enter into its standard indemnification agreement for directors with Mr. Oren, the form of which was previously filed by the Company as Exhibit 10.4 to the Company s Registration Statement on Form S-1 initially filed with the SEC on May 11, 2015 (File No. 333-204073).

Item 7.01 **Regulation FD Disclosure.**

On June 6, 2018, the Company issued a press release announcing, among other things, the entry into the License Agreement, the Private Placement and entry into the related Purchase Agreement and its conference call to be held at 8:00 a.m., Eastern time, on June 6, 2018.

A copy of the press release and the presentation discussed on the conference call are furnished as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K and are incorporated by reference into this Item 7.01. The information furnished under this Item 7.01, including Exhibit 99.1 and Exhibit 99.2, shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section. The information shall not be deemed incorporated by reference into any other filing with the SEC made by the Company, regardless of any general incorporation language in such filing.

Item 9.01 **Financial Statements and Exhibits.**

(d) Exhibits.

Exhibit No.

99.1	Press release dated June 6, 2018.
99.2	Corporate Presentation dated June 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.

Axovant Sciences Ltd.

Date: June 6, 2018	By:	/s/ Gregory Weinhoff	
		Name:	Gregory Weinhoff
		Title:	Principal Financial Officer