SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

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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): September 27, 2022

ALLARITY THERAPEUTICS, INC.
(Exact name of registrant as specified in our charter)

Delaware 001-41160 87-2147982
(State or Other Jurisdiction (Commission File Number) (IRS Employer
of Incorporation) Identification No.)

210 Broadway, Suite 201
Cambridge, MA 02139
(Address of Principal Executive Offices) (Zip Code)

(401) 426-4664
(Registrant’s telephone number, including area code)

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 (see General Instruction A.2. below):

☐ 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))

Securities registered pursuant to Section 12(b) of the Act:

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<th>Title of each class</th>
<th>Trading Symbol(s)</th>
<th>Name of each exchange on which registered</th>
</tr>
</thead>
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<td>ALLR</td>
<td>The Nasdaq Stock Market LLC</td>
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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

Second Amendment to License Agreement with Novartis

On September 27, 2022, Allarity Therapeutics Europe Aps (“Allarity Europe”), a wholly-owned subsidiary of Allarity Therapeutics, Inc. (the “Company”), entered into a Second Amendment to License Agreement (the “Second Amendment”) with Novartis Pharma AG, a company organized under the laws of Switzerland (“Novartis”), which amended the terms of the License Agreement dated April 6, 2018 (the “Original Agreement”), as amended by that certain First Amendment to License Agreement effective as of March 30, 2022 (“Amendment” and together with the Original Agreement, the “Agreement”) and that certain Promissory Note dated April 6, 2018, which was re-issued by Allarity Therapeutics Denmark Aps (“Allarity Denmark,” or “OV-SPV2”), a subsidiary of Allarity Europe, in favor of Novartis on March 30, 2022, to modify the terms and timing of the Outstanding Milestone Payment (as defined in the Second Amendment). The Second Amendment became effective upon receipt by Novartis of the first portion of the Outstanding Milestone Payment, which was made on or about September 28, 2022.

Under Clause 7.2 of the Original Agreement, the Company agreed to pay Novartis a milestone payment in one lump sum (“Third Milestone Payment”) upon submission of the first NDA with the FDA for a Licensed Product in the United States (the “Third Milestone”). The Second Amendment restructured the terms of the Third Milestone Payment to an installment plan (with the final installment due in 2023), allowing the Company more time to make the Third Milestone Payment.

In addition, the Second Amendment amended (1) Clause 1.1 of the Agreement to include the definitions of Financing Transaction, Phase 1 Clinical Trial and Phase 1b/2 Clinical Trial, (2) Clause 2.1 of the Agreement to clarify that the Company would not be permitted to sublicense any rights granted to the Company prior to completion of a Phase II Clinical Trial without the prior written consent of Novartis, and (3) Clause 7.3 to provide for the acceleration of certain milestone payments in the event the Company enters into a Financing Transaction (as defined in the Second Amendment). If all milestones under the Second Amendment are achieved, the Company may be obligated to pay Novartis up to a maximum of $26.5 million.

The Original Agreement, First Amendment and the Note are filed as Exhibit 10.7 to our Registration Statement on Form S-4 filed with the Securities and Exchange Commission (the “SEC”) on August 20, 2021, and Exhibits 10.1 and 10.2 to our Current Report on Form 8-K filed with the SEC on April 18, 2022, respectively. The foregoing description of the Second Amendment does not purport to be complete and is qualified in its entirety by reference to the Second Amendment, a copy of which is filed herewith as Exhibit 10.1 and is incorporated herein by reference.

Item 2.03 Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant

The information disclosed in Item 1.01 of this Current Report on Form 8-K is incorporated by reference into this Item 2.03.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<table>
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<tr>
<th>Exhibit</th>
<th>Exhibit Description</th>
</tr>
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<tbody>
<tr>
<td>10.1†</td>
<td>Second Amendment to License Agreement</td>
</tr>
<tr>
<td>104</td>
<td>Cover Page Interactive Data File (embedded within the Inline XBRL document)</td>
</tr>
</tbody>
</table>
In accordance with Item 601 of Regulation S-K, certain portions of this exhibit will be omitted because they are not material and would likely cause competitive harm to the registrant if disclosed. The registrant agrees to provide an unredacted copy of the exhibit on a supplemental basis to the SEC or its staff upon request.

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.

Allarity Therapeutics, Inc.

By: /s/ James G. Cullem

James G. Cullem
Chief Executive Officer

Dated: September 30, 2022
CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

SECOND AMENDMENT TO LICENSE AGREEMENT

THIS SECOND AMENDMENT (this “Second Amendment”) to the License Agreement dated April 6, 2018, by and between Novartis Pharma AG, a Swiss corporation (“Novartis”), and Allarity Therapeutics Europe ApS (formerly known as Oncology Venture ApS), a company organized under the laws of Denmark, with headquarters at Venlighedsvæj 1, DK-2970 Hoersholm, Denmark, and a wholly-owned subsidiary of Allarity Therapeutics, Inc. (Delaware, U.S.A.) (“Allarity”) as amended by that certain First Amendment to License Agreement effective as of March 30, 2022 (such agreement as amended, the “Agreement”), is entered into by and between Novartis and Allarity as of September 27, 2022 (the “Second Amendment Execution Date”) and shall be effective on the Second Amendment Effective Date (as defined below). In this Second Amendment, Novartis and Allarity each may be referred to individually as a “Party” and together as the “Parties.”

WHEREAS, Allarity has achieved the Milestone Event for submission of the first NDA with the FDA for a Licensed Product in the United States which triggers a [***] Dollars (US$[***]) Milestone Payment to Novartis (the “Outstanding Milestone Payment”);

WHEREAS, Novartis submitted Invoice No. 90465316 to Allarity on January 31, 2022 (the “Invoice Date”) for payment of the Outstanding Milestone Payment, which payment has not yet been made by Allarity;

WHEREAS, from the Invoice Date to the the Second Amendment Execution Date, the Parties have been in continuous negotiations regarding restructuring of the Outstanding Milestone Payment to Novartis;

WHEREAS, the Parties desire to amend the terms of the Agreement and that certain Promissory Note dated April 6, 2018, issued by OV-SPV2 ApS (now Allarity Therapeutics Denmark ApS), a company organized under the laws of Denmark in favor of Novartis, in order to alter the terms and timing of the Outstanding Milestone Payment;

WHEREAS, the Parties therefore desire to amend the Agreement as set forth herein.

NOW, THEREFORE, for good and valuable consideration, the receipt and consideration is hereby acknowledged, and intending to be legally bound hereby, the Parties agree as follows:

1. Defined Terms. All capitalized terms used but not defined herein shall have the same meaning as set forth in the Agreement.

Effectiveness. This Second Amendment shall become effective only upon receipt by Novartis of the First Portion of Outstanding Milestone Payment (as defined below) from Allarity (such date, the “Second Amendment Effective Date”). If Novartis has not received the First Portion of Outstanding Milestone Payment within three (3) Business Days of the Second Amendment Execution Date then this Second Amendment shall be automatically be deemed to have been terminated and shall have no force or effect.

3. Definitions. Clause 1.1 of the Agreement is hereby amended to include the following definitions:

“Financing Transaction” means the incurrence by Allarity or any of its Affiliates of any indebtedness to, or any investment, financing, or funding arrangement with, any Third Party, or the issuance, sale, pledge, or encumbrance of any capital stock or other debt or equity securities (or rights to acquire any capital stock or other debt or equity securities) to any Third Party”. Provided that, a Financing Transaction shall not include any restructuring of Allarity’s existing investment financing agreements with 3i, LLP (New York, NY).
“Phase 1 Clinical Trial” means a human clinical trial that is intended to initially evaluate the safety and/or pharmacological effect of a product or that would otherwise satisfy the requirements of 21 C.F.R. 312.21(a) or an equivalent clinical trial in a country other than the United States.

“Phase 1b/2 Clinical Trial” means a human clinical trial of a product as a single agent or in combination for any indication that (a) is intended for dose exploration, examination of pharmacological or clinical activity (including dose response, dose escalation, duration of effect or kinetic/dynamic relationship assessments) and preliminary determination of efficacy and safety in the target patient population, and (b) contains a sufficient number of well characterized and clinically uniform subjects for the applicable indication using a pre-specified and uniform dose, or, if in combination, a fixed combination regimen, to assess the response rate and safety of the investigational agent(s). The distinction between the Phase 1b and Phase 2 portion of the trial will be designated in the protocol (examples including, but not exclusive of, the time when ineffective doses are dropped, a standard or care/comparator group is introduced or the sample size of the responding cohorts is increased as a result of the observed response rate from the Phase 1b portion to confirm the robustness of the result and/or further characterize safety.

4. **Sublicensing.** Clause 2.2(a) of the Agreement is hereby amended to add the following sentence to the end of such Clause:

“For the avoidance of doubt, Allarity shall not be permitted to sublicense any rights granted to it under Clause 2.1 of this License Agreement prior to completion of such Phase II Clinical Trial without the prior written consent of Novartis.”

5. **Milestone Payments.** Clause 7.2 of the Agreement is hereby superseded and replaced in its entirety with the following:

**7.2 Milestone Payments.** In further consideration for the licenses and rights granted to Allarity hereunder, Allarity shall pay to Novartis the following Milestones upon achievement of the respective Milestones events as set forth below, in each case related to the Development of the Compound in the Field in the Territory, by Allarity or on behalf of Allarity, itself or through any of its Affiliates or sublicensees, the corresponding one-time, non-refundable, non-creditable payments (“Milestone Payments”):

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<th>Milestone Event</th>
<th>Milestone Payment (US$)</th>
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<tr>
<td>1. Upon the earlier of (i) enrollment of half of the patients required in the planned Phase 2 portion of a first Phase 1b/2 Clinical Trial for a Licensed Product; (ii) 2 years following start of First Patient First Visit of the first planned Phase 1b/2 Clinical Trial for the Licensed Product; or (iii) the conversion of any first Phase 1b/2 Clinical Trial to a Phase 2 Clinical Trial.</td>
<td>[[[<em><strong>] United States Dollars (US$[</strong></em>])]</td>
</tr>
<tr>
<td>2. Upon dosing of the first patient in the first Phase III Clinical Trial for a Licensed Product.</td>
<td>[[[<em><strong>] United States Dollars (US$[</strong></em>])]</td>
</tr>
<tr>
<td>3. Upon submission of the first NDA with the FDA for a Licensed Product in the United States.</td>
<td>[[[<em><strong>] United States Dollars (US$[</strong></em>]) (the “Outstanding Milestone Amount”) to be paid as follows:</td>
</tr>
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<td></td>
<td>• [[[<em><strong>] United States Dollars (US$[</strong></em>])] on the Second Amendment Execution Date (the “First Portion of Outstanding Milestone Payment”)</td>
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<td>• [[[<em><strong>] United States Dollars (US$[</strong></em>])] by December 31, 2022 (the “Second Portion of Outstanding Milestone Payment”)</td>
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<td>• [[[<em><strong>] United States Dollars (US$[</strong></em>])] by April 1, 2023 (the “Third Portion of Outstanding Milestone Payment”)</td>
</tr>
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<td></td>
<td>• [[[<em><strong>] United States Dollars (US$[</strong></em>])] by July 15, 2023 (the “Fourth Portion of Outstanding Milestone Payment”)</td>
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</tbody>
</table>
4 Submission of a first MAA to the EMA or any other Regulatory Authority for a Licensed Product in the Main European Countries

[***] United States Dollars (US$[***])

5 Upon receipt of the first authorization for a Licensed Product by the FDA in the United States to market and sell such Licensed Product (but explicitly excluding any pricing or reimbursement approvals).

[***] United States Dollars (US$[***])

6 Upon receipt of a first MAA (including a respective pricing and reimbursement approval) for a Licensed Product in one or more countries belonging to the Main European Countries

[***] United States Dollars (US$[***])

If Milestone Events 4 or 5 in the foregoing table occur before (or without) the occurrence of a Milestone Event higher in the foregoing table (i.e., Milestone Events 1 or 2, as the case may be), then all payments corresponding to Milestone Events 1 or 2 above and not yet paid shall be paid simultaneously with the Milestone Payment for Milestone Events 4 or 5.

6. Payment of Milestones. Clause 7.3 of the Agreement is hereby superseded and replaced in its entirety with the following:

7.3 Payment of Milestones.

(a) Each Milestone shall be deemed earned as of the first achievement of the respective Milestone event, and, except with respect to Milestone Event 3, is payable one time only regardless of the number of Licensed Products (provided that, Milestone Event 3 is also only payable for the first Licensed Product). Subject to this Clause 7.3, from and after the date of any notice of termination by Novartis according to Clause 14.3(a) is received by Allarity, no further milestones with respect to the Licensed Product shall be payable by Allarity to Novartis, except to the extent those Milestone Payments relate to Milestones that have been achieved prior to Allarity’s receipt of the termination notice which are unpaid.

(b) Notwithstanding anything in this Agreement to the contrary, upon Allarity or any of its Affiliates entering into a Financing Transaction, the Milestone Payment for Milestone Event 3 shall be accelerated as follows:

(i) if the Financing Transaction is less than [***] United States Dollars (US$[***]) then [***] percent ([***]% of the gross amount raised in such Financing Transaction shall be immediately due and payable to Novartis;

(ii) if the Financing Transaction is greater than or equal to [***] United States Dollars (US$[***]) but less than [***] United States Dollars (US$[***]) then the Second Portion of Outstanding Milestone Payment and the Third Portion of Outstanding Milestone Payment, if not already paid, shall be immediately due and payable to Novartis;

(iii) if the Financing Transaction is greater than [***] Million United States Dollars (US$[***]) then the Second Portion of Outstanding Milestone Payment, Third Portion of Outstanding Milestone Payment and Fourth Portion of Outstanding Milestone Amount, if not already paid, shall be immediately due and payable to Novartis.

(c) For the avoidance of doubt, in no event shall the sum of all payments in respect of Milestone Event 3 exceed the Outstanding Milestone Amount.

Applicable Law. The interpretation and performance of this Second Amendment shall be governed by, construed and enforced in accordance with the laws of the State of New York without giving effect to any choice of law rules that would cause the application of laws in any jurisdiction other than those of the State of New York.

7. Other Terms. All other terms of the Agreement shall remain in full force and effect. To the extent any provision of the Agreement conflicts with any provision of this Second Amendment, this Second Amendment will control.
9. Counterparts. This Second Amendment may be executed in multiple counterparts, all of which shall be considered one and the same agreement. The Parties recognize the use of simple electronic signatures (e.g. DocuSign) as legally valid and binding for this Second Amendment, unless applicable laws mandates any other form of execution.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the Parties have caused this Second Amendment to the Agreement to be executed by their duly authorized representatives.

NOVARTIS PHARMA AG

Signature: /s/ Guillaume Vignon
Name: Guillaume Vignon
Title: Global Head of BD&L Partnering
Date: 09/28/22

ALLARITY THERAPEUTICS EUROPE ApS (f/k/a Oncology Ventures ApS)

Signature: /s/ James G. Cullem, J.D.
Name: James G. Cullem, J.D.
Title: Chief Executive Officer
Date: September 27, 2022

NOVARTIS PHARMA AG

Signature: /s/ Sven Werner
Name: Sven Werner
Title: Gbl BD&L Exec Dir Divestment & Outlicensing
Date: 09/28/2022

[Signature Page to Second Amendment to License Agreement]
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