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): July 26, 2023 (July 21, 2023)

Alnylam Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-36407**	**77-0602661**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

675 West Kendall Street, **Henri A. Termeer Square** **Cambridge, Massachusetts**	**02142**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 551-8200

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:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.01 par value per share	ALNY	The Nasdaq Stock Market LLC

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 July 21, 2023 (the "Effective Date"), Alnylam Pharmaceuticals, Inc. (the "Company"), entered into a Collaboration and License Agreement (the "Agreement") with F. Hoffmann-La Roche Ltd. ("Roche Basel") and Genentech, Inc. ("Genentech," each of Roche Basel and Genentech, individually and collectively, "Roche"), pursuant to which the Company and Roche established a worldwide, strategic collaboration for the joint development of pharmaceutical products containing zilebesiran, the Company's proprietary siRNA therapeutic targeting liver-expressed angiotensinogen or AGT01-RVR ("Licensed Products"). Under the Agreement, the Company granted to Roche (i) co-exclusive rights to develop and commercialize Licensed Products in the United States (the "Shared Territory") and (ii) exclusive rights to develop and commercialize Licensed Products outside the United States (the "Roche Territory").

Under the Agreement, Roche will make an upfront payment of $310 million to the Company. In addition, the Company will be eligible to receive up to $2.5 billion in contingent payments based on the achievement of specified development, regulatory and sales-based milestones.

The Company and Roche will conduct development of Licensed Products in the Shared Territory and Roche Territory in accordance with a global development plan. The Company will have primary responsibility for the day-to-day operational activities with respect to (i) those clinical trials included in the global development plan as of the Effective Date and (ii) development of Licensed Products for use in the treatment of hypertension. Subject to the foregoing, Roche will be responsible for any development activities conducted primarily to support regulatory approval of Licensed Products in the Roche Territory. Each party is required to use commercially reasonable efforts to carry out the tasks assigned to it under the global development plan.

The Company will be responsible for forty percent (40%) and Roche will be responsible for the remaining sixty percent (60%) of development costs incurred in the conduct of development activities that support regulatory approval of Licensed Products in both the Shared Territory and the Roche Territory. To the extent development activities are conducted primarily to support the regulatory approval of Licensed Products in the Shared Territory or Roche Territory, Roche will be solely responsible for all costs incurred primarily to support regulatory approval in the Roche Territory and the parties will share equally (50/50) all costs incurred primarily to support regulatory approval in the Shared Territory. Notwithstanding the foregoing, the Company will remain solely responsible for costs incurred in connection with the conduct of clinical trials for Licensed Products ongoing as of the Effective Date.

If development is successful and regulatory approval is granted by applicable regulatory authorities for a Licensed Product, the Company will hold marketing authorizations for such Licensed Product in the Shared Territory and Roche will hold marketing authorizations for such Licensed Product in the Roche Territory. Upon receipt of any such regulatory approval, as applicable, the parties must use commercially reasonable efforts to commercialize such Licensed Product in the Shared Territory and Roche must use commercially reasonable efforts to commercialize such Licensed Product in certain major market countries in the Roche Territory.

Roche will be solely responsible for costs incurred in connection with commercialization of Licensed Products in the Roche Territory and will pay the Company tiered, low double digit royalties based on net sales of Licensed Products on a Licensed Product-by-Licensed Product and country-by-country basis in the Roche Territory during the royalty term. The parties will share equally (50/50) profits and losses (including commercialization costs) of Licensed Products in the Shared Territory.

The Company will be responsible for supply of Licensed Products for clinical and commercial use in the Shared Territory. The parties must use commercially reasonable efforts to complete a technology transfer of the manufacturing process for zilebesiran prior to first commercial sale of zilebesiran. The Company will be responsible for supply of Licensed Products in the Roche Territory until completion of such technology transfer, and Roche will be responsible for supply of Licensed Products for clinical and commercial use in the Roche Territory following completion of such technology transfer.

Following the occurrence of certain specified events, Roche may terminate the Agreement in its entirety or on a region-by-region basis without cause, upon prior notice to the Company. The Company may terminate the Agreement if Roche or any of its affiliates or sublicensees challenges certain patents licensed to Roche under the Agreement and Roche fails to timely withdraw such challenge. Either party may terminate the Agreement upon the other party's insolvency or material breach, subject to a cure period.

Upon termination of the Agreement, certain reversion rights with respect to the Licensed Products will be granted between the parties. The Agreement contains, among other provisions, customary representations and warranties, indemnification obligations and confidentiality and intellectual property provisions.

The foregoing description of the Agreement does not purport to be complete and is subject to, and qualified in its entirety by reference to, the 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 September 30, 2023.

Item 7.01 Regulation FD Disclosure.

On July 24, 2023, the Company issued a press release announcing entry into the Agreement. A copy of this press release is furnished as Exhibit 99.1 to this Report on Form 8-K.

The information in this Item 7.01 and Exhibit 99.1 attached hereto is intended to be 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 from by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit shall be deemed to be furnished, and not filed:

99.1	Press Release dated July 24, 2023 announcing entry into the Collaboration and License Agreement.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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.

Date: July 26, 2023

ALNYLAM PHARMACEUTICALS, INC.

By: /s/ Jeffrey V. Poulton
Jeffrey V. Poulton
Executive Vice President, Chief Financial Officer

Exhibit 99.1

Contacts:
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Alnylam Announces Partnership with Roche to Co-Develop and Co-Commercialize Zilebesiran, an Investigational RNAi Therapeutic for the Treatment of Hypertension in Patients with High Cardiovascular Risk

– Partnership Combines Alnylam's Leadership in RNAi Therapeutics with Roche's Proven Track Record of Successfully Developing and Launching Innovative Medicines Worldwide –

– Zilebesiran Represents a Potentially Transformative Approach to Reducing CV Morbidity and Mortality in Hypertension Patients at High CV Risk by Robustly and Durably Lowering Blood Pressure –

– Alnylam will Receive an Upfront Cash Payment of $310 Million and is Eligible to Receive Development, Regulatory, and Sales Milestones, Including Substantial Near-Term Milestones, for a Potential Deal Value of up to $2.8 Billion, as well as an Equal Share of Profits and Losses in the United States and Royalties on Net Sales Outside the U.S. –

– Alnylam will Lead Joint Clinical Development Plan for First Indication, Including Cardiovascular Outcome Trial, with Development Costs Shared Between the Companies –

– Alnylam and Roche will Co-Commercialize Zilebesiran in the U.S., While Roche Obtains Exclusive Right to Commercialize Zilebesiran Outside the U.S. –

Alnylam to Host Conference Call Today, Monday, July 24, at 08:00 a.m. ET to Discuss Collaboration –

CAMBRIDGE, Mass.— July 24, 2023 — Alnylam Pharmaceuticals, Inc. (Nasdaq: ALNY), the leading RNAi therapeutics company, today announced it has entered into a strategic agreement with Roche to develop and commercialize zilebesiran, Alnylam's investigational RNAi therapeutic for the treatment of hypertension, which is currently in Phase 2 of development. The partnership allows for a bold development plan with the goal of disrupting the hypertension treatment paradigm globally while advancing Alnylam's *P^5x25* strategy.

Roche provides Alnylam the benefits of an outstanding partner with a global footprint and a proven track record of developing and commercializing novel therapies in complex markets. Roche has a proven history of innovating and commercializing medicines building upon their extensive global footprint which may potentially enable zilebesiran to reach more patients with hypertension, a disease that affects more than 1.2 billion patients globally.

“We are thrilled to announce this collaboration, as it combines Alnylam’s proven track record in RNAi therapeutics with Roche’s global commercial reach, commitment to innovation and desire to transform the landscape for patients with severe cardiovascular diseases,” said Yvonne Greenstreet MBChB, Chief Executive Officer of Alnylam. “With this collaboration, we now can develop zilebesiran in a more robust way, allowing us to have cardiovascular outcomes data in hand at launch to ensure results relevant not only for health authorities but also for access and clinical practice in order to ultimately reach as many patients as possible.”

“We are excited to work together with Alnylam and leverage our strong R&D capabilities, our leadership in cardiovascular diagnostics and our global commercial footprint to further develop and provide this promising therapy with best-in-disease potential to patients,” said Teresa Graham, CEO Roche Pharma. “Throughout our history, we have redefined the standard of care across various disease areas. Together with a strong partner like Alnylam, we are looking forward to making a significant impact for patients living with hypertension at high cardiovascular risk and potentially other cardiovascular indications.”

In a Phase 1 study, zilebesiran, compared to placebo, was associated with dose-dependent reductions in serum angiotensinogen (AGT), achieving tonic blood pressure control with consistent and durable blood pressure reduction throughout a 24-hour period, sustained up to six months after single doses of ≥200 mg. Zilebesiran also demonstrated an acceptable safety profile supporting continued clinical development. The safety and efficacy of zilebesiran are being investigated in Alnylam’s KARDIA Phase 2 clinical program either as a monotherapy (KARDIA-1) or in combination with one of three standard-of-care antihypertensive medications (KARDIA-2). Based on the positive Phase 1 data, zilebesiran could potentially be a best-in-disease treatment and provide transformational benefit, especially for patients with hypertension at high cardiovascular risk. Zilebesiran also has the potential to improve adherence to treatment due to its possible biannual subcutaneous dosing regimen. In addition, zilebesiran may be effective in additional potential cardiovascular indications with high unmet need.

Under the terms of the agreement, Alnylam will receive an upfront cash payment of $310 million and is eligible to receive additional substantial near-term payments, including development milestone payments over the next few years, as well as regulatory and sales milestones, for a potential deal value of up to $2.8 billion. In addition, Alnylam is entitled to an equal profit share in the U.S., where Alnylam and Roche will co-commercialize zilebesiran. Roche obtained the exclusive right to commercialize zilebesiran outside the U.S. in exchange for low double digit royalties on net sales of zilebesiran outside of the U.S. Alnylam believes that this partnership will allow the companies to pursue a joint development plan and commercialization approach that has the potential to unlock the full value of zilebesiran. Additionally, Alnylam will lead a joint clinical development plan for the first indication with Roche’s participation, which includes a cardiovascular outcomes trial prior to submission of zilebesiran for regulatory approval, with all development costs shared 40% by Alnylam and 60% by Roche. Roche may lead development for additional indications in the future.

Goldman Sachs & Co. LLC served as exclusive financial advisor to Alnylam.

Alnylam Conference Call Information

Alnylam management will discuss the new collaboration via conference call on Monday, July 24, 2023 at 8:00 am ET. To access the call, please register online at https://register.vevent.com/register/BIceae6347f7d14f5cb144ead1cf7cc974. Participants are requested to register a minimum of 15 minutes before the start of the call. A replay of the call will be available two hours after the call and archived on the same web page for six months.

A live audio webcast of the call will be available on the Investors section of the Company's website at www.alnylam.com/events. An archived webcast will be available on the Company's website approximately two hours after the event.

About Zilebesiran

Zilebesiran is an investigational, subcutaneously administered RNAi therapeutic targeting angiotensinogen (AGT) in Phase 2 development for the treatment of hypertension in high unmet need populations. AGT is the most upstream precursor in the Renin-Angiotensin-Aldosterone System (RAAS), a cascade which has a demonstrated role in blood pressure (BP) regulation and its inhibition has well-established anti-hypertensive effects. Zilebesiran inhibits the synthesis of AGT in the liver, potentially leading to durable reductions in AGT protein and ultimately, in the vasoconstrictor angiotensin (Ang) II. Zilebesiran utilizes Alnylam's Enhanced Stabilization Chemistry Plus (ESC+) GalNAc-conjugate technology, which enables subcutaneous dosing with increased selectivity and a wide therapeutic index. The safety and efficacy of zilebesiran have not been established or evaluated by the FDA, EMA or any other health authority.

About Hypertension

Hypertension is a complex multifactorial disease clinically defined by most major guidelines as a systolic blood pressure (SBP) of above 140 mm Hg and/or a diastolic blood pressure (DBP) greater than 90 mm Hg, though AHA/ACC guidelines have a lower threshold of a SBP above 130 mm Hg and/or a DBP greater than 80 mm Hg. More than one billion people worldwide live with hypertension.[1] In the U.S. alone, approximately 47 percent of adults live with hypertension, with more than half of patients on medication remaining above the blood pressure (BP) target level. Despite the availability of anti-hypertensive medications, there remains a significant unmet medical need, especially given the poor rates of adherence to existing daily oral medications and daily peak and trough effects, resulting in inconsistent BP control and an increased risk for stroke, heart attack and premature death.[2] In particular, there are a number of high unmet need settings where novel approaches to hypertension warrant additional development focus, including patients with poor medication adherence, difficult-to-treat and resistant hypertension, and in patients with high cardiovascular risk.

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1 Hypertension. World Health Organization. https://www.who.int/news-room/fact-sheets/detail/hypertension. Published September 2019. Accessed November 2021.

2 Carey, R. M., Muntner, P., Bosworth, H. B., & Whelton, P. K. (2018). Prevention and Control of Hypertension: JACC Health Promotion Series. Journal of the American College of Cardiology, 72(11), 1278–1293. https://doi.org/10.1016/j.jacc.2018.07.008

About RNAi

RNAi (RNA interference) is a natural cellular process of gene silencing that represents one of the most promising and rapidly advancing frontiers in biology and drug development today. Its discovery has been heralded as “a major scientific breakthrough that happens once every decade or so,” and was recognized with the award of the 2006 Nobel Prize for Physiology or Medicine. By harnessing the natural biological process of RNAi occurring in our cells, a new class of medicines known as RNAi therapeutics is now a reality. Small interfering RNA (siRNA), the molecules that mediate RNAi and comprise Alnylam’s RNAi therapeutic platform, function upstream of today’s medicines by potently silencing messenger RNA (mRNA) – the genetic precursors – that encode for disease-causing or disease pathway proteins, thus preventing them from being made. This is a revolutionary approach with the potential to transform the care of patients with genetic and other diseases.

About Alnylam Pharmaceuticals

Alnylam Pharmaceuticals (Nasdaq: ALNY) has led the translation of RNA interference (RNAi) into a whole new class of innovative medicines with the potential to transform the lives of people afflicted with rare and prevalent diseases with unmet need. Based on Nobel Prize-winning science, RNAi therapeutics represent a powerful, clinically validated approach yielding transformative medicines. Since its founding in 2002, Alnylam has led the *RNAi Revolution* and continues to deliver on a bold vision to turn scientific possibility into reality. Alnylam’s commercial RNAi therapeutic products are ONPATTRO® (patisiran), AMVUTTRA® (vutrisiran), GIVLAARI® (givosiran), OXLUMO® (lumasiran), and Leqvio® (inclisiran), which is being developed and commercialized by Alnylam’s partner, Novartis. Alnylam has a deep pipeline of investigational medicines, including multiple product candidates that are in late-stage development. Alnylam is executing on its *“Alnylam P^{5}x25”* strategy to deliver transformative medicines in both rare and common diseases benefiting patients around the world through sustainable innovation and exceptional financial performance, resulting in a leading biotech profile. Alnylam is headquartered in Cambridge, MA. For more information about our people, science and pipeline, please visit www.alnylam.com and engage with us on Twitter at @Alnylam, on LinkedIn, or on Instagram.

Alnylam Forward Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. All statements other than historical statements of fact regarding Alnylam’s expectations, beliefs, goals, plans or prospects including, without limitation, expectations regarding Alnylam’s aspiration to become a leading biotech company and the planned achievement of its “*Alnylam P^{5}x25*” strategy, Roche’s participation in the development and commercialization of zilebesiran, the potential for zilebesiran to disrupt the treatment paradigm in hypertension, Alnylam’s expectations regarding the receipt of upfront cash, as well as potential development, regulatory and sales milestones and royalties from Roche, Alnylam’s ability to obtain approval for new commercial products or additional indications for its existing products, and Alnylam’s projected commercial and financial performance, should be considered forward-looking statements. Actual results and future plans may differ materially

from those indicated by these forward-looking statements as a result of various important risks, uncertainties and other factors, including, without limitation: the direct or indirect impact of the COVID-19 global pandemic or any future pandemic on Alnylam's business, results of operations and financial condition and the effectiveness or timeliness of Alnylam's efforts to mitigate the impact of the pandemic; Alnylam's ability to successfully execute on its "*Alnylam P^{5}x25*" strategy; Alnylam's ability to discover and develop novel drug candidates and delivery approaches and successfully demonstrate the efficacy and safety of its product candidates; the pre-clinical and clinical results for Alnylam's product candidates, including patisiran and vutrisiran; actions or advice of regulatory agencies and Alnylam's ability to obtain and maintain regulatory approval for its product candidates, including patisiran and vutrisiran, as well as favorable pricing and reimbursement; successfully launching, marketing and selling Alnylam's approved products globally; delays, interruptions or failures in the manufacture and supply of Alnylam's product candidates or its marketed products; delays or interruptions in the supply of resources needed to advance Alnylam's research and development programs, including as may arise from recent disruptions in the supply of non-human primates; obtaining, maintaining and protecting intellectual property; Alnylam's ability to successfully expand the indication for ONPATTRO or AMVUTTRA in the future; Alnylam's ability to manage its growth and operating expenses through disciplined investment in operations and its ability to achieve a self-sustainable financial profile in the future without the need for future equity financing; Alnylam's ability to maintain strategic business collaborations; Alnylam's dependence on third parties for the development and commercialization of certain products, including Roche, Novartis, Sanofi, Regeneron and Vir; the outcome of litigation; the potential impact of a current government investigation and the risk of future government investigations; and unexpected expenditures; as well as those risks more fully discussed in the "Risk Factors" filed with Alnylam's 2022 Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC), as may be updated from time to time in Alnylam's subsequent Quarterly Reports on Form 10-Q and in its other SEC filings. In addition, any forward-looking statements represent Alnylam's views only as of today and should not be relied upon as representing its views as of any subsequent date. Alnylam explicitly disclaims any obligation, except to the extent required by law, to update any forward-looking statements.

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