

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 29, 2024**

uniQure N.V.

(Exact Name of Registrant as Specified in Charter)

The Netherlands
(State or Other
Jurisdiction of Incorporation)

001-36294
(Commission
File Number)

N/A
(IRS Employer
Identification No.)

**Paasheuvelweg 25a,
1105 BP Amsterdam, The Netherlands**
(Address of Principal Executive Offices)

N/A
(Zip Code)

Registrant's telephone number, including area code: **+31-20-566-7394**

(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:
Ordinary Shares, par value €0.05 per share	QURE	The Nasdaq Stock Market LLC The Nasdaq Global Select Market

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 June 29, 2024, uniQure Inc., a Delaware corporation (“**Seller**”), uniQure biopharma B.V., a Netherlands private limited company and wholly owned subsidiary of the Registrant (“**Seller Parent**”, together with Seller, “**uniQure**”), Genezen Holdings Inc., a Delaware corporation (“**Purchaser Parent**”), Genezen MA, Inc., a Delaware corporation and a wholly-owned indirect subsidiary of Genezen (“**Purchaser**”, together with Purchaser Parent, “**Genezen**”), entered into an asset purchase agreement (the “**Asset Purchase Agreement**”) pursuant to which uniQure has agreed to sell to Genezen and Genezen has agreed to purchase certain assets and assume certain liabilities related to uniQure’s manufacturing facility (the “**Lexington Facility**”) and operations in Lexington, Massachusetts (the “**Transaction**”). As consideration for the Transaction, uniQure will receive (i) shares of newly issued Series C preferred stock of Purchaser Parent valued at \$12.5 million, which are convertible into Purchaser common stock and will accrue an 8% per annum cumulative dividend, and (ii) a \$12.5 million convertible promissory note from Purchaser Parent, bearing interest at 8% per annum and maturing 63 months following the date of issuance.

Pursuant to the Asset Purchase Agreement, Genezen agreed to acquire the manufacturing equipment and related manufacturing operations along with certain other assets associated with the Lexington Facility. Genezen agreed to extend offers of employment to a majority of the uniQure employees currently located at the Lexington Facility. In addition, uniQure’s Chief Executive Officer, Matt Kapusta will join the board of directors of Genezen in connection with the closing of the Transaction, which is expected to occur in the third quarter of 2024.

The Asset Purchase Agreement contains customary representations, warranties and covenants related to the transferred assets and the Transaction. Between the date of the Asset Purchase Agreement and the closing of the Transaction, uniQure has agreed to use commercially reasonable efforts to operate the Lexington Facility in the ordinary course of business consistent with past practices, and has agreed to certain other operating covenants with respect to the transferred assets, as more fully set forth in the Asset Purchase Agreement. The closing of the Transaction is subject to customary closing conditions, including, among others, the receipt of certain third party consents and approvals.

The Asset Purchase Agreement includes customary termination provisions in favor of both parties, including upon mutual written consent of the parties and for uncured breaches of representations and warranties contained in the Asset Purchase Agreement. Both uniQure and Genezen have agreed to indemnify the other party for losses arising from certain breaches of the Asset Purchase Agreement and other specified liabilities, subject to certain limitations. The indemnification provisions are subject to certain limitations with respect to recovery for losses. Either party may terminate the Asset Purchase Agreement if the Transaction has not closed by September 27, 2024.

In connection with the closing of the Transaction, the uniQure and Genezen expect to enter into certain additional agreements, including (i) a commercial supply agreement (“**CSA**”) pursuant to which Genezen will manufacture and supply for uniQure its requirements of HEMGENIX® pursuant to uniQure’s manufacturing and supply obligations to CSL Behring, (ii) a development and other manufacturing services agreement (“**DSMA**”) pursuant to which Genezen will manufacture, supply and provide certain development services to support the requirements of uniQure’s investigational gene therapy programs and for other services related to the manufacture of HEMGENIX® under the CSA, (iii) a transition services agreement pursuant to which each party will provide transitional services to the other related to the operation of the Lexington Facility for a period following the closing of the Transaction, and (iv) an assignment and assumption of the lease agreement for the Lexington Facility, along with other customary agreements.

In addition, upon the closing of the Transaction, uniQure is expected to repay approximately \$50 million of outstanding debt under its amended and restated loan facility with Hercules Capital, Inc.

The foregoing description of the Asset Purchase Agreement does not purport to be complete and is qualified in its entirety by reference to such document, which will be filed as an exhibit to a future periodic or current report of the Registrant. The Asset Purchase Agreement contains representations, warranties, covenants and other provisions that were made only for purposes of such agreement and as of specific dates, are solely for the benefit of the parties thereto, and may be subject to limitations agreed upon by such parties. The Asset Purchase Agreement is not intended to provide any other factual information about the Company.

Item 7.01 Regulation FD Disclosure

On July 1, 2024, uniQure N.V. (the “**Company**”) issued a press release announcing the Asset Purchase Agreement and the Transaction, as described in more detail in Item 1.01 of this Current Report on Form 8-K. A copy of the press release is being furnished as Exhibit 99.1 and is incorporated herein by reference.

The information provided in this Item 7.01, including the accompanying Exhibit 99.1, shall be deemed “furnished” and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”), or otherwise subject to the liability of such section, nor shall it be incorporated by reference in any filing made by the Company pursuant to the Securities Act of 1933, as amended (the “**Securities Act**”), or the Exchange Act, regardless of the general incorporation language of such filing, except to the extent that such filing incorporates by reference any or all of such information by express reference.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. All statements other than statements of historical fact are forward-looking statements, which are often indicated by terms such as “anticipate,” “believe,” “could,” “establish,” “estimate,” “expect,” “goal,” “intend,” “look forward to,” “may,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “will,” “would” and similar expressions and the negatives of those terms. Forward-looking statements are based on management's beliefs and assumptions and on information available to management only as of the date of this report. Examples of these forward-looking statements include, but are not limited to, statements concerning the consideration to be received in the Transaction, expectations regarding additional agreements to be entered into in connection with the Transaction and the timing thereof, the expected timing regarding the closing of the Transaction and the Company's plans to pay off certain existing indebtedness in connection with the Transaction. The Company's actual results could differ materially from those anticipated in these forward-looking statements for many reasons. These risks and uncertainties include, among others: the occurrence of any event, change or other circumstances that could give rise to the termination of the Asset Purchase Agreement or failure to close the Transaction; the institution or outcome of any legal proceedings that may be instituted against the Company or Genezen following the announcement of the proposed Transaction; the inability of the parties to complete the proposed Transaction, including due to the failure to satisfy the conditions to closing; the risk that the Transaction disrupts current plans and operations as a result of the announcement and consummation of the Transaction; the Company's ability to recognize the anticipated benefits of the Transaction; changes in applicable laws or regulations; costs related to the Transaction; the possibility that the Company may be adversely affected by other economic, business and/or competitive factors; risks associated with the clinical results and the development and timing of the Company's programs; the Company's interactions with regulatory authorities, which may affect the initiation, timing and progress of clinical trials and pathways to approval; the Company's ability to continue to build and maintain the infrastructure and personnel needed to achieve its goals; the continued development and acceptance of gene therapies; the Company's ability to fund its operations and to raise additional capital as needed; and the impact of global economic uncertainty, rising inflation, rising interest rates or market disruptions on its business. These risks and uncertainties are more fully described under the heading “Risk Factors” in the Company's periodic filings with the U.S. Securities & Exchange Commission (“**SEC**”), including its Annual Report on Form 10-K filed with the SEC on February 28, 2024, and in other filings that the Company makes with the SEC from time to time. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements and, except as required by law, the Company assumes no obligation to update these forward-looking statements, even if new information becomes available in the future.

Item 9.01 Financial Statements and Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
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99.1	Press Release dated July 1, 2024
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104	Cover Page Interactive Data File (embedded within the Inline XBRL document)
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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, thereunto duly authorized.

UNIQUE N.V.

Date: July 1, 2024

By: /s/ JEANNETTE POTTS

Jeannette Potts

Chief Legal and Compliance Officer



uniQure Announces Sale of Commercial Manufacturing Facility to Genezen

~ Proposed divestiture streamlines uniQure's focus and represents an important milestone in its ongoing effort to significantly reduce operating expenses ~

~ Genezen to manufacture global commercial supply of HEMGENIX[®] and support uniQure's pipeline programs as a preferred customer ~

~ uniQure to reduce cash burn by \$40 million per year and receive total consideration of \$25 million ~

~ uniQure's comprehensive review of operations and options to reduce expenses is ongoing and expected to be complete in the third quarter of 2024 ~

Lexington, MA and Amsterdam, the Netherlands, July 1, 2024 — uniQure N.V. (NASDAQ: QURE), a leading gene therapy company advancing transformative therapies for patients with severe medical needs, today announced that it has entered into an agreement for the sale of its global manufacturing facility in Lexington, Massachusetts to Genezen, a leading contract development and manufacturing organization specializing in the supply of retroviral vectors, lentiviral vectors, and adeno-associated virus (AAV) technologies.

Genezen agreed to acquire uniQure's commercial-scale gene-therapy manufacturing facility for total consideration of \$25 million, comprised of \$12.5 million of newly issued Series C Preferred Stock and a \$12.5 million convertible note. In addition, Matt Kapusta, chief executive officer of uniQure, will join the Board of Genezen upon the closing of the transaction, which is expected early in the third quarter of 2024 subject to satisfaction of customary closing conditions.

Under the proposed transaction, Genezen will be responsible for manufacturing global commercial supply of HEMGENIX[®] for CSL and providing development and manufacturing services to support uniQure's investigational gene therapies. uniQure and CSL will be entitled to preferred customer status. The majority of uniQure's employees at the Lexington facility will be offered employment at Genezen to facilitate a seamless transition.

"Today marks a significant step forward in achieving a key strategic goal for uniQure," stated Matt Kapusta, chief executive officer of uniQure. "We have been focused on meaningfully reducing costs while maintaining our ability to develop and potentially commercialize our gene therapy product candidates. This transaction achieves these objectives by unlocking significant cost savings while maintaining preferential access to world-class gene therapy manufacturing."

"Additionally, we are continuing to closely review the business to identify additional cost reduction opportunities and expect to announce further progress in the third quarter of 2024," he added. "We believe a more streamlined uniQure enhances our strategic flexibility for value-creating opportunities and furthers our mission to deliver transformative medicines for patients in need."

As a result of this transaction, uniQure expects to reduce cash burn by approximately \$40 million annually. Upon the closing of the transaction, uniQure anticipates repaying \$50 million of outstanding debt, which is expected to yield additional savings in interest expense.

Leerink Partners is serving as financial advisor, and Covington & Burling LLP is serving as legal counsel to uniQure.

About Genezen

Genezen is a contract development and manufacturing organization with a decade's experience at the heart of the rapid growth in the gene and cell therapy market. Genezen is a leader in the supply of retroviral vectors, lentiviral vectors, and AAV. Led by an extremely experienced team, a science-first approach influences continual investment in scalable, high-yield manufacturing processes and best-in-class technologies. For more information about Genezen, please visit genezen.com.

About uniQure

uniQure's mission is to reimagine the future of medicine by delivering innovative cures that transform lives. The recent approvals of our gene therapy for hemophilia B – a historic achievement based on more than a decade of research and clinical development – represent a major milestone in the field of genomic medicine and ushers in a new treatment approach for patients living with hemophilia. We are now leveraging our modular and validated technology to advance a pipeline of proprietary gene therapies for the treatment of patients with Huntington's disease, refractory mesial temporal lobe epilepsy, amyotrophic lateral sclerosis (ALS), Fabry disease, and other severe diseases. www.uniQure.com

uniQure Forward-Looking Statements

This press release contains forward-looking statements. All statements other than statements of historical fact are forward-looking statements, which are often indicated by terms such as "anticipate," "believe," "could," "establish," "estimate," "expect," "goal," "intend," "look forward to", "may," "plan," "potential," "predict," "project," "seek," "should," "will," "would" and similar expressions. Forward-looking statements are based on management's beliefs and assumptions and on information available to management only as of the date of this press release. Examples of these forward-looking statements include, but are not limited to, statements concerning the completion of the transaction (including the timing thereof), the acquisition of the Company's manufacturing facility and assets and the consideration to be received by the Company therefor; the terms of the transaction and the post-transaction ownership of Genezen by uniQure; the Company's expectations that the transaction will reduce operating expenses and cash burn by approximately \$40 million per year; the Company's plans to repay \$50 million of outstanding debt in conjunction with the closing of the transaction and related cost savings; and the Company's ongoing review of operations and options to reduce expenses and expectations regarding the timeline for completion and announcement thereof and whether such review will be successful in reducing operation expenses and increasing shareholder value. The Company's actual results could differ materially from those anticipated in these forward-looking statements for many reasons. These risks and uncertainties include, among others: (i) the occurrence of any event, change or other circumstances that could give rise to the termination of the asset purchase agreement for the transaction or failure to close the transaction; (ii) the institution or outcome of any legal proceedings that may be instituted against the Company or Genezen following the announcement of the proposed transaction; (iii) the inability of the parties to complete the proposed transaction, including due to the failure to satisfy the conditions to closing the transaction; (iv) the risk that the proposed transaction disrupts current plans and operations as a result of the announcement and consummation of the proposed transaction; (v) the ability to recognize the anticipated benefits of the proposed transaction; (vi) changes in applicable laws or regulations; (vii) costs related to the proposed transaction; (viii) the possibility that the Company may be adversely affected by other economic, business and/or competitive factors; (ix) risks associated with the clinical results and the development and timing of the Company's programs; (x) the Company's interactions with regulatory authorities, which may affect the initiation, timing and progress of clinical trials and pathways to approval; (xi) the Company's ability to continue to build and maintain the company infrastructure and personnel needed to achieve its goals; (xii) the continued development and acceptance of gene therapies; (xiii) the Company's ability to fund its operations and to raise additional capital as needed; and (xiv) the impact of global economic uncertainty, rising inflation, rising interest rates or market disruptions on its business. These risks and uncertainties are more fully described under the heading "Risk Factors" in the Company's periodic filings with the U.S. Securities & Exchange Commission ("SEC"), including its Annual Report on Form 10-K filed February 28, 2024 and in other filings that the Company makes with the SEC from time to time. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, and the Company assumes no obligation to update these forward-looking statements, even if new information becomes available in the future.

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