
**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 8, 2019

Prevail Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware
(state or other jurisdiction
of incorporation)

001-38939
(Commission
File Number)

82-2129632
(I.R.S. Employer
Identification No.)

430 East 29th Street, Suite 1520
New York, New York
(Address of principal executive offices)

10016
(Zip Code)

Registrant's telephone number, including area code: (917) 336-9310

(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))

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, par value \$0.0001 per share	PRVL	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 8.01. Other Information.

On October 8, 2019, Prevail Therapeutics Inc. (“Prevail”) issued a press release regarding its strategic collaboration with Lonza Group Ltd. to develop and manufacture Prevail’s novel AAV9 gene therapy programs for patients with neurodegenerative diseases.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated October 8, 2019.

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.

PREVAIL THERAPEUTICS INC.

By: /s/ Asa Abeliovich, M.D., Ph.D. _____
Asa Abeliovich, M.D., Ph.D.
President and Chief Executive Officer

Dated: October 8, 2019



Prevail Therapeutics and Lonza Establish Strategic Collaboration to Develop and Manufacture Prevail's Novel AAV9 Gene Therapy Programs for Patients with Neurodegenerative Diseases

Strategic collaboration focuses on baculovirus/Sf9 expression system for Prevail's pipeline of novel AAV9-based gene therapy programs for patients with neurodegenerative diseases

Companies to partner on process development, analytical development, and large-scale manufacturing for late-stage clinical and commercial supply

Process development and manufacturing to be located in Lonza's cGMP facility in Houston, Texas

Basel, Switzerland and New York, USA, October 8, 2019 – Prevail Therapeutics Inc. (Nasdaq: PRVL), a biotechnology company developing potentially disease-modifying AAV-based gene therapies for patients with neurodegenerative disorders, and Lonza (SWX: LONN) today announced that the companies have entered into a strategic collaboration.

Lonza and Prevail have been working together since 2018, with an initial focus on process development, towards the GMP manufacturing of Prevail's two lead programs, PR001 and PR006. Under this collaboration, focused on the baculovirus/Sf9 production system for gene therapies, Lonza will manufacture Prevail's pipeline of novel AAV-based gene therapy programs for patients with neurodegenerative diseases at its gene therapy center of excellence in Houston, TX.

"Prevail is a brilliant trailblazer and it is a privilege to partner with them," said Alberto Santagostino, SVP Head of Cell & Gene Technologies, Lonza Pharma & Biotech. "This strategic collaboration reflects both companies' commitment to fueling the innovation of novel medicines. The partnership combines Prevail's frontier science with Lonza's operational expertise to support the development and commercialization of potentially life-changing treatments. Our cell and gene therapy center of excellence in Houston, TX, will support Prevail in their journey as they develop and potentially bring to market AAV-based gene therapies for patients suffering from debilitating neurodegenerative diseases."

Prevail's pipeline includes PR001, an AAV9-based gene therapy delivering *GBA1*, in development for Parkinson's disease patients with *GBA1* mutations (PD-GBA) and neuronopathic Gaucher disease patients (nGD). Prevail plans to initiate a Phase 1/2 clinical trial of PR001 in PD-GBA in 2019. The company is also developing PR006, an AAV9-based gene therapy delivering *GRN*, for frontotemporal dementia patients with a *GRN* mutation (FTD-GRN). Prevail anticipates PR006 will enter the clinic in 2020. The collaboration also has the potential to extend to Prevail's future pipeline of AAV-based gene therapy programs.

"We are pleased to partner with Lonza, a leader in the manufacturing of AAV gene therapy vectors, to enable large-scale production of our novel gene therapies that we believe hold potential to halt the course of neurodegenerative diseases for patient populations with urgent unmet needs," said Asa Abeliovich, M.D., Ph.D., Founder and Chief Executive Officer, Prevail Therapeutics. "Lonza

and Prevail will work together closely on process development and scaling up production of PR001, our gene therapy for Parkinson's disease with *GBA1* mutations and neuronopathic Gaucher disease, to supply late-stage clinical trials and for commercial production. In addition, we look forward to a collaborative relationship to support our PR006 gene therapy program for patients with frontotemporal dementia with GRN mutations, and for future gene therapy programs in our pipeline."

Prevail has built in-house process and analytical development capabilities utilizing both HEK293 and baculovirus/Sf9 AAV expression systems. Under this collaboration, Prevail and Lonza will work closely together on process development, analytical development, and large-scale production using the baculovirus/Sf9 process for late-stage clinical and commercial supply at Lonza's GMP facility in Houston.

About Lonza

Lonza is an integrated solutions provider that creates value along the Healthcare Continuum®. Through our Pharma Biotech & Nutrition segment and our Specialty Ingredients segment businesses, we harness science and technology to serve markets along this continuum. We focus on creating a healthy environment, promoting a healthier lifestyle and preventing illness through consumers' preventive healthcare, as well as improving patient healthcare by supporting our customers to deliver innovative medicines that help treat or even cure severe diseases.

Patients and consumers benefit from our ability to transfer our pharmaknow-how to the healthcare, hygiene and fast-moving consumer goods environment and to the preservation and protection of the world where we live.

Founded in 1897 in the Swiss Alps, Lonza today is a well-respected global company with more than 100 sites and offices and approximately 15,500 full-time employees worldwide at the end of 2018. The company generated sales of CHF 5.5 billion in 2018 with a CORE EBITDA of CHF 1.5 billion. Further information can be found at www.lonza.com.

About Prevail Therapeutics

Prevail is a gene therapy company leveraging breakthroughs in human genetics with the goal of developing and commercializing disease-modifying AAV-based gene therapies for patients with neurodegenerative diseases. Prevail was founded by Dr. Asa Abeliovich in 2017, through a collaborative effort with The Silverstein Foundation for Parkinson's with GBA and OrbiMed, and is headquartered in New York, NY.

Forward-Looking Statements Related to Prevail

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Examples of these forward-looking statements include statements concerning: the potential of Prevail's gene therapies to halt the course of neurodegenerative diseases; the anticipated timing of Prevail's Phase 1/2 clinical trial of PR001 in PD-GBA and Prevail's clinical trial of PR006; Prevail's ability to work with Lonza to supply Prevail's late stage trials and commercial production; and the applicability of the collaboration to Prevail's future pipeline of AAV-based gene therapy programs. Because such statements are subject to risks and

uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties include, among others: Prevail's novel approach to gene therapy makes it difficult to predict the time, cost and potential success of product candidate development or regulatory approval; Prevail's gene therapy programs may not meet safety and efficacy levels needed to support ongoing clinical development or regulatory approval; the regulatory landscape for gene therapy is rigorous, complex, uncertain and subject to change; and the fact that gene therapies are novel, complex and difficult to manufacture. These and other risks are described more fully in Prevail's filings with the Securities and Exchange Commission (SEC), including the "Risk Factors" section of the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2019, filed with the SEC on August 14, 2019, and its other documents subsequently filed with or furnished to the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except to the extent required by law, Prevail undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Additional Information and Disclaimer

Lonza Group Ltd has its headquarters in Basel, Switzerland, and is listed on the SIX Swiss Exchange. It has a secondary listing on the Singapore Exchange Securities Trading Limited ("SGX-ST"). Lonza Group Ltd is not subject to the SGX-ST's continuing listing requirements but remains subject to Rules 217 and 751 of the SGX-ST Listing Manual.

Certain matters discussed in this news release may constitute forward-looking statements. These statements are based on current expectations and estimates of Lonza Group Ltd, although Lonza Group Ltd can give no assurance that these expectations and estimates will be achieved. Investors are cautioned that all forward-looking statements involve risks and uncertainty and are qualified in their entirety. The actual results may differ materially in the future from the forward-looking statements included in this news release due to various factors. Furthermore, except as otherwise required by law, Lonza Group Ltd disclaims any intention or obligation to update the statements contained in this news release.

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