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 11, 2020

VIELA BIO, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-39067**	**82-4187338**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

One Medimmune Way, First Floor, Area Two Gaithersburg, Maryland	**20878**
(Address of principal executive offices)	**(zip code)**

Registrant's telephone number, including area code: (240) 558-0038

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, $0.001 par value per share	VIE	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 7.01 Regulation FD Disclosure.

On June 11, 2020, Viela Bio, Inc. (the "Company") issued a press release entitled "Viela Bio Announces U.S. FDA Approval of UPLIZNA™ (inebilizumab-cdon) for the Treatment of Neuromyelitis Optica Spectrum Disorder (NMOSD)", which is attached here as Exhibit 99.1.

The information contained in this Item 7.01 and Exhibit 99.1 attached hereto is being 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 under that Section, nor shall it be deemed incorporated by reference into any registration statement or other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On June 11, 2020, the Company announced that the U.S. Food and Drug Administration (FDA) has approved UPLIZNA™ (inebilizumab-cdon) for the treatment of adult patients with neuromyelitis optica spectrum disorder who are anti-aquaporin-4 (AQP4) antibody positive as a twice-a-year maintenance regimen following initial doses.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated June 11, 2020

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.

VIELA BIO, INC.

By: /s/ Mitchell Chan
Mitchell Chan
Chief Financial Officer

Date: June 11, 2020

Viela Bio Announces U.S. FDA Approval of UPLIZNA™ (inebilizumab-cdon) for the Treatment of Neuromyelitis Optica Spectrum Disorder (NMOSD)

UPLIZNA™ is the first and only B cell depleter approved for the treatment of NMOSD in adults who are anti-aquaporin-4 (AQP4) antibody positive

Gaithersburg, MD—June 11, 2020—Viela Bio (Nasdaq:VIE) today announced that the U.S. Food and Drug Administration (FDA) has approved *UPLIZNA*™ (inebilizumab-cdon) for the treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-AQP4 antibody positive as a twice-a-year maintenance regimen following initial doses. Approximately 80%[1] of all patients with NMOSD test positive for anti-AQP4 antibodies.

"NMOSD is an extremely challenging disease to treat. Patients experience unpredictable attacks that can lead to permanent disability from blindness and paralysis. In addition, each subsequent attack may result in a cumulative worsening of disability. In the pivotal N-MOmentum trial, *UPLIZNA*™—a humanized CD19-directed monoclonal antibody—significantly reduced the risk of attacks and also reduced hospitalizations when given as a monotherapy," said Bruce Cree, M.D., Ph.D., MAS, the lead investigator for the N-MOmentum trial and Professor of Clinical Neurology at the University of California San Francisco Weill Institute for Neurosciences. "*UPLIZNA*™ is an important new treatment option that provides prescribing physicians and patients living with NMOSD a therapy with proven efficacy, a favorable safety profile and a twice-a-year maintenance dosing schedule."

NMOSD is a rare, severe, neuroinflammatory autoimmune disease that attacks the optic nerve, spinal cord and brain stem. In addition to potentially irreversible blindness and paralysis, patients may also experience loss of sensation, bladder and bowel dysfunction, nerve pain and respiratory failure. It is estimated that there are approximately 10,000 people in the U.S. suffering from NMOSD[2]. Multiple lines of evidence suggest that NMOSD is a B-cell-mediated disorder.

"As an organization that understands and represents the struggle of patients and their loved ones affected by NMOSD, we are pleased that now there is another treatment option that could reduce their attacks, which can lead to devastating and irreversible disability," said Victoria Jackson, co-founder of the Guthy-Jackson Charitable Foundation, a non-profit organization dedicated to funding research and raising awareness about NMOSD. "We have been proud to partner with Viela Bio and congratulate them and the NMOSD community on this important milestone."

The approval of *UPLIZNA*™—which previously received Breakthrough Therapy and Orphan Drug designations from the FDA—is based in part on results from the pivotal N-MOmentum trial, the largest study ever conducted in a real-world spectrum of adults with NMOSD. The global, placebo-controlled study—which enrolled 213 anti-AQP4 antibody positive patients and 17 anti-AQP4 antibody negative patients—met its primary endpoint by demonstrating a statistically significant reduction in risk of NMOSD attacks. Specifically, 89% of patients in the anti-AQP4 antibody positive group remained relapse-free during the six-month period post-treatment, compared to 58% of the patients taking placebo. *UPLIZNA*™ also demonstrated statistically

significant benefits in key secondary endpoints, including reductions in NMOSD-related hospitalizations. Additionally, *UPLIZNA*™ demonstrated a favorable safety and tolerability profile. Across both the randomized and open-label treatment in Study 1, the most common adverse reactions (greater than 10%) were urinary tract infection (20%), nasopharyngitis (13%), infusion reaction (12%), arthralgia (11%), and headache (10%). The results from the N-MOmentum trial were published in the peer-reviewed journal, *The Lancet*, in September 2019 ("Inebilizumab for the treatment of neuromyelitis optica spectrum disorder (N-MOmentum): a double-blind, randomised placebo-controlled phase 2/3 trial").

Commented Bing Yao, Ph.D., Chief Executive Officer at Viela Bio: "We are proud that Viela Bio's first approved medicine has the potential to help thousands of patients with NMOSD, a progressive and debilitating neuroinflammatory disease. We are incredibly grateful to the patients, families and care partners who participated in and supported our research."

Viela anticipates product launch in June.

Study Design Overview and Efficacy Results Summary

Patients in the N-MOmentum trial were randomized 3:1 (*UPLIZNA*™ to placebo) to receive two introductory doses of 300 mg of *UPLIZNA*™ monotherapy or placebo at Day 1 and Day 15. The patients were followed for a total of 197 days. Following that randomized-controlled period (RCP), patients were given the option to enter an open-label extension period, in which every participant received 300 mg of *UPLIZNA*™ monotherapy every 6 months. The study was concluded early on the recommendation of the independent data monitoring committee, based on evidence of efficacy. Results from the anti-AQP4 antibody positive patient subgroup are shown in the chart below.

	Treatment Group	
	***UPLIZNA*™ N = 161**	**Placebo N = 52**
Time to Adjudication Committee-Determined Relapse (Primary Efficacy Endpoint)		
Number (%) of patients with relapse	18 (11.2%)	22 (42.3%)
Hazard ratio (95% CI)[a]	0.227 (0.121, 0.423)	
p-value[a]	< 0.0001	

[a] Cox regression method, with placebo as the reference group.

[1] Jarius S, Wildemann B. Aquaporin-4 antibodies (NMO-IgG) as a serological marker of neuromyelitis optica: a critical review of the literature. *Brain Pathol*. 2013;23(6):661-683.
[2] Flanagan EP. Ann Neurol. 2016;79(5):775-783.

About Neuromyelitis Optica Spectrum Disorders (NMOSD)

NMOSD is a unifying term for neuromyelitis optica (NMO) and related syndromes. NMOSD is a rare, severe, relapsing, neuroinflammatory autoimmune disease that can be fatal. Approximately 80% of all patients with NMOSD test positive for anti-AQP4 antibodies. These AQP4 autoantibodies are produced by CD19+ B cells and bind primarily to astrocytes in the central nervous system. Binding of AQP4 antibodies to central and peripheral nervous system cells is believed to trigger attacks, which can damage the optic nerve, spinal cord and brain. Loss of vision, paralysis, loss of sensation, bladder and bowel dysfunction, nerve pain and respiratory failure can all be manifestations of the disease. Each NMOSD attack can lead to further damage and disability. NMOSD occurs more commonly in women and may be more common in individuals of African and Asian descent.

About N-MOmentum

N-MOmentum, the largest clinical study ever conducted in NMOSD, was a double-blind, placebo-controlled clinical trial of 213 patients who are anti-AQP4 antibody positive and 17 who are anti-AQP4 antibody negative (n=230). In the trial, patients were randomized to receive two intravenous doses of *UPLIZNA*™ (inebilizumab-cdon) monotherapy or placebo and followed for 6.5 months. Patients were subsequently given the option to enter into an open-label extension in which all patients receive inebilizumab every 6 months. The primary endpoint was time from treatment initiation to occurrence of an NMOSD attack, which was reviewed by an independent, blinded external Adjudication Committee. NMOSD attack diagnosis was standardized using 18 clinically meaningful criteria that were developed for the study. The open-label extension portion of the study is ongoing. More information can be found on clinicaltrials.gov (Study NCT02200770).

Additional Clinical Investigation

A Phase 2 trial with inebilizumab is ongoing in kidney transplant desensitization, with an additional Phase 3 trial planned in myasthenia gravis and a Phase 2b trial planned in IgG4-related disease. For more information on ongoing clinical trials, please visit www.clinicaltrials.gov and enter the search term “Viela.”

IMPORTANT SAFETY INFORMATION

UPLIZNA™ is contraindicated in patients with:

- A history of life-threatening infusion reaction to *UPLIZNA*™
- Active hepatitis B infection
- Active or untreated latent tuberculosis

WARNINGS AND PRECAUTIONS

Infusion Reactions: *UPLIZNA*™ can cause infusion reactions, which can include headache, nausea, somnolence, dyspnea, fever, myalgia, rash, or other symptoms. Infusion reactions were most common with the first infusion but were also observed during subsequent infusions. Administer pre-medication with a corticosteroid, an antihistamine, and an anti-pyretic.

Infections: The most common infections reported by *UPLIZNA*™-treated patients in the randomized and open-label periods included urinary tract infection (20%), nasopharyngitis (13%), upper respiratory tract infection (8%), and influenza (7%). Delay *UPLIZNA*™ administration in patients with an active infection until the infection is resolved.

Increased immunosuppressive effects are possible if combining *UPLIZNA*™ with another immunosuppressive therapy.

The risk of hepatitis B virus (HBV) reactivation has been observed with other B-cell-depleting antibodies. Perform HBV screening in all patients before initiation of treatment with *UPLIZNA*™. Do not administer to patients with active hepatitis.

Although no confirmed cases of Progressive Multifocal Leukoencephalopathy (PML) were identified in *UPLIZNA*™ clinical trials, JC virus infection resulting in PML has been observed in patients treated with other B-cell-depleting antibodies and other therapies that affect immune competence. At the first sign or symptom suggestive of PML, withhold *UPLIZNA*™ and perform an appropriate diagnostic evaluation.

Patients should be evaluated for tuberculosis risk factors and tested for latent infection prior to initiating *UPLIZNA*™.

Vaccination with live-attenuated or live vaccines is not recommended during treatment and after discontinuation, until B-cell repletion.

Reduction in Immunoglobulins: There may be a progressive and prolonged hypogammaglobulinemia or decline in the levels of total and individual immunoglobulins such as immunoglobulins G and M (IgG and IgM) with continued *UPLIZNA*™ treatment. Monitor the level of immunoglobulins at the beginning, during, and after discontinuation of treatment with *UPLIZNA*™ until B-cell repletion especially in patients with opportunistic or recurrent infections.

Fetal Risk: May cause fetal harm based on animal data. Advise females of reproductive potential of the potential risk to a fetus and to use an effective method of contraception during treatment and for 6 months after stopping *UPLIZNA*™.

Adverse Reactions: The most common adverse reactions (at least 10% of patients treated with *UPLIZNA*™ and greater than placebo) were urinary tract infection and arthralgia.

About Viela Bio

Viela Bio, headquartered in Gaithersburg, Maryland, is a biotechnology company dedicated to the discovery, development and commercialization of novel treatments for autoimmune and severe inflammatory diseases. For more information, please visit www.vielabio.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, contained in this press release, including statements regarding our strategy, future

operations, prospects, plans, objectives of management, our belief that *UPLIZNA*™ provides prescribing physicians an important new treatment option for patients living with NMOSD; our belief that *UPLIZNA*™ could reduce attacks which can lead to devastating and irreversible disability in patients living with NMOSD; our estimate of the number of people in the U.S. suffering from NMOSD; our estimate of the percentage of patients with NMOSD that test positive for anti-AQP4 antibodies; results of the N-MOmentum trial; statements regarding the timing and progress of our ongoing clinical trials under the captions "Additional Clinical Investigation"; potential benefits of *UPLIZNA*™; and our expectations regarding the availability of *UPLIZNA*™; and the commercialization and market acceptance of *UPLIZNA*™, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue" or the negative of these terms or other comparable terminology, which are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. Various factors may cause differences between our expectations and actual results as discussed in greater detail in our filings with the Securities and Exchange Commission (SEC), including without limitation, the risks and uncertainties described in the section entitled "Risk Factors" in our annual report on Form 10-K for the year ended December 31, 2020 that was filed with the SEC on March 25, 2020 and our subsequent periodic and current reports filed with the SEC. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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