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): May 13, 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 2.02 Results of Operations and Financial Condition.

On May 13, 2020, Viela Bio, Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 2020 and providing business highlights. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 8.01 Other Events.

On May 13, 2020, the Company issued a press release announcing positive interim Phase 1b data from a study of VIB7734, its novel anti-ILT7 therapy, in patients with cutaneous lupus erythematosus. The full text of the press release is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibits 99.1 and 99.2) shall not be deemed to be "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 forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release announcing the Company's financial results for the first quarter ended March 31, 2020, dated May 13, 2020.
99.2	Press release announcing positive interim Phase 1b data from a study of VIB7734, dated May 13, 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: May 13, 2020

Viela Bio Reports First Quarter 2020 Financial Results and Program Highlights

Company to host investor conference call and webcast today at 5:00 pm ET

Gaithersburg, MD—May 13, 2020—Viela Bio (Nasdaq:VIE), a clinical-stage biotechnology company pioneering treatments for autoimmune and severe inflammatory disease, today reported financial results and provided program highlights for the first quarter ended March 31, 2020.

"With the PDUFA date for our lead product candidate, inebilizumab, approaching in about one month, we are nearing another major company milestone—our first potential U.S. regulatory approval," said Bing Yao, Ph.D., Chief Executive Officer at Viela Bio. "In anticipation, our field teams have been hard at work continuing to prepare for the potential product launch. Based on positive efficacy and safety data in the pivotal N-MOmentum trial—which studied a broad, real-world spectrum of adults with neuromyelitis optica spectrum disorder, or NMOSD—we believe inebilizumab has the potential to be a first-line monotherapy option that could change the treatment paradigm for thousands of patients affected by this rare and devastating neuroinflammatory disease."

Continued Dr. Yao: "While it is still too early to gauge the full potential impact of the COVID-19 pandemic, at present, we have been fortunate to experience minimal effects on our business and we continue to make solid progress advancing our entire pipeline. Today, we announced positive interim results from cohorts of patients with cutaneous lupus erythematosus in our ongoing Phase 1b trial of VIB7734 and we recently initiated a Phase 2b trial of VIB4920 for the treatment of Sjögren's syndrome."

PROGRAM HIGHLIGHTS

Inebilizumab

- **Company Advances Field Planning Activities**

  The U.S. Food and Drug Administration (FDA) is continuing its review of the Biologics License Application (BLA) for inebilizumab, with a Prescription Drug User Fee Act (PDUFA) action date of June 11, 2020. In preparation for the potential U.S. regulatory approval of inebilizumab, Viela has hired and trained market access and sales teams, and deployed MSLs. Should Viela secure product approval, the Company anticipates being able to initiate commercial launch activities shortly thereafter.

- **Viela Preparing for Additional Clinical Trials with Inebilizumab**

  Viela Bio recently submitted two Investigational New Drug (IND) applications to the FDA to begin human studies of inebilizumab in myasthenia gravis and IgG4-related disease, and plans to initiate Phase 3 pivotal and Phase 2b trials, respectively, in mid-year 2020. Viela Bio initiated a Phase 2 trial in 2019 for kidney transplant desensitization. Due to the COVID-19 pandemic, the Company has voluntarily paused enrollment of new patients in the kidney transplant desensitization trial.

VIB4920

- **Viela Advancing Multiple Mid-Stage Studies with VIB4920**

  Viela dosed the first patient at the end of 2019 in a Phase 2b trial of VIB4920 for the treatment of Sjögren's syndrome—a chronic, systemic autoimmune disease involving inflammation and destruction of the salivary and lacrimal glands which leads to severe dryness and chronic pain. Due to the COVID-19 pandemic, the Company has voluntarily paused enrollment of new patients, while those currently enrolled continue in the trial. VIB4920 is an investigational fusion protein designed to bind to CD40L, blocking the T cells' interaction with CD40-expressing cells. In earlier clinical studies, VIB4920 demonstrated the ability to address immune overactivation in T and B cell-driven diseases such as Sjögren's syndrome. In response to COVID-19, the Company has voluntarily paused enrollment in its Phase 2 trial in patients with kidney transplant rejection. The Company is exploring other potential indications associated with the CD40/CD40L co-stimulatory pathway in which to pursue additional clinical studies with VIB4920.

VIB7734

- **Company Reports Promising Interim Results from Phase 1b Trial**

  Viela today reported positive interim Phase 1b data from a study with VIB7734, its novel anti-ILT7 therapy, in patients with cutaneous lupus erythematosus (CLE). The data provide preliminary evidence that VIB7734 can safely deplete plasmacytoid dendritic cells (pDCs) in these patients. In addition, the skin biopsy results, interferon signature and the Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI) scores—an important indicator that quantifies disease activity and damage in CLE patients—indicated clinically meaningful change from baseline. The drug candidate is designed to deplete pDCs by binding to ILT7, a cell surface molecule specific to pDCs. Viela looks forward to the final data from this trial and plans to provide additional information at a future medical conference.

CORPORATE UPDATE

Viela Strengthens its Board of Directors

Viela announced the election of Rachelle Jacques to its Board of Directors in April 2020. As a veteran of the biotechnology and pharmaceutical industries, she has held various leadership roles of increasing responsibility throughout her career and currently serves as the Chief Executive Officer at Enzyvant Therapeutics, Inc., a biopharmaceutical company focused on developing therapies for patients with rare diseases.

FINANCIAL RESULTS

- For the first quarter of 2020, Viela reported a net loss of $40.8 million, compared to a net loss of $21.0 million for the first quarter of 2019.
- As of March 31, 2020, Viela had $335.2 million in cash, cash equivalents, and investments and no outstanding debt. Viela received $30.0 million in cash for the upfront licensing fee from Mitsubishi Tanabe Pharma Corporation in the first quarter of 2020.

- Research and development expenses were $26.8 million for the first quarter of 2020, which include $1.6 million of non-cash stock-based compensation expenses.
- General and administrative expenses were $15.3 million for the first quarter of 2020, which include $1.1 million of non-cash stock-based compensation expenses.
- Total operating expenses for the first quarter of 2020 totaled $42.1 million, compared to $21.7 million for the first quarter of 2019. Non-cash share-based compensation expenses totaled $2.7 million for the first quarter of 2020, compared to $0.6 million for the first quarter of 2019.

2020 Financial Guidance

Viela Bio expects that its cash, cash equivalents and investments will fund its operating plans into mid-year 2022.

Conference Call and Webcast

The Company will host a live webcast and conference call to discuss financial results and program highlights for the first quarter of 2020 today at 5:00 p.m. ET.

The webcast will be accessible on the Events & Presentations page of Viela Bio's website. Individuals can participate in the conference call by dialing (877) 783-8848 (domestic) or (631) 350-0960 (international) and referring to conference ID #: 3052446.

The archived webcast will be available for replay on the Viela Bio website approximately two hours after the event.

About Viela Bio

Viela Bio, headquartered in Gaithersburg, Maryland, is a clinical-stage 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, potential benefits of inebilizumab and our other product candidates, the timing and progress of clinical development and potential commercialization of our product candidates, if approved, our expectations about sufficiency of our existing cash balance and the anticipated impact of the COVID-19 pandemic on our business, operations and clinical trials 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 around the duration and severity of the novel coronavirus outbreak and impact of it and COVID-19 on our product candidates clinical trials, any failure to obtain FDA approval of our BLA for inebilizumab, development and, if approved, commercialization plans and business operations and 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, 2019 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.

Statements of Operations and Comprehensive Loss (Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2020	2019
Operating expenses:		
Research and development	$ 26,829	$ 16,615
General and administrative	15,282	5,037
Total operating expenses	42,111	21,652
Loss from operations	(42,111)	(21,652)
Other income:		
Interest income	1,334	676
Total other income	1,334	676
Net loss	$ (40,777)	$ (20,976)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.80)	$ (167.38)
Weighted average common shares outstanding—basic and diluted	50,752,998	125,315
Other comprehensive loss		
Unrealized gains (losses) on marketable securities, net	$ (126)	$ —
Total other comprehensive loss	(126)	—
Total comprehensive loss	$ (40,903)	$ (20,976)

Balance Sheets
(Unaudited)
(In thousands, except share and per share amounts)

	March 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 163,575	$ 200,851
Marketable securities	151,255	113,945
Accounts receivable	—	30,000
Prepaid and other current assets	6,475	6,242
Total current assets	321,305	351,038
Marketable securities, non-current	20,355	31,415
Property and equipment, net	1,495	1,499
Other assets	102	102
Total assets	$ 343,257	$ 384,054
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 7,380	$ 7,459
Accrued expenses and other current liabilities	9,527	9,192
Related party liability	9,929	12,892
Total current liabilities	26,836	29,543
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized as of March 31, 2020 and December 31, 2019; no shares issued or outstanding as of March 31, 2020 and December 31, 2019	—	—
Common stock, $.001 par value; 200,000,000 shares authorized as of March 31, 2020 and December 31, 2019; 50,997,300 and 50,617,868 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	51	51
Additional paid-in capital	633,967	631,154
Accumulated other comprehensive income (loss)	(121)	5
Accumulated deficit	(317,476)	(276,699)
Total stockholders' equity	316,421	354,511
Total liabilities and stockholders' equity	$ 343,257	$ 384,054

Source: Viela Bio

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Viela Bio Announces Positive Interim Results from a Phase 1b Study of VIB7734 in Patients with Cutaneous Lupus Erythematosus

-Safety profile comparable to placebo control-

-Potent depletion of plasmacytoid dendritic cells in peripheral blood and skin biopsies-

-Dose-dependent improvements in Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI) scores-

Gaithersburg, MD—May 13, 2020—Viela Bio, Inc. (Nasdaq:VIE), a clinical-stage biotechnology company pioneering treatments for autoimmune and severe inflammatory diseases, today announced positive interim Phase 1b data from a study with VIB7734, its novel anti-ILT7 therapy, in patients with cutaneous lupus erythematosus (CLE). VIB7734 was designed to deplete plasmacytoid dendritic cells (pDCs), an important source of inflammatory mediators in autoimmune diseases. This trial includes three cohorts of patients at ascending dose levels. Cohorts 2 and 3 enrolled patients with CLE. Key measures include safety and tolerability, pDC depletion in peripheral blood and skin lesions of patients with CLE, and Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI) scores. Interim results include safety data from patients in cohorts 1 and 2 and a subset of patients in cohort 3, pharmacodynamics results from cohort 2, and CLASI results from cohort 2 and a subset of patients in cohort 3. The interim findings indicated safety and tolerability comparable to placebo control across all cohorts, potent depletion of pDC both in peripheral blood and in inflamed CLE skin lesion biopsies in cohort 2, and dose-dependent reduction in CLASI scores of 4 points or more, which is considered a clinically meaningful change, in cohorts 2 and 3.

“We are very pleased with the interim safety, tolerability and pharmacodynamics results observed in this trial, indicating VIB7734’s potential ability to safely deplete pDCs—a specialized innate immune cell implicated in various autoimmune diseases, including lupus—in inflamed tissues,” said Jorn Drappa, M.D., Ph.D., Viela’s Chief Medical Officer. “The skin biopsy results measuring pDCs and interferon related biomarkers before and after treatment as well as the CLASI scores—a scale that quantifies skin disease activity in CLE patients—indicated clinically meaningful change from baseline in all three measurements when compared to placebo. The safety profile and depletion of pDCs in peripheral blood were consistent with our Phase 1a trial. We look forward to the final data from this trial and providing additional information at a future medical conference.”

Continued Dr. Drappa: “Based on these encouraging results, we intend to advance the program into several Phase 2 clinical studies in indications with high unmet need that are thought to be driven by pDCs.”

Study Details:

This Phase 1b clinical study enrolled three cohorts and is designed to evaluate the safety and tolerability of VIB7734 when given by three monthly subcutaneous doses at escalating dose levels. Cohort 1 enrolled patients with several autoimmune diseases thought to be driven by

pDCs. Cohorts 2 and 3 enrolled patients with CLE. In cohorts 2 and 3, skin biopsies were taken before and after treatment to enumerate pDCs and measure interferon mediated gene expression. A clinical disease activity score (CLASI) was also periodically measured in cohorts 2 and 3. The study enrolled a total of 31 patients. Cohort 1 enrolled 8 patients, cohort 2 enrolled 12 patients, and cohort 3 enrolled 11 patients. Each cohort included placebo controls. Final results from cohort 3 are expected in 3Q 2020. The trial was not powered to detect statistically significant changes in pDC depletion and the CLASI scores between placebo and treatment arms.

For more information about the trial, please visit clinicaltrials.gov

About VIB7734

VIB7734 is a novel candidate in development for the treatment of autoimmune diseases caused by the overproduction of type I interferons and other cytokines secreted by specialized innate immune cells called plasmacytoid dendritic cells (pDCs). VIB7734, a monoclonal antibody, is designed to target and bind to ILT7, a cell surface molecule specific to pDCs, leading to their depletion. In turn, this may also decrease other inflammatory cytokines such as TNF-α and IL-6, which are critical to the pathogenesis of a number of autoimmune diseases.

About Viela Bio

Viela Bio, headquartered in Gaithersburg, Maryland, is a clinical-stage biotechnology company pioneering 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 the timing and progress of our Phase 1b trial of VIB7734 in patients with CLE, and the potential benefits of VIB7734 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 around the duration and severity of the novel coronavirus outbreak and impact of it and COVID-19 on our product candidates clinical trials, development and, if approved, commercialization plans and business operations and 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, 2019 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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Source: Viela Bio