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): March 25, 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 March 25, 2020, Viela Bio, Inc. issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2019 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.

The information in this Current Report on Form 8-K (including Exhibit 99.1) 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 dated March 25, 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: March 25, 2020

93300804v.1

Viela Bio Reports Fourth Quarter and Full Year 2019 Financial Results and Business Highlights

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

Gaithersburg, MD—March 25, 2020—Viela Bio (Nasdaq:VIE), a clinical-stage biotechnology company pioneering treatments for autoimmune and severe inflammatory diseases, today reported financial results and provided program highlights for the fourth quarter and full year ended December 31, 2019.

“2019 was a pivotal year for Viela as we achieved many important financial, clinical and regulatory milestones. Supported by our recently completed initial public offering, we ended the year with a strong cash position, enabling continued pipeline growth and expansion,” said Bing Yao, Ph.D., Chief Executive Officer at Viela Bio. “With a Biologics License Application (BLA) under review by the U.S. Food and Drug Administration (FDA) for our lead product candidate inebilizumab for the treatment of neuromyelitis optica spectrum disorder (NMOSD), we have hired and trained a talented and experienced commercial team in anticipation of its potential approval. Based on strong efficacy and safety results, we believe that inebilizumab has the potential to be an important new treatment option for patients who suffer from NMOSD, a devastating, rare neuroinflammatory disease.

“While our top priority remains preparing to launch inebilizumab, we continue to make strong progress throughout our entire pipeline. We recently dosed the first patient in our Phase 2b trial of VIB4920 for the treatment of Sjögren’s syndrome and expect to report interim results from a cohort of patients with cutaneous lupus erythematosus in our ongoing Phase 1b trial of VIB7734 in the second quarter of 2020.”

PROGRAM HIGHLIGHTS

Inebilizumab

- **BLA for the Treatment of NMOSD Under FDA Review**
  In August 2019, the FDA accepted for review Viela’s BLA for inebilizumab and set a Prescription Drug User Fee Act, or PDUFA, action date of June 11, 2020. Inebilizumab, which was studied as a potential first-line monotherapy in patients with NMOSD, previously received Orphan Drug and Breakthrough Therapy designations from the FDA. The safety and efficacy data from the pivotal N-MOmentum trial—which formed the basis of the BLA filing—were recently published in the peer-reviewed journal, *The Lancet*.

- **Commercial Planning Activities On Track**
  In anticipation of the potential FDA approval of inebilizumab for the treatment of NMOSD under the Company's first BLA, Viela has hired and trained a seasoned sales force with extensive experience leading neurology or rare disease product launches. Commercial efforts will focus on community and top centers of excellence. There are an estimated 10,000 NMOSD patients in the U.S.

- **Viela Planning to Initiate Additional Clinical Trials, Including a Pivotal Trial**
  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.

VIB4920

- **Phase 2b Trial in Patients with Sjögren's Syndrome**
  In 2019, Viela initiated a Phase 2b trial for VIB4920 in patients with Sjögren's syndrome— a common rheumatic disease for which there are currently no approved disease-modifying therapies. Patients with Sjögren's syndrome suffer from debilitating fatigue and mouth and eye dryness, and in some cases, lung and kidney disease as well as an increased risk of lymphoma. Based on earlier clinical data, Viela believes that treatment with VIB4920—a fusion protein designed to bind to CD40L—could address immune overactivation in T and B cell-driven diseases such as Sjögren's syndrome.

- **Additional Ongoing and Potential VIB4920 Clinical Trials**
  In 2019, Viela initiated a Phase 2 trial in patients with kidney transplant rejection. The Company is also exploring other potential indications associated with the CD40/CD40L co-stimulatory pathway in which to pursue additional clinical studies with VIB4920.

VIB7734

- **Interim Results Anticipated from Phase 1b Trial**
  Viela plans to report interim results from a cohort of patients with cutaneous lupus erythematosus from the ongoing Phase 1b trial of VIB7734 in the second quarter of 2020. The drug candidate is designed to target and bind to ILT7, a cell surface molecule specific to plasmacytoid dendritic cells (pDCs), leading to their depletion. Assuming the trial is able to establish proof of concept, Viela plans to progress VIB7734 to Phase 2 clinical trials in other autoimmune diseases that are also driven by the overproduction of type I interferons, cytokines and other chemokines secreted by pDCs.

CORPORATE UPDATES

- **Viela Raised Over $172 Million in Successful Initial Public Offering (IPO)**
  In October 2019, Viela closed its IPO of 9,085,000 shares of common stock, which included 1,185,000 shares sold pursuant to the full exercise by the underwriters of their option to purchase additional shares, at a price to the public of $19.00 per share, for gross proceeds of approximately $172.6 million, before deducting the underwriting discounts and commissions and estimated offering expenses.

- **Expanded Partnerships for Global Development and Commercialization of Inebilizumab**
  In October 2019, Viela announced a partnership with Mitsubishi Tanabe Pharma Corporation to develop and commercialize inebilizumab in Japan and eight additional Asian countries for NMOSD and other potential indications. Viela received an upfront licensing fee of $30 million and will receive development and commercialization milestones and payments based, in part, on sales revenue.

  Viela is also partnered with Hansoh Pharmaceuticals Group Company Limited for the development and commercialization of inebilizumab for autoimmune diseases and hematologic cancers in China, Hong Kong and Macau. Viela received a $20 million upfront payment and is eligible to receive milestone payments of up to an aggregate of $203 million, plus royalties on sales revenue.

FINANCIAL RESULTS

- For the fourth quarter of 2019, Viela reported a net loss of $11.6 million, compared to a net loss of $15.1 million for the fourth quarter of 2018. For the full-year 2019, Viela Bio reported a net loss of $86.4 million, compared to a net loss of $190.3 million for the full year 2018.
- As of December 31, 2019, Viela had $346.2 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 1Q 2020.
- Research and development expenses were $32.5 million for the fourth quarter of 2019, which include $0.7 million of non-cash stock-based compensation expenses. For the full year of 2019, research and development expenses were $104.6 million. Research and development expenses for the year include $1.8 million of non-cash stock-based compensation expenses.
- General and administrative expenses were $10.5 million for the fourth quarter of 2019, which include $0.7 million of non-cash stock-based compensation expenses. For the full year of 2019, general and administrative expenses were $35.1 million, which include $1.8 million of non-cash stock-based compensation expenses.
- Total operating expenses for the fourth quarter of 2019 totaled $43.0 million, compared to $15.7 million for the fourth quarter of 2018. Non-cash share-based compensation expenses totaled $1.4 million for the fourth quarter of 2019, compared to $0.6 million for the fourth quarter of 2018.
- Total operating expenses for the full-year 2019 totaled $139.7 million, compared to $192.3 million for the full-year 2018. Non-cash share-based compensation expense totaled $3.6 million for the full-year 2019, compared to $1.9 million for the full-year 2018.

2020 Financial Guidance

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

Conference Call and Webcast

The Company will host a live webcast and conference call to discuss its fourth quarter and full year financial results for 2019 and provide an update on recent corporate activities 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 #: 5057166.

The archived webcast will be available for replay on the Viela Bio website approximately two hours after the event.*(i) General. This section must describe clinically significant adverse reactions (including any that are potentially fatal, are serious even if infrequent, or can be prevented or mitigated through appropriate use of the drug), other potential safety hazards (including those that are expected for the pharmacological class or those resulting from drug/drug interactions), limitations in use imposed by them (eg, avoiding certain concomitant therapy), and steps that should be taken if they occur (eg, dosage modification). The frequency of all clinically significant adverse reactions and the approximate mortality and morbidity rates for patients experiencing the reaction, if known and necessary for the safe and effective use of the drug, must be expressed as provided under paragraph ©(7) of this section. In accordance with § 314.70 and § 601.12 of this chapter, the labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established. A specific warning relating to a use not provided for under the "Indications and Usage" section may be required by FDA in accordance with sections 201(n) and 502(a) of the act if the drug is commonly prescribed for a disease or condition and such usage is associated with a clinically significant risk or hazard.(ii) Other special care precautions. This section must contain information regarding any special care to be exercised by the practitioner for safe and effective use of the drug (eg, precautions not required under any other specific section or subsection).*

(iii) Monitoring: Laboratory tests. This section must identify any laboratory tests helpful in following the patient's response or in identifying possible adverse reactions. If appropriate, information must be provided on such factors as the range of normal and abnormal values expected in the particular situation and the recommended frequency with which tests should be performed before, during, and after therapy.

(iv) Interference with laboratory tests. This section must briefly note information on any known interference by the product with laboratory tests and reference the section where the detailed information is presented (eg, "Drug Interactions" section).

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, 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 expected timing and the potential for payments under the agreements with Hansoh and MTPC 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. 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.

Viela Bio Inc.
Selected Financial Data

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

	Year Ended December 31,	
	2019	2018
Revenue:		
License revenue	$ 50,000	$ —
Total revenue	50,000	—
Operating expenses:		
Research and development	104,641	42,414
General and administrative	35,050	6,565
Acquisition of in-process research and development	—	143,333
Total operating expenses	139,691	192,312
Loss from operations	(89,691)	(192,312)
Other income:		
Interest income	3,262	2,042
Total other income	3,262	2,042
Net loss	$ (86,429)	$ (190,270)
Net loss per share attributable to common stockholders—basic and diluted	$ (7.02)	$ (19,027,000)
Weighted average common shares outstanding—basic and diluted	12,309,231	10
Other comprehensive income		
Unrealized gains (losses) on marketable securities, net	$ 5	$ —
Total other comprehensive income	5	—
Total comprehensive loss	$ (86,424)	$ (190,270)

Balance Sheets
(In thousands)

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 200,851	$ 126,898
Marketable securities	113,945	—
Receivable from stockholders	—	12,000
Accounts receivable	30,000	—
Prepaid and other current assets	6,242	456
Total current assets	351,038	139,354
Marketable securities, non-current	31,415	—
Property and equipment, net	1,499	473
Other assets	102	—
Total assets	384,054	139,827
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	7,459	1,142
Accrued expenses and other current liabilities	9,192	2,769
Related party liability	12,892	12,054
Total current liabilities	29,543	15,965
Commitments and contingencies		
Redeemable convertible preferred stock (Series A-1, A-2 and A-3), $.001 par value; no shares authorized, issued and outstanding as of December 31, 2019, and 37,695,912 shares authorized, and 31,225,324 shares issued and outstanding as of December 31, 2018	—	312,253
Total redeemable convertible preferred stock	—	312,253
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value; 5,000,000 shares and no shares authorized as of December 31, 2019 and 2018, respectively; no shares issued or outstanding as of December 31, 2019 and 2018	—	—
Common stock, $.001 par value; 200,000,000 and 41,254,509 shares authorized as of December 31, 2019 and 2018, respectively; 50,617,868 and 10 shares issued and outstanding as of December 31, 2019 and 2018, respectively	51	—
Additional paid-in capital	631,154	1,879
Accumulated other comprehensive income	5	—
Accumulated deficit	(276,699)	(190,270)
Total stockholders' equity (deficit)	354,511	(188,391)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 384,054	$ 139,827

Contacts:

Investors:
Solebury Trout
Chad Rubin
646-378-2947
crubin@soleburytrout.com

Media:
Solebury Trout
Amy Bonanno
914-450-0349
abonanno@soleburytrout.com

Source: Viela Bio Inc.