
**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): November 14, 2019

VIELA BIO, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39067
(Commission
File Number)

82-4187338
(IRS Employer
Identification No.)

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

20878
(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 November 14, 2019, Viela Bio, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 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 November 14, 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 thereunto duly authorized.

VIELA BIO, INC.

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

Date: November 14, 2019

93300804v.1



Viela Bio Reports Third Quarter 2019 Financial Results and Business Highlights

Gaithersburg, MD—November 14, 2019—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 third quarter ended September 30, 2019.

“Our Company has achieved significant financial, regulatory and business development milestones underscored by our successful recent initial public offering and listing on the Nasdaq Global Select Market,” said Bing Yao, Ph.D., Chief Executive Officer at Viela Bio. “In August 2019, the U.S. FDA accepted for review our Biologics License Application for inebilizumab, and we now look forward to supporting global development and commercialization activities for this candidate, if approved. In preparation for the potential approval of inebilizumab, our commercial team is hard at work on product launch preparation, while our clinical team prepares to initiate a number of studies across our pipeline of novel autoimmune and severe inflammatory disease therapies.”

Continued Dr. Yao, “Based on the positive results from our pivotal study of inebilizumab in neuromyelitis optica spectrum disorder, or NMOSD, we believe it may represent a transformative therapy for patients suffering from this rare and devastating disease. While we look forward to the continued planned expansion of our pipeline, our near-term priority remains delivering inebilizumab to the many patients who currently lack a viable treatment option.”

PROGRAM HIGHLIGHTS

Inebilizumab

- **U.S. FDA Reviewing Inebilizumab BLA for NMOSD**
In August 2019, the U.S. Food and Drug Administration (FDA) accepted for review the Company’s Biologics License Application (BLA) for inebilizumab, clinically studied as a first-line monotherapy for neuromyelitis optica spectrum disorder (NMOSD). The FDA set a Prescription Drug User Fee Act, or PDUFA, date of June 11, 2020.
- **Inebilizumab Commercial Planning Activities Underway**
In preparation for inebilizumab’s potential commercialization, if approved, in the United States, Viela is focused on developing a dedicated commercial team to target medical centers of excellence.
- **Pivotal Trial Data Published in *The Lancet***
Peer-reviewed journal, *The Lancet*, published safety and efficacy results from the pivotal N-MOMentum trial, the largest global, placebo-controlled study in NMOSD. The data were also presented earlier this year during a plenary session at the 2019 American Academy of Neurology (AAN) Annual Meeting.

- **Company Preparing to Initiate Additional Inebilizumab Clinical Trial**

Viela is planning to submit an investigational new drug (IND) application and initiate a pivotal trial in myasthenia gravis in first half of 2020. In addition, Viela is planning to submit an IND and initiate a Phase 2b trial in IgG4-Related Disease in the first half of 2020. Furthermore, Viela is planning to initiate a Phase 2 proof-of-concept study to explore the potential of inebilizumab, used alone or in combination with VIB4920, to reduce levels of alloantibodies in kidney transplant candidates thereby improving transplant outcomes before the end of 2019.

VIB4920

- **Company Prepares to Initiate Phase 2b Trial with VIB4920**

Before the end of 2019, Viela expects to initiate a Phase 2b trial in Sjögren's syndrome. Viela is also expected to initiate a Phase 2 proof-of-concept study with VIB4920 in kidney transplant.

VIB7734

- **VIB7734 Phase 1b Ongoing**

The VIB7734 Phase 1b multiple ascending dose trial is ongoing. The trial includes a cohort of patients with multiple autoimmune diseases as well as separate cohorts of patients with cutaneous lupus erythematosus, in the presence or absence of SLE.

CORPORATE UPDATES

- **Viela Closed Initial Public Offering (IPO)**

In October 2019, the Company closed its IPO of 9,085,000 shares of common stock, which included 1,185,000 shares sold pursuant to the exercise in full by the underwriters of their option to purchase additional shares, at a price to the public of \$19.00 per share. Including the option exercise, the gross proceeds to Viela Bio from the offering, before deducting the underwriting discounts and commissions and estimated offering expenses, were approximately \$172.6 million.

- **Viela Entered into Collaborations to Expand Global Commercial Efforts for Inebilizumab**

In October 2019, Viela announced a partnership with Mitsubishi Tanabe Pharma Corporation to develop and commercialize inebilizumab in nine Asia regions –including Japan– for NMOSD and other potential future indications. The Company will receive an upfront licensing fee of \$30 million as well as development and commercialization milestones and payments based, in part, on sales revenue.

Viela is also currently 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 collaboration fee and is eligible to receive milestone payments of more than \$203 million plus royalties on product sales.

FINANCIAL RESULTS

- **Cash Position:** Viela reported cash, cash equivalents and current marketable securities of \$198.2 million as of September 30, 2019. This does not include net proceeds from the IPO of approximately \$157.2 million, which was subsequent to September 30, 2019. Also, upfront payments from the Company's strategic partnerships of \$35.0 million is expected before end of 2019, which was subsequent to September 30, 2019.
- **Research and Development Expenses:** Research and development expenses were \$38.7 million and \$72.1 million for the three and nine months ended September 30, 2019, respectively.
- **General and Administrative Expenses:** General and administrative expenses were \$10.2 million and \$24.6 million for the three and nine months ended September 30, 2019, respectively.
- **Net Loss:** Net loss was \$48.4 million and \$74.9 million, or \$65 and \$150 per share, for the three and nine months ended September 30, 2019, respectively.

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 Statement

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, the timing and progress of clinical development and potential commercialization of our product candidates, if approved; our expectations with respect to the potential regulatory approval, global development and commercialization of inebilizumab; our planned and ongoing clinical trials for our product candidates and the potential advantages of those product candidates, including inebilizumab, VIB4920 and VIB7734; the initiation, enrollment, timing, progress, release of data from and results of those planned and ongoing clinical trials; our goals with respect to the development and potential use, if approved, of each of its product candidates; the utility of prior non-clinical and clinical data in determining future clinical results; and the expected timing and the potential for payments under our collaboration agreements 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 final prospectus dated October 2, 2019 and filed with the SEC on October 4, 2019. 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 (Unaudited)

Statements of Operations
(Unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue:				
License revenue	\$ —	\$ —	\$ 20,000	\$ —
Total revenue	—	—	20,000	—
Operating expenses:				
Research and development	38,700	13,928	72,113	28,892
General and administrative	10,230	2,401	24,575	4,399
Acquisition of in-process research and development	—	—	—	143,333
Total operating expenses	48,930	16,329	96,688	176,624
Loss from operations	(48,930)	(16,329)	(76,688)	(176,624)
Other income:				
Interest income	520	647	1,829	1,408
Total other income	520	647	1,829	1,408
Net loss	\$ (48,410)	\$ (15,682)	\$ (74,859)	\$ (175,216)
Net loss per share attributable to common stockholders— basic and diluted	\$ (65)	\$ (1,568,200)	\$ (150)	\$ (17,521,600)
Weighted average common shares outstanding— basic and diluted	749,539	10	497,924	10
Other comprehensive loss				
Change in unrealized gains losses on marketable securities, net	\$ (30)	\$ —	\$ (30)	\$ —
Total other comprehensive loss	(30)	—	(30)	—
Total comprehensive loss	\$ (48,440)	\$ (15,682)	\$ (74,889)	\$ (175,216)

Balance Sheets
(Unaudited)
(In thousands)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 155,747	\$ 126,898
Marketable securities	42,495	—
Receivable from stockholders	—	12,000
Accounts receivable	5,128	—
Prepaid and other current assets	4,577	456
Total current assets	207,947	139,354
Marketable securities, non-current	24,915	—
Property and equipment, net	905	473
Other assets	73	—
Total assets	<u>\$ 233,840</u>	<u>\$ 139,827</u>
Liabilities, redeemable convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 5,660	\$ 1,142
Accrued expenses	7,487	2,769
Related party liability	13,100	12,054
Total current liabilities	<u>\$ 26,247</u>	<u>15,965</u>
Commitments and contingencies		
Series A-1 preferred stock, \$.001 par value; 14,225,324 shares authorized, issued and outstanding as of September 30, 2019 and December 31, 2018	142,253	142,253
Series A-2 preferred stock, \$.001 par value; 17,000,000 shares authorized, issued and outstanding as of September 30, 2019 and December 31, 2018	170,000	170,000
Series A-3 preferred stock, \$.001 par value; 4,705,882 shares authorized, issued and outstanding as of September 30, 2019; 6,470,588 shares authorized and no shares issued or outstanding as of December 31, 2018	80,000	—
Series B preferred stock, \$.001 par value; 4,687,500 shares authorized, issued and outstanding as of September 30, 2019; no shares authorized, issued or outstanding as of December 31, 2018	75,000	—
Total redeemable convertible preferred stock	467,253	312,253
Stockholders' deficit:		
Common stock, \$.001 par value; 46,159,941 and 41,254,509 shares authorized as of September 30, 2019 and December 31, 2018; 872,324 and 10 shares issued and outstanding as of September 30, 2019 and December 31, 2018	1	—
Additional paid-in capital	5,498	1,879
Accumulated other comprehensive loss	(30)	—
Accumulated deficit	(265,129)	(190,270)
Total stockholders' deficit	<u>(259,660)</u>	<u>(188,391)</u>
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	<u>\$ 233,840</u>	<u>\$ 139,827</u>

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.