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 10, 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 November 10, 2020, Viela Bio, Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 30, 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.

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 announcing the Company's financial results for the third quarter ended September 30, 2020, dated November 10, 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: November 10, 2020

Viela Bio Reports Third Quarter 2020 Financial Results and Program Highlights

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

Gaithersburg, MD—November 10, 2020—Viela Bio (Nasdaq:VIE), a biotechnology company dedicated to the discovery, development and commercialization of novel treatments for autoimmune and severe inflammatory diseases, today reported financial results and provided program highlights for the third quarter ended September 30, 2020.

“Several months into UPLIZNA’s launch, we have gained valuable insights into how to meet our customer’s needs, which continue to evolve during the COVID-19 pandemic. We are encouraged by the increasing product uptake and our commercial team remains nimble in how we engage with individual practitioners and centers of excellence across the U.S.,” said Bing Yao, Ph.D., Chief Executive Officer at Viela Bio. “As we and our partners await the potential approval of UPLIZNA in several Asian countries, we continue to expand its development in the U.S. in various diseases, including myasthenia gravis and IgG4-related disease, where we believe it could have a significant clinical benefit over existing therapies.”

Added Dr. Yao: “While we pursue the potential expansion of UPLIZNA to additional patient populations, we continue to make solid progress across our entire pipeline. Recently, we presented data from our Phase 1b study of VIB7734 in an oral presentation at ACR Convergence 2020, confirming its potential to reduce lesions in lupus patients and have selected systemic lupus erythematosus for our planned Phase 2 trial. Additionally, we continue to enroll new patients into our ongoing trials with VIB4920, which include mid-stage studies in Sjögren’s syndrome, rheumatoid arthritis and kidney transplant rejection and are planning to submit an IND for a new preclinical candidate by the end of this year.”

PROGRAM HIGHLIGHTS

UPLIZNA® (inebilizumab-cdon)

UPLIZNA® is a CD19-directed cytolytic antibody indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

- As part of its commercialization strategy for *UPLIZNA*®, Viela continues to focus on both centers of excellence and community neurologists throughout the U.S. To date, *UPLIZNA*® has been prescribed to a mix of newly diagnosed patients and those experiencing an inadequate response to their current maintenance regimen.
- Viela recently initiated a Phase 3 trial with inebilizumab in patients with myasthenia gravis, a chronic, rare autoimmune neuromuscular disorder which affects about 56,000 people in the U.S.

- Viela initiated a Phase 3 trial in patients with IgG4-related disease, a group of disorders marked by tumor-like swelling and fibrosis of affected organs.
- The Phase 2 trial for kidney transplant desensitization remains voluntarily paused due to the COVID-19 pandemic.
- Regulatory applications have been filed in several Asian countries based on results from the N-MOmentum study. If approved, Mitsubishi Tanabe Pharma Corporation (MTPC) and Hansoh Pharma—Viela's partners in Asia—will be responsible for commercializing inebilizumab in their respective territories, and Viela will be eligible for payments based on certain commercial milestones, as well as royalties on sales revenue.

VIB4920

VIB4920 is an investigational fusion protein designed to bind to CD40L on activated T cells, blocking their interaction with CD40-expressing B cells.

- Viela is currently conducting a Phase 2b trial with VIB4920 in Sjögren's syndrome in addition to Phase 2 trials in patients with kidney transplant rejection and rheumatoid arthritis. Due to the COVID-19 pandemic, new patient enrollment in the Sjögren's syndrome and kidney transplant rejection trials had been voluntarily paused, but has recently resumed in both trials.

VIB7734

VIB7734 is designed to target and bind to ILT7, a cell surface molecule specific to pDCs, leading to their depletion. This depletion may also decrease other inflammatory cytokines such as TNF-alpha and IL-6, which are critical to the pathogenesis of a number of autoimmune diseases.

- Viela recently reported the final data from its Phase 1b trial with VIB7734 in an oral presentation during a late-breaking session at the American College of Rheumatology (ACR) Convergence 2020—a premiere medical conference for inflammatory disease research. The results confirmed previously reported data, demonstrating that VIB7734 effectively reduced blood and skin plasmacytoid dendritic cells, leading to reduced type I Interferon levels in the blood and inflamed skin of patients with cutaneous lupus erythematosus (CLE). More CLE subjects treated with VIB7734 than placebo had a clinically significant improvement in CLASI-A scores—a scale that quantifies skin disease activity. Rates of adverse events were similar between VIB7734 and placebo groups.
- Based on results from the Phase 1b study, Viela has selected systemic lupus erythematosus (SLE) as the lead indication of a planned Phase 2 trial, anticipated to initiate in H1 2021.
- Viela is currently enrolling patients into its Phase 1 study with VIB7734 for the treatment of COVID-19-related acute lung injury. Results from this study are anticipated in H1

2021, at which time the Company will decide whether to pursue additional clinical trials in this indication.

FINANCIAL RESULTS

- Total net product sales for the third quarter of 2020 were $2.3 million, resulting from sales of UPLIZNA®. The company did not generate product sales in the third quarter of 2019.
- For the third quarter of 2020, Viela reported a net loss of $37.6 million, compared to a net loss of $48.4 million for the third quarter of 2019. As of September 30, 2020, Viela had $387.5 million in cash, cash equivalents, and investments and no outstanding debt.
- Research and development expenses were $26.0 million for the third quarter of 2020, which include $1.4 million of non-cash stock-based compensation expenses.
- Selling, general and administrative expenses were $14.0 million for the third quarter of 2020, which include $2.0 million of non-cash stock-based compensation expenses.
- Total operating expenses for the third quarter of 2020 totaled $38.2 million, compared to $48.9 million for the third quarter of 2019. Non-cash share-based compensation expenses totaled $3.4 million for the third quarter of 2020, compared to $0.9 million for the third quarter of 2019.

Conference Call and Webcast

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

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 #: 1237908.

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 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 expectations regarding the commercialization of UPLIZNA®; 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; statements regarding the timing and progress of our ongoing clinical trials with inebilizumab in additional indications, as well as the initiation, timing, progress and results of our completed, ongoing and planned clinical trials for our other product candidates; statements regarding the timing and potential approval of UPLIZNA® in countries outside the United States; potential benefits of UPLIZNA®; our expectations regarding the availability of UPLIZNA®; and the commercialization and market acceptance of UPLIZNA®; our expectations about sufficiency of our existing cash balance and the anticipated impact of the COVID-19 pandemic on our commercialization efforts, business, operations and clinical trials; and our plans and the expected timing for the availability and reporting of data from our ongoing 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 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue:				
Product revenue, net	$ 2,316	$ —	$ 2,316	$ —
License revenue	—	—	—	20,000
Total revenue	2,316	—	2,316	20,000
Operating expenses:				
Cost of products sold	650	—	650	—
Research and development	25,890	38,700	78,131	72,113
Selling, general and administrative	13,995	10,230	43,685	24,575
Total operating expenses	40,535	48,930	122,466	96,688
Loss from operations	(38,219)	(48,930)	(120,150)	(76,688)
Other income:				
Interest income	574	520	2,871	1,829
Total other income	574	520	2,871	1,829
Net loss	$ (37,645)	$ (48,410)	$ (117,279)	$ (74,859)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.69)	$ (64.59)	$ (2.23)	$ (150.34)
Weighted average common shares outstanding—basic and diluted	54,760,381	749,539	52,583,103	497,924
Other comprehensive income (loss)				
Unrealized gains (loss) on marketable securities, net	$ (302)	$ (30)	$ 348	$ (30)
Total other comprehensive income (loss)	(302)	(30)	348	(30)
Total comprehensive loss	$ (37,947)	$ (48,440)	$ (116,931)	$ (74,889)

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

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 111,649	$ 200,851
Marketable securities	273,534	113,945
Accounts receivable, net	2,507	30,000
Inventory	438	—
Prepaid and other current assets	14,944	6,242
Total current assets	403,072	351,038
Marketable securities, non-current	2,354	31,415
Property and equipment, net	1,933	1,499
Capital lease assets	965	—
Intangible assets, net	19,151	—
Other assets	122	102
Total assets	$ 427,597	$ 384,054
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,083	$ 7,459
Accrued expenses and other current liabilities	10,752	9,192
Related party liability	4,638	12,892
Capital lease liability—current	186	—
Total current liabilities	20,659	29,543
Capital lease liability—non-current	788	—
Total liabilities	21,447	29,543
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized as of September 30, 2020 and December 31, 2019; no shares issued or outstanding as of September 30, 2020 and December 31, 2019	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized as of September 30, 2020 and December 31, 2019; 54,835,873 and 50,617,868 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	55	51
Additional paid-in capital	799,720	631,154
Accumulated other comprehensive income	353	5
Accumulated deficit	(393,978)	(276,699)
Total stockholders' equity	406,150	354,511
Total liabilities and stockholders' equity	$ 427,597	$ 384,054

Source: Viela Bio

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