Viela Bio Reports First Quarter 2020 Financial Results and Program Highlights

May 13, 2020

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

GAITHERSBURG, Md., May 13, 2020 (GLOBE NEWSWIRE) -- 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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Source: Viela Bio