
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): September 19, 2016

CV SCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

000-54677
(Commission File Number)

80-0944970
(I.R.S. Employer Identification No.)

2688 South Rainbow Boulevard, Suite B
Las Vegas, Nevada 89146
(Address of principal executive offices, Zip Code)

(866) 290-2157
(Registrant's telephone number, including area code)

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-(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-(c))
-
-

Item 7.01 Regulation FD Disclosure

On September 19, 2016, CV Sciences, Inc. (the “Company”) mailed a letter to its shareholders regarding the Company’s activities and achievements since December 2015. A copy of the shareholder letter issued by the Company is attached hereto as Exhibit 99.1 and incorporated herein by reference solely for purposes of this Item 7.01 disclosure.

Exhibit 99.1 contains forward-looking statements. These forward-looking statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Forward-looking statements are based upon assumptions as to future events that may not prove to be accurate. Actual outcomes and results may differ materially from what is expressed in these forward-looking statements.

The information set forth under Item 7.01 of this Current Report on Form 8-K (“Current Report”), including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed “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 such section. The information in Item 7.01 of this Current Report, including Exhibit 99.1, shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any incorporation by reference language in any such filing, except as expressly set forth by specific reference in such a filing. This Current Report will not be deemed an admission as to the materiality of any information in this Current Report that is required to be disclosed solely by Regulation FD.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Letter to Shareholders, dated September 19, 2016.

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 hereunto duly authorized.

Date: September 22, 2016

CV SCIENCES, INC.

By: /s/ Michael Mona, Jr.
Michael Mona, Jr.
President and Chief Executive Officer



September 19, 2016

Dear Fellow Shareholders of CV Sciences,

In just a short period of time, we have achieved several tremendous milestones since our last shareholder letter, issued in December 2015. Shortly afterward, in January of this year, we announced the acquisition of CanX Inc., to pivot our strategic focus from leading the market of hemp-derived cannabidiol (“CBD”) oil products into an expansive pharmaceutical company focused on the development and commercialization of innovative medicines. Given our already established position as a market leader in CBD consumer products, the shift in our corporate strategy to include drug development was a critical move because it positioned CV Sciences as a life science company, addressed sizeable multi-billion dollar markets and expanded our potential to increase shareholder value.

In June 2016, we announced the approval by Financial Industry Regulatory Authority (“FINRA”) for a name change to CV Sciences and our trading symbol of our common stock to “CVSL” This has prompted our rebranding initiative to include value-enhancing actions that we feel will drive long-term shareholder value. As a result, it is even more important for you as shareholders to understand with full transparency our ongoing objective, our growth initiatives and why this is a great time to be involved with CV Sciences as we move forward in this exciting time ahead.

Pivot into Drug Development to Address a \$5.3 Billion Market Opportunity

In our previous shareholder letter, we discussed the significant infrastructure investments made to facilitate our growth and the importance of expanding our exposure to broader audiences interested in the overall health and wellness sector. We remain laser focused on this initiative and consistent in our message. With our acquisition of CanX Inc., we evolved into a life science company now operating in two distinct yet complementary segments: specialty pharmaceutical and consumer products, together diversifying and expanding our growth and value proposition.

Through CanX, we also acquired a proprietary drug portfolio, including a lead drug candidate utilizing synthetically formulated CBD for use in treatment of smokeless tobacco addiction. Nicotine is the largest drug addiction problem worldwide and represents a significant opportunity to develop an effective treatment for this addiction. According to Statista, there was approximately \$5.3 billion in retail sales of smokeless tobacco products in 2014, and approximately 1.3 billion units of smokeless tobacco products were sold during that time. Smokeless tobacco addiction is an unmet need that addresses a massive market opportunity, and we believe that our initial drug candidate to treat smokeless tobacco addiction will dramatically improve patient outcomes for millions.

Our initial drug candidate (CVSI-007) is a chewing gum that combines synthetic CBD and nicotine, which we believe has the potential to effectively treat smokeless tobacco and tobacco addiction. We have a patent pending on the technology and are pursuing the 505(b)(2) FDA drug-approval pathway to bring to market. Our CVSI-007 drug candidate meets the three well-established requirements for successfully treating nicotine addiction, which include the following:

- 1) **CBD:** Inhibits MAO (monoamine oxidase) and provides antidepressant effects to replace tobacco alkaloids
- 2) **Nicotine:** Addresses nicotine addiction and cravings
- 3) **Chewing Gum:** Provides oral stimulation

Given that there are no FDA-approved drugs to treat smokeless tobacco addiction and that the FDA has approved numerous nicotine replacement therapy drugs (NRTs), we believe that our drug candidate will be extremely well-received in the market. Also, the FDA has recent drug development experience with CBD, which we believe could accelerate the drug development process and approval.

Accelerated Progress in Drug Development

Thus far, our drug development program has achieved great success. We have been hitting our milestones in great strides and are excited to share our progress in the following areas:

- Design of initial drug candidate ✓
- Filing of initial patent (provisional) ✓
- Formulation and production of proprietary CGMP synthetic CBD ✓
- In-vitro assay of CBD as an MAO inhibitor ✓
- Finalization of internal drug development program ✓
- Establishment of drug development team ✓
- Selection of contract manufacturer for drug candidate -in progress
- Preclinical animal studies: safety -in progress
- Preparation for pre-IND meeting - ongoing
- Preparation for IND filing -ongoing

We have been progressing well with our preclinical efforts and will keep you updated on all the latest developments as we plan on commencing our human studies in 2017.

CBD Division Continues to Drive Revenues

Those of you following our story the past several years are familiar with our consumer products division, which delivers botanical-based CBD products in the natural products market. Plus CBD Oil™, our top-selling brand, has more than 30 SKUs, including capsules, sprays, oils and topicals, and is sold in over 700 retail stores. This is a significant increase from the 120 locations we had a year ago and is a testament to the value of our brand, which continues to provide a strong platform for growth and value creation. As we've reiterated in the past, the natural products market continues to skyrocket, and we have been very fortunate to be one of the early movers in the CBD space. In fact, NEXT, the industry's leading source of forward-looking insights into what's next in natural, estimates that U.S. consumer sales of natural, organic and healthy products are forecasted to expand 64% from \$153 billion in 2013 to \$252 billion by 2019. This is a compound average growth rate (CAGR) of 8.6%, which is more than four times the projected growth rate of mainstream consumer packaged goods.

According to Hemp Industries Association (HIA), total retail value of hemp products sold in the U.S. in 2015 is estimated at \$573 million, with \$65 million coming from CBD products.

Our products are distributed nationally in health food stores, in health care providers' offices and online, and we will continue expanding existing and new sales channels through the education and marketing efforts in partnership with broker relationships and physician educators. In the coming weeks, we will be announcing other upcoming product line extensions and new launches that include a new vape brand, a point-of-sale specialty beverage and a body care line, which will further contribute to our growth strategy.

Looking Ahead

We believe that we are establishing a framework for future progress. This includes the potential of our drug development company and the growth trajectory from our consumer products division. We have several important upcoming milestones that will increase the value of CV Sciences if our expectations of results prove successful.

On the capital markets side, we will continue to work toward an uplisting of our shares so that we can generate increased visibility, better liquidity and lower cost of capital, as well as attract a broader range of institutional investors.

Given that our priority is to serve our investors, we will continue exploring options to unlock value for the Company, including how to effectively finance and operate both our pharmaceutical and consumer product divisions. We are considering all possibilities to maximize the value of our operating assets for the benefit of our shareholders. With these developments in place, and meaningful milestones right in front of us, we believe this is an extremely opportune time to invest in CV Sciences, as what we are building here has all the ingredients required for long-term success and value creation for our stock, including:

- A stellar management team and board of directors
- A \$5.3 billion addressable market focused on an unmet medical need for cessation of smokeless tobacco
- A proprietary drug in development that is undergoing review by the FDA for fast-track approval
- Our already established leadership in the multi-billion dollar natural products market
- An intellectual property portfolio
- Over 50 SKUs -products in over 700 retail stores
- The No. 1 selling brand of CBD supplements to consumers

On behalf of our board of directors and management team, we thank you for your investment in our company and your continued support. Together we believe we can provide significant value accretion to our stockholders.

/s/ Michael Mona Jr.

Michael Mona Jr.
CEO, President & Founder

Forward-Looking Disclaimer

This shareholder letter contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements are valid only as of today, and we disclaim any obligation to update this information. Actual results may differ significantly from management's expectations.

2688 S. Rainbow Boulevard, Suite B, Las Vegas, NV 89146 p: 800-290-2157
website: www.cvsciences.com