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): December 7, 2020

DARÉ BIOSCIENCE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36395**	**20-4139823**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

3655 Nobel Drive, Suite 260
San Diego, CA 92122
(Address of Principal Executive Offices and Zip Code)

Registrant's telephone number, including area code: **(858) 926-7655**

Not Applicable
(Former name or former address, if changed since last report.)

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 (*see* General Instruction A.2. below):

☐ 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	**DARE**	**Nasdaq Capital Market**

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 7.01 Regulation FD Disclosure.

On December 7, 2020, Daré Bioscience, Inc. ("Daré"), issued a press release reporting the clinical trial results discussed in Item 8.01 below. A copy of the press release is attached as Exhibit 99.1 to this report.

The information contained in this Item 7.01, including in Exhibit 99.1 hereto, is being “furnished” and shall not be deemed “filed” for the 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 or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”). The information contained in this Item 7.01 and in Exhibit 99.1 shall not be incorporated by reference into any filing with the Securities and Exchange Commission made by Daré, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01 Other Events.

On December 7, 2020, Daré announced topline results from its DARE-BVFREE Phase 3 clinical trial of DARE-BV1 for the treatment of bacterial vaginosis. DARE-BVFREE was a randomized, multicenter, double-blind, placebo-controlled study that randomized 307 women diagnosed with bacterial vaginosis at 32 centers across the United States in a 2:1 ratio to receive a single vaginal dose of DARE-BV1 (clindamycin phosphate vaginal gel, 2%) (N=204) or a single vaginal dose of placebo gel (HEC Universal Placebo Gel) (N=103) to be applied intravaginally within one day of randomization. Subjects were evaluated during three clinic visits: Day 1 (screening and randomization visit), Day 7-14 (assessment visit that occurred 7 to 14 days after study drug administration), and Day 21-30 (test-of-cure visit that occurred 21 to 30 days after study drug administration).

As further discussed below, the study met its primary endpoint demonstrating that a single administration of DARE-BV1 was superior to placebo as a primary therapeutic intervention for women diagnosed with bacterial vaginosis. The primary endpoint for the study was clinical cure of bacterial vaginosis determined at the Day 21-30 visit in the modified intent-to-treat (mITT) study population (N=180). In accordance with U.S. Food and Drug Administration (FDA) guidance, the mITT population excludes subjects from the intent-to-treat (ITT) population (N=307) who subsequently demonstrated a positive test result for other concomitant vaginal or cervical infections at baseline. Clinical cure was defined as resolution of the specific clinical signs that comprise the Amsel criteria; specifically, resolution of abnormal vaginal discharge associated with bacterial vaginosis, clue cells less than 20% of total epithelial cells on microscopy, and a negative 10% KOH “whiff” test. The total study duration was approximately one month for each individual subject.

DARE-BV1 demonstrated statistically significant efficacy in the primary endpoint and in all five pre-specified secondary efficacy assessments. The clinical cure endpoint results are shown in the following table:

Summary of Clinical Cure Results (mITT Population), p-value < 0.001:

	DARE-BV1 (N = 121)	Placebo (N = 59)
Clinical Cure at Day 7-14 visit	76.0%	23.7%
Clinical Cure at Day 21-30 visit (primary endpoint)	70.2%	35.6%

The clinical cure rate at the Day 21-30 visit for the ITT population was similar to that for the mITT population (70.1% for the DARE-BV1 group (N=204) and 36.9% for the placebo group (N=103), p-value < 0.001).

DARE-BV1 was well-tolerated in the study. There were no early discontinuations due to adverse events (AEs), and the only serious AE occurred in a woman in the placebo group. In the DARE-BV1 group, 15.3% of patients reported AEs that were considered to be possibly, probably or definitely related to study treatment compared to 9.7% of patients in the placebo group. Only two AEs were reported by more than 2% of patients in the DARE-BV1 arm and at a rate higher than in patients in the placebo arm – vulvovaginal candidiasis, commonly called a vaginal yeast infection (17.2% in the DARE-BV1 group and 3.9% in the placebo group), and vulvovaginal pruritus, commonly referred to as vaginal itching (4.4% in the DARE-BV1 group and 1.9% in the placebo group). Over half of the vaginal yeast infections reported in the DARE-BV1 group and exactly half of those reported in the placebo group occurred in patients who exhibited a positive yeast culture prior to dosing.

Based on the topline results from the DARE-BVFREE study, Daré expects to have a pre-NDA meeting with the U.S. Food and Drug Administration (FDA) in early 2021 and to submit a new drug application (NDA) to the FDA during the first half of 2021. DARE-BV1 received both Fast Track and Qualified Infectious Disease Product designations from the FDA for the treatment of bacterial vaginosis. Given these designations, the NDA could be eligible for priority review, which, if granted, could allow for a FDA review period of six months. Assuming a six-month review period and an approval from the FDA in 2021, Daré would expect a commercial launch of DARE-BV1 in the United States in early 2022.

Cautionary Statement Regarding Forward-Looking Statements

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. Forward-looking statements, in some cases, can be identified by terms such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “design,” “intend,” “expect,” “could,” “plan,” “potential,” “predict,” “seek,” “should,” “would,” “contemplate,” “project,” “target,” “tend to,” or the negative version of these words and similar expressions. Statements contained in this report regarding matters that are not historical facts are forward-looking statements. Forward-looking statements in this report include, but are not limited to, statements regarding Daré’s plans and strategies for achieving regulatory approval and commercialization of DARE-BV1, including expected timing of Daré’s engagement with the FDA regarding an NDA for DARE-BV1, submission of an NDA for DARE-BV1, FDA review and approval of the NDA, and commercial launch of DARE-BV1 in the U.S. if approved. Forward-looking statements are based on Daré’s current beliefs, expectations and assumptions, which are subject to risks and uncertainties. Actual results could differ materially from those anticipated as a result of various factors, including, without limitation: topline clinical trial results are based on Daré’s preliminary analysis of key efficacy and safety data, and such results may change following a more comprehensive review of the data from the clinical trial and such topline results may not accurately reflect the complete results from the clinical trial; the risk that the FDA, other regulatory authorities or members of the scientific or medical communities may not accept or agree with Daré’s interpretation of or conclusions regarding the study data; Daré’s ability to raise additional capital when and as needed to advance its product candidates and continue as a going concern; the effects of the COVID-19 pandemic on Daré’s operations, financial results and condition, and ability to achieve current plans and objectives, including the potential impact of the pandemic on the ability of third parties on which Daré relies to assist in the conduct of its business, including its clinical trials, to fulfill their contractual obligations to Daré; Daré’s ability to develop, obtain regulatory approval for, and commercialize its product candidates; the failure or delay in starting, conducting and completing clinical trials or obtaining FDA or foreign regulatory approval for Daré’s product candidates in a timely manner; Daré’s ability to conduct and design successful clinical trials, to enroll a sufficient number of patients, to meet established clinical endpoints, to avoid undesirable side effects and other safety concerns, and to demonstrate sufficient safety and efficacy of its product candidates; the risk that positive findings in early clinical and/or nonclinical studies of a product candidate may not be predictive of success in subsequent clinical and/or nonclinical studies of that candidate; Daré’s ability to retain its licensed rights to develop and commercialize a product candidate; Daré’s ability to satisfy the monetary obligations and other requirements in connection with its exclusive, in-license agreements covering the critical patents and related intellectual property related to its product candidates; the risks that the license agreement with Bayer may not become effective and, if it becomes effective, that future payments to Daré under the agreement may be significantly less than anticipated or potential amounts; developments by Daré’s competitors that make its product candidates less competitive or obsolete; Daré’s dependence on third parties to conduct clinical trials and manufacture clinical trial material; Daré’s ability to adequately protect or enforce its, or its licensor’s, intellectual property rights; the lack of patent protection for the active ingredients in certain of Daré’s product candidates which could expose its products to competition from other formulations using the same active ingredients; the risk of failure associated with product candidates in preclinical stages of development that may lead investors to assign them little to no value and make these assets difficult to fund; cyber attacks, security breaches or similar events that compromise Daré’s technology systems or those of third parties on which it relies and/or significantly disrupt Daré’s business; and disputes or other developments concerning Daré’s intellectual property rights. Daré’s forward-looking statements are based upon its current expectations and involve assumptions that may never materialize or may prove to be incorrect. Additional factors that may affect Daré’s strategy, future operations, future financial position, projected costs, prospects, plans and objectives are set forth in its filings with the SEC, including Daré’s recent filings on Form 8-K, Form 10-K and Form 10-Q. You are urged to consider these factors carefully in evaluating the forward-looking statements in this report and are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this report and are qualified in their entirety by this cautionary statement. Unless otherwise required by law, Daré

expressly disclaims any obligation to update publicly any forward-looking statements, whether as result of new information, future events or otherwise, although it may do so from time to time as it believes appropriate.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued on December 7, 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 hereunto duly authorized.

DARÉ BIOSCIENCE, INC.

Dated: December 7, 2020

By: /s/ Sabrina Martucci Johnson
Name: Sabrina Martucci Johnson
Title: President and Chief Executive Officer

Exhibit 99.1

Daré Bioscience Announces Positive Topline Results From DARE-BVFREE, a Phase 3 Trial of DARE-BV1 in Patients Diagnosed with Bacterial Vaginosis

DARE-BV1 met the primary endpoint of the study and all pre-specified secondary efficacy endpoints; demonstrated significantly greater clinical cure rates compared to placebo

DARE-BV1 has Fast Track and QIDP designations from FDA

New drug application (NDA) submission planned 1H of 2021

SAN DIEGO, Dec. 7, 2020 (GLOBE NEWSWIRE) -- Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today announced positive topline results from the DARE-BVFREE Phase 3 randomized, double-blinded, placebo-controlled clinical trial evaluating DARE-BV1 in 307 women diagnosed with bacterial vaginosis, a serious condition estimated to affect approximately 21 million women in the United States. DARE-BV1 is an investigational thermosetting bioadhesive hydrogel containing clindamycin phosphate 2% designed as a convenient, one-time vaginally-administered treatment for bacterial vaginosis. The trial met its primary endpoint demonstrating that a single administration of DARE-BV1 was superior to placebo as a primary therapeutic intervention for women diagnosed with bacterial vaginosis.

"Based on these topline results, DARE-BV1 delivered clinical cure rate values greater than those of currently marketed FDA-approved products for the treatment of bacterial vaginosis. This successful Phase 3 clinical trial marks another important achievement for Daré. We began 2020 with the announcement of a commercial partnership for Ovaprene® with Bayer, marketer of one of the most successful contraceptive products in women's health, and we're concluding the year with another exciting milestone, the successful completion of our Phase 3 clinical trial of DARE-BV1 to support an NDA for the treatment of bacterial vaginosis," said Sabrina Martucci Johnson, President and CEO of Daré Bioscience. "We believe there is a large unmet need for a more efficacious and convenient, single-dose vaginally-administered product to treat bacterial vaginosis, and we believe DARE-BV1 could become a new front-line treatment option. DARE-BV1 received Fast Track designation from the FDA earlier this year and, based on the topline results of this trial, we plan to file our NDA in the first half of 2021."

Topline Results of the Phase 3 Randomized Clinical Trial

DARE-BVFREE randomized 307 women at 32 centers across the United States in a 2:1 ratio to receive a single vaginal dose of DARE-BV1 (N=204) or a single vaginal dose of placebo gel (N=103) to be applied intravaginally within one day of randomization.

The primary endpoint for the study was clinical cure of bacterial vaginosis determined at the final study visit which occurred 21 to 30 days after study drug administration, also

referred to as the test-of-cure (TOC) visit, in the modified intent-to-treat (mITT) study population (N=180). In accordance with U.S. Food and Drug Administration (FDA) guidance, the mITT population excludes subjects from the intent-to-treat (ITT) population (N=307) who subsequently demonstrated a positive test result for other concomitant vaginal or cervical infections at baseline.

A single vaginal dose of DARE-BV1 proved statistically superior to placebo at p-value < 0.001 at the TOC visit that occurred 21 to 30 days after study drug administration (primary efficacy endpoint) and also at the assessment visit that occurred 7 to 14 days after study drug administration. DARE-BV1 also demonstrated statistically significant efficacy in all four additional pre-specified secondary efficacy assessments. The clinical cure endpoint results are shown in the following table:

Summary of Clinical Cure Results (mITT Population), p-value < 0.001:

	DARE-BV1 (N = 121)	Placebo (N = 59)
Clinical Cure at Day 7-14 visit	76.0%	23.7%
Clinical Cure at Day 21-30 visit (primary endpoint)	70.2%	35.6%

The clinical cure rate at the Day 21-30 visit for the ITT population was similar to that for the mITT population (70.1% for the DARE-BV1 group (N=204) and 36.9% for the placebo group (N=103), p-value < 0.001), demonstrating effectiveness of DARE-BV1 in treating bacterial vaginosis even when other concomitant vaginal or cervical infections were present.

The DARE-BVFREE study's two treatment arms were well balanced in terms of age, race, ethnicity, bacterial vaginosis history, and body mass index (BMI). The ITT population comprised primarily patients aged 15 to 51 years, with a mean age of 34.8 (standard deviation 8.84) and median age of 35. Over 53% of the ITT population qualified as obese (BMI ≥30.0), with a mean BMI of 31.50 (standard deviation 8.499). In the ITT population, 56.0% of women identified as Black or African American, 41% identified as white and 25.5% identified as of Hispanic or Latino origin (compared to 74.5% as not of Hispanic or Latino origin). In addition, more than 75% of the women in the ITT population reported one or more episodes of bacterial vaginosis diagnosed in the 12 months before they were randomized into the study (76.9% in the DARE-BV1 group and 73.8% in the placebo group).

DARE-BV1 was well-tolerated in the study. There were no early discontinuations due to adverse events (AEs), and the only serious AE occurred in a woman in the placebo group. In the DARE-BV1 group, 15.3% of patients reported AEs that were considered to be possibly, probably or definitely related to study treatment compared to 9.7% of patients in the placebo group.

Only two AEs were reported by more than 2% of patients in the DARE-BV1 arm and at a rate higher than in patients in the placebo arm – vulvovaginal candidiasis, commonly called a vaginal yeast infection (17.2% in the DARE-BV1 group and 3.9% in the placebo group), and vulvovaginal pruritus, commonly referred to as vaginal itching (4.4% in the DARE-BV1 group and 1.9% in the placebo group). Over half of the vaginal yeast infections reported in the DARE-BV1 group and exactly half of those reported in the placebo group occurred in patients who exhibited a positive yeast culture prior to dosing.

"We believe these data demonstrate that DARE-BV1 is significantly effective in a representative patient population, including a large proportion of patients who have been previously treated for this infection. Today, about half of the patients treated for bacterial vaginosis experience recurrence of the infection within 12 months of their treatment, and currently marketed FDA-approved products for the treatment of bacterial vaginosis have clinical cure rates in the mid-30% to the high-60% range," said David Friend, PhD, Chief Scientific Officer of Daré Bioscience. "If approved, we believe DARE-BV1 will be an important new and convenient one-time vaginally-administered treatment option with the potential to improve clinical outcomes and overall quality of life for women suffering with bacterial vaginosis."

Based on the topline results from the study, Daré expects to have a pre-NDA meeting with the FDA in early 2021 and to submit an NDA during the first half of 2021. DARE-BV1 received both Fast Track and Qualified Infectious Disease Product (QIDP) designations from the FDA for the treatment of bacterial vaginosis. Given these designations, the NDA could be eligible for priority review, which, if granted, could allow for a 2021 PDUFA date, and, assuming approval, an early 2022 commercial launch in the U.S.

About the Phase 3 Study

DARE-BVFREE was a randomized, multicenter, double-blind, placebo-controlled study of a single administration of DARE-BV1 (clindamycin phosphate vaginal gel, 2%) compared to a single administration of placebo vaginal gel (HEC Universal Placebo Gel) for the treatment of bacterial vaginosis. Patients were evaluated during three clinic visits: Day 1 (screening and randomization visit), Day 7-14 (assessment visit), and Day 21-30 (TOC visit). Clinical cure was defined as resolution of the specific clinical signs that comprise the Amsel criteria; specifically, resolution of abnormal vaginal discharge associated with bacterial vaginosis, clue cells less than 20% of total epithelial cells on microscopy, and a negative 10% KOH "whiff" test. The total study duration was approximately one month for each individual patient.

About Bacterial Vaginosis

Bacterial vaginosis is the most common cause of vaginitis worldwide and is estimated to affect approximately 21 million women in the United States.[1,2] Prevalence of bacterial vaginosis among non-white women in the U.S. is higher than among white women (African American 51%, Mexican American 32%, white 23%).[2] While there are several

therapeutic options for women in the U.S. diagnosed with bacterial vaginosis, currently approved options have relatively insufficient clinical cure rates, require sequential daily administrations or can be otherwise inconvenient for women to use. It is estimated that as many as 50% of women treated for bacterial vaginosis will experience a recurrence within 12 months of their treatment.[3]

1. Clinical Infectious Diseases 2007; 44:213–9; https://doi.org/10.1086/509577
2. Centers for Disease Control and Prevention Bacterial Vaginosis (BV) Statistics; https://www.cdc.gov/std/bv/stats.htm. Accessed December 5, 2020.
3. The Journal of Infectious Diseases 2006; 193:1478–86; https://www.ncbi.nlm.nih.gov/pubmed/16652274

About DARE-BV1

DARE-BV1 is an investigational thermosetting bioadhesive hydrogel containing clindamycin phosphate 2% being evaluated as a one-time, vaginally-administered treatment for bacterial vaginosis.

About Daré Bioscience

Daré Bioscience is a clinical-stage biopharmaceutical company committed to the advancement of innovative products for women's health. The company's mission is to identify, develop and bring to market a diverse portfolio of differentiated therapies that expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, vaginal health, sexual health, and fertility.

Daré's product portfolio includes potential first-in-category candidates in clinical development: Ovaprene®, a hormone-free, monthly contraceptive intravaginal ring whose U.S. commercial rights are under a license agreement with Bayer; Sildenafil Cream, 3.6%, a novel cream formulation of sildenafil to treat female sexual arousal disorder utilizing the active ingredient in Viagra®; DARE-BV1, a unique hydrogel formulation of clindamycin phosphate 2% to treat bacterial vaginosis via a single application; and DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for hormone replacement therapy following menopause. To learn more about Daré's full portfolio of women's health product candidates, and mission to deliver differentiated therapies for women, please visit www.darebioscience.com.

Daré may announce material information about its finances, product candidates, clinical trials and other matters using the Investors section of its website (http://ir.darebioscience.com), SEC filings, press releases, public conference calls and webcasts. Daré will use these channels to distribute material information about the company, and may also use social media to communicate important information about the company, its finances, product candidates, clinical trials and other matters. The information Daré posts on its investor relations website or through social media channels may be deemed to be material information. Daré encourages investors, the media, and others interested in the company to review the information Daré posts in the Investors section of its website and to follow these Twitter accounts: @SabrinaDareCEO and @DareBioscience. Any updates to the list of social media channels the company may use to communicate information will be posted on the investor relations page of Daré's website mentioned above.

Forward-Looking Statements

Daré cautions you that all statements, other than statements of historical facts, contained in this press release, are forward-looking statements. Forward-looking statements, in some cases, can be identified by terms such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “design,” “intend,” “expect,” “could,” “plan,” “potential,” “predict,” “seek,” “should,” “would,” “contemplate,” “project,” “target,” “tend to,” or the negative version of these words and similar expressions. In this press release, forward-looking statements include, but are not limited to, statements regarding Daré’s plans and strategies for regulatory approval and commercialization of DARE-BV1, including expected timing of Daré’s engagement with the FDA regarding an NDA for DARE-BV1, submission of an NDA for DARE-BV1, FDA review and approval of the NDA, and commercial launch of DARE-BV1 in the U.S. if approved; DARE-BV1’s potential importance to and utilization by women with bacterial vaginosis, including its potential ability to improve clinical outcomes and overall quality of life compared to currently available therapeutic options for bacterial vaginosis if approved; and DARE-BV1’s commercial potential. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Daré’s actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by the forward-looking statements in this press release, including, without limitation, risk and uncertainties related to: the risk that topline results from a clinical trial, including the DARE-BVFREE study, are based on Daré’s preliminary analysis of key efficacy and safety data and, following a comprehensive review of study data, such results may change and topline results may not accurately reflect the complete results from the clinical trial; the risk that the FDA, other regulatory authorities or members of the scientific or medical communities may not accept or agree with Daré’s interpretation of or conclusions regarding the study data; Daré’s ability to raise additional capital when and as needed to advance its product candidates and continue as a going concern; the effects of the COVID-19 pandemic on Daré’s operations, financial results and condition, and ability to achieve current plans and objectives, including the potential impact of the pandemic on the ability of third parties on which Daré relies to assist in the conduct of its business, including its clinical trials, to fulfill their contractual obligations to Daré; Daré’s ability to develop, obtain regulatory approval for, and commercialize its product candidates; the failure or delay in starting, conducting and completing clinical trials or obtaining FDA or foreign regulatory approval for Daré’s product candidates in a timely manner; Daré’s ability to conduct and design successful clinical trials, to enroll a sufficient number of patients, to meet established clinical endpoints, to avoid undesirable side effects and other safety concerns, and to demonstrate sufficient safety and efficacy of its product candidates; the risk that positive findings in early clinical and/or nonclinical studies of a product candidate may not be predictive of success in subsequent clinical and/or nonclinical studies of that candidate; Daré’s ability to retain its licensed rights to develop and commercialize a product candidate; Daré’s ability to satisfy the monetary obligations and other requirements in connection with its exclusive, in-license agreements covering

the critical patents and related intellectual property related to its product candidates; the risks that the license agreement with Bayer may not become effective and, if it becomes effective, that future payments to Daré under the agreement may be significantly less than anticipated or potential amounts; developments by Daré's competitors that make its product candidates less competitive or obsolete; Daré's dependence on third parties to conduct clinical trials and manufacture clinical trial material; Daré's ability to adequately protect or enforce its, or its licensor's, intellectual property rights; the lack of patent protection for the active ingredients in certain of Daré's product candidates which could expose its products to competition from other formulations using the same active ingredients; the risk of failure associated with product candidates in preclinical stages of development that may lead investors to assign them little to no value and make these assets difficult to fund; cyber attacks, security breaches or similar events that compromise Daré's technology systems or those of third parties on which it relies and/or significantly disrupt Daré's business; and disputes or other developments concerning Daré's intellectual property rights. Daré's forward-looking statements are based upon its current expectations and involve assumptions that may never materialize or may prove to be incorrect. All forward-looking statements are expressly qualified in their entirety by these cautionary statements. For a detailed description of Daré's risks and uncertainties, you are encouraged to review its documents filed with the SEC including Daré's recent filings on Form 8-K, Form 10-K and Form 10-Q. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Daré undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

Investors on behalf of Daré Bioscience, Inc.:

Lee Roth

Burns McClellan

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Source: Daré Bioscience, Inc.