Daré Bioscience, Inc.



# 6,380,126 Shares of Common Stock

This prospectus relates to the offer and sale or other disposition of up to 6,380,126 shares of our common stock, par value \$0.0001, by Lincoln Park Capital Fund, LLC, or Lincoln Park or the selling stockholder.

The shares of common stock being offered by Lincoln Park have been or may be issued pursuant to the purchase agreement dated April 22, 2020 that we entered into with Lincoln Park, which we refer to in this prospectus as the Purchase Agreement. See "Our Agreements with Lincoln Park" for a description of that agreement and "Selling Stockholder" for additional information regarding Lincoln Park. The prices at which Lincoln Park may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions.

We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale of shares by the selling stockholder.

We filed a registration statement on Form S–1 (File No. 333-237954) with the Securities and Exchange Commission on May 1, 2020 that was declared effective on May 12, 2020, which we refer to in this prospectus as the Prior Registration Statement. The Prior Registration Statement registered 7,500,000 shares of our common stock that have been or may be issued pursuant to the Purchase Agreement, of which 130,126 shares remain registered and unsold thereunder as of January 4, 2021. Such registered and unsold shares of common stock are being carried over from the Prior Registration Statement and are being offered and sold under this prospectus pursuant to Rule 429 under the Securities Act of 1933, as amended, or the Securities Act. In addition, 6,250,000 shares of our common stock, which were not registered under the Prior Registration Statement, are being offered and sold under this prospectus.

The selling stockholder may sell or otherwise dispose of the shares of common stock described in this prospectus in a number of different ways and at varying prices. See "Plan of Distribution" beginning on page 25 of this prospectus for more information about how and the prices at which the selling stockholder may sell or otherwise dispose of the shares of our common stock being offered. The selling stockholder is an "underwriter" within the meaning of Section 2(a)(11) of the Securities Act.

The selling stockholder will pay all brokerage fees and commissions and similar expenses. We will pay all expenses (except brokerage fees and commissions and similar expenses) relating to the registration of the shares with the Securities and Exchange Commission.

Our common stock is listed on the Nasdaq Capital Market under the symbol "DARE." On January 5, 2021, the last reported sale price of our common stock was \$1.39 per share.

Investing in our common stock involves a high degree of risk. Before deciding whether to invest in our common stock, you should consider carefully the risks described under the caption "Risk Factors" beginning on page 10 of this prospectus, and under similar headings in the documents incorporated by reference in this prospectus, as well as in any amendments or supplements to this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is January 7, 2021

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# ABOUT THIS PROSPECTUS

This prospectus does not contain all of the information included in the registration statement of which this prospectus forms a part. For a more complete understanding of the offering of the securities, you should refer to the registration statement, including its exhibits. You should carefully read this prospectus, any prospectus supplement or free writing prospectus that we subsequently authorize for use in connection with this offering, the information and documents incorporated herein by reference and the additional information under the heading "Where You Can Find More Information" before making an investment decision. You should rely only on the information we have provided or incorporated by reference in this prospectus, or in any prospectus supplement or free writing prospectus that we subsequently authorize for use in connection with this offering. Neither we, nor the selling stockholder, have authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus, or any related prospectus supplement or free writing prospectus, is accurate only as of the date on the front of the document and that any information we have incorporated herein by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus, or such prospectus supplement or free writing prospectus, or any sale of a security.

Neither we, nor the selling stockholder, are offering to sell or seeking offers to purchase these securities in any jurisdiction where the offer or sale is not permitted. We have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities hereunder and the distribution of this prospectus outside the United States.

The representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference in this prospectus were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market size, is based on information from various sources, including peer reviewed journals, formal presentations at medical society meetings and third-parties commissioned by us or our licensors to provide market research and analysis, and is subject to a number of assumptions and limitations. Although we are responsible for all of the disclosure contained in this prospectus and we believe the information from industry publications and other third-party sources included in this prospectus is reliable, such information is inherently imprecise. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section captioned "Risk Factors."

To the extent there are inconsistencies between this prospectus, any related prospectus supplement or free writing prospectus, and any documents incorporated by reference, the document with the most recent date will control.

Unless the context otherwise requires, "Daré," "Daré Bioscience," "the Company," "we," "us," "our" and similar terms refer to Daré Bioscience, Inc. and its subsidiaries.

# **PROSPECTUS SUMMARY**

This summary highlights information contained elsewhere in this prospectus. This summary provides an overview of selected information and does not contain all of the information you should consider before investing in our securities. We urge you to read this entire prospectus, including our consolidated financial statements, notes to the consolidated financial statements, the information in the section captioned "Risk Factors," and other information incorporated herein by reference to our other filings with the Securities and Exchange Commission, or SEC, or included in any applicable prospectus supplement.

#### About Daré Bioscience

We are a clinical-stage biopharmaceutical company committed to the acceleration of innovative products for women's health. We are driven by a mission to identify, acquire and develop a diverse portfolio of differentiated therapies that expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, fertility, and sexual and vaginal health. Our business strategy is to in-license or otherwise acquire the rights to differentiated product candidates in our areas of focus, some of which have existing clinical proof-of-concept data, to take those candidates through mid- to late-stage clinical development, and to establish and leverage strategic partnerships to achieve commercialization.

Since July 2017, we have assembled a portfolio of clinical-stage and pre-clinical-stage candidates. While we will continue to assess opportunities to expand our portfolio, our current focus is on advancing our existing product candidates through mid- and late stages of clinical development or approval. Our portfolio includes three product candidates in advanced clinical development:

- DARE-BV1, a novel thermosetting bioadhesive hydrogel formulated with clindamycin phosphate 2% to be administered in a single vaginally delivered application, as a first line treatment for bacterial vaginosis;
- **Ovaprene**®, a hormone-free, monthly vaginal contraceptive; and
- **Sildenafil Cream, 3.6%**, a proprietary cream formulation of sildenafil for topical administration to the vulva and vagina for treatment of female sexual arousal disorder.

Our portfolio also includes three product candidates in Phase 1 clinical development or that we believe are Phase 1-ready:

- DARE-HRT1, a combination bio-identical estradiol and progesterone intravaginal ring for the treatment of menopausal symptoms, including vasomotor symptoms, as part of a hormone replacement therapy following menopause;
- **DARE-FRT1**, an intravaginal ring containing bio-identical progesterone for the prevention of preterm birth and broader luteal phase support as part of an in vitro fertilization treatment plan; and
- DARE-VVA1, a vaginally delivered formulation of tamoxifen to treat vulvar vaginal atrophy in patients with hormone-receptor positive breast cancer.

In addition, our portfolio includes these pre-clinical stage product candidates:

- DARE-LARC1, a combination product designed to provide long-acting, reversible contraception comprising an implantable, user-controlled wireless drug delivery system and levonorgestrel;
- **ORB-204 and ORB-214**, injectable formulations of etonogestrel designed to provide contraception over 6-month and 12-month periods, respectively; and

 DARE-RH1, a novel approach to non-hormonal contraception for both men and women by targeting the CatSper ion channel.

Our primary operations have consisted of, and are expected to continue to consist of, product research and development and advancing our portfolio of product candidates through clinical development and regulatory approval. To date, we have not obtained any regulatory approvals for any of our product candidates, commercialized any of our product candidates or generated any product revenue. The majority of our development expenses incurred during the fourth quarter of 2020 and that we expect to incur in 2021 will support the advancement of DARE-BV1, Ovaprene and Sildenafil Cream, 3.6%.

The effect of the COVID-19 pandemic and efforts to reduce the spread of COVID-19 remain a rapidly evolving and uncertain risk to our business, operating results, financial condition and stock price. In November 2020, the U.S. began to experience a substantial surge in cases and hospitalizations and intensive care unit capacity became strained. States and counties across the country imposed or re-imposed stay-at-home orders and shutdowns of non-essential businesses in efforts to reduce spread of the disease. In December 2020, the U.S. Food and Drug Administration (FDA) issued the first emergency use authorization for a vaccine for the prevention of COVID-19. However, experts have cautioned it is unlikely that an authorized vaccine will be available to a significant proportion of people in the U.S. before late spring or early summer 2021, and the timeline for the pandemic and its associated restrictions to end remain uncertain. Given the high level of uncertainty regarding the duration and impact of the pandemic on the U.S. and global economies, workplace environments and capital markets, we are unable to assess the full extent of the effects of the pandemic on our business. These effects could have a material adverse impact on our business, operating results and financial condition, including, without limitation, by adversely impacting our ability to raise capital when needed or on terms favorable or acceptable to us and increasing the anticipated aggregate costs and timelines for the development and marketing approval of our product candidates. For further discussion of risks and uncertainties related to the COVID-19 pandemic, see the risk factor titled, The COVID-19 pandemic and efforts to reduce the spread of COVID-19 could negatively impact our business, including by increasing the cost and timelines for our clinical development programs, in Part II, Item 1A. Risk Factors of the Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020 that is incorporated by reference into this prospectus, as well as any risk factor similarly subcaptioned in any document subsequently incorporated by reference into this prospectus or any amendment or supplement to this prospectus.

### **Recent Development**

On December 7, 2020, we announced positive topline results from our DARE-BVFREE Phase 3 clinical trial of DARE-BV1 for the treatment of bacterial vaginosis. 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.

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). 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 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	ue < 0.001							
DARE-BV1 Placebo (N = 121) (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, we expect to have a pre-NDA meeting with the 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, we would expect a commercial launch of DARE-BV1 in the United States in early 2022.

# **Summary of Risk Factors**

Investing in our common stock involves a high degree of risk. Before deciding whether to purchase our common stock, you should carefully consider the risks and uncertainties described in the section captioned "Risk Factors" in this prospectus, and under similar headings in the documents incorporated by reference into this prospectus, as well as in any amendments or supplements to this prospectus. The occurrence of any of these risk factors could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment in our common stock. These risk factors include, but are not limited to, the following:

- We will need to raise additional capital to continue our operations and remain a going concern, and our ability to do so may be limited and more expensive due to our low public float, low market capitalization, limited operating history and lack of revenue, and/or applicable laws and regulations.
- We have a limited operating history, have incurred significant losses since our inception and expect to continue to incur losses for the foreseeable future, which, together with our limited financial resources, makes it difficult to assess our prospects.
- The COVID-19 pandemic and efforts to reduce the spread of COVID-19 could negatively impact our business, including by increasing the cost and timelines for our clinical development programs.

- We may not receive any additional payments under our license agreement with Bayer, and Bayer may terminate the agreement at any time without cause upon limited prior notice.
- Due in part to our limited financial resources, we may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable indications or therapeutic areas for our product candidates, we may be unable to pursue and complete the clinical trials we would like to pursue and complete, and we may be unable to commence or complete clinical trials in accordance with our current timeline expectations.
- We have a relatively small number of employees and if we fail to attract and retain key personnel, we may not successfully complete development of, obtain regulatory approval for or commercialize our product candidates, or otherwise implement our business plan.
- Cyber-attacks, security breaches, loss of data and other disruptions to our information technology systems or those of our third-party service providers could compromise sensitive information related to our business, delay or prevent us from accessing critical information or expose us to liability, any of which could adversely affect our business and our reputation.
- We depend heavily on the success of our clinical-stage product candidates, DARE-BV1, Ovaprene and Sildenafil Cream, 3.6%. Clinical development is a lengthy and expensive process with an inherently uncertain outcome. Failure to successfully develop and obtain regulatory approval to market and sell any of these product candidates on our anticipated timelines, or at all, could have a materially adverse effect on our business, operating results and financial condition.
- We depend highly on our license agreements for our clinical-stage product candidates and the loss or impairment of our rights under any license could have a materially adverse effect on our business prospects, operations and viability.
- We rely on, and intend to continue to rely on, third parties for the execution of significant aspects of our development programs, including the conduct of our clinical and non-clinical studies and the supply and manufacture of our product candidates. Failure of these third parties, including multiple single source suppliers and manufacturers, to successfully carry out their contractual duties, comply with regulatory requirements and applicable law, or meet expected deadlines may cause significant delays in our product development timelines and/or failure of our programs.
- Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time
  may change as more patient data become available and are subject to audit and verification procedures that
  could result in material changes in the final data, and others, including regulatory authorities, may not agree
  with our interpretation of study data.
- Our business depends on obtaining the approval of regulatory authorities, and in particular, FDA approval, for our product candidates in a timely manner, and the requirements for obtaining approval for our product candidates may change over time, requiring more financial resources and development time than we currently anticipate.
- Our business strategy is to establish and leverage strategic partnerships to achieve commercialization of
  our product candidates, if approved. We have no internal sales, marketing or distribution capabilities. Under
  any such collaborations, we may not have control over several key elements relating to the development
  and commercialization of our product candidates, and any failure by such third parties to adequately
  perform their obligations under our agreements could negatively impact our business, operating results and
  financial condition.
- The product candidates we are developing or may develop are likely to face significant competition. If we
  receive marketing approval for any of our product candidates, their ability to compete and potential to
  generate revenue will be impacted by the efficacy and safety outcomes of our clinical trials, the label claims
  that the FDA or other regulatory authorities approve for the product, and the degree of acceptance among
  the medical community and consumers and their preference of our products over available alternative
  products.

- Even if we obtain regulatory approval in the United States or elsewhere to market any of our products, the reimbursement environment at the time of approval may hurt our financial prospects. If the out-of-pocket costs for our products are deemed by women to be high, a commercial market may never develop.
- Our failure to adequately protect or enforce our and our licensors' intellectual property rights could materially
  harm our proprietary position in the marketplace or prevent or impede the commercialization of our current
  and potential future products.
- Lack of patent protection for the active ingredients in certain of our product candidates, including DARE-BV1 and Sildenafil Cream, 3.6%, may limit the commercial opportunity for those products if competitors are able to develop and commercialize safe and effective alternative formulations or methods of delivery of the active ingredients.
- The price of our common stock may be volatile and could subject us to securities litigation, including classaction lawsuits.
- There is no assurance that we will continue satisfying the listing requirements of the Nasdaq Capital Market, and such failure could result in the suspension or delisting of our common stock, which could, among other things, substantially impair our ability to raise additional capital and have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock.
- The sale of our common stock to Lincoln Park may cause dilution to our other stockholders and the subsequent sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.
- There may be future sales or other dilution of our equity, including sales and issuances of our common stock under our ATM sales agreement and upon exercise of stock options and warrants, which may adversely affect the market price of our common stock, even if our business is doing well.

# Additional Information

For additional information related to our business and operations, please refer to the annual and quarterly reports incorporated herein by reference, as described under the caption "Incorporation of Documents by Reference" on page 31 of this prospectus.

#### **Corporate Information**

Our principal executive offices are located at 3655 Nobel Drive, Suite 260, San Diego, California 92122, and our telephone number at that address is (858) 926-7655. We maintain a website at www.darebioscience.com, to which we regularly post copies of our press releases as well as additional information about us. The information contained on, or that can be accessed through, our website is not a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

Daré Bioscience® is a registered trademark of Daré Bioscience, Inc. Ovaprene® is a registered trademark licensed to Daré Bioscience, Inc. All brand names or trademarks appearing in this prospectus are the property of their respective holders. Use or display by us of other parties' trademarks, trade dress, or products in this prospectus is not intended to, and does not, imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owners.

# The Offering

This prospectus relates to the resale by Lincoln Park Capital Fund, LLC, the selling stockholder identified in this prospectus, of shares of our common stock, par value \$0.0001 per share, as follows:

Common stock offered by the selling stockholder	Up to 6,380,126 shares, which includes 130,126 shares outstanding as of the date of this prospectus
Common stock outstanding prior to this offering	41,596,253 shares
Common stock to be outstanding after giving effect to the issuance of 6,250,000 shares under the Purchase Agreement offered under this prospectus that are not outstanding as of the date of this prospectus	47,846,253 shares
Use of proceeds	We will receive no proceeds from the sale of shares of common stock by Lincoln Park in this offering. We may receive up to approximately \$7.0 million in aggregate gross proceeds from sales we make to Lincoln Park on or after the date of this prospectus under the Purchase Agreement. Any such proceeds we receive will be used for working capital and general corporate purposes. See "Use of Proceeds" on page 20 of this prospectus.
Risk factors	Investment in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 10 of this prospectus, as well as the other information included in or incorporated by reference in this prospectus, for a discussion of risks you should carefully consider before investing in our common stock.
Nasdaq Capital Market symbol	"DARE"

The actual number of shares of our common stock outstanding after this offering will vary depending on the actual number of shares we sell to Lincoln Park under the Purchase Agreement after the date of this prospectus. The number of shares of our common stock outstanding prior to and after this offering in the table above is based on 41,596,253 shares outstanding as of January 4, 2021, and excludes:

- 2,786,591 shares of common stock issuable upon exercise of stock options outstanding as of January 4, 2021, with a weighted-average exercise price of \$1.16 per share;
- 2,168,366 shares of common stock reserved and available for future issuance as of January 4, 2021 under our Amended and Restated 2014 Stock Incentive Plan; and
- 1,908,643 shares of common stock issuable upon exercise of warrants outstanding as of January 4, 2021, with a weighted-average exercise price of \$1.41 per share.

# Purchase Agreement with Lincoln Park

On April 22, 2020, we entered into a purchase agreement with Lincoln Park, which we refer to in this prospectus as the Purchase Agreement, pursuant to which Lincoln Park agreed to purchase from us up to an aggregate of \$15.0 million of our common stock (subject to certain limitations) from time to time over the term of the Purchase Agreement. Through the date of this prospectus, Lincoln Park has purchased an aggregate of approximately \$8.0 million of our common stock under the Purchase Agreement. Also on April 22, 2020, we entered into a registration rights agreement with Lincoln Park, which we refer to in this prospectus as the Registration Rights Agreement, pursuant to which we have filed with the SEC the registration statement that includes this prospectus to register for resale under the Securities Act, the shares of common stock that have been or may be issued to Lincoln Park under the Purchase Agreement.

We did not have the right to commence any sales of our common stock to Lincoln Park under the Purchase Agreement until the conditions set forth in the Purchase Agreement, all of which were outside of Lincoln Park's control, were satisfied, including that the SEC declared effective a registration statement covering the resale by Lincoln Park of the shares that have been or may be issued pursuant to the Purchase Agreement, which time we refer to in this prospectus as the Commencement. The Commencement occurred on May 19, 2020. On or after the date of the Commencement, we had the right, which we exercised, to direct Lincoln Park to purchase \$500.000 in shares of our common stock, which we refer to in this prospectus as the "Commencement Purchase." Thereafter, from time to time, at our sole discretion, we may direct Lincoln Park to purchase shares of our common stock in amounts up to 200,000 shares on any single business day, which amounts may be increased to up to 300,000 shares depending on the market price of our common stock at the time we initiate the sale and subject to a maximum commitment by Lincoln Park of \$1.0 million per single purchase, which we refer to in this prospectus as "Regular Purchases," plus other "accelerated amounts" and/or "additional accelerated amounts" under certain circumstances. We will control the timing and amount of any sales of our common stock to Lincoln Park under the Purchase Agreement. The purchase price of the shares that were sold to Lincoln Park in the Commencement Purchase and that have been sold and may be sold in any Regular Purchase was and will be the lower of (i) the lowest sale price of our common stock on the business day on which we initiate the purchase and (ii) the average of the three lowest closing sale prices of our common stock during the 10 consecutive business day period immediately preceding the business day on which we initiate the purchase. The purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the business days used to compute such price. We may terminate the Purchase Agreement at any time after the date of Commencement, at no penalty or cost, other than the Commitment Shares (as defined below). There are no restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement or Registration Rights Agreement, other than a prohibition on our issuing, or entering into any agreement to effect the issuance of, shares of our common stock or common stock equivalents involving a transaction that is defined in the Purchase Agreement as "Variable Rate Transaction." Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement.

On April 22, 2020, in consideration for its commitment to purchase shares of our common stock under the Purchase Agreement, we issued 285,714 shares of our common stock to Lincoln Park, which we refer to in this prospectus as the "Commitment Shares."

As of January 4, 2021, there were 41,596,253 shares of our common stock outstanding, of which 39,933,706 shares were held by non-affiliates. The 41,596,253 shares of our common stock outstanding as of January 4, 2021 includes 7,214,286 shares issued and/or sold to Lincoln Park under the Purchase Agreement. If all of the 6,380,126 shares offered by Lincoln Park under this prospectus were issued and outstanding, such shares would represent approximately 13.3% of the total number of shares of our common stock outstanding and approximately 13.8% of the total number of outstanding shares held by non-affiliates, in each case as of January 4, 2021. The Purchase Agreement provides that we may sell up to \$15.0 million of our common stock to Lincoln Park. Through the date of this prospectus, we have sold approximately \$8.0 million of our common stock to Lincoln Park under the Purchase Agreement. Depending on the price per share at which we sell shares to Lincoln Park under the Purchase Agreement, we may need to sell more shares to Lincoln Park than are offered under this prospectus to receive aggregate gross proceeds equal to the approximately \$7.0 million balance of the \$15.0 million total commitment of Lincoln Park under the Purchase Agreement, in which case we must first register for resale under the Securities Act additional shares of our common stock. The number of shares ultimately offered for resale by Lincoln Park will depend upon the number of shares we elect to sell to Lincoln Park under the Purchase Agreement. Sales of our common stock to Lincoln Park by us under the Purchase Agreement could result in substantial dilution to our stockholders.

Under applicable rules of The Nasdaq Stock Market, in no event may we issue or sell to Lincoln Park under the Purchase Agreement more than 19.99% of the shares of our common stock outstanding immediately prior to the execution of the Purchase Agreement (which is 4,941,089 shares based on 24,705,453 shares outstanding immediately prior to the execution of the Purchase Agreement), which limitation we refer to in this prospectus as the "Exchange Cap," unless (i) we obtain stockholder approval to issue shares of common stock to Lincoln Park under the Purchase Agreement equals or exceeds \$1.0117 (which represents the closing sale price per share of our common stock on April 21, 2020, plus an incremental amount), such that issuances and sales of our common stock to Lincoln Park under the Purchase Agreement would not be subject to the Exchange Cap under applicable Nasdaq rules. The average price per share of the sales we made to Lincoln Park under the Purchase Agreement through the date of this prospectus was in excess of \$1.0117. In any event, the Purchase Agreement if such issuance or sale would breach any applicable Nasdaq rules.

The Purchase Agreement also prohibits us from directing Lincoln Park to purchase any shares of common stock if those shares, when aggregated with all other shares of our common stock then beneficially owned by Lincoln Park and its affiliates, would result in Lincoln Park and its affiliates having beneficial ownership, at any single point in time, of more than 9.99% of the then total outstanding shares of our common stock, as calculated pursuant to Section 13(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and Rule 13d-3 thereunder, which limitation we refer to as the Beneficial Ownership Cap.

The sale of shares of our common stock to Lincoln Park will not affect the rights or privileges of our other stockholders, except that the economic and voting interests of each of our other stockholders will be diluted as a result of any such sale. Although the number of shares of common stock that our other stockholders own will not decrease, the shares owned by our other stockholders will represent a smaller percentage of our total outstanding shares after any such sale to Lincoln Park.

#### **RISK FACTORS**

Investing in our securities involves significant risk. In addition to the other information included or incorporated by reference in this prospectus, including the risks, uncertainties and assumptions discussed under the heading "Risk Factors" included in our most recent annual report on Form 10-K, as revised or supplemented by our subsequent quarterly reports on Form 10-Q or our current reports on Form 8-K that we have filed with the SEC, all of which are incorporated herein by reference (other than current reports on Form 8-K, or portions thereof, furnished under Items 2.02 or 7.01 of Form 8-K), you should consider the risks described below before making an investment decision with respect to the shares of our common stock in this offering. We expect to update these risk factors and our other risk factors from time to time in periodic and current reports we file with the SEC in the future. Such updated risk factors will be incorporated by reference in this prospectus. Please refer to our subsequently filed reports for additional information relating to the risks and uncertainties described in our risk factors are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our operations. The occurrence of any of these risks might cause you to lose all or part of your investment.

# **Risks Related to this Offering**

# The sale of our common stock to Lincoln Park may cause dilution to our other stockholders and the subsequent sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.

Lincoln Park committed to purchase up to \$15.0 million of our common stock under the Purchase Agreement. Through the date of this prospectus, we have sold approximately \$8.0 million of our common stock to Lincoln Park under the Purchase Agreement, leaving an approximately \$7.0 million balance of the \$15.0 million total commitment of Lincoln Park under the Purchase Agreement. The purchase price for the shares that we may sell to Lincoln Park under the Purchase Agreement remains subject to the pricing formula in the Purchase Agreement and will vary based on the price of our common stock at the time we initiate the sale. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

We generally have the right to control the timing and amount of any future sales of our shares to Lincoln Park under the Purchase Agreement. Sales of shares of our common stock to Lincoln Park under the Purchase Agreement, if any, will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Lincoln Park all, some or none of the shares of our common stock that may be available for us to sell pursuant to the Purchase Agreement. If and when we do sell shares to Lincoln Park, after Lincoln Park has acquired the shares, Lincoln Park may resell all, some or none of those shares at any time or from time to time in its discretion. Therefore, sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

# There may be future sales or other dilution of our equity, which may adversely affect the market price of our common stock, even if our business is doing well.

We are generally not restricted from issuing additional common stock, including any securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. To raise additional capital, we may in the future sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that are lower than the prices paid by existing stockholders, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders, which could result in substantial dilution to the interests of existing stockholders. The market price of our common stock could decline as a result of sales of common stock or securities that are convertible into or exchangeable for, or that represent the right to receive, common stock or the perception that such sales could occur.

In January 2018, we entered into a common stock sales agreement with H.C. Wainwright & Co., LLC, in connection with an "at the market" offering, under which, from time to time, we may offer and sell shares of our common stock. We call that sales agreement our "ATM sales agreement." To the extent we sell shares of our common stock under the ATM sales agreement, such sales may result in substantial dilution to our existing stockholders, and such sales, or the anticipation of such sales, may cause the trading price of our common stock to decline.

As of January 4, 2021, we had outstanding options to purchase up to approximately 2.8 million shares of our common stock and outstanding warrants to purchase up to approximately 1.9 million shares of our common stock. The exercise of a significant portion of our outstanding options and/or warrants may result in significant dilution to our stockholders. In addition, assuming the registration statements under which the shares issuable upon exercise of such options and warrants remain effective, after issuance by us the underlying shares can be freely sold in the public market, except to the extent any such shares are held by an affiliate of ours, in which case such shares will become eligible for sale in the public market as permitted by Rule 144 under the Securities Act or another applicable exemption from registration. The exercise of a significant portion of our outstanding options and/or warrants may result in significant dilution to our stockholders.

In addition, under our Agreement and Plan of Merger with Microchips Biotech, Inc., we agreed to pay contingent consideration to the former stockholders of Microchips upon achievement of specified milestones, up to \$2.3 million of which we may elect to pay in shares of our common stock, subject to subject to approval of our stockholders to the extent necessary to comply with Nasdaq Listing Rule 5635. A decision by us to pay contingent consideration that becomes payable to the former stockholders of Microchips in shares of our common stock may result in dilution to our existing stockholders.

# Outstanding warrants to purchase up to approximately 1.9 million shares of our common stock contain anti-dilution provisions that may be triggered by future sales of our common stock, including to Lincoln Park under the Purchase Agreement.

Outstanding warrants to purchase up to approximately 1.9 million shares of our common stock include price-based anti-dilution provisions. As of January 4, 2021, the exercise price of those warrants was \$0.96 per share. Under the terms of those warrants, subject to certain limited exceptions, their exercise price will be reduced each time we issue or sell any securities, including to Lincoln Park under the Purchase Agreement and under the ATM sales agreement, for a consideration per share less than a price equal to the exercise price of those warrants in effect immediately prior to such issuance or sale. If we issue shares of our common stock for cash, the consideration received therefor will be deemed to be the net amount of consideration we received therefor. Investors in this offering and our other stockholders may be diluted to the extent those warrants are exercised, and the exercise of those warrants or the sale of a significant number of shares issued upon such exercise in the public markets, or the perception that such exercise and/or sales could occur, could adversely affect the price of our common stock.

# We will require additional financing to sustain our operations and without it we may not be able to execute our current operating plan or continue operations.

We incurred a loss of approximately \$19.0 million for the nine months ended September 30, 2020. As of September 30, 2020, we had an accumulated deficit of approximately \$63.0 million and cash and cash equivalents of approximately \$5.4 million. We also had negative cash flow from operations of approximately \$16.0 million during the nine months ended September 30, 2020. We have a history of losses from operations, we expect negative cash flows from our operations to continue for the foreseeable future, and we expect that our net losses will continue for at least the next several years as we develop our existing product candidates and seek to acquire, license or develop additional product candidates. Based on our current operating plan estimates and cash resources, not taking into account any future sales of our shares to Lincoln Park under the Purchase Agreement, we do not believe our existing resources will be sufficient to satisfy our working capital needs and other liquidity requirements over at least the next 12 months. For the foreseeable future, our ability to continue as a going concern. The Report of Independent Registered Public Accounting Firm included in our annual report on Form 10-K for the year ended December 31, 2019 includes an explanatory statement that our recurring losses from operations, negative cash flow from operations and dependence on additional financing to fund operations raise substantial doubt about our ability to continue as a going concern. We will need to raise substantial additional capital to continue to fund our operations and to successfully execute our current operating plan, including the development of our current product candidates.

We may direct Lincoln Park to purchase up to \$15.0 million worth of shares of our common stock under the Purchase Agreement over a 36-month period that began on May 19, 2020, generally in amounts up to 200,000 shares of our common stock on any business day, which amount may be increased to up to 300,000 shares of our common stock depending on the market price of our common stock at the time we initiate the sale and subject to a maximum limit of \$1.0 million in any single Regular Purchase. Through the date of this prospectus, we have directed Lincoln Park to purchase approximately \$8.0 million worth of shares of our common stock under the Purchase Agreement, leaving an approximately \$7.0 million balance of the \$15.0 million total commitment of Lincoln Park under the Purchase Agreement.

The extent we rely on Lincoln Park as a source of funding will depend on a number of factors including, the market price of our common stock over the remaining portion of the 36-month period during which we may sell shares to Lincoln Park under the Purchase Agreement described above, and the extent to which we are able to secure funding from other sources. If obtaining sufficient funding from Lincoln Park were to prove unavailable or prohibitively dilutive, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we were to receive all of the approximately \$7.0 million in gross proceeds remaining under the Purchase Agreement, we will still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, we will not be able to continue development of our product candidates or we will be required to delay, scale back or eliminate some or all of our development programs or cease operations, and the consequences could be a material adverse effect on our business, operating results, financial condition and prospects.

# Our management will have broad discretion over the use of the net proceeds from sales of shares of our common stock to Lincoln Park, you may not agree with how we use the proceeds and the proceeds may not be invested successfully.

Our management will have broad discretion as to the use of the net proceeds from our sale of shares of common stock to Lincoln Park under the Purchase Agreement, and we could use them for purposes other than those contemplated at the time of commencement of this offering. Accordingly, you will be relying on the judgment of our management with regard to the use of those net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that, pending their use, we may invest those net proceeds in a way that does not yield a favorable, or any, return for us or that loses value. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flows.

# SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference in this prospectus contain or incorporate by reference forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, are forward-looking statements, including statements regarding our strategy, future operations, future financial position, projected costs, prospects, plans and objectives of management. 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.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including those factors discussed under the heading "Risk Factors" contained or incorporated in this prospectus and in any related prospectus supplement or free writing prospectus we may authorize for use in connection with this offering. These factors and the other cautionary statements contained or incorporated in this prospectus should be read as being applicable to all related forward-looking statements whenever they appear in this prospectus. Given these uncertainties, you should not place undue reliance on any forward-looking statement. The following factors are among those that may cause such differences:

- Inability to continue as a going concern;
- Inability to raise additional capital, under favorable terms or at all, including as a result of the effects of the COVID-19 pandemic;
- Inability to successfully attract partners and enter into collaborations relating to the development and/or commercialization of our product candidates on a timely basis or on acceptable terms, or at all;
- A decision by Bayer HealthCare LLC to discontinue its commercial interest in Ovaprene and/or to terminate our license agreement;
- Inability or an increase in projected costs to timely develop, obtain regulatory approval for and commercialize our product candidates;
- Failure or delay in starting, conducting and completing clinical trials or obtaining FDA or foreign regulatory approval for our
  product candidates in a timely manner, including as a result of matters beyond our control such as the effects related to
  geopolitical actions, natural disasters, or public health emergencies or pandemics, such as the COVID-19 pandemic;
- A change in the FDA Center assigned primary oversight responsibility for our combination product candidates;
- A change in regulatory requirements for our product candidates, including the development pathway pursuant to Section 505(b) (2) of the Federal Food, Drug, and Cosmetic Act, or the FDA's 505(b)(2) pathway;
- Unsuccessful clinical trial outcomes stemming from clinical trial designs, failure to enroll a sufficient number of patients, higher than anticipated patient dropout rates, failure to meet established clinical endpoints, undesirable side effects and other safety concerns;
- Reaching a conclusion regarding the efficacy or safety of a product candidate following full evaluation of complete clinical study data that is materially different from topline study results we may report;
- Communication from the FDA or another regulatory authority that it does not accept or agree with our assumptions, estimates, calculations, conclusions or analyses of clinical or nonclinical study data regarding a product candidate, or that it interprets or weighs the importance of study data differently than we have in a manner that negatively impacts the candidate's prospects for regulatory approval in a timely manner, or at all;
- Negative publicity concerning the safety and efficacy of our product candidates, or of product candidates being developed by others that share characteristics similar to our candidates;
- Inability to demonstrate sufficient efficacy of our product candidates;
- Failure to select or capitalize on the most scientifically, clinically or commercially promising or profitable indications or therapeutic areas for our product candidates due to limited financial resources;
- Loss of our licensed rights to develop and commercialize a product candidate as a result of the termination of the underlying licensing agreement;



- Monetary obligations and other requirements in connection with our exclusive, in-license agreements covering the patents and related intellectual property related to our product candidates, or our merger or asset purchase agreements relating to the acquisition of our product candidates;
- Developments by our competitors that make our product candidates less competitive or obsolete;
- Dependence on third parties to conduct nonclinical studies and clinical trials of our product candidates;
- Dependence on third parties to supply and manufacture clinical trial materials and, if any of our candidates are approved, commercial product, including components of our products as well as the finished product, in accordance with current good manufacturing practices and in the quantities needed;
- Cyber-attacks, security breaches or similar events compromising our technology systems or the technology systems of third parties on which we rely;
- Interruptions in, or the complete shutdown of, the operations of third parties on which we rely, including clinical sites, manufacturers, suppliers, and other vendors, from matters beyond their control, such as the effects related to geopolitical actions, natural disasters, or public health emergencies or pandemics, such as the COVID-19 pandemic, and our lack of recourse against such third parties if their inability to perform is excused under the terms of our agreements with such parties;
- Failure of our product candidates, if approved, to gain market acceptance or obtain adequate coverage for third party reimbursement;
- A reduction in demand for contraceptives caused by an elimination of current requirements that health insurance plans cover and reimburse certain FDA-cleared or approved contraceptive products without cost sharing;
- Uncertainty as to whether health insurance plans will cover our product candidates even if we successfully develop and obtain regulatory approval for them;
- Unfavorable or inadequate reimbursement rates for our product candidates set by the United States government and other thirdparty payers even if they become covered products under health insurance plans;
- Difficulty in introducing branded products in a market made up of generic products;
- Inability to adequately protect or enforce our, or our licensor's, intellectual property rights;
- Lack of patent protection for the active ingredients in certain of our product candidates which could expose those product candidates to competition from other formulations using the same active ingredients;
- Higher risk of failure associated with product candidates in pre-clinical stages of development that may lead investors to assign them little to no value and make these assets difficult to fund;
- Disputes or other developments concerning our intellectual property rights;
- Actual and anticipated fluctuations in our quarterly or annual operating results;
- Price and volume fluctuations in the stock market, and in our stock in particular, which could subject us to securities class-action litigation;
- Failure to maintain the listing of our common stock on the Nasdaq Capital Market or another nationally recognized exchange;
- Litigation or public concern about the safety of our potential products;
- Strict government regulations on our business, including various fraud and abuse laws, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal False Claims Act and the U.S. Foreign Corrupt Practices Act;
- Regulations governing the production or marketing of our product candidates;
- Loss of, or inability to attract, key personnel; and
- Increased costs as a result of operating as a public company, and substantial time devoted by our management to compliance initiatives and corporate governance practices.

Investors are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this prospectus or the date of the document incorporated by reference in this prospectus. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any statement is made or to reflect the occurrence of unanticipated events, except as required by law.

### OUR AGREEMENTS WITH LINCOLN PARK

#### Overview

On April 22, 2020, we entered into the Purchase Agreement and the Registration Rights Agreement with Lincoln Park. Pursuant to the terms of the Purchase Agreement, Lincoln Park agreed to purchase from us up to \$15.0 million of our common stock (subject to certain limitations) from time to time during the term of the Purchase Agreement. Pursuant to the terms of the Registration Rights Agreement, we filed with the SEC the registration statement that includes this prospectus to register for resale under the Securities Act shares that have been or may be issued to Lincoln Park under the Purchase Agreement.

We did not have the right to commence any sales of our common stock to Lincoln Park under the Purchase Agreement until the Commencement occurred, which is the time at which all of the conditions set forth in the Purchase Agreement, all of which were outside of Lincoln Park's control, were satisfied, including that the SEC declared effective a registration statement covering the resale by Lincoln Park of the shares that have been or may be issued pursuant to the Purchase Agreement. The Commencement occurred on May 19, 2020. On or after the date of the Commencement, we had the right, which we exercised, to direct Lincoln Park to purchase \$500,000 in shares of our common stock. After the Commencement Purchase, from time to time, at our sole discretion, we had the right to direct and may continue to direct Lincoln Park to purchase shares of our common stock in amounts up to 200,000 shares on any single business day as a Regular Purchase. The amount of a Regular Purchase may be increased to up to 300,000 shares depending on the market price of our common stock at the time we initiate the sale, subject to a maximum commitment by Lincoln Park of \$1.0 million per single Regular Purchase. In addition, at our discretion, Lincoln Park committed to purchase other "accelerated amounts" and/or "additional accelerated amounts" under certain circumstances. The purchase price per share of the shares that were sold to Lincoln Park in the Commencement Purchase and that have been sold and may be sold in any Regular Purchase was and will be the lower of (i) the lowest sale price of our common stock on the business day on which we initiate the purchase and (ii) the arithmetic average of the three lowest closing sale prices of our common stock during the 10 consecutive business day period immediately preceding the business day on which we initiate the purchase. The purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the business days used to compute such price. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement.

Under applicable rules of The Nasdaq Stock Market, in no event may we issue or sell to Lincoln Park under the Purchase Agreement more than 19.99% of the shares of our common stock outstanding immediately prior to the execution of the Purchase Agreement (which is 4,941,089 shares based on 24,705,453 shares outstanding immediately prior to the execution of the Purchase Agreement), unless (i) we obtain stockholder approval to issue shares of common stock in excess of the Exchange Cap or (ii) the average price per share of all applicable sales of our common stock to Lincoln Park under the Purchase Agreement equals or exceeds \$1.0117 (which represents the closing sale price of our common stock on April 21, 2020, plus an incremental amount), such that issuances and sales of our common stock to Lincoln Park under the Exchange Cap under applicable Nasdaq rules. In any event, the Purchase Agreement specifically provides that we may not issue or sell any shares of our common stock under the Purchase Agreement if such issuance or sale would breach any applicable Nasdaq rules.

The Purchase Agreement also prohibits us from directing Lincoln Park to purchase any shares of common stock if those shares, when aggregated with all other shares of our common stock then beneficially owned by Lincoln Park and its affiliates, would result in Lincoln Park exceeding the Beneficial Ownership Cap.

On April 22, 2020, the day we entered into the Purchase Agreement, we issued the Commitment Shares to Lincoln Park in consideration for its commitment to purchase shares of our common stock under the Purchase Agreement.

#### **Purchase of Shares Under the Purchase Agreement**

From time to time, at our sole discretion, we may direct Lincoln Park to purchase shares of our common stock in amounts up to 200,000 shares on any single business day as a Regular Purchase; provided that such share limit increases to 250,000 shares if the closing sale price of our common stock is not below \$1.50 per share on the business day on which we initiate the purchase, and to 300,000 shares if the closing sale price of our common stock is not below \$3.00 per share on the business day on which we initiate the purchase. We refer to such share amount limitation in this prospectus as the "Regular Purchase Share Limit." The Regular Purchase Share Limit is subject to proportionate adjustment in the event of a reorganization, recapitalization, non-cash dividend, stock split or other similar transactior; provided, that if, after giving effect to such full proportionate adjustment, the adjusted Regular Purchase Share Limit would preclude us from requiring Lincoln Park to purchase Common stock at an aggregate purchase price equal to or greater than \$100,000 in any single Regular Purchase shall be adjusted as specified in the Purchase Agreement, such that, after giving effect to such adjustment, the Regular Purchase Share Limit for such Regular Purchase Share Limit will be equal to (or as close as can be derived from such adjustment without exceeding) \$100,000. In any case, Lincoln Park's maximum commitment in any single Regular Purchase may not exceed \$1.0 million.

The purchase price per share for the shares that may be sold to Lincoln Park in any Regular Purchase will be the lower of:

- the lowest sale price of our common stock on the business day on which we initiate the purchase; or
- the arithmetic average of the three lowest closing sale prices for our common stock during the 10-consecutive-business-day
  period immediately preceding the business day on which we initiate the purchase.

In addition to Regular Purchases described above, on any business day on which we have properly submitted a notice directing Lincoln Park to purchase the then applicable Regular Purchase Share Limit and properly delivered all the shares purchased in all prior purchases under the Purchase Agreement, we may direct Lincoln Park to purchase an additional amount of shares of our common stock, which we refer to as an "Accelerated Purchase," not to exceed the lesser of:

- 30% of the aggregate shares of our common stock traded during the Accelerated Purchase Measurement Period (as defined below); and
- three times the number of shares we directed Lincoln Park to purchase in the corresponding Regular Purchase notice.

In this prospectus, the Accelerated Purchase Measurement Period refers to the period that begins at the official open of trading on the business day immediately following the date on which we initiated the corresponding Regular Purchase and ends on the earliest to occur of (a) the official close of trading on that day, (b) the time on that day that the trading volume for our common stock exceeds 3.3 times the number of shares we specified in the Accelerated Purchase notice, and (c) such time on that day when any share of our common stock trades at a price less than the minimum price per share threshold we set in the applicable Accelerated Purchase notice.

We may also direct Lincoln Park, by notice delivered before 1:00 p.m. Eastern time on a business day on which an Accelerated Purchase has been completed and all of the shares to be purchased thereunder (and under the corresponding Regular Purchase) have been properly delivered to Lincoln Park in accordance with the Purchase Agreement prior to such time on such business day, to purchase an additional amount of shares of our common stock, which we refer to as an Additional Accelerated Purchase, of up to the lesser of:

- 30% of the aggregate shares of our common stock traded during a certain portion of the normal trading hours on such Accelerated Purchase date as determined in accordance with the Purchase Agreement, which period of time we refer to as the Additional Accelerated Purchase Measurement Period; and
- three times the number of shares we directed Lincoln Park to purchase in Regular Purchase notice corresponding to the Accelerated Purchase that was completed on such Accelerated Purchase date on which an Additional Accelerated Purchase notice was properly received.

We may, in our sole discretion, submit multiple Additional Accelerated Purchase notices to Lincoln Park prior to 1:00 p.m. Eastern time, on a single Accelerated Purchase date, provided that all prior Accelerated Purchases and Additional Accelerated Purchases (including those that have occurred earlier on the same day) have been completed and all of the shares to be purchased thereunder (and under the corresponding Regular Purchase) have been properly delivered to Lincoln Park in accordance with the Purchase Agreement.

The purchase price per share for each Accelerated Purchase and each Additional Accelerated Purchase will be equal to the lower of:

- 95% of the volume weighted average price of our common stock during the applicable Accelerated Purchase Measurement Period on the applicable Accelerated Purchase date; and
- the closing sale price of our common stock on the applicable Accelerated Purchase date.

In the case of any Regular Purchase, Accelerated Purchase and Additional Accelerated Purchase, the purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction occurring during the business days used to compute the such price.

Other than as described above, there are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Lincoln Park.

# **Events of Default**

Events of default under the Purchase Agreement include the following:

- a lapse in the effectiveness of the registration statement of which this prospectus forms for any reason (including, without limitation, the issuance of a stop order or similar order) or unavailability of such registration statement or this prospectus for the resale by Lincoln Park of the shares of our common stock offered hereby that, in each case, continues for a period of 10 consecutive business days or for more than an aggregate of 30 business days in any 365-day period;
- the suspension of our common stock from trading on The Nasdaq Capital Market (or such other nationally recognized market or exchange on which our common stock may be listed or traded) for a period of one business day;
- the delisting of our common stock from The Nasdaq Capital Market, unless our common stock is immediately thereafter trading
  or quoted on the New York Stock Exchange, The Nasdaq Global Market, The Nasdaq Global Select Market, the NYSE
  American, the NYSE Arca, the OTC Bulletin Board, or OTCQX or OTCQB operated by the OTC Markets Group, Inc. (or
  nationally recognized successor to any of the foregoing);
- the failure for any reason by our transfer agent to issue to Lincoln Park the shares purchased by Lincoln Park under the Purchase Agreement within two business days after the date on which Lincoln Park is entitled to receive such shares;
- any breach by us of any of our representations, warranties or covenants or other term or condition in the Purchase Agreement or Registration Rights Agreement if such breach would reasonably be expected to have a material adverse effect (as defined in the Purchase Agreement) and, in the case of a breach of a covenant that is reasonably curable, only if such breach is not cured within five business days;
- we become insolvent or we, voluntarily or involuntarily, become the subject of any insolvency or bankruptcy proceeding or any such proceeding is threatened against us, as more fully described in the Purchase Agreement;
- if at any time we are not eligible to transfer shares of our stock electronically through the Depository Trust Company's (DTC) Deposit and Withdrawal at Custodian (DWAC) service, or any similar program hereafter adopted by DTC performing substantially the same function; or
- if at any time the Exchange Cap is reached (to the extent applicable) and our stockholders have not approved the issuance and sale to Lincoln Park of shares in excess of the Exchange Cap.

Lincoln Park does not have the right to terminate the Purchase Agreement upon any of the events of default set forth above. During an event of default, or if any event has occurred which, after notice and/or lapse of time, would reasonably be expected to become an event of default under the Purchase Agreement, all of which are outside of Lincoln Park's control, we may not direct Lincoln Park to purchase any shares of our common stock under the Purchase Agreement.

# Term of the Purchase Agreement; Termination Rights

The Purchase Agreement will automatically terminate upon the earlier of (a) the date we sell all \$15.0 million in shares of our common stock to Lincoln Park under the Purchase Agreement, and (b) the first day of the month immediately following the 36-month anniversary of the date of the Commencement. The Purchase Agreement will also automatically terminate upon commencement of a voluntary or involuntary bankruptcy proceeding by or against us, as more fully described in the Purchase Agreement. Now that the Commencement date occurred, we may also, at any time, for any reason or for no reason, terminate the Purchase Agreement upon one business day prior notice to Lincoln Park.

#### No Short-Selling or Hedging by Lincoln Park

Lincoln Park agreed that neither it nor any of its affiliates will engage, directly or indirectly, in any short-selling or hedging of our common stock during the term of the Purchase Agreement.

# **Prohibitions on Variable Rate Transactions**

There are no restrictions or limitations on our ability to raise capital from other sources at our sole discretion, except that (subject to certain exceptions) we may not enter into any variable rate transaction, as such term is defined in the Purchase Agreement, including any transaction to effect any issuance of shares of our common stock or common stock equivalents with a floating conversion rate or variable purchase price, until the earlier of (a) the 36-month anniversary of the date of the Purchase Agreement and (b) the termination of the Purchase Agreement; provided, however, that, if we terminate the Purchase Agreement, we may not enter into an equity line or similar transaction for 12 months from the date of such termination.

# Effect of Performance of the Purchase Agreement on Our Stockholders

All shares registered in this offering which have been or may be issued or sold by us to Lincoln Park under the Purchase Agreement are expected to be freely tradable. Of the 6,380,126 total shares offered for sale by Lincoln Park under this prospectus 130,126 shares were issued by us to Lincoln Park under the Purchase Agreement on or before the date of this prospectus, and 6,250,000 shares may be sold, at our discretion, by us to Lincoln Park under the Purchase Agreement on or after the date of this prospectus and through May 19, 2023. The sale by Lincoln Park of a significant amount of the shares registered in this offering at any given time could cause the market price of our common stock to decline and to be highly volatile. Sales of our common stock to Lincoln Park, if any, will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Lincoln Park all, some or none of the shares of our common stock that may be available for us to sell pursuant to the Purchase Agreement. If and when we do sell shares to Lincoln Park, after Lincoln Park has acquired the shares, Lincoln Park may resell all, some or none of those shares at any time or from time to time in its discretion. Therefore, sales to Lincoln Park by us under the Purchase Agreement may result in substantial dilution to the interests of other holders of our common stock. In addition, if we sell a substantial number of shares to Lincoln Park under the Purchase Agreement, or if investors expect that we will do so, the actual sales of shares or the mere existence of our arrangement with Lincoln Park may make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect such sales. However, we have the right to control the timing and amount of any additional sales of our shares to Lincoln Park and the Purchase Agreement may be terminated by us at any time at our discretion without any additional cost to us.

Depending on the price per share at which we sell our common stock to Lincoln Park pursuant to the Purchase Agreement, we may need to sell more shares to Lincoln Park than are offered under this prospectus to receive aggregate gross proceeds equal to the approximately \$7.0 million balance of the \$15.0 million total commitment of Lincoln Park under the Purchase Agreement, which could cause additional substantial dilution to our stockholders. If we choose to sell more shares to Lincoln Park than are offered under this prospectus, we must first register for resale under the Securities Act such additional shares of our common stock. The number of shares ultimately offered for resale by Lincoln Park will depend upon the number of shares we elect to sell to Lincoln Park under the Purchase Agreement.

The Purchase Agreement prohibits us from issuing or selling to Lincoln Park (a) shares of our common stock in excess of the Exchange Cap (which is 4,941,089 shares, or 19.99% of the 24,705,453 shares of our common stock outstanding immediately prior to the execution of the Purchase Agreement), unless (i) we obtain stockholder approval to issue shares in excess of the Exchange Cap or (ii) the average price per share of all applicable sales of our common stock to Lincoln Park under the Purchase Agreement equals or exceeds \$1.0117, such that issuances and sales of our common stock to Lincoln Park under the Purchase Agreement would not be subject to the Exchange Cap under applicable Nasdaq rules, and (b) any shares of our common stock if those shares, when aggregated with all other shares of our common stock then beneficially owned by Lincoln Park and its affiliates, would exceed the Beneficial Ownership Cap.

Through the date of this prospectus, we have received approximately \$8.0 million in aggregate gross proceeds from our sale of shares to Lincoln Park under the Purchase Agreement. The average price per share of all such sales was in excess of \$1.0117. The following table sets forth the amount of gross proceeds we may receive from Lincoln Park from our sale of shares of our common stock to Lincoln Park at varying assumed average purchase prices per share on or after the date of this prospectus under the Purchase Agreement that are offered for sale by Lincoln Park under this prospectus:

Assumed Average Purchase Price Per Share	Number of Shares to be Issued if Full Purchase (1)	Percentage of Outstanding Shares After Giving Effect to Sales to Lincoln Park (2)	Proceeds from the Future Sale of Shares to Lincoln Park Under the Purchase Agreement (3)
\$1.00	6,250,000	13.1%	\$6,250,000
\$1.34 (4)	5,234,771	11.2%	\$7,014,593
\$2.00	3,507,297	7.8%	\$7,014,593
\$3.00	2,338,198	5.3%	\$7,014,593
\$4.00	1,753,648	4.0%	\$7,014,593

- (1) The number in this column takes into account that as of the date of this prospectus the remaining balance of the \$15.0 million total commitment of Lincoln Park under the Purchase Agreement is approximately \$7.0 million, but does not take into account the Beneficial Ownership Cap.
- (2) The numerator is the number of shares set forth in the adjacent column which we would have sold under the Purchase Agreement at the corresponding assumed average purchase price set forth in the adjacent column. The denominator is the sum of (a) 41,596,253 shares outstanding as of January 4, 2021 and (b) the number of shares set forth in the adjacent column which we would have sold under the Purchase Agreement at the corresponding assumed average purchase price set forth in the adjacent column.
- (3) Reflects the aggregate gross proceeds we would receive from the sale of the shares indicated in this table to Lincoln Park under the Purchase Agreement on or after the date of this prospectus, based on the corresponding assumed average purchase price per share indicated in this table.
- (4) The closing price of our common stock on December 31, 2020.

### **USE OF PROCEEDS**

This prospectus relates to shares of our common stock that may be offered and sold from time to time by Lincoln Park. See "Plan of Distribution" elsewhere in this prospectus for more information. We will not receive any proceeds from the sale of shares by Lincoln Park in this offering.

We may receive up to \$15.0 million in aggregate gross proceeds from sales of shares of our common stock we make to Lincoln Park pursuant to the Purchase Agreement. Through the date of this prospectus, we received approximately \$8.0 million in aggregate gross proceeds from sales of shares of our common stock we made to Lincoln Park pursuant to the Purchase Agreement, leaving an approximately \$7.0 million balance of the \$15.0 million total commitment of Lincoln Park under the Purchase Agreement. We may choose to sell fewer than \$15.0 million in shares of our common stock, or, due to the Exchange Cap and/or the Beneficial Ownership Cap, we may not be able to sell all \$15.0 million in shares of our common stock under the Purchase Agreement, in which case we would raise less than \$15.0 million in aggregate gross proceeds under the Purchase Agreement. We did not and will not receive any proceeds from the issuance of the Commitment Shares to Lincoln Park.

We will have broad discretion in the use of the net proceeds from any sale of shares of our common stock to Lincoln Park under the Purchase Agreement. We intend to use net proceeds from such sales for working capital and general corporate purposes, which include, but are not limited to, advancing our investigational product portfolio and general and administrative expenses. We have not determined the amount of net proceeds to be used specifically for such purposes. Pending the use of any net proceeds, we expect to invest the net proceeds in interest-bearing, marketable securities.

We will bear all of the costs, fees and expenses incurred in effecting the registration of the shares covered by this prospectus, including, without limitation, the registration and filing fees, printing fees, Nasdaq listing fees and fees and expenses of our counsel and our accountants.

#### SELLING STOCKHOLDER

This prospectus relates to the possible resale by the selling stockholder, Lincoln Park, of shares of our common stock that have been or may be issued to Lincoln Park pursuant to the Purchase Agreement. We are filing the registration statement of which this prospectus forms a part pursuant to the provisions of the Registration Rights Agreement, which we entered into with Lincoln Park on April 22, 2020 concurrently with our execution of the Purchase Agreement, in which we agreed to provide certain registration rights with respect to sales by Lincoln Park of the shares of our common stock that have been or may be issued to Lincoln Park under the Purchase Agreement.

Lincoln Park, as the selling stockholder, may, from time to time, offer and sell pursuant to this prospectus any or all of the shares that we have issued or may issue and sell to Lincoln Park under the Purchase Agreement. The selling stockholder may sell some, all or none of those shares. We do not know how long the selling stockholder will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the selling stockholder regarding its sale of any of the shares.

The following table presents information regarding the selling stockholder and the shares that it may offer and sell from time to time under this prospectus. The table is prepared based on information supplied to us by the selling stockholder and reflects its holdings as of January 4, 2021. Neither Lincoln Park nor any of its affiliates has held a position or office, or had any other material relationship, with us or any of our predecessors or affiliates. Beneficial ownership is determined in accordance with Section 13(d) of the Exchange Act and Rule 13d-3 thereunder.

Selling Stockholder	Shares Beneficially Owned Before	Percentage of Outstanding Shares Beneficially Owned Before	Shares to be Sold in this Offering Assuming the Company issues the Maximum Number of Shares Under the Purchase	Percentage of Outstanding Shares Beneficially Owned After
Selling Stockholder	this Offering	this Offering	Agreement	this Offering
Lincoln Park Capital Fund, LLC (1)	385,626 (2)	* (3)	6,380,126 (4)	* (5)

\*Less than 1%

- (1) Josh Scheinfeld and Jonathan Cope, the Managing Members of Lincoln Park Capital, LLC, the manager of Lincoln Park Capital Fund, LLC, are deemed to be beneficial owners of all of the shares of common stock owned by Lincoln Park Capital Fund, LLC. Messrs. Cope and Scheinfeld have shared voting and investment power over the shares being offered under this prospectus. Lincoln Park Capital, LLC is not a licensed broker dealer or an affiliate of a licensed broker dealer.
- (2) Includes 255,500 shares of our common stock issuable to Lincoln Park upon exercise of outstanding and exercisable warrants to purchase our common stock issued on February 15, 2018, which, as of January 4, 2021, have an exercise price of \$0.96 per share and expire on February 15, 2023, which we refer to as the February 2018 Warrants. We have excluded from the number of shares beneficially owned by Lincoln Park prior to the offering all of the shares of common stock that Lincoln Park may be required to purchase on or after the date of this prospectus pursuant to the Purchase Agreement, because the issuance of such shares is solely at our discretion and is subject to certain conditions, the satisfaction of all of which are outside of Lincoln Park's control, including the registration statement of which this prospectus is a part becoming and remaining effective. Furthermore, under the terms of the Purchase Agreement, issuances and sales of shares of our common stock to Lincoln Park are subject to certain limitations on the amounts we may sell to Lincoln Park at any time, including the Exchange Cap and the Beneficial Ownership Cap. See the description under the heading "Our Agreements with Lincoln Park" for more information about the Purchase Agreement.
- (3) Calculated by dividing (a) the shares in the adjacent column titled "Shares Beneficially Owned Before this Offering," by (b) the sum of (i) the 41,596,253 shares of our common stock outstanding as of January 4, 2021 and (ii) the 255,500 shares of our common stock issuable to Lincoln Park upon exercise of the February 2018 Warrants. Although we may at our discretion elect to sell to Lincoln Park up to an aggregate amount of an additional approximately \$7.0 million of our common stock under the Purchase Agreement, such shares are not included in determining the percentage of shares beneficially owned before this offering.

- (4) Assumes issuance of the maximum 6,250,000 shares that are offered for sale by Lincoln Park under this prospectus that are not outstanding as of the date of this prospectus. The Purchase Agreement provides that we may sell up to \$15.0 million in shares of our common stock to Lincoln Park. Through the date of this prospectus we have sold approximately \$8.0 million in shares of our common stock to Lincoln Park under the Purchase Agreement. Depending on the price per share at which we sell our common stock to Lincoln Park on or after the date of this prospectus pursuant to the Purchase Agreement, we may need to sell to Lincoln Park under the Purchase Agreement more shares of our common stock than are offered under this prospectus to receive aggregate gross proceeds equal to the \$15.0 million total commitment of Lincoln Park under the Purchase Agreement. If we choose to do so, we must first register for resale under the Securities Act such additional shares. The number of shares ultimately offered for resale by Lincoln Park will depend upon the number of shares we elect to sell to Lincoln Park under the Purchase Agreement.
- (5) Assumes the sale by Lincoln Park of all 6,380,126 shares of our common stock offered for sale by Lincoln Park under this prospectus, although Lincoln Park is under no obligation to sell any shares of common stock at this time. Calculated by dividing (a) the 255,500 shares of our common stock issuable to Lincoln Park upon exercise of the February 2018 Warrants, by (b) the sum of (i) the 41,596,253 shares of common stock outstanding as of January 4, 2021, which includes 7,214,286 shares issued and/or sold to Lincoln Park under the Purchase Agreement through such date, (ii) the 6,250,000 shares which we may sell to Lincoln Park on or after the date of this prospectus under the Purchase Agreement that Lincoln Park may offer and sell under this prospectus and (iii) the 255,500 shares of our common stock issuable to Lincoln Park upon exercise of the February 2018 Warrants.

# DILUTION

Our sale of shares of our common stock to Lincoln Park under the Purchase Agreement will have a dilutive impact on our stockholders. In addition, the lower our stock price is at the time we elect to sell shares to Lincoln Park under the Purchase Agreement, the more shares we will have to issue to Lincoln Park to achieve the same gross proceeds amount, in which case our existing stockholders would experience greater dilution.

Our net tangible book value as of September 30, 2020 was approximately \$(1,385,888), or \$(0.0412) per share of common stock. Net tangible book value per share is determined by dividing our total tangible assets, excluding goodwill and intangible assets, less total liabilities, by the number of shares of our common stock outstanding as of September 30, 2020.

Through the date of this prospectus, we have sold approximately \$8.0 million of our common stock to Lincoln Park under the Purchase Agreement, leaving an approximately \$7.0 million balance of the \$15.0 million total commitment of Lincoln Park under the Purchase Agreement. Assuming a purchase price of \$1.34 per share (which was the closing price of our common stock on December 31, 2020), we would need to sell 5,234,771 shares of common stock to Lincoln Park on or after the date of this prospectus under the Purchase Agreement to exhaust such approximately \$7.0 million balance. After giving effect to the sale and issuance of such 5,234,771 shares of common stock to Lincoln Park under the Purchase Agreement at an assumed average sale price of \$1.34 per share of common stock, our as adjusted net tangible book value as of September 30, 2020 would have been approximately \$5,597,790, or \$0.1441 per share. This represents an immediate increase in net tangible book value of \$0.1854 per share to existing stockholders.

Purchasers of our common stock in this offering will experience an immediate dilution of the net tangible book value per share of our common stock. Dilution in net tangible book value per share represents the difference between the amount per share paid by purchasers of common stock in this offering, assuming a purchase price of \$1.34 per share of common stock (which was the closing price of our common stock on December 31, 2020), and our as adjusted net tangible book value per share after giving effect to this offering.

Assumed offering price per share of common stock		\$ 1.34
Net tangible book value per share as of September 30, 2020	\$ (0.0412)	
Increase in net tangible book value per share attributable to this offering	\$ 0.1854	
As adjusted net tangible book value per share after giving effect to this offering		\$ 0.1441
Dilution per share to new investors		\$ 1.1959

The number of shares of our common stock to be outstanding as shown above is based on 33,602,516 shares outstanding as of September 30, 2020, and excludes:

• 1,908,643 shares of common stock issuable upon exercise of warrants outstanding as of September 30, 2020, having a weighted average exercise price of \$1.41 per share;

- 2,783,591 shares of common stock issuable upon exercise of stock options outstanding as of September 30, 2020, having a weighted average exercise price of \$1.16 per share;
- 507,516 shares of common stock reserved for future issuance under our Amended and Restated 2014 Stock Incentive Plan as of September 30, 2020;
- 4,661,611 shares of common stock issued after September 30, 2020 pursuant to our "at the market" offering program; and
- 3,332,126 shares of common stock we sold to Lincoln Park under the Purchase Agreement after September 30, 2020 and through the date of this prospectus.

To the extent that outstanding options or warrants have been or may be exercised, the exercise price of the February 2018 Warrants is adjusted downward in accordance with the price-based anti-dilution provisions of such warrants, new equity awards were are or issued, shares of our common stock are sold under our employee stock purchase plan, or we otherwise issued or issue additional shares of common stock, including to Lincoln Park under the Purchase Agreement and in our "at the market" offering program through H.C. Wainwright & Co., LLC, investors purchasing our common stock in this offering may experience further dilution.

# PLAN OF DISTRIBUTION

The common stock offered by this prospectus is being offered by the selling stockholder, Lincoln Park. The common stock may be sold or distributed from time to time by the selling stockholder directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the common stock offered by this prospectus could be effected in one or more of the following methods:

- · ordinary brokers' transactions;
- transactions involving cross or block trades;
- through brokers, dealers, or underwriters who may act solely as agents;
- "at the market" into an existing market for the common stock;

 in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;

- in privately negotiated transactions; or
- any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the state's registration or qualification requirement is available and complied with.

Lincoln Park is an "underwriter" within the meaning of Section 2(a)(11) of the Securities Act.

Lincoln Park has informed us that it intends to use an unaffiliated broker-dealer to effectuate all sales, if any, of the common stock that it may purchase from us pursuant to the Purchase Agreement. Such sales will be made at prices and at terms then prevailing or at prices related to the then current market price. Each such unaffiliated broker-dealer will be an underwriter within the meaning of Section 2(a)(11) of the Securities Act. Lincoln Park has informed us that each such broker-dealer will receive commissions from Lincoln Park that will not exceed customary brokerage commissions.

Brokers, dealers, underwriters or agents participating in the distribution of the shares as agents may receive compensation in the form of commissions, discounts, or concessions from the selling stockholder and/or purchasers of the common stock for whom the broker-dealers may act as agent. The compensation paid to a particular broker-dealer may be less than or in excess of customary commissions. Neither we nor Lincoln Park can presently estimate the amount of compensation that any agent will receive.

We know of no existing arrangements between Lincoln Park or any other stockholder, broker, dealer, underwriter or agent relating to the sale or distribution of the shares offered by this prospectus. At the time a particular offer of shares is made, a prospectus supplement, if required, will be distributed that will set forth the names of any agents, underwriters or dealers and any compensation from the selling stockholder, and any other required information.

We will pay the expenses incident to the registration, offering, and sale of the shares to Lincoln Park. We have agreed to indemnify Lincoln Park and certain other persons against certain liabilities in connection with the offering of shares of common stock offered hereby, including liabilities arising under the Securities Act or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities. Lincoln Park has agreed to indemnify us against liabilities under the Securities Act that may arise from certain written information furnished to us by Lincoln Park specifically for use in this prospectus or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities.

Lincoln Park has represented to us that at no time prior to the Purchase Agreement has Lincoln Park or its agents, representatives or affiliates engaged in or effected, in any manner whatsoever, directly or indirectly, any short sale (as such term is defined in Rule 200 of Regulation SHO of the Exchange Act) of our common stock or any hedging transaction, which establishes a net short position with respect to our common stock. Lincoln Park agreed that during the term of the Purchase Agreement, it, its agents, representatives or affiliates will not enter into or effect, directly or indirectly, any of the foregoing transactions.

We have advised Lincoln Park that it is required to comply with Regulation M promulgated under the Exchange Act. With certain exceptions, Regulation M precludes the selling stockholder, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the securities offered by this prospectus.

This offering will terminate on the earlier of (i) termination of the Purchase Agreement or (ii) the date that all shares offered by this prospectus have been sold by Lincoln Park.

# EXECUTIVE AND DIRECTOR COMPENSATION

#### **Executive Compensation**

#### Overview

The compensation committee of our board of directors assists our board in discharging its responsibilities in respect of compensation of our executive officers. The compensation committee is currently comprised of three non-employee members of our board, Cheryl R. Blanchard, Ph.D., William H. Rastetter, Ph.D. and Robin J. Steele, J.D., L.L.M.

Executive compensation is intended to attract and retain qualified executive officers and to align the interests of our executive officers with those of our stockholders by incentivizing and rewarding achievement of business objectives that we believe will enhance our value and by promoting commitment to long-term success. As a clinical-stage biopharmaceutical company, these objectives are to be accomplished primarily by positioning us to successfully execute our drug product development and regulatory approval efforts and to translate those efforts, over time, into revenues and income from commercialization of, or strategic collaborations with respect to, our product candidates.

Our current executive compensation program primarily includes (1) base salary, (2) annual performance-based incentive compensation, and (3) long-term incentive compensation in the form of stock options with the goal of aligning the long-term interests of executive officers with those of our stockholders and otherwise encouraging the achievement of superior results over an extended time period.

With respect to the compensation of our Chief Executive Officer, the compensation committee annually reviews and recommends to our board corporate objectives relevant to compensation, evaluates performance in light of those objectives, and recommends to our board compensation levels based on this evaluation. Our Chief Executive Officer may not be present during any deliberations or voting with respect to her compensation. The compensation committee annually reviews and approves the compensation of our other executive officers.

With respect to our executive officer compensation program, the compensation committee also: (1) reviews competitive practices and trends to determine the adequacy of our executive compensation program; (2) reviews and considers participation and eligibility in the various components of our total executive compensation package; and (3) as deemed necessary or appropriate, approves employment contracts, severance arrangements, change in control provisions and other agreements.

We have a formal policy for the timing of granting annual equity awards to our existing employees, including our named executive officers, to provide for a consistent process and to ensure the integrity and efficiency of the company's award process. Under this policy, annual equity awards will be granted on the date of the compensation committee's first regularly scheduled meeting held each year, subject to the compensation committee's ability to change the annual grant date for any particular year if the compensation committee determines that granting annual awards on such date would not be in the company's best interest.

The table below shows the compensation awarded to or paid to, or earned by our named executive officers for the years ended December 31, 2020 and 2019. Mr. Fair was not a named executive officer for the year ended December 31, 2019, and therefore information in the table below is provided only with respect to his compensation for the year ended December 31, 2020.

2020 Summary Compensation Table										
Name and Principal Position	Fiscal YearSalary (\$)Bonus (\$)Option Awards (\$)Non-equity incentive plan compensationAll Other CompensationYear(\$)(\$)(1)(\$) (2)(\$) (3)								Total (\$)	
						•				
Sabrina Martucci Johnson	2020	\$368,225	\$	—	\$272,845	\$		\$	13,241	\$ 654,311
President and Chief Executive Officer	2019	\$334,750	\$	_	\$ 140,534	\$	142,269	\$	11,200	\$628,753
Lisa Walters-Hoffert	2020	\$294,580	\$	_	\$ 66,262	\$		\$	12,952	\$373,794
Chief Financial Officer	2019	\$267,800	\$		\$ 54,051	\$	79,671	\$	11,200	\$412,722
John Fair	2020	\$294,580	\$	_	\$ 66,262	\$		\$	7,320	\$368,162
Chief Strategy Officer										

(1) The amounts in this column represent the grant date fair value, determined in accordance with ASC Topic 718, Compensation-Stock Compensation (ASC Topic 718), of stock options granted to the applicable individual. With respect to the stock options granted during 2019, see Note 8. Stock-Based Compensation to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 27, 2020 for details as to the assumptions used to determine the fair value of the awards. With respect to the stock options granted during 2020, the following assumptions were used to determine the fair value of the awards:

Expected life in years	10.0
Risk-free interest rate	0.82 %
Expected volatility	120 %
Forfeiture rate	_
Dividend yield	— %
Weighted-average fair value of options granted	\$ 1.00

- (2) Amounts represent performance bonuses earned for the years indicated. As of the date of this prospectus, the bonus earned by our named executive officers for 2020 have not yet been determined. Such bonuses are expected to be determined by the end of March 2021 and will be based on our company's achievement, as determined by the compensation committee and/or our board of directors, of performance objectives. The target bonus amounts for Ms. Johnson, Ms. Walters-Hoffert and Mr. Fair will be up to 50%, 35% and 35%, respectively, of their respective 2020 annual base salary, and the compensation committee will have the sole discretion to apply a weighting of 0 to 150% against the target bonus percentage.
- (3) Amount reflects a company 401(k) match. We provide the named executive officers with health, medical and other non-cash benefits generally available to all employees, which are not included in these columns pursuant to SEC rules.

# Narrative to Summary Compensation Table

As reflected in the table above, the 2020 compensation of our named executive officers consisted of three primary components: (1) base salary; (2) equity compensation in the form of stock options; and (3) performance-based cash compensation. As noted in the table above, the amount of the performance-based cash compensation for 2020 has not yet been determined.

*Base Salary*. The 2020 annual base salary of our named executive officers was \$368,225 for Ms. Ms. Johnson, \$294,580 for Ms. Walters-Hoffert, and \$294,580 for Mr. Fair.

Option Awards. Our named executive officers were each granted a stock option during 2020. Stock options are a key tool in our payfor-performance philosophy and align the interests of our employees, including our named executive officers, with our stockholders' interests. Stock options are inherently performance-based, and automatically link executive pay to stockholder return, as the value realized, if any, by the recipient from a stock option depends upon, and directly proportionate to, the appreciation in our stock price. In preparation for making 2020 executive officer compensation decisions, the compensation committee evaluated the appropriate form of long-term incentive compensation and determined to use stock options as the primary incentive for long-term compensation in part because of the foregoing reasons.

# Employment Agreements and Termination of Employment & Change in Control Arrangements

We have written agreements with each of Ms. Johnson, Ms. Walters-Hoffert and Mr. Fair governing the terms of their employment with us. The following is a summary of the material terms of such agreements, as amended to date, necessary to an understanding of the information disclosed in the summary compensation table.

Each executive is eligible to receive an annual base salary, which may be adjusted at the discretion of our board.

In our sole discretion, Ms. Johnson and Ms. Walters-Hoffert are each eligible to receive an annual bonus in an amount equal to up to 50% and 35%, respectively, of each their respective then-current annual base salary. Under the terms of his agreement, Mr. Fair's annual bonus was initially targeted at 30% of his base salary, which was increased to 35% in 2020. The amount of their annual bonus, if any, will be based on the applicable executive's performance and our company's performance as measured against performance objectives and determined by the compensation committee and/or our board of directors.

Each executive is entitled to (1) participate in all equity, pension, savings and retirement plans, welfare and insurance plans, practices, policies, programs and perquisites of employment applicable generally to our senior executives, (2) receive reimbursement for reasonably incurred business expenses and (3) receive paid vacation and holiday time in accordance with policies generally applicable to our senior executives.

Subject to earlier termination, including in the event of death, the employment agreement with each of Ms. Johnson and Ms. Walters-Hoffert is for a two-year term and automatically renews for successive one-year terms unless either party provides notice of her intent not to renew at least 60 days prior to the applicable expiration date. Ms. Johnson and Ms. Walters-Hoffert may terminate her respective employment for good reason after giving us 14 days to correct or "cure" the circumstances giving rise to a termination for good reason, or for any reason other than for good reason a upon at least 14 days' prior written notice. We may terminate the employment of Ms. Johnson and Ms. Walters-Hoffert without prior written notice for cause, without cause on 14 days' prior written notice, or in the event of the executive's disability. Their employment agreement automatically terminates upon the executive's death. Our agreement with Mr. Fair is "at will," meaning that either he or we may terminate his employment at any time and for any reason, with or without cause.

The following table summarizes our obligations and the payments and other benefits to which Ms. Johnson and Ms. Walters-Hoffert may be entitled if her employment is terminated for the reason specified, other than in connection with a change of control, which is discussed in the paragraph below the table.

Reason for Termination	Accrued Obligations <sup>(1)</sup>	Cash Payments <sup>(2)</sup>	Other Benefits <sup>(2)</sup>
By us for cause. By the executive without good reason. Executive's death or disability. Executive elects not to renew agreement.	We must pay the executive any accrued obligations as of the date of termination	None.	None.
By us other than for cause. By the executive with good reason. We elect not to renew agreement.	We must pay the executive any accrued obligations as of the date of termination	We must pay the executive: <sup>(1)</sup> any accrued but unpaid bonus (or a pro rata portion of such bonus) as of the date of termination; and <sup>(2)</sup> an amount equal to a specified number of months of the executive's then-current base salary. <sup>(3)</sup>	We must provide the executive continuing health benefits coverage for a specified number of months. <sup>(3)</sup>

- (1) Consists of any earned but unpaid base salary, unpaid expense reimbursements, and any vested benefits the executive may have under any employee benefit plan, in each case, as of the date of termination.
- (2) Payment and benefits are conditioned on (a) the executive's continued compliance with her obligations under the employment agreement related to confidentiality and non-interference and intellectual property covenants and (b) the executive (or her estate) executing and delivering a full release of all claims in favor of Daré.
- (3) The number of months is 12 for Ms. Johnson and 9 for Ms. Walters-Hoffert.

Under the terms of our employment agreements with Ms. Johnson and Ms. Walters-Hoffert, if their respective employment is terminated by us without cause or by the executive for good reason, in each case, within three months prior to or 12 months following a change of control, then, subject to the applicable executive's continued compliance with customary confidentiality, intellectual property assignment and similar obligations to us, and subject to the delivery of a full release of claims in our favor by the executive, (1) the executive is eligible to receive an amount equal to a specified number of months (18 for Ms. Johnson and 12 for Ms. Walters-Hoffert) of the executive's then-current base salary and target bonus at the rate in effect immediately prior to such termination, (2) the executive will receive continuing health benefits coverage for a specified number of months (18 for Ms. Johnson and 12 for Ms. Walters-Hoffert) and (3) any unvested and outstanding equity interests such executive may have in Daré will fully vest and accelerate.

Under the terms of our change in control policy in which our employees at vice president and above are eligible to participate, if the employment of an employee covered by such policy is terminated by us without cause or if such employee resigns for good reason, in either case, within 90 days before, or 365 days following, the effective date of a change in control, then, subject to the applicable employee's continued compliance with customary confidentiality, intellectual property assignment and similar obligations to us, and subject to the delivery of a full release of claims in our favor by such employee, the vesting of all of such employee's equity awards then outstanding that are subject solely to time-based vesting conditions that have not been satisfied will be accelerated in full. The vesting of any equity award that is subject only to performance-based vesting condition(s) or to both performance-based vesting condition(s) and time-based vesting condition(s), will not be accelerated unless such performance-based vesting condition(s) have been satisfied as of the effective date of the termination of employment or, in the case of a termination that occurs before a change in control, as of the effective date of the change in control. Mr. Fair is covered by our change in control policy, however, neither Ms. Johnson nor Ms. Walters-Hoffert are so covered.

All payments made and benefits available to each executive in connection with their employment agreement and under our change in control policy will comply with Internal Revenue Code Section 409A in accordance with the terms of such documents.

# Other Benefits

We maintain a defined contribution employee retirement plan for all our employees. Our 401(k) plan is intended to qualify as a taxqualified plan under Section 401 of the Internal Revenue Code so that contributions to our 401(k) plan, and income earned on such contributions, are not taxable to participants until withdrawn or distributed from the 401(k) plan. If a participant contributes 5% or more of their compensation, we match their contribution up to 4% of their annual compensation, subject to statutory limits.

We currently do not have any annuity, pension or deferred compensation plan or other arrangements for our executive officers or any employees.

# **Outstanding Equity Awards at Fiscal Year-End**

The following table sets forth information concerning equity awards held by our named executive officers that were outstanding as of December 31, 2020:

#### 2020 Outstanding Equity Awards at Fiscal Year-End Option Awards

Name	Date of Grant	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price (\$)	Option Expiration Date
Sabrina Martucci Johnson	9/7/2018	108,000	84,000	\$ 1.01	9/7/2028
	1/29/2019	93,437	101,563	\$ 0.759	1/29/2029
	3/6/2020	52,500	227,500	\$ 1.03	3/6/2030
Lisa Walters-Hoffert	9/7/2018	56,250	43,750	\$ 1.01	9/7/2028
	1/29/2019	35,937	39,063	\$ 0.759	1/29/2029
	3/6/2020	12,750	55,250	\$ 1.03	3/6/2030
John Fair	9/7/2018	84,375	65,625	\$ 1.01	9/7/2028
	1/29/2019	35,937	39,063	\$ 0.759	1/29/2029
	3/6/2020	12,750	55,250	\$ 1.03	3/6/2030

# **Director Compensation**

With the assistance of the compensation committee, our board of directors periodically reviews and evaluates our non-employee director compensation policy. The following is an overview of our non-employee director compensation policy during 2020, which was designed to allow us to recruit and retain individuals with the requisite experience, skills and characteristics for membership on our board of directors, and to align the interests of our directors with those of our stockholders through the grant of stock options.

Retainers. Each of our non-employee directors was paid a retainer for service on our board and for each board committee on which the director served as shown in the table below. Retainers are paid in cash in arrears in four equal quarterly installments, prorated to reflect the actual time served by the director during such quarter. Directors may elect to receive up to 100% of their retainer in the form of awards of unrestricted shares of our common stock. If so elected, on the first trading day of the quarter following the quarter to which the retainer relates, we would issue a number of shares of common stock equal to (x) the amount of the cash retainer that would otherwise have been payable to such director on the date of grant divided by (y) the fair market value of our common stock on the date of grant. Directors wishing to make this election for a given calendar year must make the election on or before the last day of the prior calendar year, except that the election with respect to any year in which a director is newly elected must be made on or before June 30th of such year or such other date as determined by our board.

	Annual Retainer (\$)
Board of Directors	
Chair	65,000
Member	35,000
Board Committees	
Audit Chair	20,000
Audit Member	7,500
Compensation Chair	15,000
Compensation Member	5,000
Nominating and Corporate Governance Chair	10,000
Nominating and Corporate Governance Member	3,500

Equity Awards.

Initial Award. Each director newly elected to our board receives an option to purchase 45,000 shares of our common stock, which vests as to 15,000 shares on each anniversary of the grant date until the third anniversary of the grant date, subject to the director's continued service as a director, and will become exercisable in full upon a change in control.

Annual Award. On the date of each annual meeting of stockholders, each director that has served on our board for at least six months (and, if up for election at such annual meeting, is elected at such annual meeting) receives an option to purchase 22,500 shares of our common stock, which will vest in full on the earlier of the first anniversary of the grant date or immediately prior to our first annual meeting of stockholders occurring after the grant date, subject to the director's continued service as a director, and will become exercisable in full upon a change in control.

The exercise price of each option granted under our non-employee director compensation policy is set at the fair market value of our common stock on the grant date.

*Expense Reimbursement.* We reimburse our non-employee directors for reasonable travel and other expenses incurred in connection with attending board and committee meetings.

# 2020 Director Compensation

The following table sets forth the compensation of our non-employee directors during 2020.

2020 Director Compensation									
Name		Total							
Cheryl R. Blanchard, Ph.D.	\$	39,629	\$	21,806	\$	_	\$	61,435	
Jessica D. Grossman, M.D.	\$	46,000	\$	21,806	\$	_	\$	67,806	
Susan L. Kelley, M.D.	\$	45,000	\$	21,806	\$	_	\$	66,806	
Gregory W. Matz, CPA	\$	55,000	\$	21,806	\$	_	\$	76,806	
William H. Rastetter, Ph.D.	\$	80,000	\$	21,806	\$	_	\$	101,806	
Robin J. Steele	\$	47,500	\$	21,806	\$		\$	69,306	

(1) The amounts in this column represent the grant date fair value, determined in accordance with ASC Topic 718, Compensation-Stock Compensation (ASC Topic 718), of stock options granted to the applicable individual. See Footnote 1 to the 2020 Summary Compensation Table for our named executive officers under the section entitled "—Executive Compensation," above, for the assumptions used to determine the fair value of these awards.

As of December 31, 2020, our non-employee directors had stock options outstanding to purchase the following number of shares of our common stock:

Name	# of Shares Subject to Outstanding Options
Cheryl R. Blanchard, Ph.D.	67,500
Jessica D. Grossman, M.D.	90,000
Susan L. Kelley, M.D.	97,300
Gregory W. Matz, CPA	90,000
William H. Rastetter, Ph.D.	97,301
Robin Steele, J.D.,L.L.M.	92,200

# LEGAL MATTERS

Breakwater Law Group, LLP, Solana Beach, California, will pass upon the validity of the common stock being offered by this prospectus.

# EXPERTS

Mayer Hoffman McCann P.C., an independent registered public accounting firm, has audited our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2019, as set forth in its report, which is incorporated by reference in this prospectus and the registration statement. Our financial statements are incorporated by reference in reliance on Mayer Hoffman McCann P.C.'s report, given on the authority of said firm as experts in accounting and auditing.

# WHERE YOU CAN FIND MORE INFORMATION

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers, such as our company, that file documents electronically with the SEC. Our SEC filings are available to the public at the SEC's website address at http://www.sec.gov. The information on the SEC's website is not part of this prospectus, and any references to the SEC's website or any other website are inactive textual references only. We also maintain a website at www.darebioscience.com, through which you can access our SEC filings. The information set forth on our website is not part of this prospectus.

This prospectus is only part of a registration statement on Form S-1 that we have filed with the SEC. This prospectus omits some information contained in the registration statement in accordance with SEC rules and regulations. You should review the information in and schedules and/or exhibits to the registration statement for further information about us and the securities being offered pursuant to this prospectus. Statements in this prospectus concerning any document we filed as an exhibit or schedule to the registration statement or that we otherwise filed with the SEC are not intended to be comprehensive and are qualified by reference to these filings. You should review the complete document to evaluate these statements.

#### **INCORPORATION OF DOCUMENTS BY REFERENCE**

The SEC allows us to "incorporate by reference" into this prospectus much of the information that we file with the SEC, which means that we can disclose important information to you by referring you to those publicly available documents. The information that we incorporate by reference into this prospectus is an important part of this prospectus. This prospectus incorporates by reference the documents listed below and any future filings we make with the SEC pursuant to Sections 13(a), 13,(c), 14 or 15(d) of the Exchange Act after the effective date of the registration statement of which this prospectus is a part and prior to the termination or completion of this offering, other than information furnished to, rather than filed with the SEC:

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on March 27, 2020 (the "Annual Report"), including all material incorporated by reference therein, which includes the portions of our definitive proxy statement on Schedule 14A filed with the SEC on April 22, 2020 incorporated by reference into Part III of the Annual Report;
- our Quarterly Reports on Form 10-Q for each of the three months ended March 31, 2020, June 30, 2020 and September 30, 2020, filed with the SEC on May 14, 2020, August 12, 2020 and November 12, 2020, respectively;
- our Current Reports on Form 8-K and on Form 8-K/A filed with the SEC on January 9, 2020, January 13, 2020, January 30, 2020, February 5, 2020, February 6, 2020, February 10, 2020, March 16, 2020, April 23, 2020, April 27, 2020, June 3, 2020, June 8, 2020, June 26, 2020, September 9, 2020, October 6, 2020, November 18, 2020, December 7, 2020 and December 9, 2020 (except for the information furnished under Items 2.02 or 7.01 and the exhibits furnished thereto); and
- the description of our common stock contained in our Registration Statement on Form 8-A filed on April 4, 2014, including any amendments thereto or reports filed for the purpose of updating such description, including the description of our common stock in Exhibit 4.6 of the Annual Report.

The SEC file number for each of the documents listed above is 001-36395.

Any statement contained in this prospectus or in a document incorporated or deemed to be incorporated by reference into this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

We will provide to each person, including any beneficial owner, to whom this prospectus is delivered, upon written or oral request and at no cost to the requester, a copy of any or all reports or documents that are incorporated by reference into this prospectus, but not delivered with the prospectus. Such written or oral requests should be directed to:

Daré Bioscience, Inc. 3655 Nobel Drive, Suite 260 San Diego, CA 92122 Attn: Chief Financial Officer Telephone: (858) 926-7655

You may also access these incorporated reports and other documents on our website, www.darebioscience.com. The information contained on, or that can be accessed through, our website is not a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

You should rely only on information contained in, or incorporated by reference into, this prospectus and any related prospectus supplement. We have not authorized anyone to provide you with information different from that contained in this prospectus or incorporated by reference in this prospectus. We are not making offers to sell the securities in any jurisdiction in which such an offer or solicitation is not authorized or in which the person making such offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make such offer or solicitation.



6,380,126 Shares of Common Stock

# PROSPECTUS

January 7, 2021