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92122 Cerulean Pharma Inc. 20090714 Tempo Pharmaceuticals Inc 20070604 S-1 1 forms-1.htm Â As filed with the
Securities and Exchange Commission on November 15, 2024 Â Registration No. 333- _____ Â Â Â UNITED
STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549 Â Â Â FORM S-1 REGISTRATION
STATEMENT UNDER THE SECURITIES ACT OF 1933 Â Â Â DarÂ© Bioscience, Inc. (Exact name of registrant as
specified in its charter) Â Delaware Â 2834 Â 20-4139823 (State or other jurisdiction of Â (Primary Standard
Industrial Â (I.R.S. Employer incorporation or organization) Â Classification Code Number) Â Identification No.) Â
3655 Nobel Drive, Suite 260 San Diego, California 92122 (858) 926-7655 (Address, including zip code, and telephone
number, including area code, of registrantâ™s principal executive offices) Â Â Â Sabrina Martucci Johnson Chief
Executive Officer DarÂ© Bioscience, Inc. 3655 Nobel Drive, Suite 260 San Diego, California 92122 (858) 926-7655
(Name, address, including zip code, and telephone number, including area code, of agent for service) Â Â Â Copies to:
Â Edwin Astudillo, Esq. Sheppard, Mullin, Richter & Hampton LLP 12275 El Camino Real, Suite 100 San Diego,
California 92130 (858) 720-8953 Â Â Â Approximate date of commencement of proposed sale to the public: As soon as
practicable after this registration statement becomes effective. Â If any of the securities being registered on this Form
are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the
following box: â˜' Â If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under
the Securities Act, please check the following box and list the Securities Act registration statement number of the
earlier effective registration statement for the same offering. â˜ Â If this Form is a post-effective amendment filed
pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration
statement number of the earlier effective registration statement for the same offering. â˜ Â If this Form is a post-
effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the
Securities Act registration statement number of the earlier effective registration statement for the same offering. â˜ Â
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer,
smaller reporting company, or an emerging growth company. See the definitions of âœlarge accelerated filer,âœ
âœaccelerated filer,âœ âœsmaller reporting companyâœ and âœemerging growth companyâœ in Rule 12b-2 of the
Exchange Act. Â Large accelerated filer â˜ Â Accelerated filer â˜ Â Non-accelerated filer â˜ Â Smaller reporting
company â˜ Â Emerging growth company â˜ Â If an emerging growth company, indicate by check mark if the
registrant has elected not to use the extended transition period for complying with any new or revised financial
accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. â˜ Â THE REGISTRANT HEREBY
AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS
EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT THAT SPECIFICALLY STATES
THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH
SECTION 8(a) OF THE SECURITIES ACT OF 1933, AS AMENDED, OR UNTIL THE REGISTRATION STATEMENT
SHALL BECOME EFFECTIVE ON SUCH DATE AS THE SECURITIES AND EXCHANGE COMMISSION, ACTING
PURSUANT TO SAID SECTION 8(a), MAY DETERMINE. Â Â Â Â Â The information in this prospectus is not
complete and may be changed. These securities may not be sold until the registration statement of which this
prospectus forms a part filed with the Securities and Exchange Commission is effective. This preliminary prospectus is
not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or
sale is not permitted. Â SUBJECT TO COMPLETION, DATED NOVEMBER 15, 2024 Â PROSPECTUS Â DarÂ©
Bioscience, Inc. Â 2,750,000 Shares of Common Stock Â This prospectus relates to the resale, from time to time, of
up to 2,750,000 shares of our common stock, par value \$0.0001, by Lincoln Park Capital Fund, LLC, or Lincoln Park or
the selling stockholder. Â The shares of common stock to which this prospectus relates are shares that have been or
may be issued to Lincoln Park pursuant to the purchase agreement dated October 21, 2024 that we entered into with
Lincoln Park, which we refer to in this prospectus as the Purchase Agreement. See âœOur Agreements with Lincoln
Parkâœ for a description of that agreement and âœSelling Stockholderâœ 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. Â 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. Â 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 âœPlan of Distributionâœ 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 âœunderwriterâœ within the meaning of Section 2(a)(11) of the Securities Act of 1933, as
amended. Â 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. Â Our common stock is listed on The Nasdaq Capital Market under the
symbol âœDARE.âœ On November 14, 2024, the last reported sale price of our common stock was \$3.57 per share. Â
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 âœRisk Factorsâœ beginning on page 8 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. Â 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. Â The date of this prospectus is
Â , 2024 Â Â Â TABLE OF CONTENTS Â About This Prospectus 1 Prospectus
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You Can Find More Information 27 Incorporation of Documents by Reference 27 Â Â Â ABOUT THIS PROSPECTUS
Â 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 described herein, 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 the
offering of the securities described herein, the information and documents incorporated herein by reference and the
additional information under the heading âœWhere You Can Find More Informationâœ 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 the offering of the securities described herein. 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. If anyone provides you with different or inconsistent information, you should not rely on it. You should assume that the information in this prospectus, or any related prospectus supplement or free writing prospectus, is accurate only as of the date set forth on the cover page of any such document or any earlier date as of which such information is given, as applicable, and that any information we have incorporated herein by reference is accurate only as of the date set forth on the cover page of any such document containing such information or any earlier date as of which such information is given, as applicable, regardless of the time of delivery of this prospectus, or such prospectus supplement or free writing prospectus, or any sale of a security. Our business, financial condition, results of operations and prospects may have changed since that date. Â 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. Â The representations, warranties and covenants made by us in any agreement that is filed as an exhibit to the registration statement of which this prospectus forms a part or 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. Â 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." Â 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. Â Unless the context otherwise requires, "DarÃ©, " "DarÃ© Bioscience, " "the Company, " "we, " "us, " "our" and similar terms refer to DarÃ© Bioscience, Inc. and its subsidiaries. Â 1 Â Â Â PROSPECTUS SUMMARY Â 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. Investing in our securities involves a high degree of risk and uncertainty. Therefore, carefully consider the risk factors described in this prospectus, including those incorporated herein by reference to our most recent annual and quarterly filings with the SEC, before purchasing our securities. Each of the risk factors could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our securities. Â About DarÃ© Bioscience Â We are a biopharmaceutical company committed to advancing innovative products for womenâ€™s health. We are driven by a mission to identify, develop and bring to market a diverse portfolio of differentiated therapies that prioritize womenâ€™s health and well-being, expand treatment options, and improve outcomes, primarily in the areas of contraception, sexual health, pelvic pain, fertility, infectious disease and menopause. 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 or regulatory approval, and to establish and leverage strategic collaborations to achieve commercialization. We and our wholly-owned subsidiaries operate in one business segment. Â The first product approved by the United States Food and Drug Administration, or FDA, to emerge from our portfolio of womenâ€™s health product candidates is Xaciato, (clindamycin phosphate) vaginal gel 2%, or Xaciato (pronounced zah-she-AH-toe). We achieved FDA approval of Xaciato three years after acquiring rights to the program. Xaciato was approved by the FDA in December 2021 as a single-dose prescription medication for the treatment of bacterial vaginosis in females 12 years of age and older. In March 2022, we entered into an agreement with an affiliate of Organon & Co., Organon International GmbH, or Organon, which became fully effective in June 2022, whereby Organon licensed exclusive worldwide rights to develop, manufacture and commercialize Xaciato. In accordance with the license agreement, as amended, we are no longer working on the development, manufacture or commercialization of Xaciato. Organon commenced U.S. marketing of Xaciato in the fourth quarter of 2023 and, in January 2024, Organon announced that Xaciato was available nationwide. Â Our product pipeline includes diverse programs that target unmet needs in womenâ€™s health in the areas of contraception, sexual health, pelvic pain, fertility, infectious disease and menopause, and aim to expand treatment options, enhance outcomes and improve ease of use for women. We are primarily focused on progressing the development of our existing portfolio of product candidates. However, we also explore opportunities to expand our portfolio by leveraging assets to which we hold rights or obtaining rights to new assets, with continued focus solely on womenâ€™s health. Â 2 Â Â Â Our current portfolio includes five product candidates in advanced clinical development (Phase 2-ready to Phase 3): Â â—OvapreneÂ®, a hormone-free, monthly intravaginal contraceptive; Â â—Sildenafil Cream, 3.6%, a proprietary cream formulation of sildenafil for topical administration to the female genitalia on demand for the treatment of female sexual arousal disorder (FSAD); Â â—DARE-HRT1, an intravaginal ring designed to deliver both bio-identical estradiol and progesterone together, continuously over a 28-day period, for the treatment of moderate-to-severe vasomotor symptoms, as part of menopausal hormone therapy; Â â—DARE-VVA1, a

proprietary formulation of tamoxifen for intravaginal administration being developed as a hormone-free alternative to estrogen-based therapies for the treatment of moderate-to-severe dyspareunia, or pain during sexual intercourse, a symptom of vulvar and vaginal atrophy associated with menopause; and A DARE-HPV, a proprietary, fixed-dose formulation of lopinavir and ritonavir in a soft gel vaginal insert for the treatment of human papillomavirus (HPV)-related cervical diseases. A Our portfolio also includes five product candidates in Phase 1 clinical development or that we believe are Phase 1-ready: A DARE-PDM1, a proprietary hydrogel formulation of diclofenac, a nonsteroidal anti-inflammatory drug, for vaginal administration as a treatment for primary dysmenorrhea; A DARE-204 and DARE-214, injectable formulations of etonogestrel designed to provide contraception over 6-month and 12-month periods, respectively; A DARE-FRT1, an intravaginal ring designed to deliver bio-identical progesterone continuously for up to 14 days for luteal phase support as part of an in vitro fertilization treatment plan; and A DARE-PTB1, an intravaginal ring designed to deliver bio-identical progesterone continuously for up to 14 days for the prevention of preterm birth. A In addition, our portfolio includes five preclinical stage programs: A DARE-LARC1, a contraceptive implant delivering levonorgestrel with a woman-centered design that has the potential to be a long-acting, yet convenient and user-controlled contraceptive option; A DARE-LBT, a novel hydrogel formulation for vaginal delivery of live biotherapeutics to support vaginal health; A DARE-GML, an intravaginally-delivered potential multi-target antimicrobial agent formulated with glycerol monolaurate (GML), which has shown broad antimicrobial activity, killing bacteria and viruses; A DARE-RH1, a novel approach to non-hormonal contraception for both men and women by targeting the CatSper ion channel; and A DARE-PTB2, a novel approach for the prevention and treatment of idiopathic preterm birth through inhibition of a stress response protein. A A 3 A A A The product candidates and potential product candidates in our portfolio will require review and approval from the FDA, or a comparable foreign regulatory authority, prior to being marketed or sold. A Our primary operations have consisted of research and development activities to advance our portfolio of product candidates through late-stage clinical development and/or regulatory approval. We expect our research and development expenses will continue to represent the majority of our operating expenses for at least the next twelve months. Until we secure additional capital to fund our operating needs, we will focus our resources primarily on advancement of Ovaprene and Sildenafil Cream. In addition, we expect to incur significant research and development expenses for the DARE-LARC1 and DARE-HPV programs, but we also expect such expenses will be supported, with respect to DARE-LARC1, through at least 2026 by non-dilutive funding provided under a grant agreement we entered into in June 2021, and with respect to DARE-HPV, through October 2026 by non-dilutive funding provided under a subaward agreement we entered into in October 2024. A We will need to raise substantial additional capital to continue to fund our operations and execute our current business strategy. We are also subject to a number of other risks common to biopharmaceutical companies, including, but not limited to, dependence on key employees, reliance on third-party collaborators, service providers and suppliers, being able to develop commercially viable products in a timely and cost-effective manner, dependence on intellectual property we own or in-license and the need to protect that intellectual property and maintain those license agreements, uncertainty of market acceptance of products, uncertainty of third-party payor coverage, pricing and reimbursement for products, rapid technology change, intense competition, compliance with government regulations, product liability claims, and exposure to cybersecurity threats and incidents. A The process of developing and obtaining regulatory approvals for prescription drug and drug/device products in the United States and in foreign jurisdictions is inherently uncertain and requires the expenditure of substantial financial resources without any guarantee of success. To the extent we receive regulatory approvals to market and sell our product candidates, the commercialization of any product and compliance with subsequently applicable laws and regulations requires the expenditure of further substantial financial resources without any guarantee of commercial success. The amount of post-approval financial resources required for commercialization and the potential revenue we may receive from sales of any product will vary significantly depending on many factors, including whether, and the extent to which, we establish our own sales and marketing capabilities and/or enter into and maintain commercial collaborations with third parties with established commercialization infrastructure. A Purchase Agreement with Lincoln Park A On October 21, 2024, 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 \$15,000,000 of our common stock (subject to certain limitations) from time to time over the term of the Purchase Agreement. Also on October 21, 2024, 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 filed with the SEC the registration statement of which this prospectus forms a part to register for resale under the Securities Act of 1933, as amended, or the Securities Act, the shares of common stock that have been or may be issued to Lincoln Park under the Purchase Agreement. A A 4 A A A We do 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 are outside of Lincoln Park's control, have been satisfied, including that the SEC has declared effective the registration statement of which this prospectus forms a part, which time we refer to in this prospectus as the Commencement. From time to time after the Commencement, at our sole discretion, on any business day selected by us on which the closing sale price of our common stock is not below \$0.50 per share, we may direct Lincoln Park to purchase up to 30,000 shares of our common stock (each, a "Regular Purchase"); provided that the share amount under a Regular Purchase may be increased to up to 35,000 shares or up to 40,000 shares if the closing sale price of our common stock is not below \$5.00 or \$7.50, respectively, on the business day on which we initiate the purchase, subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction as provided in the Purchase Agreement. However, Lincoln Park's maximum commitment in any single Regular Purchase may not exceed \$500,000. The purchase price per share for each Regular Purchase will be the lower of (i) the lowest sale price of our common stock on the business day on which we initiate the Regular Purchase and (ii) the average of the three lowest closing sale prices of our common stock during the 10-business day period immediately preceding the business day on which we initiate the Regular Purchase. In addition to Regular Purchases, we may also direct Lincoln Park to purchase other amounts of common stock as accelerated purchases and as additional accelerated purchases, subject to limits specified in the Purchase Agreement, at a purchase price per share calculated as specified in the Purchase Agreement, but in no case lower than the minimum price per share we stipulate in our notice to Lincoln Park initiating these purchases. We will control the timing and amount of any sales of our common stock to Lincoln Park. A On October 21, 2024, in consideration for its commitment to purchase shares of our common stock under the Purchase Agreement, we issued 137,614 shares of our common stock to Lincoln Park, which we refer to in this prospectus as the "Commitment Shares." A We may terminate the Purchase Agreement at any time after the date of Commencement, at no penalty or cost, other than the Commitment Shares.

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 a "Variable Rate Transaction." Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement. As of September 30, 2024, there were 8,546,364 shares of our common stock outstanding, excluding the Commitment Shares, of which 8,444,775 shares were held by non-affiliates. Although the Purchase Agreement provides that we may sell up to \$15,000,000 of our common stock to Lincoln Park, only 2,750,000 shares of our common stock are being offered under this prospectus, which represents the Commitment Shares and up to 2,612,386 shares which may be issued to Lincoln Park in the future under the Purchase Agreement, if and when we sell shares to Lincoln Park under the Purchase Agreement. If all of the 2,750,000 shares offered by Lincoln Park under this prospectus were issued and outstanding, such shares would represent approximately 24% of the total number of shares of our common stock outstanding and approximately 25% of the total number of outstanding shares held by non-affiliates, in each case as of September 30, 2024. 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 \$15,000,000 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. A 5 A A 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 1,711,172 shares based on 8,555,864 shares outstanding immediately prior to the execution of the Purchase Agreement (the "Exchange Cap"), unless (i) we obtain stockholder approval to issue shares in excess of the Exchange Cap or (ii) the average price of all applicable sales of our common stock to Lincoln Park under the Purchase Agreement equals or exceeds \$3.59 per share (which represents the lower of (A) the official closing price of our common stock on Nasdaq immediately preceding the signing of the Purchase Agreement and (B) the average official closing price of our common stock on Nasdaq for the five consecutive trading days ending on the trading day immediately preceding the date of the Purchase Agreement), such that issuances and sales of common stock to Lincoln Park under the Purchase Agreement would not be subject to 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. A 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 4.99% 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. Lincoln Park, upon written notice to us, may increase the Beneficial Ownership Cap to up to 9.99%. Any increase in the Beneficial Ownership Cap will not be effective until the 61st day after such written notice is delivered to us. A Issuances of our common stock to Lincoln Park will not affect the rights or privileges of our existing stockholders, except that the economic and voting interests of each of our existing stockholders will be diluted as a result of any such issuance. Although the number of shares of common stock that our existing stockholders own will not decrease, the shares owned by our existing stockholders will represent a smaller percentage of our total outstanding shares after any such issuance to Lincoln Park. A Additional Information A 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 27 of this prospectus. A Corporate Information A 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. A DarÃ© BioscienceÂ® is a registered trademark of DarÃ© Bioscience, Inc. OvapreneÂ® is a registered trademark licensed to DarÃ© 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. A 6 A A The Offering A 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: A Common stock offered by the selling stockholder A Up to 2,750,000 shares consisting of: A A 137,614 shares issued to Lincoln Park in consideration for its commitment to purchase shares of our common stock under the Purchase Agreement; and A A 2,612,386 shares we may sell to Lincoln Park under the Purchase Agreement from time to time after the date of this prospectus. A A Common stock outstanding prior to this offering (which excludes the 137,614 shares issued to Lincoln Park described above) A 8,546,364 shares A A A Common stock to be outstanding after giving effect to the issuance of 2,750,000 shares under the Purchase Agreement registered hereunder A 11,296,364 shares A A Use of proceeds A We will receive no proceeds from the sale of shares of common stock by Lincoln Park in this offering. We may receive up to \$15,000,000 in aggregate gross proceeds under the Purchase Agreement from any sales we make to Lincoln Park pursuant to the Purchase Agreement after the date of this prospectus. Any such proceeds we receive will be used for working capital and general corporate purposes. See "Use of Proceeds" on page 22 of this prospectus. A A Risk factors A Investment in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 8 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. A Nasdaq Capital Market symbol A "DARE" A 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. The number of shares of our common stock outstanding prior to and after this offering in the table above is based on 8,546,364 shares outstanding as of September 30, 2024 and excludes: A A 137,614 shares issued to Lincoln Park on October 21, 2024 in consideration for its commitment to purchase shares under the Purchase Agreement; A A 903,424 shares of common stock issuable upon exercise of stock

options outstanding as of September 30, 2024, with a weighted-average exercise price of \$14.73 per share; and approximately 445,661 shares of common stock reserved and available for future issuance as of September 30, 2024 under our equity incentive plans; approximately 1,268,572 shares of common stock issuable upon exercise of warrants outstanding as of September 30, 2024, with a weighted-average exercise price of \$7.49 per share; and approximately 16,408 shares of common stock issued after September 30, 2024 pursuant to our [at the market](#) offering program. **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 risks 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 associated with investing in our common stock. The risks and uncertainties we have described 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. The sale of our common stock to Lincoln Park may cause dilution 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. **On October 21, 2024, we entered into the Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park committed to purchase up to \$15,000,000 of our common stock, and we issued the Commitment Shares.** Other than the Commitment Shares, the shares of our common stock that may be issued under the Purchase Agreement may be sold by us to Lincoln Park from time to time at our discretion over a 24-month period commencing on the date that the conditions set forth in the Purchase Agreement are satisfied, including that the registration statement of which this prospectus forms a part is declared effective by the SEC. The purchase price for the shares that we may sell to Lincoln Park under the Purchase Agreement 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. 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. See also, **“The sale of our common stock in ATM offerings may cause substantial dilution to our existing stockholders, and such sales, or the anticipation of such sales, may cause the price of our common stock to decline.”** **It is not possible to predict the actual number of shares of common stock we may sell to Lincoln Park under the Purchase Agreement, or the actual gross proceeds resulting from those sales.** **Because the purchase price per share to be paid by Lincoln Park for the shares of common stock that we may elect to sell to Lincoln Park under the Purchase Agreement, if any, will fluctuate based on the market prices of our common stock at the time we elect to sell shares to Lincoln Park pursuant to the Purchase Agreement, if any, it is not possible for us to predict, as of the date of this prospectus and prior to any such sales, the number of shares of common stock that we will sell to Lincoln Park under the Purchase Agreement, the purchase price per share that Lincoln Park will pay for shares purchased from us under the Purchase Agreement, or the aggregate gross proceeds that we will receive from those purchases by Lincoln Park under the Purchase Agreement.** **Moreover, although the Purchase Agreement provides that we may sell up to an aggregate of \$15.0 million of our common stock to Lincoln Park, only 2,750,000 shares of common stock are being registered under the Securities Act for resale by Lincoln Park under the registration statement of which this prospectus forms a part, consisting of (i) the 137,614 Commitment Shares that we issued to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the Purchase Agreement and (ii) up to 2,612,386 shares of our common stock that we may elect to sell to Lincoln Park, in our sole discretion, from time to time from and after the Commencement under the Purchase Agreement.** **If after the Commencement we elect to sell to the selling stockholder all of the 2,612,386 shares of common stock being registered for resale by Lincoln Park under this prospectus that are available for sale by us to the selling stockholder under the Purchase Agreement, depending on the market prices of our common stock at the time of such sales, the actual gross proceeds from the sale of all such shares of common stock by us to Lincoln Park may be substantially less than the \$15.0 million total purchase commitment available to us under the Purchase Agreement, which could materially adversely affect our liquidity.** **If it becomes necessary for us to issue and sell to Lincoln Park shares of common stock in excess of the Exchange Cap under the Purchase Agreement in order to receive aggregate gross proceeds equal to \$15.0 million under the Purchase Agreement, then for so long as the Exchange Cap continues to apply to issuances and sales of common stock under the Purchase Agreement, we must first obtain stockholder approval to issue shares of common stock in excess of the Exchange Cap in accordance with applicable Nasdaq listing rules.** **Furthermore, if we elect to issue and sell to Lincoln Park more than the 2,612,386 shares of our common stock that we may elect to issue and sell to Lincoln Park under the Purchase Agreement that are being registered for resale by Lincoln Park hereunder, which we have the right, but not the obligation, to do, we must first file with the SEC one or more additional registration statements to register under the Securities Act for resale by Lincoln Park such additional shares of our common stock we wish to sell from time to time under the Purchase Agreement, which the SEC must declare effective, in each case before we may elect to sell any additional shares of our common stock to Lincoln Park under the Purchase Agreement. Any issuance and sale by us under the Purchase Agreement of a substantial amount of shares of common stock in addition to the 2,612,386 shares of common stock that we may elect to issue and sell to Lincoln Park under the Purchase Agreement that are being registered for resale by Lincoln Park hereunder could cause additional substantial dilution to our stockholders.** The number of shares of our common stock ultimately offered for sale by Lincoln Park is dependent upon the number of shares of common stock, if any, we ultimately sell to Lincoln Park under the Purchase Agreement, and the sale of common stock under the Purchase Agreement may cause the trading

price of our common stock to decline. Â 9 Â Investors who buy shares at different times will likely pay different prices, and the sale of the shares of common stock acquired by Lincoln Park could cause the price of our common stock to decline. Â Pursuant to the Purchase Agreement, we will have discretion, subject to market demand, to vary the timing, prices, and numbers of shares sold to Lincoln Park. If and when we do elect to sell shares of our common stock to Lincoln Park pursuant to the Purchase Agreement, after Lincoln Park has acquired such shares, Lincoln Park may resell all, some or none of such shares at any time or from time to time in its discretion and at different prices. As a result, investors who purchase shares from Lincoln Park in this offering at different times will likely pay different prices for those shares, and so may experience different levels of dilution and in some cases substantial dilution and different outcomes in their investment results. Investors may experience a decline in the value of the shares they purchase from Lincoln Park in this offering as a result of future sales made by us to Lincoln Park at prices lower than the prices such investors paid for their shares in this offering. Further, the sale of a substantial number of shares of our common stock by Lincoln Park, or anticipation of such sales, could cause the trading price of our common stock to decline or 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 desire. Â We may not have access to the full amount available under the Purchase Agreement with Lincoln Park. We may require additional financing to sustain our operations, without which we may not be able to continue operations, and the terms of subsequent financings may adversely impact our stockholders. Â We may direct Lincoln Park to purchase up to \$15.0 million worth of shares of our common stock in a Regular Purchase from time to time under the Purchase Agreement over a 24-month period generally in amounts up to 30,000 shares of our common stock, which may be increased to up to 40,000 shares of our common stock depending on the closing sale price of our common stock at the time of sale, provided that Lincoln Parkâ€™s maximum purchase obligation under any single Regular Purchase shall not exceed \$500,000. Moreover, under certain circumstances as set forth in the Purchase Agreement, we may, in our sole discretion, also direct Lincoln Park to purchase additional shares of common stock in â€œaccelerated purchases,â€ and â€œadditional accelerated purchasesâ€ as set forth in the Purchase Agreement. Â Depending on the prevailing market price of our common stock, we may not be able to sell shares to Lincoln Park for the maximum \$15.0 million over the term of the Purchase Agreement. We will need to seek stockholder approval before issuing more than the Exchange Cap limit of 1,711,172 shares of common stock under the Purchase Agreement, unless the average price per share of common stock for all shares of common stock sold by us to Lincoln Park under the Purchase Agreement equals or exceeds \$3.59 per share (which represents the lower of (A) the official closing price of our common stock on Nasdaq immediately preceding the signing of the Purchase Agreement and (B) the average official closing price of our common stock on Nasdaq for the five consecutive trading days ending on the trading day immediately preceding the date of the Purchase Agreement), such that the Exchange Cap limitation would no longer apply to issuances and sales of common stock by us to Lincoln Park under the Purchase Agreement under applicable Nasdaq listing rules. In addition, Lincoln Park will not be required to purchase any shares of our common stock if such sale would result in Lincoln Parkâ€™s beneficial ownership of our common stock exceeding the Beneficial Ownership Cap. Our inability to access a portion or the full amount available under the Purchase Agreement, in the absence of any other financing sources, could have a material adverse effect on our business. Â 10 Â The extent we rely on Lincoln Park as a source of funding will depend on a number of factors including the prevailing market price of our common stock and the extent to which we are able to raise capital from other sources. Assuming a purchase price of \$4.41 per share (which represents the closing price of our common stock on November 12, 2024), the purchase by Lincoln Park of the entire 2,612,386 shares of common stock issuable under the Purchase Agreement being registered for resale by Lincoln Park hereunder would result in gross proceeds to us of approximately \$11.5 million. If obtaining sufficient funding from Lincoln Park were to prove unavailable or prohibitively dilutive, we will need to secure another source of capital in order to satisfy our working capital needs. Even if we sell all \$15.0 million of shares of our common stock to Lincoln Park under the Purchase Agreement, we will need to raise substantial additional capital to continue to fund our operations and execute our current business strategy. Â If we fail to regain and maintain compliance with the continued listing requirements of The Nasdaq Capital Market, our common stock could be suspended and delisted, which could, among other things, limit demand for our common stock, 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. Â Our common stock is listed on The Nasdaq Capital Market. On August 12, 2024, we received written notice from Nasdaq notifying us that we do not meet the requirement in Nasdaq Listing Rule 5550(b)(2) to maintain a minimum Market Value of Listed Securities, or MVLS, of \$35.0 million that is required for continued listing on The Nasdaq Capital Market. The notice has no effect at this time on the listing of our common stock on The Nasdaq Capital Market. Â We have a period of 180 days, or until February 10, 2025, to regain compliance with the minimum MVLS rule. We will regain compliance if at any time during the 180-day period, our MVLS closes at \$35.0 million or more for a minimum of 10 consecutive business days. If we do not regain compliance prior to February 10, 2025, Nasdaq will notify us that our securities are subject to delisting, at which time we may appeal the delisting determination to a Nasdaq hearings panel. There can be no assurance that, if we were to appeal the delisting determination, such an appeal would be successful. Â There are many factors that affect the trading price of our common stock, and many of those factors are outside of our control. We intend to actively monitor our MVLS and may, if appropriate, consider implementing available options to regain compliance with the minimum MVLS rule. There can be no assurance that we will be able to regain compliance with such rule or that we will be able to satisfy all other continued listing requirements of The Nasdaq Capital Market and maintain the listing of our common stock on The Nasdaq Capital Market even if we regain compliance with the minimum MVLS rule. For example, until we regained compliance on July 18, 2024, we were not in compliance with the continued listing standard commonly referred to as the minimum bid price rule since July 19, 2023. Â The suspension or delisting of our common stock, for whatever reason, could, among other things, substantially impair our ability to raise additional capital; result in the loss of interest from institutional investors, the loss of confidence in our company by investors and employees, and in fewer financing, strategic and business development opportunities; and result in potential breaches of agreements under which we made representations or covenants relating to our compliance with applicable listing requirements. Claims related to any such breaches, with or without merit, could result in costly litigation, significant liabilities and diversion of our managementâ€™s time and attention and could have a material adverse effect on our financial condition, business and results of operations. In addition, the suspension or delisting of our common stock, for whatever reason, may materially impair our stockholdersâ€™ ability to buy and sell shares of our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. Â 11 Â The sale of our common stock in ATM offerings may cause substantial dilution to our existing stockholders, and such sales, or the anticipation of

such sales, may cause the price of our common stock to decline. We have used at-the-market, or ATM, offerings to fund a significant portion of our operations in prior years, and we may continue to use ATM offerings to raise additional capital in the future. For example, in 2021, we sold an aggregate of approximately 3.0 million shares of our common stock in ATM offerings. We sold substantially fewer shares in ATM offerings in 2022 and 2023 and to-date in 2024, however, we may sell significant amounts of shares in ATM offerings again in the future. While sales of shares of our common stock in ATM offerings may enable us to raise capital at a lower cost compared with other types of equity financing transactions; 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. Our management will have broad discretion over the use of the net proceeds, if any, 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 used effectively. This prospectus relates to shares of our common stock that may be offered and sold from time to time by Lincoln Park. We will not receive any proceeds upon the sale of shares by Lincoln Park. However, we may receive gross proceeds of up to \$15.0 million from the sale of shares under the Purchase Agreement to Lincoln Park. The anticipated use of net proceeds from the sale of our common stock to Lincoln Park under the Purchase Agreement represents our intentions based upon our current plans and business conditions. Because we have not designated the amount of net proceeds from the sale of shares under the Purchase Agreement to be used for any particular purpose, 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. 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. Further, our management may use the net proceeds for corporate purposes that may not improve our financial condition or market 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.

12 A A SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS A 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 fact, including statements regarding our strategy, future operations, future financial position, projected revenue, funding and expenses, prospects, plans and objectives of management, are forward-looking statements. Forward-looking statements, in some cases, can be identified by terms such as "believe," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect," "could," "plan," "potential," "predict," "seek," "pursue," "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 described under the headings "Risk Factors" of this prospectus and in our Annual Report on Form 10-K for the year ended December 31, 2023 and in our subsequent Quarterly Reports on Form 10-Q, all of which are incorporated herein by reference, as may be updated or superseded by the risks and uncertainties described under similar headings in the other documents that are filed after the date hereof and incorporated by reference into 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:

- A — Inability to raise additional capital, under favorable terms or at all, to fund our operating needs and continue as a going concern;
- A — The number and scope of product development programs we pursue;
- A — Difficulties or delays in commencement or completion, or the termination or suspension, of our current or planned clinical or preclinical studies;
- A — Clinical trial outcomes and results of preclinical development;
- A — Failure to complete development of our product candidates or submit and obtain FDA or foreign regulatory authority approval for our product candidates on projected timelines or budgets, or at all;
- A — Challenges and delays in obtaining timely supplies of our product candidates, including their components as well as the finished product, in the quantities needed in accordance with current good manufacturing practices, our specifications and other applicable requirements;
- A — The performance of third parties on which we rely to conduct nonclinical studies and clinical trials of our product candidates;
- A — Our failure, or a failure of a strategic collaborator, to successfully commercialize our product candidates, if approved, or our failure to otherwise monetize our portfolio programs and assets;
- A — Termination by a collaborator of our respective out-license agreements for commercialization of XACIATO and Ovaprene®, or, in the case of Ovaprene, a decision by the collaborator not to make the license grant fully effective following its review of the results of the ongoing pivotal clinical trial of Ovaprene;
- A — The timing and amount of future royalty, milestone or other payments to us, if any, under our out-license agreement for Ovaprene, and of upside-sharing milestone payments from XOMA (US) LLC under our traditional and synthetic royalty purchase agreements, if any;
- A — The performance of third parties on which we rely to commercialize, or assist us in commercializing, XACIATO and any future product;
- A — Difficulties with maintaining existing collaborations relating to the development and/or commercialization of our product candidates, or establishing new ones on a timely basis or on acceptable terms, or at all;
- A — The terms and conditions of any future strategic collaborations relating to our product candidates;
- A — The degree of market acceptance that XACIATO and any future product achieves;
- A — Coverage and reimbursement levels for XACIATO and any future product by government health care programs, private health insurance companies and other third-party payors;
- A — Our loss of, or inability to attract, key personnel;
- A — A change in the FDA's prior determination that the Center for Devices and Radiological Health would lead the review of a premarket approval application for potential marketing approval of Ovaprene;
- A — 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;
- A — Unfavorable differences between preliminary, interim or topline clinical study data reported by us and final study results;
- A — Communication from the FDA or another regulatory authority, including a complete response letter, that such agency 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 such agency 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;
- A — Failure to select product candidates that capitalize on the most scientifically, clinically or commercially promising or profitable indications or therapeutic areas within women's health including due to our limited financial resources;
- A — Loss or impairment of our in-licensed rights to develop and commercialize XACIATO and our product candidates;
- A — The timing and amount of our payment and other

obligations under our in-license and acquisition agreements for XACIATO and our product candidates; Δ Δ —Developments by our competitors that make XACIATO, or any potential product we develop, less competitive or obsolete; Δ Δ —Unfavorable or unanticipated macroeconomic factors, geopolitical events or conflicts, public health emergencies, or natural disasters; Δ Δ —Weak interest in women's health relative to other healthcare sectors from the investment community or from pharmaceutical companies and other potential development and commercialization collaborators; Δ 14 Δ Δ —Cyber-attacks, security breaches or similar events compromising our technology systems and data, our financial resources and other assets, or the technology systems and data of third parties on which we rely; Δ Δ —Difficulty in introducing branded products in a market made up of generic products; Δ Δ —Inability to adequately protect or enforce our, or our licensor's, intellectual property rights; Δ Δ —Lack of patent protection for the active ingredients in XACIATO and certain of our product candidates that expose them to competition from other formulations using the same active ingredients; Δ Δ —Higher risk of failure associated with product candidates in preclinical stages of development that may lead investors to assign them little to no value and make these assets difficult to fund; Δ Δ —Dependence on grants and other financial awards from governmental entities and private foundations to advance the development of several of our product candidates; Δ Δ —Disputes or other developments concerning our intellectual property rights; Δ Δ —Actual and anticipated fluctuations in our quarterly or annual operating results or results that differ from investors' expectations for such results; Δ Δ —Price and volume fluctuations in the stock market, and in our stock in particular, which could cause investors to experience losses and subject us to securities class-action litigation; Δ Δ —Failure to maintain the listing of our common stock on The Nasdaq Capital Market or another nationally recognized exchange; Δ Δ —Development of safety, efficacy or quality concerns related to our product or product candidates (or third-party products or product candidates that share similar characteristics or drug substances), whether or not scientifically justified, leading to delays in or discontinuation of product development, product recalls or withdrawals, diminished sales, and/or other significant negative consequences; Δ Δ —Product liability claims or governmental investigations; Δ Δ —Changes in government laws and regulations in the United States and other jurisdictions, including laws and regulations governing the research, development, approval, clearance, manufacturing, supply, distribution, pricing and/or marketing of our products, product candidates and related intellectual property, health care information and data privacy and security laws, transparency laws and fraud and abuse laws, and the enforcement thereof affecting our business; and Δ Δ —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. Δ In addition, statements that we believe and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date they are made, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. Δ 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. Δ 15 Δ Δ OUR AGREEMENTS WITH LINCOLN PARK Δ Overview Δ On October 21, 2024, we entered into the Purchase Agreement and the Registration Rights Agreement with Lincoln Park. Pursuant to the terms of the Purchase Agreement, Lincoln Park has agreed to purchase from us up to \$15,000,000 of our common stock (subject to certain limitations) from time to time during the 24-month term of the Purchase Agreement. Pursuant to the terms of the Registration Rights Agreement, we filed with the SEC the registration statement of which this prospectus forms a part to register for resale under the Securities Act shares that have been or may be issued to Lincoln Park under the Purchase Agreement. Δ We do not have the right to commence sales of our shares of common stock to Lincoln Park under the Purchase Agreement until the Commencement has occurred, which is the time at which all of the conditions set forth in the Purchase Agreement, all of which are outside of Lincoln Park's control, have been satisfied, including that the SEC has declared effective the registration statement of which this prospectus forms a part. On or after the Commencement, from time to time, at our sole discretion, we may direct Lincoln Park to purchase shares of our common stock in amounts of up to 30,000 shares on any single business day as a Regular Purchase. The amount of a Regular Purchase may be increased to up to 40,000 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 \$500,000 per single Regular Purchase. In addition, at our discretion, Lincoln Park has committed to purchase other accelerated amounts and/or additional accelerated amounts under certain circumstances. The purchase price per share sold in any Regular Purchase 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, reverse 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. Δ 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 1,711,172 shares based on 8,555,864 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 \$3.59 (which represents the lower of (A) the official closing price of our common stock on Nasdaq immediately preceding the signing of the Purchase Agreement and (B) the average official closing price of our common stock on Nasdaq for the five consecutive trading days ending on the trading day immediately preceding the date of the Purchase Agreement), 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. 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. Δ 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. Δ 16 Δ Δ On October 21, 2024, 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. A Purchase of Shares Under the Purchase Agreement A On or after the Commencement, from time to time, at our sole discretion, on any business day selected by us on which the closing sale price of the common stock is not below \$0.50 per share, we may direct Lincoln Park to purchase shares of our common stock in amounts up to 30,000 shares on any single business day as a Regular Purchase; provided that such share limit increases to up to 35,000 shares if the closing sale price of our common stock is not below \$5.00 per share on the business day on which we initiate the purchase, and to up to 40,000 shares if the closing sale price of our common stock is not below \$7.50 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." In any case, Lincoln Park's maximum commitment in any single Regular Purchase may not exceed \$500,000. The Regular Purchase Share Limit is subject to proportionate adjustment in the event of a reorganization, recapitalization, non-cash dividend, stock split, reverse stock split, or other similar transaction; 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 \$50,000 in any single Regular Purchase, then the Regular Purchase Share Limit will not be fully adjusted, but rather the Regular Purchase Share Limit for such Regular Purchase shall be adjusted as specified in the Purchase Agreement, such that, after giving effect to such adjustment, the Regular Purchase Share Limit will be equal to (or as close as can be derived from such adjustment without exceeding) \$50,000. A The purchase price per share for the shares that may be sold to Lincoln Park in any Regular Purchase will be the lesser of: A -the lowest sale price of our common stock on the business day on which we initiate the purchase; or A -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. A In addition to Regular Purchases, 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: A -30% of the total volume of shares of our common stock traded during the Accelerated Purchase Period (as defined in the Purchase Agreement); and A -three times the number of shares of common stock purchased pursuant to the corresponding Regular Purchase. A 17 A 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: A -30% of the total volume of shares of our common stock traded during the Additional Accelerated Purchase Period (as defined in the Purchase Agreement); and A -three times the number of shares of common stock purchased pursuant to the corresponding Regular Purchase. A We may, in our sole discretion, submit multiple Additional Accelerated Purchase notices to Lincoln Park 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. A The purchase price per share for each Accelerated Purchase and each Additional Accelerated Purchase will be equal to 95% of the lesser of: A -the volume weighted average price of our common stock during the applicable Accelerated Purchase Period or Additional Accelerated Purchase Period; and A -the closing sale price of our common stock on the applicable Accelerated Purchase date. A 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, reverse stock split or other similar transaction occurring during the business days used to compute such price. A 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. A Suspension Events A Suspension Events under the Purchase Agreement include, among others, the following: A -a lapse in the effectiveness of the registration statement of which this prospectus forms a party for any reason (including, without limitation, the issuance of a stop order or similar order) or any required prospectus is unavailable for the resale by Lincoln Park of the shares of our common stock offered hereby and such lapse or unavailability continues for a period of 10 consecutive business days or for more than an aggregate of 30 business days in any 365-day period, subject to certain exceptions described in the Purchase Agreement; A -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; A -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 OTCQX Best Market or the OTCQB Venture Market operated by OTC Markets Group, Inc. (or any nationally recognized successor to any of the foregoing); A 18 A -the failure 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 applicable date on which Lincoln Park is entitled to receive such shares; A A A -any breach by us of any of our representations, warranties or covenants 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 continues for a period of at least five business days; A A A -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; A A A -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 A A A -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. A Lincoln Park does not have the right to terminate the Purchase Agreement upon any of the Suspension Events set forth above. During a Suspension Event, or if any event has occurred which, after notice and/or lapse of time, would reasonably be expected to become a Suspension Event 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. A Term of the Purchase Agreement; Termination Rights A The Purchase Agreement will automatically terminate upon the earlier of (a) the date we sell all \$15,000,000 in shares

of our common stock to Lincoln Park under the Purchase Agreement, and (b) the first day of the month immediately following the 24-month anniversary 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. Â If the Commencement shall not have occurred on or before January 31, 2025 due to the failure to satisfy the conditions required for the Commencement to occur, subject to customary exceptions, either we or Lincoln Park may terminate the Purchase Agreement at the close of business on such date or thereafter. Â After the Commencement, we may, at any time, for any reason or for no reason, terminate the Purchase Agreement upon one business day prior notice to Lincoln Park. Â No Short-Selling or Hedging by Lincoln Park Â Lincoln Park has represented to us that at no time prior to the time of execution of 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 under 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. Â 19 Â Â Prohibitions on Variable Rate Transactions Â There are no restrictions or limitations on our ability to raise capital from other sources at our sole discretion, except that for so long as the Purchase Agreement is in effect, we agreed not to effect any issuance of, or enter into any agreement to effect any issuance of, shares of common stock or common stock equivalents involving a â€œvariable rate transaction,â€ which is defined in the Purchase Agreement as an â€œequity line of creditâ€ or substantially similar transaction whereby an investor is irrevocably bound to purchase securities over a period of time from us at a price based on the market price of our common stock at the time of each such purchase; provided that foregoing prohibition does prohibit the issuance and sale of our common stock pursuant to an â€œat-the-market offeringâ€ by us exclusively through a registered broker-dealer acting as agent of ours pursuant to a written agreement between us and such registered broker-dealer. Â Effect of Performance of the Purchase Agreement on Our Stockholders Â 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. Other than the Commitment Shares, which were issued to Lincoln Park on October 21, 2024, the shares registered in this offering may be sold to Lincoln Park at our discretion over a period of up to 24-months commencing after the satisfaction of certain conditions set forth in the Purchase Agreement, including that the SEC has declared effective the registration statement of which this prospectus forms a part. 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. Â 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 \$15,000,000 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. Â 20 Â Â The following table sets forth the amount of gross proceeds we would receive from Lincoln Park from our sale of up to 2,612,386 shares of our common stock (which excludes the Commitment Shares that we issued to Lincoln Park for which we will receive no cash proceeds) that we are registering hereby that we may issue and sell to Lincoln Park in the future under the Purchase Agreement at varying purchase prices: Â Assumed Average Purchase Price Per ShareÂ Â Number of Shares to be Issued if Full Purchase (1)Â Â Percentage of Outstanding Shares After Giving Effect to the Sales to Lincoln Park (2)Â Â Gross Proceeds from the Sales to Lincoln Park Under the Purchase AgreementÂ \$1.00Â Â 1,573,558 Â Â 17 % Â \$ 1,573,558 Â \$2.00Â Â 1,573,558 Â Â 17 % Â \$ 3,147,116 Â \$3.00Â Â 1,573,558 Â Â 17 % Â \$ 4,720,674 Â \$4.00Â Â 2,612,386Â Â 24%Â \$10,449,544Â \$4.41(3)Â Â 2,612,386Â Â 24%Â \$11,520,622Â \$5.00Â Â 2,612,386Â Â 24%Â \$13,061,930Â \$6.00Â Â 2,500,000Â Â 24%Â \$15,000,000Â \$7.00Â Â 2,142,857Â Â 21%Â \$ 14,999,999 Â Â (1)Although the Purchase Agreement provides that we may sell up to \$15,000,000 of our common stock to Lincoln Park, we are only registering the Commitment Shares (137,614 shares) and 2,612,386 shares that may be sold to Lincoln Park under this prospectus, which may or may not cover all the shares we ultimately sell to Lincoln Park under the Purchase Agreement, depending on the purchase price per share. The number of shares included in this column reflects only those shares that we are registering in this offering, excluding the Commitment Shares because no proceeds are attributable to the Commitment Shares, giving effect to the Exchange Cap, and without regard for the Beneficial Ownership Cap. Â Â (2)The denominator is based on 8,700,389 shares outstanding as of November 12, 2024, which includes the Commitment Shares, adjusted to include the number of shares set forth in the adjacent column which we would have sold to Lincoln Park, assuming the purchase price in the adjacent column. The numerator reflects 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, and the Commitment Shares. Â Â (3)The closing sale price of our shares on November 12, 2024. Â 21 Â Â USE OF PROCEEDS Â This prospectus relates to shares of our common stock that may be offered and sold from time to time by Lincoln Park. See â€œPlan of Distributionâ€ elsewhere in this prospectus for more information. We are not selling any securities under this prospectus and we will not receive any proceeds from the sale of shares by Lincoln Park under this prospectus. Â We may receive up to \$15,000,000 in aggregate gross proceeds from sales of shares of our common stock we make to Lincoln Park under the Purchase Agreement. We may choose to sell fewer than \$15,000,000 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 \$15,000,000 in shares of our common stock under

the Purchase Agreement, in which case we would raise less than \$15,000,000 in aggregate gross proceeds under the Purchase Agreement. It is also possible that we do not sell any shares 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. Based upon our current plans and business conditions, we intend to use net proceeds from such sales for working capital and general corporate purposes, which include, but are not limited to, research and development expenses and general and administrative expenses. We have not determined the amount of net proceeds to be used specifically for such purposes. The amounts and timing of our actual expenditures may vary significantly and will depend on numerous factors, including market conditions, cash generated or used by our operations, business developments and opportunities that may arise. We may find it necessary or advisable to use portions of the proceeds we receive from our sale of shares of common stock to Lincoln Park under the Purchase Agreement for other 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, but all selling and other expenses incurred by the selling stockholder will be paid by the selling stockholder. **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 October 21, 2024 concurrently with our execution of the Purchase Agreement, in which we agreed to provide certain registration rights with respect to resales 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. Lincoln Park may sell some, all or none of those shares. We do not know how long Lincoln Park will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with Lincoln Park regarding its sale of any of the shares. See **Plan of Distribution.** The table below sets forth, to our knowledge, information concerning the beneficial ownership of shares of our common stock by the selling stockholder as of November 12, 2024. The percentages of shares owned prior to and after the offering are based on 8,700,389 shares of common stock outstanding as of November 12, 2024, which includes the Commitment Shares we issued to Lincoln Park on October 21, 2024. The information in the table below with respect to the selling stockholder has been obtained from the selling stockholder. Other than as described under **Our Agreements With Lincoln Park**, above, 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 Prior to this Offering **Percentage of Outstanding Shares Beneficially Owned Prior to this Offering** **Shares to be Sold in this Offering Assuming the Company issues the Maximum Number of Shares Under the Purchase Agreement** **Percentage of Outstanding Shares Beneficially Owned After this Offering** Lincoln Park Capital Fund, LLC (1) 137,614 (2) 1.6% (3) 2,750,000 (4) *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. Neither Lincoln Park Capital, LLC nor Lincoln Park Capital Fund, LLC is a licensed broker dealer or an affiliate of a licensed broker dealer. (2)Represents the Commitment Shares issued to Lincoln Park on October 21, 2024 in consideration for its commitment to purchase shares of our common stock under the Purchase Agreement. In accordance with Rule 13d-3(d) of the Exchange Act, we have excluded from the number of shares beneficially owned prior to this offering all the shares of common stock that we may issue and sell to Lincoln Park under the Purchase Agreement from and after the Commencement that are being registered for resale under the registration statement of which this prospectus forms a part, 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 forms 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)Assumes issuance of the maximum 2,750,000 shares being registered hereby, 137,614 of which were issued to Lincoln Park on October 21, 2024. Although the Purchase Agreement provides that we may sell up to \$15,000,000 in shares of our common stock to Lincoln Park, only 2,612,386 shares of our common stock are being offered under this prospectus that may be sold by us to Lincoln Park at our discretion from time to time over a 24-month period following the Commencement. 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 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 \$15,000,000 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. (4)Assumes the sale by Lincoln Park of all 2,750,000 shares of our common stock registered hereby, although the selling stockholder is under no obligation known to us to sell any shares of common stock at any particular time. **DILUTION** Our sale of shares of our common stock to Lincoln Park pursuant to 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 of our common stock we will have to sell to Lincoln Park to achieve the same gross proceeds amount, in which case our existing stockholders would experience greater dilution. The amount that Lincoln Park will receive for our common stock when resold pursuant to this prospectus will depend upon the timing of sales and will fluctuate based on the trading price of our common stock. Our net tangible book value (deficit) as of September 30, 2024 was approximately (\$1.5 million), or (\$0.17) 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, 2024. After giving effect to (a) the sale and issuance of 2,612,386 shares of common stock to Lincoln

Park pursuant to the Purchase Agreement at an assumed average sale price of \$4.41 per share of common stock (which was the closing sale price of our common stock on November 12, 2024) and deducting estimated offering expenses payable by us of approximately \$47,000, and (b) the issuance of 137,614 shares of our common stock to Lincoln Park on October 21, 2024 in consideration for its commitment to purchase shares of our common stock under the Purchase Agreement, our as adjusted net tangible book value as of September 30, 2024 would have been approximately \$10.0 million, or \$0.90 per share. This represents an immediate increase in net tangible book value of \$1.07 per share to existing stockholders and an immediate dilution of \$3.51 per share to new investors. 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 \$4.41 per share of common stock (which was the closing sale price of our common stock on November 12, 2024), and our as adjusted net tangible book value per share after giving effect to this offering. The following table illustrates this dilution on a per share basis: Assumed offering price per share of common stock \$4.41 Net tangible book value (deficit) per share as of September 30, 2024 \$(0.17) Increase in net tangible book value per share attributable to this offering \$1.07 As adjusted net tangible book value per share after giving effect to this offering \$0.90 Dilution per share to new investors \$ 3.51 The number of shares of our common stock to be outstanding as shown above is based on 8,546,364 shares outstanding as of September 30, 2024, and excludes: 137,614 shares issued to Lincoln Park on October 21, 2024 in consideration for its commitment to purchase shares under the Purchase Agreement; 903,424 shares of common stock issuable upon exercise of stock options outstanding as of September 30, 2024, with a weighted-average exercise price of \$7.36 per share; 445,661 shares of common stock reserved and available for future issuance as of September 30, 2024 under our equity incentive plans; and 1,268,572 shares of common stock issuable upon exercise of warrants outstanding as of September 30, 2024, with a weighted-average exercise price of \$7.49 per share; and 16,408 shares of common stock issued after September 30, 2024 pursuant to our at the market offering program. To the extent that outstanding options or warrants have been or may be exercised, new equity awards were 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 in our at the market offering program, investors purchasing our common stock in this offering may experience further dilution.

24 PLAN OF DISTRIBUTION

The shares of our common stock offered by this prospectus are being offered by the selling stockholder, Lincoln Park. The shares 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 shares 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 shares of our 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 of our common stock offered by this prospectus may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares of our common stock offered by this prospectus 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 has acquired and 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 of our common stock offered by this prospectus may receive compensation in the form of commissions, discounts, or concessions from the purchasers, for whom the broker-dealers may act as agent, of shares of our common stock sold by Lincoln Park through this prospectus. The compensation paid to any such particular broker-dealer by any such purchasers of shares of our common stock sold by Lincoln Park 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 from any purchasers of shares of our common stock sold by Lincoln Park.

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. We may from time to time file with the SEC one or more supplements to this prospectus or amendments to the registration statement of which this prospectus forms a part to amend, supplement or update information contained in this prospectus, including, if and when required under the Securities Act, to disclose certain information relating to a particular sale of shares of our common stock offered by this prospectus by the selling stockholder, including the names of any brokers, dealers, underwriters or agents participating in the distribution of such shares of our common stock by the selling stockholder, any compensation paid by Lincoln Park to any such brokers, dealers, underwriters or agents, and any other required information.

We will pay the expenses incident to the registration under the Securities Act of the offer and sale of the shares of our common stock covered by this prospectus by Lincoln Park. We estimate the total of such expenses will be approximately \$47,000.

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. Â 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. Â **LEGAL MATTERS** Â Sheppard, Mullin, Richter & Hampton LLP, San Diego, California, will pass upon the validity of the common stock being offered by this prospectus. Â **EXPERTS** Â Haskell & White LLP, 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, 2023, as set forth in its report (which report includes an explanatory paragraph regarding the existence of substantial doubt about our ability to continue as a going concern), which is incorporated by reference in this prospectus and the registration statement. Our financial statements are incorporated by reference in reliance on Haskell & White LLPâ€™s report, given on the authority of said firm as experts in accounting and auditing. Â 26 Â CBIZ CPAs P.C. (formerly 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, 2022, as set forth in its report (which report includes an explanatory paragraph regarding the existence of substantial doubt about our ability to continue as a going concern), which is incorporated by reference in this prospectus and the registration statement. Our financial statements are incorporated by reference in reliance on CBIZ CPAs P.C.â€™s report, given on the authority of said firm as experts in accounting and auditing. Â **WHERE YOU CAN FIND MORE INFORMATION** Â 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 a website 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 SECâ€™s website address at <http://www.sec.gov>. You may also request a copy of these filings, at no cost, by writing us at the address below or telephoning us at number below. Â 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. Â 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. Â **INCORPORATION OF CERTAIN INFORMATION BY REFERENCE** Â The SEC allows us to âœincorporate by referenceâ€ into this prospectus information from other documents that we file with the SEC, which means that we can disclose important information to you by referring you to those 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: Â â—our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on March 28, 2024 (the âœAnnual Reportâ€), 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 26, 2024 incorporated by reference into Part III of the Annual Report; Â Â Â â—our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2024, June 30, 2024 and September 30, 2024, filed with the SEC on May 14, 2024, August 12, 2024 and November 14, 2024, respectively; Â 27 Â â—our Current Reports on Form 8-K filed with the SEC on January 19, 2024, January 26, 2024, April 30, 2024, June 7, 2024, June 27, 2024, July 19, 2024, October 21, 2024, and October 23, 2024 (except for the information furnished under Items 2.02 or 7.01 and the exhibits furnished thereto); Â Â Â â—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; Â The SEC file number for each of the documents listed above is 001-36395. Â 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. Â 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: Â DarÃ© Bioscience, Inc. 3655 Nobel Drive, Suite 260 San Diego, CA 92122 Attn: Chief Accounting Officer Telephone: (858) 926-7655 Â 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. Â 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. Â **DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITY** Â Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling the registrant pursuant to the foregoing provisions, the registrant has been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. Â 28 Â 2,750,000 Shares of Common Stock Â **PROSPECTUS** Â 2024 Â 29 Â **PART II** Â **INFORMATION NOT REQUIRED IN PROSPECTUS** Â Item 13. Other Expenses of Issuance and Distribution Â The following table sets forth the fees and expenses incurred or expected to be incurred by us in

connection with the sale and issuance of the securities being registered hereby. Other than the SEC registration fee, the amounts stated are estimates. A SEC registration fee A \$1,734 A Legal fees and expenses A 15,000 A Accounting fees and expenses A 30,000 A Total A \$ 46,734 A A Item 14. Indemnification of Directors and Officers A Delaware Law A Section 102 of the Delaware General Corporation Law, or the DGCL, permits a corporation to provide in its certificate of incorporation that a director or officer of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director or officer, except for liability (i) for any breach of the directorâ€™s or officerâ€™s duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) for payments of unlawful dividends or unlawful stock purchases or redemptions, (iv) for any transaction from which the director or officer derived an improper personal benefit, or (v) of officers in any action by or in the right of the corporation. A Section 145 of the DGCL provides that a corporation has the power to indemnify a director, officer, employee, or agent of the corporation, or a person serving at the request of the corporation for another corporation, partnership, joint venture, trust or other enterprise in related capacities against expenses, including attorneysâ€™ fees, judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he was or is a party or is threatened to be made a party to any threatened, ending or completed action, suit or proceeding by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper. A Restated Certificate of Incorporation A Our restated certificate of incorporation provides that no director of our corporation shall be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the DGCL prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty. A II-I A In addition, our restated certificate of incorporation provides that we will indemnify each individual who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of us), by reason of the fact that such individual is or was, or has agreed to become, our director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such individuals being referred to as an Indemnitee), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneysâ€™ fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom if such Indemnitee acted in good faith and in a manner the Indemnitee reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, such Indemnitee had no reasonable cause to believe the Indemniteeâ€™s conduct was unlawful. A Our restated certificate of incorporation also provides that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, our director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee or, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneysâ€™ fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred by Indemnitee in connection with such action, suit or proceeding and any appeal therefrom, if the Indemnitee acted in good faith and in a manner which the Indemnitee reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made in respect of any claim, issue or matter as to which the Indemnitee shall have been adjudged to be liable to us, unless, and only to the extent, that the Court of Chancery of Delaware or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of such liability but in view of all the circumstances of the case, the Indemnitee is fairly and reasonably entitled to indemnity for such expenses (including attorneysâ€™ fees) which the Court of Chancery of Delaware or such other court shall deem proper. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, such Indemnitee will be indemnified by us against all expenses (including attorneysâ€™ fees) actually and reasonably incurred by or on behalf of the Indemnitee in connection therewith. Without limiting the foregoing, if any action, suit or proceeding is disposed of, on the merits or otherwise (including a disposition without prejudice), without (i) the disposition being adverse to the Indemnitee, (ii) an adjudication that the Indemnitee was liable to us, (iii) a plea of guilty or nolo contendere by the Indemnitee, (iv) an adjudication that the Indemnitee did not act in good faith and in a manner the Indemnitee reasonably believed to be in or not opposed to our best interests, and (v) with respect to any criminal proceeding, an adjudication that Indemnitee had reasonable cause to believe his or her conduct was unlawful, the Indemnitee shall be considered for the purposes hereof to have been wholly successful with respect thereto. If we do not assume the defense, expenses must be advanced to an Indemnitee under certain circumstances. A Indemnification Agreements A We have entered into indemnification agreements with our directors and executive officers. In general, these agreements provide that we will indemnify the director or executive officer to the fullest extent permitted by law for claims arising in his or her capacity as a director or officer of our company or in connection with their service at our request for another entity. The indemnification agreements also provide for procedures that will apply in the event that a director or executive officer makes a claim for indemnification and establish certain presumptions that are favorable to the director or executive officer. A II-II A A We maintain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers. A Insofar as the forgoing provisions permit indemnification of our directors and officers, or persons controlling us, for liability arising under the Securities Act we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. A Item 15. Recent Sales of Unregistered Securities A The following is a summary of all securities that we have sold within the past three years without registration under the Securities Act: A â— In December 2023, in connection with entering into a royalty interest financing agreement with United in Endeavour, LLC, we issued to United in Endeavour, LLC a warrant to purchase shares of our common stock. The warrant is exercisable to purchase 422,804 shares of our common stock and has a five-year term and a current exercise

1934 that are incorporated by reference in the registration statement. (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering. II-X (4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser: each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use. (b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. (c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue. II-XI SIGNATURES Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Diego, State of California, on November 15, 2024. Dar© Bioscience, Inc. By: /s/ Sabrina Martucci Johnson Sabrina Martucci Johnson Chief Executive Officer POWER OF ATTORNEY We, the undersigned officers and directors of Dar© Bioscience, Inc., hereby severally constitute and appoint Sabrina Martucci Johnson and MarDee Haring-Layton, and each of them singly (with full power to each of them to act alone), our true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution in each of them for her or him and in her or his name, place and stead, and in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement (or any other registration statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933), and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as full to all intents and purposes as she or he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or her or his substitute or substitutes may lawfully do or cause to be done by virtue hereof. Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed below by the following persons in the capacities and on the dates indicated. Signature Title Date /s/ Sabrina Martucci Johnson President, Chief Executive Officer, Secretary and Director November 15, 2024 Sabrina Martucci Johnson (Principal Executive and Financial Officer) /s/ MarDee Haring-Layton Chief Accounting Officer November 15, 2024 MarDee Haring-Layton (Principal Accounting Officer) /s/ William H. Rastetter Chairman of the Board November 15, 2024 William H. Rastetter, Ph.D. /s/ Jessica D. Grossman Director November 15, 2024 Jessica D. Grossman, M.D. /s/ Susan L. Kelley Director November 15, 2024 Susan L. Kelley, M.D. /s/ Gregory W. Matz Director November 15, 2024 Gregory W. Matz /s/ Robin J. Steele Director November 15, 2024 Robin J. Steele, J.D., L.L.M. II-XII EX-5.1 2 ex5-1.htm Exhibit 5.1 Sheppard, Mullin, Richter & Hampton LLP 12275 El Camino Real, Suite 100 San Diego, CA 92130 www.sheppardmullin.com November 15, 2024 Dar© Bioscience, Inc. Attn: Board of Directors 3655 Nobel Drive, Suite 260 San Diego, CA 92122. Re: Registration Statement on Form S-1 Ladies and Gentlemen: We have acted as counsel to Dar© Bioscience, Inc., a Delaware corporation (the "Company"), in connection with the filing with the U.S. Securities and Exchange Commission (the "Commission") on or about the date hereof of a registration statement on Form S-1 (the "Registration Statement") under the Securities Act of 1933, as amended (the "Act"). The Registration Statement registers the resale of up to 2,750,000 shares (the "Shares") of the Company's common stock, par value \$0.0001 per share ("Common Stock"), by the selling stockholder (the "Selling Stockholder") identified in the Registration Statement. The Shares consist of 137,614 shares of Common Stock issued by the Company to the Selling Stockholder on October 21, 2024 (the "Commitment Shares"), and up to 2,612,386 shares of Common Stock (the "Purchase Shares") that the Company may issue and sell to the Selling Stockholder from time to time, in each case, pursuant to the purchase agreement dated October 21, 2024 between the Selling Stockholder and the Company (the "Agreement"). This opinion is being furnished in connection with the requirements of Item 601(b)(5) of Regulation S-K under the Act. It is understood that this opinion is to be used only in connection with the offer and sale of the Shares while the Registration Statement is effective under the Act. In connection with this opinion letter, we have examined and relied upon originals or copies, certified or otherwise identified to our satisfaction, of the Registration Statement and the Prospectus, the Company's certificate of incorporation and bylaws, each as currently in effect, the Agreement, and such records, documents, certificates, memoranda and other instruments as in our judgment are necessary or appropriate to enable us to render the opinion expressed below. We have assumed: the genuineness of all signatures, including endorsements; the legal capacity and competency of all natural persons; the authenticity of all documents submitted to us as originals; the conformity to originals of all documents submitted to us as copies, including facsimile, electronic, certified or photostatic copies; the

