# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# FORM 8-K

#### **CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 18, 2023

# Kala Pharmaceuticals, Inc.

(Exact Name of Company as Specified in its Charter)

**Delaware** (State or Other Jurisdiction of Incorporation) 001-38150 (Commission File Number) 27-0604595 (IRS Employer Identification No.)

1167 Massachusetts Avenue Arlington, MA 02476

(Address of Principal Executive Offices) (Zip Code) Company's telephone number, including area code: (781) 996-5252

#### Not applicable

(Former Name or Former Address, if Changed Since Last Report)

(Former Name	e of Former Address, if Changed Since L	ast Report)
Check the appropriate box below if the Foregistrant under any of the following provi	•	, , , ,
☐Written communications pursuant to Rul	le 425 under the Securities Act (17 CFR 2	230.425)
☐Soliciting material pursuant to Rule 14a-	-12 under the Exchange Act (17 CFR 240	).14a-12)
□Pre-commencement communications pu	rsuant to Rule 14d-2(b) under the Exchan	ge Act (17 CFR 240.14d-2(b))
□Pre-commencement communications pu	rsuant to Rule 13e-4(c) under the Exchan	ge Act (17 CFR 240.13e-4(c))
Securities registered pursuant to Section 12	2(b) of the Act:	
Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	KALA	The Nasdaq Capital Market
Indicate by check mark whether Securities Act of 1933 (§230.405 of this chapter).	the registrant is an emerging growth conapter) or Rule 12b-2 of the Securities Ex	
Emerging growth company $\Box$		
If an emerging growth company transition period for complying with a Section 13(a) of the Exchange Act. □	, indicate by check mark if the registra any new or revised financial accoun	

#### Item 1.01. Entry into a Material Definitive Agreement.

On January 19, 2023, Kala Pharmaceuticals, Inc., a Delaware corporation (the "Company"), entered into an Open Market Sale Agreement<sup>SM</sup> (the "Sales Agreement") with Jefferies LLC, as agent ("Jefferies"), pursuant to which the Company may offer and sell shares of its common stock, \$0.001 par value per share (the "Common Stock"), from time to time through Jefferies. The Company has also filed a prospectus supplement (the "Prospectus Supplement") relating to the Sales Agreement with the Securities and Exchange Commission (the "SEC") under the Company's existing shelf Registration Statement on Form S-3 (File No. 333-238087), which was declared effective on May 19, 2020 (the "Registration Statement"). Pursuant to the Prospectus Supplement, the Company may offer and sell shares of Common Stock having an aggregate offering price of up to \$40.0 million under the Sales Agreement (the "Shares").

Upon delivery of an issuance notice and subject to the terms and conditions of the Sales Agreement, Jefferies may sell the shares of Common Stock at market prices by any method deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended (the "Securities Act").

The Company or Jefferies may suspend or terminate the offering of shares of Common Stock upon notice to the other party, subject to certain conditions. Jefferies will act as sales agent on a commercially reasonable efforts basis consistent with its normal trading and sales practices.

The Company has agreed to pay Jefferies commissions for its services of acting as agent of up to 3.0% of the gross proceeds from the sale of shares of Common Stock pursuant to the Sales Agreement. The Company has also agreed to provide Jefferies with customary indemnification and contribution rights.

A copy of the Sales Agreement is attached as Exhibit 1.1 hereto and is incorporated herein by reference. The foregoing description of the material terms of the Sales Agreement is qualified in its entirety by reference to such exhibit.

Wilmer Cutler Pickering Hale and Dorr LLP, counsel to the Company, has issued a legal opinion relating to the Shares. A copy of such legal opinion, including the consent included therein, is attached as Exhibit 5.1 hereto.

The Shares will be sold pursuant to the Registration Statement, and offerings of the Shares will be made only by means of the Prospectus Supplement. This Current Report on Form 8-K shall not constitute an offer to sell or solicitation of an offer to buy the Shares, nor shall there be any sale of the Shares in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities law of such state or jurisdiction.

#### Item 8.01. Other Events.

#### Prior Sales Agreement

The Company previously was party to an Amended and Restated Sales Agreement with Jefferies, dated May 7, 2020 (the "<u>Prior Sales Agreement</u>"), pursuant to which the Company could offer and sell shares of its Common Stock for aggregate gross sale proceeds of up to \$75.0 million through Jefferies by any method deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act. On January 10, 2023, the Prior Sales Agreement terminated in accordance with its terms when the Company completed the sale of \$75.0 million of its shares of Common Stock pursuant to the Prior Sales Agreement. The Company will not make any further sales of its Common Stock pursuant to the Prior Sales Agreement or the related prospectus, dated May 19, 2020, under the Registration Statement. As of the date of termination of the Prior Sales Agreement, the Company had sold an aggregate of 565,974 shares of its Common Stock under the Prior Sales Agreement for aggregate gross proceeds of \$75.0 million. From September 30, 2022 through January 10, 2023, the Company issued and sold an aggregate of 394,348 shares of Common Stock pursuant to the Prior Sales Agreement for aggregate net proceeds of \$11.0 million.

#### Oxford Loan Agreement Prepayments

As previously disclosed, on December 27, 2022, the Company and Combangio, Inc., its wholly-owned subsidiary, entered into an amendment (the "<u>Amendment</u>") with Oxford Finance LLC to the Loan and Security Agreement, dated May 4, 2021 (as amended, the "<u>Loan Agreement</u>"), by and among the Company, Combangio, Inc. and Oxford Finance LLC, in its capacity as lender (in such capacity, the "<u>Lender</u>"), and in its capacity as collateral agent (in such capacity, the "<u>Agent</u>"). Pursuant to the Amendment, the Company agreed, among other things, to make partial prepayments of the

principal amount of the term loan outstanding under the Loan Agreement as follows (collectively, the "<u>Prepayments</u>"): (1) a payment of \$5,000,000 on or before June 30, 2023, representing a partial prepayment of principal in the amount of \$4,672,897.20, plus a final payment fee of \$327,102.80 and (2) a payment of \$5,000,000 on or before January 31, 2024, representing a partial prepayment of principal in the amount of \$4,672,897.20, plus a final payment fee of 327,102.80, plus in each case accrued and unpaid interest through the date of prepayment. Following recent sales under the Prior Sales Agreement, on January 18, 2023, the Company notified the Lender and Agent of its intention to make the Prepayments, including the final payment fees and accrued and unpaid interest thereon, on February 2, 2023 in satisfaction of the Company's obligations under the Amendment. Upon such payments, the principal amount of the term loan outstanding under the Loan Agreement will total approximately \$34.0 million.

#### Item 9.01. Financial Statements and Exhibits.

#### (d) Exhibits:

Exhibit	
No.	Description
1.1	Open Market Sale Agreement SM, dated as of January 19, 2023, by and between Kala
	Pharmaceuticals, Inc. and Jefferies LLC.
5.1	Opinion of Wilmer Cutler Pickering Hale and Dorr LLP.
23.1	Consent of Wilmer Cutler Pickering Hale and Dorr LLP (contained in Exhibit 5.1 above).
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: January 19, 2023

KALA PHARMACEUTICALS, INC.

By: /s/ Eric L. Trachtenberg

Name: Eric L. Trachtenberg

Fitle: General Counsel, Chief Compliance Officer &

Corporate Secretary

#### KALA PHARMACEUTICALS, INC. Shares of Common Stock

(par value \$0.001 per share)

#### OPEN MARKET SALE AGREEMENTSM

January 19, 2023

JEFFERIES LLC 520 Madison Avenue New York, New York 10022

Ladies and Gentlemen:

Kala Pharmaceuticals, Inc., a Delaware corporation (the "Company"), proposes, subject to the terms and conditions stated herein, to issue and sell from time to time through Jefferies LLC, as sales agent and/or principal (the "Agent"), shares of the Company's common stock, par value \$0.001 per share (the "Common Shares"), on the terms set forth in this agreement (this "Agreement").

#### **Section 1. DEFINITIONS**

- (a) <u>Certain Definitions</u>. For purposes of this Agreement, capitalized terms used herein and not otherwise defined shall have the following respective meanings:
- "Affiliate" of a Person means another Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such first- mentioned Person. The term "control" (including the terms "controlling," "controlled by" and "under common control with") means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise.
- "Agency Period" means the period commencing on the date of this Agreement and expiring on the earliest to occur of (x) the date on which the Agent shall have placed the Maximum Program Amount pursuant to this Agreement and (y) the date this Agreement is terminated pursuant to Section 7.
  - "Agent" has the meaning set forth in the introductory paragraph of this Agreement.
  - "Agreement" has the meaning set forth in the introductory paragraph of this Agreement.
  - "Anti-Money Laundering Laws" has the meaning set forth in Section 2(jj).

- "Applicable Laws" has the meaning set forth in Section 2(aa).
- "Code" has the meaning set forth in <u>Section 2(k)</u>.
- "Commission" means the U.S. Securities and Exchange Commission.
- "Common Shares" has the meaning set forth in the introductory paragraph of this Agreement.
- "Company" has the meaning set forth in the introductory paragraph of this Agreement.
- "Company Stock Plans" has the meaning set forth in Section 2(k).
- "EDGAR" has the meaning set forth in <u>Section 2(b)</u>.
- "Environmental Laws" has the meaning set forth in Section 2(s).
- "ERISA" has the meaning set forth in Section 2(ee).
- **Exchange Act**" means the Securities Exchange Act of 1934, as amended, and the rules and regulations of the Commission thereunder.
  - "FDA" has the meaning set forth in Section 2(aa).
  - "FINRA" has the meaning set forth in Section 2(s).
- "Floor Price" means the minimum price per share set by the Company in the Issuance Notice below which the Agent shall not sell Shares during the applicable Selling Period, which may be adjusted by the Company at any time during the Selling Period by delivering written notice of such change to the Agent and which in no event shall be less than \$1.00 without the prior written consent of the Agent, which may be withheld in the Agent's sole discretion.
  - "Free Writing Prospectus" has the meaning set forth in Section 4(e).
  - "GDPR" has the meaning set forth in Section 2(xx).
  - "Hazardous Materials" has the meaning set forth in Section 2(dd).
  - "Health Care Laws" has the meaning set forth in Section 2(uu).
  - "HIPAA" has the meaning set forth in Section 2(xx).
  - "IP Systems" has the meaning set forth in Section 2(xx).
- "Issuance Amount" means the aggregate Sales Price of the Shares to be sold by the Agent pursuant to any Issuance Notice.

- "Issuance Notice" means a written notice delivered to the Agent by the Company in accordance with this Agreement in the form attached hereto as <a href="Exhibit A">Exhibit A</a> that is executed by its Chief Executive Officer, President or Chief Financial Officer.
- "Issuance Notice Date" means any Trading Day during the Agency Period that an Issuance Notice is delivered pursuant to Section 3(b)(i).
  - "Issuance Price" means the Sales Price less the Selling Commission.
  - "Intellectual Property" has the meaning set forth in <u>Section 2(w)</u>.
  - "Interim Prospectus Supplement" has the meaning set forth in Section 4(a).
  - "Investment Company Act" has the meaning set forth in Section 2(y).
  - "Material Adverse Effect" has the meaning set forth in Section 2(h).
- "Maximum Program Amount" means Common Shares with an aggregate Sales Price of the lesser of (a) the number or dollar amount of Common Shares registered under the effective Registration Statement (defined below) pursuant to which the offering is being made, (b) the number of authorized but unissued Common Shares (less Common Shares issuable upon exercise, conversion or exchange of any outstanding securities of the Company or otherwise reserved from the Company's authorized capital stock), (c) the number or dollar amount of Common Shares permitted to be sold under Form S-3 (including General Instruction I.B.6 thereof, if applicable), or (d) the number or dollar amount of Common Shares for which the Company has filed a Prospectus (defined below).
  - "Original Registration Statement" has the meaning set forth in Section 2(a).
  - "PBGC" has the meaning set forth in Section 2(ee).
- "Person" means an individual or a corporation, partnership, limited liability company, trust, incorporated or unincorporated association, joint venture, joint stock company, governmental authority or other entity of any kind.
  - "Personal Data" has the meaning set forth in Section 2(xx).
  - "Plan" has the meaning set forth in Section 2(ee).
  - "Policy" has the meaning set forth in Section 2(yy).
- "Principal Market" means the Nasdaq Capital Market or such other national securities exchange on which the Common Shares, including any Shares, are then listed.
  - "Privacy Laws" has the meaning set forth in Section 2(yy).
  - "Prospectus" has the meaning set forth in Section 2(a).

- "Registration Statement" has the meaning set forth in <u>Section 2(a)</u>.
- "Regulation M" has the meaning set forth in Section 2(nn).
- "Regulatory Authorities" has the meaning set forth in <u>Section 2(ss)</u>.
- "Related Proceedings" has the meaning set forth in Section 8(g).
- "Release" has the meaning set forth in Section 2(dd).
- "Renewal Deadline" has the meaning set forth in <u>Section 4(w)</u>.
- "Representation Date" has the meaning set forth in the introductory paragraph of Section 2.
- "Rule 102" has the meaning set forth in Section 4(v).
- "Sales Price" means the actual sale execution price of each Share placed by the Agent pursuant to this Agreement.
  - "Sarbanes-Oxley Act" has the meaning set forth in Section 2(uu).
- "Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations of the Commission thereunder.
- "Selling Commission" means, except as otherwise agreed, three percent (3.00%) of the gross proceeds of the Shares sold pursuant to this Agreement.
- "Selling Period" means the period of Trading Days specified in the Issuance Notice (as determined by the Company in the Company's sole discretion and specified in the applicable Issuance Notice) including the Trading Day on which an Issuance Notice is delivered pursuant to Section 3(b)(i), if such notice is delivered prior to 3:00 p.m. (New York City time) and otherwise, following the Trading Day on which an Issuance Notice is delivered pursuant to Section 3(b)(i).
- "Settlement Date" means the second business day following each Trading Day during the Selling Period on which Shares are sold pursuant to this Agreement, when the Company shall deliver to the Agent the amount of Shares sold on such Trading Day and the Agent shall deliver to the Company the Issuance Price received on such sales.
  - "Shares" shall mean the Company's Common Shares issued or issuable pursuant to this Agreement.
  - "Stock Options" has the meaning set forth in Section 2(k).
  - "Time of Sale" has the meaning set forth in Section 3(b)(v).
  - "Time of Sale Information" has the meaning set forth in Section 2(b).

"Trading Day" means any day on which the Principal Market is open for trading.

"Triggering Event Date" has the meaning set forth in Section 4(0).

#### Section 2. REPRESENTATIONS AND WARRANTIES OF THE COMPANY

The Company represents and warrants to, and agrees with, the Agent that, unless such representation, warranty or agreement specifies otherwise, as of (1) the date of this Agreement, (2) each Issuance Notice Date, (3) each Settlement Date, (4) each Triggering Event Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 4(o) and (5) as of each Time of Sale (each of the times referenced above is referred to herein as a "**Representation Date**"), except as may be disclosed in the Prospectus (including any documents incorporated by reference therein and any amendments or supplements thereto) on or before a Representation Date:

Registration Statement. The Company has prepared and filed with the Commission a shelf (a) registration statement on Form S-3 (File No. 333-238087), including a base prospectus relating to certain securities, including the Common Shares to be issued from time to time by the Company. Such registration statement registers the issuance and sale by the Company of the Shares under the Securities Act. The Company may file one or more additional registration statements from time to time that will contain a base prospectus and related prospectus or prospectus supplement, if applicable, with respect to the Shares. Except where the context otherwise requires, such registration statement(s), including any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, including all financial statements, exhibits and schedules thereto and all documents incorporated or deemed to be incorporated therein by reference pursuant to Item 12 of Form S-3 under the Securities Act as from time to time amended or supplemented, is herein referred to as the "Registration **Statement**," and the prospectus constituting a part of such registration statement(s), together with any prospectus supplement filed with the Commission pursuant to Rule 424(b) under the Securities Act relating to a particular issuance of the Shares, including all documents incorporated or deemed to be incorporated therein by reference pursuant to Item 12 of Form S-3 under the Securities Act, in each case, as from time to time amended or supplemented, is referred to herein as the "Prospectus," except that if any revised prospectus is provided to the Agent by the Company for use in connection with the offering of the Shares that is not required to be filed by the Company pursuant to Rule 424(b) under the Securities Act, the term "Prospectus" shall refer to such revised prospectus from and after the time it is first provided to the Agent for such use. The Registration Statement at the time it originally became effective is herein called the "Original Registration Statement." As used in this Agreement, the terms "amendment" or "supplement" when applied to the Registration Statement or the Prospectus shall be deemed to include the filing by the Company with the Commission of any document under the Exchange Act after the date hereof that is or is deemed to be incorporated therein by reference.

All references in this Agreement to financial statements and schedules and other information which is "contained," "included" or "stated" in the Registration Statement or the Prospectus (and all other references of like import) shall be deemed to mean and include all such financial statements and schedules and other information which is or is deemed to be incorporated by reference in or otherwise deemed under the Securities Act to be a part of or included in the

Registration Statement or the Prospectus, as the case may be, as of any specified date; and all references in this Agreement to amendments or supplements to the Registration Statement or the Prospectus shall be deemed to mean and include, without limitation, the filing of any document under the Exchange Act which is or is deemed to be incorporated by reference in or otherwise deemed under the Securities Act to be a part of or included in the Registration Statement or the Prospectus, as the case may be, as of any specified date. The Company's obligations under this Agreement to furnish, provide, deliver or make available (and all other similar references) copies of any report or statement shall be deemed satisfied if the same is filed with the Commission through its Electronic Data Gathering, Analysis and Retrieval system ("EDGAR").

At the time the Original Registration Statement was declared effective and at the time the Company's most recent annual report on Form 10-K was filed with the Commission, if later, the Company met the then-applicable requirements for use of Form S-3 under the Securities Act. During the Agency Period, each time the Company files an annual report on Form 10-K with the Commission the Company will meet the then-applicable requirements for use of Form S-3 under the Securities Act.

(b) <u>Compliance with Registration Requirements</u>. The Original Registration Statement and any Rule 462(b) Registration Statement filed after the date hereof will be declared effective prior to any Issuance Notice Date following such filing. The Company has complied to the Commission's satisfaction with all requests of the Commission for additional or supplemental information. No stop order suspending the effectiveness of the Registration Statement or any Rule 462(b) Registration Statement is in effect and no proceedings for such purpose have been instituted or are pending or, to the best knowledge of the Company, are contemplated or threatened by the Commission.

The Prospectus when filed complied, or will comply, in all material respects with the Securities Act and, if filed by electronic transmission pursuant to the Commission's EDGAR system (except as may be permitted by Regulation S-T under the Securities Act), was identical to the copy thereof delivered to the Agent for use in connection with the issuance and sale of the Shares. Each of the Registration Statement, any Rule 462(b) Registration Statement and any post-effective amendment thereto, at the time it became or becomes effective and at each Representation Date, complied and will comply in all material respects with the Securities Act and did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. As of the date of this Agreement, the Prospectus and any Free Writing Prospectus consented to by the Agent pursuant to Section 4(e) considered together (collectively, the "Time of Sale Information") did not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Prospectus, as amended or supplemented, as of its date and at each Representation Date, did not and will not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the three immediately preceding sentences do not apply to statements in or omissions from the Registration Statement, any Rule 462(b) Registration Statement, or any post-effective amendment thereto, or the Prospectus, or any amendments or supplements thereto, made in reliance upon and in

conformity with information relating to the Agent furnished to the Company in writing by the Agent expressly for use therein, it being understood and agreed that the only such information furnished by the Agent to the Company consists of the information described in <u>Section 6</u> below. There are no contracts or other documents required to be described in the Prospectus or to be filed as exhibits to the Registration Statement which have not been described or filed as required. The Registration Statement and the offer and sale of the Shares as contemplated hereby meet the requirements of Rule 415 under the Securities Act and comply in all material respects with said Rule.

- (c) Ineligible Issuer Status. The Company is not an "ineligible issuer" in connection with the offering of the Shares pursuant to Rules 164, 405 and 433 under the Securities Act. Any Free Writing Prospectus that the Company is required to file pursuant to Rule 433(d) under the Securities Act has been, or will be, filed with the Commission in accordance with the requirements of the Securities Act. Each Free Writing Prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) under the Securities Act or that was prepared by or on behalf of or used or referred to by the Company complies or will comply in all material respects with the requirements of Rule 433 under the Securities Act including timely filing with the Commission or retention where required and legending, and each such Free Writing Prospectus, as of its issue date and at all subsequent times through the completion of the issuance and sale of the Shares did not, does not and will not include any information that conflicted, conflicts with or will conflict with the information contained in the Registration Statement or the Prospectus, including any document incorporated by reference therein. Except for the Free Writing Prospectuses, if any, and electronic road shows, if any, furnished to the Agent before first use, the Company has not prepared, used or referred to, and will not, without the Agent's prior consent, prepare, use or refer to, any Free Writing Prospectus.
- (d) <u>Incorporated Documents</u>. The documents incorporated or deemed to be incorporated by reference in the Registration Statement and the Prospectus, at the time they were filed with the Commission, complied in all material respects with the requirements of the Exchange Act, as applicable, and, when read together with the other information in the Prospectus, do not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.
- (e) <u>S-3 Eligibility</u>. The Company and the transactions contemplated by this Agreement meet the requirements for, and comply with the conditions for the use of, Form S-3 under the Act. The Company is not a shell company (as defined in Rule 405 of the Act) and has not been a shell company for at least 12 calendar months.
- (f) <u>Exchange Act Compliance</u>. The documents incorporated or deemed to be incorporated by reference in the Prospectus, at the time they were or hereafter are filed with the Commission, and any Free Writing Prospectus or amendment or supplement thereto complied and will comply in all material respects with the requirements of the Exchange Act, and, when read together with the other information in the Prospectus, at the time the Registration Statement and any amendments thereto become effective and at each Time of Sale, as the case may be, will not contain an untrue statement of a material fact or omit to state a material fact required to be stated

therein or necessary to make the fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

- (g) Financial Statements. The financial statements (including the related notes thereto) of the Company and its consolidated subsidiaries included or incorporated by reference in the Registration Statement, the Prospectus and the Time of Sale Information comply in all material respects with the applicable requirements of the Securities Act and present fairly in all material respects the financial position of the Company and its consolidated subsidiaries included as of the dates indicated and the results of its operations and the changes in its cash flows for the periods specified; such financial statements have been prepared in conformity with generally accepted accounting principles in the United States applied on a consistent basis throughout the periods covered thereby, and, in the case of unaudited interim financial statements, subject to normal year-end audit adjustments and the exclusion of certain footnotes as permitted by the applicable rules of the Commission, and any supporting schedules included or incorporated by reference in the Registration Statement present fairly in all material respects the information required to be stated therein; and the other financial information included or incorporated by reference in the Registration Statement, the Prospectus and the Time of Sale Information has been derived from the accounting records of the Company and its consolidated subsidiaries included and presents fairly in all material respects the information shown thereby.
- No Material Adverse Change. Since the date of the most recent financial statements of the Company included or incorporated by reference in the Registration Statement, the Prospectus and the Time of Sale Information, (i) there has not been any material change in the capital stock (other than the issuance of shares of Common Stock upon exercise of stock options and warrants described as outstanding in, and the grant of options and awards under existing equity incentive plans described in, the Registration Statement, the Prospectus and the Time of Sale Information), short-term debt or long-term debt of the Company or any of its subsidiaries, or any dividend or distribution of any kind declared, set aside for payment, paid or made by the Company on any class of capital stock, or any material adverse change in or affecting the business, properties, management, financial position, stockholders' equity, results of operations or prospects of the Company and its subsidiaries taken as a whole; (ii) neither the Company nor any of its subsidiaries has entered into any transaction or agreement (whether or not in the ordinary course of business) that is material to the Company or incurred any liability or obligation, direct or contingent, that is material to the Company and its subsidiaries taken as a whole; and (iii) neither the Company nor any of its subsidiaries has sustained any loss or interference with its business that is material to the Company and its subsidiaries taken as a whole and that is either from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor disturbance or dispute or any action, order or decree of any court or arbitrator or governmental or regulatory authority, except in each case as otherwise disclosed in the Registration Statement, the Prospectus and the Time of Sale Information.
- (i) <u>Organization and Good Standing</u>. The Company and each of its subsidiaries have been duly organized and is validly existing and in good standing under the laws of Delaware, is duly qualified to do business and is in good standing in each jurisdiction in which its ownership or lease of property or the conduct of its business requires such qualification, and has all power and authority necessary to own or hold its properties and to conduct the business in which it is engaged,

except where the failure to be so qualified or in good standing or have such power or authority would not, individually or in the aggregate, have a material adverse effect on the business, properties, management, financial position, stockholders' equity, results of operations or prospects of the Company and its subsidiaries taken as a whole or on the performance by the Company of its obligations under this Agreement (a "Material Adverse Effect"). Except as otherwise disclosed to the Agent, the Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiaries listed in Exhibit 21.1 to the most recent annual report on Form 10-K filed by the Company and incorporated by reference in the Registration Statement, the Prospectus and the Time of Sale Information.

- (j) <u>Capitalization</u>. All the outstanding shares of capital stock of the Company have been duly and validly authorized and issued and are fully paid and non-assessable and are not subject to any preemptive or similar rights that have not been validly waived; except as described in or expressly contemplated by the Registration Statement, the Prospectus and the Time of Sale Information, there are no outstanding rights (including, without limitation, preemptive rights), warrants or options to acquire, or instruments convertible into or exchangeable for, any shares of capital stock or other equity interest in the Company or any of its subsidiaries, or any contract, commitment, agreement, understanding or arrangement of any kind relating to the issuance of any capital stock of the Company, any such convertible or exchangeable securities or any such rights, warrants or options; and the capital stock of the Company conforms in all material respects to the description thereof contained in the Registration Statement and the Prospectus.
- (k) Stock Options. With respect to the stock options (the "Stock Options") granted pursuant to the stock-based compensation plans of the Company and its subsidiaries (the "Company Stock Plans"), (i) to the Company's knowledge, each Stock Option intended to qualify as an "incentive stock option" under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code") so qualifies (other than to the extent such Stock Options exceed the limitation under Section 422(d) of the Code), (ii) each grant of a Stock Option was duly authorized no later than the date on which the grant of such Stock Option was by its terms to be effective by all necessary corporate action, including, as applicable, approval by the board of directors of the Company (or a duly constituted and authorized committee thereof) and any required stockholder approval by the necessary number of votes or written consents, and, to the Company's knowledge (other than with respect to due execution and delivery by the Company), the award agreement governing such grant (if any) was duly executed by the Company and delivered to the recipient, (iii) each such grant was made in accordance with the terms of the Company Stock Plans, the Exchange Act and all other applicable laws and regulatory rules or requirements, including the rules of the Principal Market and any other exchange on which Company securities are traded, and (iv) each such grant was properly accounted for in accordance with generally accepted accounting principles in the United States in the financial statements (including the related notes) of the Company.
- (l) <u>Due Authorization</u>. The Company has full right, power and authority to execute and deliver this Agreement and to perform its obligations hereunder; and all action required to be taken for the due and proper authorization, execution and delivery by it of this Agreement and the consummation by it of the transactions contemplated hereby has been duly and validly taken.

- (m) <u>Sales Agreement</u>. This Agreement has been duly authorized, executed and delivered by the Company.
- (n) <u>The Shares</u>. The Shares to be issued and sold by the Company hereunder, when issued and delivered and paid for as provided herein, will be duly authorized and validly issued, will be fully paid and nonassessable and will conform in all material respects to the descriptions thereof in the Registration Statement, the Prospectus and the Time of Sale Information; and the issuance of the Shares is not subject to any preemptive or similar rights.
- (o) <u>Descriptions of the Sales Agreement</u>. This Agreement conforms in all material respects to the description thereof contained in the Prospectus and the Time of Sale Information.
- (p) <u>Stock Exchange Listing</u>. The Common Shares are registered pursuant to Section 12(b) of the Exchange Act and are listed on the Principal Market, and the Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Common Shares under the Exchange Act or delisting the Common Shares from the Principal Market, nor has the Company received any notification that the Commission or the Principal Market is contemplating terminating such registration or listing.
- (q) No Violation or Default. Neither the Company nor any of its subsidiaries is (i) in violation of its charter or by-laws or similar organizational documents; (ii) in default, and no event has occurred that, with notice or lapse of time or both, would constitute such a default, in the due performance or observance of any term, covenant or condition contained in any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries is bound or to which any of the property or assets of the Company or any of its subsidiaries is subject; or (iii) in violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority having jurisdiction over the Company or any of its subsidiaries, except, in the case of clauses (ii) and (iii) above, for any such default or violation that would not, individually or in the aggregate, have a Material Adverse Effect.
- (r) No Conflicts. The execution, delivery and performance by the Company of this Agreement, the issuance and sale of the Shares and the consummation of the transactions contemplated by this Agreement will not (i) conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company or any of its subsidiaries pursuant to, any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which the Company is bound or to which any of the property or assets of the Company is subject, (ii) result in any violation of the provisions of the charter or by-laws or similar organizational documents of the Company or any of its subsidiaries or (iii) result in the violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority having jurisdiction over the Company or any of its subsidiaries, except, in the case of clauses (i) and (iii) above, for any such conflict, breach, violation, default, lien, charge or encumbrance that would not, individually or in the aggregate, have a Material Adverse Effect.

- (s) No Consents Required. No consent, approval, authorization, order, license, registration or qualification of or with any court or arbitrator or governmental or regulatory authority is required for the execution, delivery and performance by the Company of this Agreement, the issuance and sale of the Shares and the consummation of the transactions contemplated by this Agreement and by each Prospectus, except for the registration of the Shares under the Securities Act and such consents, approvals, authorizations, orders and registrations or qualifications as may be required by the Financial Industry Regulatory Authority, Inc. ("FINRA"), the Principal Market or under applicable state securities laws in connection with the sale and distribution of the Shares.
- (t) <u>Legal Proceedings</u>. Except as described in the Registration Statement, the Prospectus, and the Time of Sale Information, there are no legal, governmental or regulatory investigations, actions, suits or proceedings pending to which the Company or any of its subsidiaries is a party or to which any property of the Company or any of its subsidiaries is the subject that, individually or in the aggregate would reasonably be expected to have a Material Adverse Effect; to the knowledge of the Company, no such investigations, actions, suits or proceedings are threatened or contemplated by any governmental or regulatory authority or threatened by others; and (i) there are no current or pending legal, governmental or regulatory actions, suits or proceedings that are required under the Securities Act to be described in the Registration Statement, the Prospectus, and the Time of Sale Information that are not so described in the Registration Statement, the Prospectus, or the Time of Sale Information that are not so filed as exhibits to the Registration Statement, the Prospectus, or the Time of Sale Information that are not so filed as exhibits to the Registration Statement or described in the Registration Statement, the Prospectus, and the Time of Sale Information that are not so filed as exhibits to the Registration Statement or described in the Registration Statement, the Prospectus, and the Time of Sale Information.
- (u) <u>Independent Accountants</u>. Deloitte & Touche LLP, who have certified certain financial statements of the Company and its subsidiaries, is an independent registered public accounting firm with respect to the Company and its subsidiaries within the applicable rules and regulations adopted by the Commission and the Public Company Accounting Oversight Board (United States) and as required by the Securities Act.
- (v) <u>Title to Real and Personal Property</u>. Except as described in the Registration Statement, the Prospectus and the Time of Sale Information, the Company and its subsidiaries have good title in fee simple (in the case of real property) to, or has valid rights to lease or otherwise use, all items of real and personal property and assets that are material to the business of the Company and its subsidiaries taken as a whole, in each case free and clear of all liens, encumbrances, claims and defects and imperfections of title except those that (i) do not materially interfere with the use made and proposed to be made of such property by the Company and its subsidiaries or (ii) would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect.
- (w) <u>Title to Intellectual Property</u>. Except as disclosed in the Registration Statement, the Prospectus and the Time of Sale Information, the Company and its subsidiaries own or possess valid rights to use all intellectual property rights throughout the world, including all trademarks, service marks, trade names, domain names, and all goodwill associated with the foregoing, patents,

patent rights, inventions, copyrights and copyrightable works, licenses, technology, know-how, trade secrets and other intellectual property and proprietary or confidential information, systems or procedures (including all registrations and applications for registration of the foregoing) (collectively, "Intellectual Property") necessary for or material to the conduct of its business as currently conducted or as proposed in the Registration Statement. the Prospectus, and the Time of Sale Information to be conducted, and, to the knowledge of the Company, the conduct of its business has not infringed, misappropriated or otherwise violated any Intellectual Property of others in any material respect, and, to the knowledge of the Company, the future conduct of its business as proposed in the Registration Statement, the Prospectus, and the Time of Sale Information to be conducted, will not infringe, misappropriate or otherwise violate any Intellectual Property of others in any material respect. Except as would not, individually or in the aggregate, if determined adversely to the Company and its subsidiaries, considered as one entity, reasonably be expected to have a Material Adverse Effect, there is no pending or threatened action, suit, proceeding or claim by any third party (i) challenging the Company or its subsidiaries' rights in or to any of their owned or licensed Intellectual Property; (ii) alleging that the Company or any of its subsidiaries has infringed, misappropriated or otherwise violated or conflicted with any Intellectual Property of any third party; or (iii) challenging the validity, scope or enforceability of any Intellectual Property of the Company or its subsidiaries, and in the case of each of (i), (ii) and (iii), the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim. Except as disclosed in the Prospectus and the Time of Sale Information, or as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect, all Intellectual Property owned by the Company or its subsidiaries is valid and enforceable, is owned solely by the Company or its subsidiaries, is owned free and clear of all liens, encumbrances, defects and other restrictions, and to the knowledge of the Company, no third party has infringed, misappropriated or otherwise violated any Intellectual Property owned by or exclusively licensed to the Company or its subsidiaries. The Company and its subsidiaries have complied in all material respects with the terms of each agreement pursuant to which Intellectual Property has been licensed to the Company or any subsidiary, and all such agreements are in full force and effect. To the Company's knowledge, there are no material defects in any of the patents or patent applications included in the Intellectual Property. The Company and its subsidiaries have taken commercially reasonable actions necessary to maintain and protect all material registered Intellectual Property (including all applications therefor) owned by the Company or its subsidiaries, including payment of applicable maintenance fees, filing of applicable statements of use, timely response to office actions, and disclosure of any required information. The Company and its subsidiaries have at all times taken reasonable steps in accordance with normal industry practice to maintain the confidentiality of all material Intellectual Property, the value of which to the Company is contingent upon maintaining the confidentiality thereof. Except as would not, individually or in the aggregate have a Material Adverse Effect, all founders, current and former employees, contractors, consultants and other parties involved in the development of Intellectual Property for the Company or its subsidiaries have signed confidentiality and invention assignment agreements with the Company or its subsidiaries pursuant to which the Company or any of its subsidiaries either (i) has obtained ownership of and is the exclusive owner of such Intellectual Property, or (ii) has obtained a valid right to exploit such Intellectual Property, sufficient for the conduct of its business as currently conducted and as proposed in the Registration Statement, the Prospectus, and the Time of Sale Information to be conducted. To the Company's knowledge, no

employee of the Company or its subsidiaries is in or has been in violation of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement, or any restrictive covenant to or with a former employer where the basis of such violation relates to such employee's employment with the Company or its subsidiaries, except for such violations that would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. The duty of candor and good faith as required by the United States Patent and Trademark Office during the prosecution of the United States patents and patent applications included in the Intellectual Property have been complied with in all material respects.

- (x) <u>No Undisclosed Relationships</u>. No relationship, direct or indirect, exists between or among the Company or any of its subsidiaries, on the one hand, and the directors, officers, stockholders, customers or suppliers of the Company or any of its subsidiaries, on the other, that is required by the Securities Act to be described in the Registration Statement, the Prospectus, and the Time of Sale Information and that is not so described in such documents.
- (y) <u>Investment Company Act</u>. The Company is not and, immediately after giving effect to the offering and sale of the Shares and the application of the proceeds thereof as described in the Prospectus, will not be required to register as an "investment company" or an entity "controlled" by an "investment company" within the meaning of the Investment Company Act of 1940, as amended, and the rules and regulations of the Commission thereunder (collectively, the "**Investment Company Act**").
- (z) Taxes. The Company and its subsidiaries have filed all United States federal income tax returns required by law to be filed (taking into account any timely requested extensions thereof) through the date hereof and all other material state, local and foreign tax returns required by law to be filed (taking into account any timely requested extensions thereof) through the date hereof. The Company has paid all federal, state, local and foreign taxes due, except for taxes being contested in good faith and for which adequate reserves have been taken, and except as would not, individually or in the aggregate, have a Material Adverse Effect. Except as otherwise disclosed in the Registration Statement, the Prospectus, and the Time of Sale Information, there is no tax deficiency that has been, or would reasonably be expected to be, asserted against the Company or any of its subsidiaries or any of its respective properties or assets, in each case, except as would not have a Material Adverse Effect.
- (aa) <u>Licenses and Permits</u>. The Company and its subsidiaries possess all licenses, certificates, permits and other authorizations issued by, and has made all declarations and filings with, the appropriate federal, state, local or foreign governmental or regulatory authorities that are necessary for the ownership or lease of its properties or the conduct of its business as described in the Registration Statement, the Prospectus and the Time of Sale Information, except where the failure to possess or make the same would not, individually or in the aggregate, have a Material Adverse Effect; and except as described in the Registration Statement, the Prospectus, and the Time of Sale Information, the Company has not received notice of any revocation or modification of any such license, certificate, permit or authorization and does not have any reason to believe that any such license, certificate, permit or authorization will not be renewed in the ordinary course, except where such revocation, modification, or non-renewal would not, individually or in the

aggregate, have a Material Adverse Effect. Except as described in the Registration Statement, the Prospectus, and the Time of Sale Information, as applicable, the Company and its subsidiaries (i) are, and at all times has been, in compliance with all statutes, rules and regulations of the U.S. Food and Drug Administration ("FDA") and other applicable federal, state, local or foreign governmental and regulatory authorities applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, storage, import, export or disposal of any product manufactured or distributed by the Company ("Applicable Laws"), except where such noncompliance would not, individually or in the aggregate, have a Material Adverse Effect; and (ii) have not received any FDA Form 483, written notice of adverse finding, warning letter, untitled letter or other correspondence or written notice from any court or arbitrator or governmental or regulatory authority alleging or asserting non-compliance with (x) any Applicable Laws or (y) any licenses, exemptions, certificates, approvals, clearances, authorizations, permits and supplements or amendments thereto required by any such Applicable Laws.

- (bb) <u>No Labor Disputes</u>. No labor disturbance by or dispute with employees of the Company or any of its subsidiaries exists or, to the knowledge of the Company, is contemplated or threatened, and the Company is not aware of any existing or imminent labor disturbance by, or dispute with, the employees of any of its principal suppliers, contractors or customers, except as would not have a Material Adverse Effect.
- Compliance with and Liability under Environmental Laws. (i) The Company and its subsidiaries (a) are, and at all prior times was, in compliance with any and all applicable federal, state, local and foreign laws, rules, regulations, requirements, decisions, judgments, decrees, orders and the common law relating to pollution or the protection of the environment, natural resources or human health or safety, including those relating to the generation, storage, treatment, use, handling, transportation, Release or threat of Release of Hazardous Materials (collectively, "Environmental Laws"), (b) has received and is in compliance with all permits, licenses, certificates or other authorizations or approvals required of it under applicable Environmental Laws to conduct its business, (c) has not received notice of any actual or potential liability under or relating to, or actual or potential violation of, any Environmental Laws, including for the investigation or remediation of any Release or threat of Release of Hazardous Materials, and has no knowledge of any event or condition that would reasonably be expected to result in any such notice, (d) is not conducting or paying for, in whole or in part, any investigation, remediation or other corrective action pursuant to any Environmental Law at any location, and (e) is not a party to any order, decree or agreement that imposes any obligation or liability under any Environmental Law, and (ii) there are no costs or liabilities associated with Environmental Laws of or relating to the Company or its subsidiaries, except in the case of each of (i) and (ii) above, for any such matter, as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect; and (iii) except as described in the Registration Statement, the Prospectus, and the Time of Sale Information (a) there are no proceedings that are pending, or that are, to the Company's knowledge, contemplated, against the Company or any of its subsidiaries under any Environmental Laws in which a governmental entity is also a party, other than such proceedings regarding which it is reasonably believed no monetary sanctions of \$100,000 or more will be imposed, (b) the Company and its subsidiaries are not aware of any facts or issues regarding compliance with Environmental Laws, or liabilities or other obligations under Environmental Laws, including the Release or threat of Release of Hazardous Materials, that, individually or in the aggregate, would

reasonably be expected to have a Material Adverse Effect, and (c) none of the Company or its subsidiaries anticipates material capital expenditures relating to any Environmental Laws.

- (dd) <u>Hazardous Materials</u>. There has been no storage, generation, transportation, use, handling, treatment, Release or threat of Release of Hazardous Materials by, relating to or caused by the Company (or, to the knowledge of the Company, any other entity (including any predecessor) for whose acts or omissions the Company is or would reasonably be expected to be liable) at, on, under or from any property or facility now or previously owned, operated or leased by the Company, or at, on, under or from any other property or facility, in violation of any Environmental Laws or in a manner or amount or to a location that would reasonably be expected to result in any liability under any Environmental Law, except for any violation or liability which would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. "Hazardous Materials" means any material, chemical, substance, waste, pollutant, contaminant, compound, mixture, or constituent thereof, in any form or amount, including petroleum (including crude oil or any fraction thereof) and petroleum products, natural gas liquids, asbestos and asbestos containing materials, naturally occurring radioactive materials, brine, and drilling mud, regulated or which can give rise to liability under any Environmental Law. "Release" means any spilling, leaking, seepage, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, disposing, depositing, dispersing, or migrating in, into or through the environment, or in, into, from or through any building or structure.
- Compliance with ERISA. (i) Each employee benefit plan, within the meaning of Section 3(3) of the Employee Retirement Income Security Act of 1974, as amended ("ERISA"), for which the Company or any member of its "Controlled Group" (defined as any organization which is a member of a controlled group of corporations within the meaning of Section 414 of the Code) would have any liability (each, a "Plan") has been maintained in compliance with its terms and the requirements of any applicable statutes, orders, rules and regulations, including but not limited to ERISA and the Code, except for noncompliance that would not reasonably be expected to result in material liability to the Company; (ii) no prohibited transaction, within the meaning of Section 406 of ERISA or Section 4975 of the Code, has occurred with respect to any Plan excluding transactions effected pursuant to a statutory or administrative exemption that would reasonably be expected to result in a material liability to the Company; (iii) for each Plan that is subject to the funding rules of Section 412 of the Code or Section 302 of ERISA, the minimum funding standard of Section 412 of the Code or Section 302 of ERISA, as applicable, has been satisfied (without taking into account any waiver thereof or extension of any amortization period) and is reasonably expected to be satisfied in the future (without taking into account any waiver thereof or extension of any amortization period); (iv) the fair market value of the assets of each Plan that is required to be funded exceeds the present value of all benefits accrued under such Plan (determined based on those assumptions used to fund such Plan); (v) no "reportable event" (within the meaning of Section 4043(c) of ERISA) has occurred or is reasonably expected to occur that either has resulted, or would reasonably be expected to result, in material liability to the Company; (vi) neither the Company nor any member of the Controlled Group has incurred, nor reasonably expects to incur, any liability under Title IV of ERISA (other than contributions to the Plan or premiums to the Pension Benefit Guaranty Corporation ("PBGC"), in the ordinary course and without default) in respect of a Plan (including a "multiemployer plan", within the meaning of Section 4001(a)(3) of ERISA); and (vii) there is no pending audit or investigation by the Internal

Revenue Service, the U.S. Department of Labor, the PBGC or any other governmental agency or any foreign regulatory agency with respect to any Plan that would reasonably be expected to result in material liability to the Company. None of the following events has occurred or is reasonably likely to occur: (x) a material increase in the aggregate amount of contributions required to be made to all Plans by the Company in the current fiscal year of the Company compared to the amount of such contributions made in the Company's most recently completed fiscal year; other than an increase solely attributable to (A) an increase in the number of employees covered by such Plans or (B) an increase arising from the renewal in the ordinary course of business of contracts with vendors, insurers, plan administrators or other similar service providers under which the benefits of such Plans are provided; or (y) a material increase in the Company's "accumulated post-retirement benefit obligations" (within the meaning of Statement of Financial Accounting Standards 106) compared to the amount of such obligations in the Company's most recently completed fiscal year.

- (ff) <u>Disclosure Controls</u>. The Company and its subsidiaries have established an effective system of "disclosure controls and procedures" (as defined in Rule 13a-15(e) of the Exchange Act) that complies with the requirements of the Exchange Act and that has been designed to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms, including controls and procedures designed to ensure that such information is accumulated and communicated to the Company's management as appropriate to allow timely decisions regarding required disclosure.
- Accounting Controls. The Company and its subsidiaries have established systems of "internal control over financial reporting" (as defined in Rule 13a-15(f) of the Exchange Act) that comply with the requirements of the Exchange Act and have been designed by, or under the supervision of, its principal executive and principal financial officers, or persons performing similar functions, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, including, but not limited to, internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences and (v) interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement, the Prospectus and the Time of Sale Information fairly presents the information called for in all material respects and is prepared in accordance with the Commission's rules and guidelines applicable thereto. Based on the Company's most recent evaluation of its internal controls over financial reporting pursuant to Rule 13-a15(c) of the Exchange Act, except as disclosed in the Prospectus and the Time of Sale Information, there are no material weaknesses in the Company's internal controls. The Company's auditors and the Audit Committee of the Board of Directors of the Company have been advised of: (i) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which have adversely affected or are reasonably likely to

adversely affect the Company's ability to record, process, summarize and report financial information; and (ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal controls over financial reporting.

- (hh) <u>Insurance</u>. Except as disclosed in the Prospectus and the Time of Sale Information, the Company and its subsidiaries have insurance covering its properties, operations, personnel and businesses, including business interruption insurance, which insurance is in amounts and insures against such losses and risks that the Company reasonably believes are adequate to protect the Company and its subsidiaries and their respective businesses; and neither the Company nor any of its subsidiaries has (i) received notice from any insurer or agent of such insurer that capital improvements or other expenditures are required or necessary to be made in order to continue such insurance or (ii) any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage at reasonable cost from similar insurers as may be necessary to continue its business.
- No Unlawful Payments. Neither the Company nor any of its subsidiaries nor, to the knowledge of the Company, any director, officer, employee, agent, affiliate or other person acting on behalf of the Company or any of its subsidiaries has (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (ii) made or taken an act in furtherance of an offer, promise or authorization of any direct or indirect unlawful payment or benefit to any foreign or domestic government official or employee, including of any government-owned or controlled entity or of a public international organization, or any person acting in an official capacity for or on behalf of any of the foregoing, or any political party or party official or candidate for political office; (iii) violated or is in violation of any provision of the Foreign Corrupt Practices Act of 1977, as amended, or any applicable law or regulation implementing the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, or committed an offence under the Bribery Act 2010 of the United Kingdom or any other applicable anti-bribery or anti-corruption law; or (iv) made, offered, agreed, requested or taken an act in furtherance of any unlawful bribe or other unlawful benefit, including, without limitation, any unlawful rebate, payoff, influence payment, kickback or other unlawful or improper payment or benefit. The Company and its subsidiaries have instituted, maintain and enforce, and will continue to maintain and enforce policies and procedures designed to promote and ensure compliance with all applicable anti-bribery and anti-corruption laws.
- (jj) <u>Compliance with Anti-Money Laundering Laws</u>. The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements, including those of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the applicable money laundering statutes of all jurisdictions where the Company or any of its subsidiaries conducts business, the rules and regulations thereunder and any related or similar rules or regulations issued, administered or enforced by any governmental agency of all jurisdictions where the Company conducts business (collectively, the "Anti-Money Laundering Laws") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Anti-Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

- No Conflicts with Sanctions Laws. Neither the Company nor any of its subsidiaries nor, to the knowledge of the Company, any director, officer, employee, agent, affiliate or other person acting on behalf of the Company is currently the subject or the target of any sanctions administered or enforced by the U.S. government, (including, without limitation, the Office of Foreign Assets Control of the U.S. Department of the Treasury or the U.S. Department of State and including, without limitation, the designation as a "specially designated national" or "blocked person"), the United Nations Security Council, the European Union or His Majesty's Treasury (collectively, "Sanctions"), nor is the Company or any of its subsidiaries located, organized or resident in a country or territory that is the subject or target of Sanctions, including, without limitation, Crimea, Cuba, Donetsk People's Republic, Iran, Luhansk People's Republic, North Korea and Syria (each, a "Sanctioned Country"); and the Company will not directly or indirectly use the proceeds of the offering of the Shares hereunder, or lend, contribute or otherwise make available such proceeds to any joint venture partner or other person or entity (i) to fund or facilitate any activities of or business with any person that, at the time of such funding or facilitation, is the subject or target of Sanctions, (ii) to fund or facilitate any activities of or business in any Sanctioned Country or (iii) in any other manner that will result in a violation by any person (including any person participating in the transaction, whether as agent, advisor, investor or otherwise) of Sanctions. For the past five years, the Company and its subsidiaries have not knowingly engaged in and are not now knowingly engaged in any dealings or transactions with any person that at the time of the dealing or transaction is or was the subject or the target of Sanctions or with any Sanctioned Country.
- (ll) <u>No Broker's Fees</u>. Neither the Company nor any of its subsidiaries is a party to any contract, agreement or understanding with any person (other than this Agreement) that would give rise to a valid claim against the Company for a brokerage commission, finder's fee or like payment in connection with the transactions contemplated by this Agreement or any Prospectus.
- (mm) No Registration Rights. Except as described in the Registration Statement, the Prospectus and the Time of Sale Information, no person has the right to require the Company or any of its subsidiaries to register any securities for sale under the Securities Act by reason of the filing of the Registration Statement with the Commission or the issuance and sale of the Shares, other than rights that have been validly waived.
- (nn) No Stabilization. Neither the Company nor any of its subsidiaries has taken, directly or indirectly, without given effect to activities by the Agent, any action designed to or that would reasonably be expected to cause or result in any stabilization or manipulation of the price of the Shares or any other "reference security" (as defined in Rule 100 of Regulation M under the Exchange Act ("Regulation M")) whether to facilitate the sale or resale of the Shares or otherwise, and has taken no action which would directly or indirectly violate Regulation M. The Company acknowledges that the Agent may engage in passive market making transactions in the Shares on the Nasdaq Global Select Market in accordance with Regulation M.
- (oo) <u>Margin Rules</u>. The application of the proceeds received by the Company from the issuance, sale and delivery of the Shares as described in the Prospectus or the Time of Sale Information will not violate Regulation T, U or X of the Board of Governors of the Federal Reserve System or any other regulation of such Board of Governors.

- (pp) <u>Forward-Looking Statements</u>. No forward-looking statement (within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act) contained in the Registration Statement, the Prospectus or the Time of Sale Information has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith.
- (qq) <u>Statistical and Market Data</u>. Nothing has come to the attention of the Company that has caused the Company to believe that the statistical and market-related data included or incorporated by reference in the Registration Statement, the Prospectus and the Time of Sale Information is not based on or derived from sources that are reliable and accurate in all material respects.
- (rr) <u>eXtensible Business Reporting Language</u>. The interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement, the Prospectus and the Time of Sale Information fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines applicable thereto.
- Clinical Trials. Except as described in the Registration Statement, the Prospectus, and the Time of Sale Information, the clinical and pre-clinical trials conducted by or, to the Company's knowledge, (x) on behalf of or sponsored by the Company or its subsidiaries, or (y) in which the Company or its subsidiaries have participated, that are described in the Registration Statement, the Prospectus, and the Time of Sale Information, or the results of which are referred to in the Registration Statement, the Prospectus, and the Time of Sale Information, as applicable, were, and if still pending are, being conducted in all material respects in accordance with standard medical and scientific research standards and procedures for products or product candidates comparable to those being developed by the Company or its subsidiaries and all applicable statutes and all rules and regulations of the FDA and other comparable regulatory authorities (including, without limitation, any foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA) to which they are subject (collectively, the "Regulatory Authorities") and current Good Clinical Practices and Good Laboratory Practices; the descriptions in the Registration Statement, the Prospectus, and the Time of Sale Information of the results of such studies and tests are accurate and complete descriptions in all material respects and fairly present the data derived from such trials; the Company has no knowledge of any other trials, the results of which the Company believes are inconsistent with or reasonably call into question the results described or referred to in the Registration Statement, the Prospectus or the Time of Sale Information; the Company and its subsidiaries have operated at all times and is currently in compliance in all material respects with all applicable statutes, rules and regulations of the Regulatory Authorities; the Company and its subsidiaries have not received any written notices, correspondence or other communications from the Regulatory Authorities or any other governmental agency requiring or threatening the termination, modification or suspension of any clinical or pre-clinical trials that are described in the Registration Statement, the Prospectus and the Time of Sale Information or the results of which are referred to in the Registration Statement, the Prospectus and the Time of Sale Information, and, to the Company's knowledge, there are no reasonable grounds for the same.

- (tt) Regulatory Filings. Neither the Company nor any of its subsidiaries has failed to file with the Regulatory Authorities any required filing, declaration, listing, registration, report or submission with respect to the Company's product candidates that are described or referred to in the Registration Statement, the Prospectus and the Time of Sale Information; all such filings, declarations, listings, registrations, reports or submissions were in material compliance with applicable laws when filed; and no deficiencies regarding compliance with applicable law have been asserted by any applicable Regulatory Authority with respect to any such filings, declarations, listings, registrations, reports or submissions.
- Compliance with Health Care Laws. The Company and its subsidiaries, and to the Company's knowledge their respective officers, directors, employees, and agents, are, and at all times have been, in compliance in all material respects with all Health Care Laws, to the extent applicable to the business of the Company and its subsidiaries. For purposes of this Agreement, "Health Care Laws" means: (i) the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder; (ii) all applicable federal, state, local and foreign health care fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute (42 U.S.C. Section 1320a-7b(b)), the U.S. Civil False Claims Act (31 U.S.C. Section 3729 et seq.), the criminal False Statements Law (42 U.S.C. Section 1320a-7b(a)), 18 U.S.C. Sections 286, 287, and 1349, and the health care fraud criminal provisions under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the civil monetary penalties law (42 U.S.C. Section 1320a-7a), the exclusions law (42 U.S.C. Section 1320a-7), the Physician Payments Sunshine Act (42 U.S.C Section 1320-7h), and the laws governing U.S. government funded or sponsored healthcare programs; (iii) HIPAA as amended by amended by the Health Information Technology for Economic and Clinical Health Act; (iv) similar local, state, federal, and foreign laws the directives and regulations promulgated pursuant to such statutes and any state or non-U.S. counterpart thereof; and (v) all other local, state, federal, and foreign laws applicable to the regulation of the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, advertising, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product under development, manufactured or distributed by or for the Company or any of its subsidiaries. Neither the Company nor any of its subsidiaries has received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any court or arbitrator or governmental or regulatory authority or third party alleging that any product operation or activity is in violation of any Health Care Laws nor, to the Company's knowledge, is any such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action threatened. The Company, and to the Company's knowledge, its subsidiaries, have filed, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Health Care Laws, and all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and accurate on the date filed in all material respects (or were corrected or supplemented by a subsequent submission). Neither the Company, any of its subsidiaries, nor, to the Company's knowledge, any of their respective employees, officers, directors, or agents is a party to any corporate integrity agreements, monitoring agreements, consent decrees, settlement orders, or similar agreements with or imposed by any governmental or regulatory authority. Additionally, neither the Company, any of its subsidiaries nor, to the Company's knowledge, any of their respective employees, officers,

directors, or agents has been excluded, suspended, or debarred from participation in any U.S. federal health care program or human clinical research or, to the knowledge of the Company, is subject to a governmental inquiry, investigation, proceeding, or other similar action that could reasonably be expected to result in debarment, suspension, or exclusion.

- (vv) <u>Sarbanes-Oxley Act</u>. There is and has been no material failure on the part of the Company or, to the knowledge of the Company, any of the Company's directors or officers, in their capacities as such, to comply with any applicable provision of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated in connection therewith (the "**Sarbanes-Oxley Act**"), including Section 402 related to loans.
- (ww) <u>Cybersecurity</u>. The Company's and its subsidiaries' information technology assets and equipment, computers, systems, networks, hardware, software, websites, applications, and databases (collectively, "IT Systems") are adequate for, and operate and perform in all material respects as required in connection with the operation of the business of the Company and its subsidiaries as currently conducted, and to the Company's knowledge, free and clear of all material bugs, errors, defects, Trojan horses, time bombs, malware and other corruptants. The Company and its subsidiaries have implemented and maintained commercially reasonable physical, technical and administrative controls, policies, procedures, and safeguards to maintain and protect their material confidential information and the integrity, operation, redundancy and security of all IT Systems and data, including "Personal Data," used in connection with their businesses. "Personal Data" means (i) a natural person's name, street address, telephone number, e-mail address, photograph, social security number or tax identification number, driver's license number, passport number, credit card number, bank information, or customer or account number; (ii) any information which would qualify as "personally identifying information" under the Federal Trade Commission Act, as amended; (iii) "personal data" as defined by GDPR (as defined below); (iv) any information which would qualify as "protected health information" under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (collectively, "HIPAA"); and (v) any other piece of information that allows the identification of such natural person, or his or her family, or permits the collection or analysis of any data related to an identified person's health or sexual orientation. To the Company's knowledge, there have been no breaches, violations, outages or unauthorized uses of or accesses to same, except for those that have been remedied without material cost or liability or the duty to notify any other person, nor any incidents under internal review or investigations relating to the same. The Company and its subsidiaries are presently in material compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Personal Data and to the protection of such IT Systems and Personal Data from unauthorized use. access, misappropriation or modification.
- (xx) <u>Compliance with Data Privacy Laws</u>. The Company and its subsidiaries are, and at all prior times were, in material compliance with all applicable state and federal data privacy and security laws and regulations, including without limitation HIPAA, and the Company and its subsidiaries have taken commercially reasonable actions to prepare to comply with, and since May 25, 2018, have been and currently are in compliance with, the European Union General Data Protection Regulation ("GDPR") (EU 2016/679) (collectively, the "Privacy Laws"). To ensure

compliance with the Privacy Laws, the Company and its subsidiaries have in place, comply with, and take appropriate steps reasonably designed to ensure compliance in all material respects with their policies and procedures relating to data privacy and security and the collection, storage, use, disclosure, handling, and analysis of Personal Data (the "Policies"). The Company and its subsidiaries have at all times made all disclosures to users or customers required by applicable laws and regulatory rules or requirements, and none of such disclosures made or contained in any Policy have, to the knowledge of the Company, been inaccurate or in violation of any applicable laws and regulatory rules or requirements in any material respect. The Company further certifies that neither it nor any subsidiary: (i) has received notice of any actual or potential liability under or relating to, or actual or potential violation of, any of the Privacy Laws, and has no knowledge of any event or condition that would reasonably be expected to result in any such notice; (ii) is currently conducting or paying for, in whole or in part, any investigation, remediation, or other corrective action pursuant to any Privacy Law; or (iii) is a party to any order, decree, or agreement that imposes any obligation or liability under any Privacy Law.

(yy) <u>Other Underwriting Agreements</u>. The Company is not a party to any agreement with an agent or underwriter for any other "at the market" or continuous equity transaction.

Any certificate signed by any officer or representative of the Company or any of its subsidiaries and delivered to the Agent or counsel for the Agent in connection with an issuance of Shares shall be deemed a representation and warranty by the Company to the Agent as to the matters covered thereby on the date of such certificate.

The Company acknowledges that the Agent and, for purposes of the opinions to be delivered pursuant to  $\underline{\text{Section 4(p)}}$  hereof, counsel to the Company and counsel to the Agent, will rely upon the accuracy and truthfulness of the foregoing representations and hereby consents to such reliance.

#### Section 3. ISSUANCE AND SALE OF COMMON SHARES

(a) (i) <u>Sale of Securities</u>. On the basis of the representations, warranties and agreements herein contained, but subject to the terms and conditions herein set forth, the Company and the Agent agree that the Company may from time to time seek to sell Shares through the Agent, acting as sales agent, or directly to the Agent, acting as principal, as follows, with an aggregate Sales Price of up to the Maximum Program Amount, based on and in accordance with Issuance Notices as the Company may deliver, during the Agency Period.

#### (b) Mechanics of Issuances.

(i) <u>Issuance Notice</u>. Upon the terms and subject to the conditions set forth herein, on any Trading Day during the Agency Period on which the conditions set forth in <u>Section 5(a)</u> and <u>Section 5(b)</u> shall have been satisfied, the Company may exercise its right to request an issuance of Shares by delivering to the Agent an Issuance Notice; *provided, however*, that (A) in no event may the Company deliver an Issuance Notice to the extent that (I) the sum of (x) the aggregate Sales Price of the requested Issuance Amount, plus (y) the aggregate Sales Price of all Shares issued under all previous Issuance Notices effected pursuant to this Agreement, would

exceed the Maximum Program Amount; and (B) prior to delivery of any Issuance Notice, the Selling Period for any previous Issuance Notice shall have expired or been terminated. An Issuance Notice shall be considered delivered on the Trading Day that it is received by e-mail to the persons set forth in Schedule A hereto and confirmed by the Company by telephone (including a voicemail message to the persons so identified), with the understanding that, with adequate prior written notice, the Agent may modify the list of such persons from time to time.

- (ii) Agent Efforts. Upon the terms and subject to the conditions set forth in this Agreement, upon the receipt of an Issuance Notice, the Agent will use its commercially reasonable efforts consistent with its normal sales and trading practices to place the Shares with respect to which the Agent has agreed to act as sales agent, subject to, and in accordance with the information specified in, the Issuance Notice, unless the sale of the Shares described therein has been suspended, cancelled or otherwise terminated in accordance with the terms of this Agreement. For the avoidance of doubt, the parties to this Agreement may modify an Issuance Notice at any time provided they both agree in writing to any such modification.
- (iii) Method of Offer and Sale. The Shares may be offered and sold (A) in negotiated transactions with the consent of the Company or (B) by any other method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act, including block transactions, sales made directly on the Principal Market or sales made into any other existing trading market of the Common Shares. Nothing in this Agreement shall be deemed to require either party to agree to the method of offer and sale specified in the preceding sentence, and (except as specified in clause (A) above) the method of placement of any Shares by the Agent shall be at the Agent's discretion.
- (iv) <u>Confirmation to the Company</u>. If acting as sales agent hereunder, the Agent will provide written confirmation to the Company no later than the opening of the Trading Day next following the Trading Day on which it has placed Shares hereunder setting forth the number of shares sold on such Trading Day, the corresponding Sales Price and the Issuance Price payable to the Company in respect thereof.
- (v) <u>Settlement</u>. Each issuance of Shares will be settled on the applicable Settlement Date for such issuance of Shares and, subject to the provisions of <u>Section 5</u>, on or before each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Shares being sold by crediting the Agent or its designee's account at The Depository Trust Company through its Deposit/Withdrawal At Custodian (DWAC) System, or by such other means of delivery as may be mutually agreed upon by the parties hereto and, upon receipt of such Shares, which in all cases shall be freely tradable, transferable, registered shares in good deliverable form, the Agent will deliver, by wire transfer of immediately available funds, the related aggregate Issuance Price in same day funds delivered to an account designated by the Company prior to the Settlement Date. The Company may sell Shares to the Agent as principal at a price agreed upon at each relevant time Shares are sold pursuant to this Agreement (each, a "**Time of Sale**").
- (vi) <u>Suspension or Termination of Sales</u>. Consistent with standard market settlement practices, the Company or the Agent may, upon notice to the other party hereto in writing or by telephone (confirmed immediately by verifiable email), suspend any sale of Shares,

and the Selling Period shall immediately terminate; *provided, however*, that (A) such suspension and termination shall not affect or impair either party's obligations with respect to any Shares placed or sold hereunder prior to the receipt of such notice; (B) if the Company suspends or terminates any sale of Shares after the Agent confirms such sale to the Company, the Company shall still be obligated to comply with Section 3(b)(v) with respect to such Shares; and (C) if the Company defaults in its obligation to deliver Shares on a Settlement Date, the Company agrees that it will hold the Agent harmless against any loss, claim, damage or expense (including, without limitation, penalties, interest and reasonable legal fees and expenses), as incurred, arising out of or in connection with such default by the Company. The parties hereto acknowledge and agree that, in performing its obligations under this Agreement, the Agent may borrow Common Shares from stock lenders in the event that the Company has not delivered Shares to settle sales as required by subsection (v) above, and may use the Shares to settle or close out such borrowings. The Company agrees that no such notice shall be effective against the Agent unless it is made to the persons identified in writing by the Agent pursuant to Section 3(b)(i).

- (vii) <u>No Guarantee of Placement, Etc.</u> The Company acknowledges and agrees that (A) there can be no assurance that the Agent will be successful in placing Shares, (B) the Agent will incur no liability or obligation to the Company or any other Person if it does not sell Shares, and (C) the Agent shall be under no obligation to purchase Shares on a principal basis pursuant to this Agreement, except as otherwise specifically agreed by the Agent and the Company.
- (viii) <u>Material Non-Public Information.</u> Notwithstanding any other provision of this Agreement, the Company and the Agent agree that the Company shall not deliver any Issuance Notice to the Agent, and the Agent shall not be obligated to place any Shares, during any period in which the Company is in possession of material non-public information.
- (c) <u>Fees.</u> As compensation for services rendered, the Company shall pay to the Agent, on the applicable Settlement Date, the Selling Commission for the applicable Issuance Amount (including with respect to any suspended or terminated sale pursuant to <u>Section 3(b)(vi)</u>) by the Agent deducting the Selling Commission from the applicable Issuance Amount. For the avoidance of doubt, the Company shall not be required to pay to the Agent any Selling Commission with respect to any Issuance Notice, except to the extent Shares are placed pursuant thereto.
- (d) Expenses. The Company agrees to pay all costs, fees and expenses incurred in connection with the performance of its obligations hereunder and in connection with the transactions contemplated hereby, including without limitation (i) all expenses incident to the issuance and delivery of the Shares (including all printing and engraving costs), (ii) all fees and expenses of the registrar and transfer agent of the Shares, (iii) all necessary issue, transfer and other stamp taxes in connection with the issuance and sale of the Shares, (iv) all fees and expenses of the Company's counsel, independent public or certified public accountants and other advisors, (v) all costs and expenses incurred in connection with the preparation, printing, filing, shipping and distribution of the Registration Statement (including financial statements, exhibits, schedules, consents and certificates of experts), the Prospectus, any Free Writing Prospectus (as defined below) prepared by or on behalf of, used by, or referred to by the Company, and all amendments and supplements thereto, and this Agreement, (vi) all filing fees, attorneys' fees and expenses

incurred by the Company or the Agent in connection with qualifying or registering (or obtaining exemptions from the qualification or registration of) all or any part of the Shares for offer and sale under the state securities or blue sky laws or the provincial securities laws of Canada, and, if requested by the Agent, preparing and printing a "Blue Sky Survey" or memorandum and a "Canadian wrapper", and any supplements thereto, advising the Agent of such qualifications, registrations, determinations and exemptions, (vii) the reasonable fees and disbursements of the Agent's counsel, including the reasonable fees and expenses of counsel for the Agent in connection with FINRA review, if any, and approval of the Agent's participation in the offering and distribution of the Shares, (viii) the filing fees incident to FINRA review, if any, (ix) the costs and expenses of the Company relating to investor presentations on any "road show" undertaken in connection with the marketing of the offering of the Shares, including, without limitation, expenses associated with the preparation or dissemination of any electronic road show, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations with the prior approval of the Company, travel and lodging expenses of the representatives, employees and officers of the Company and of the Agent and any such consultants, and the cost of any aircraft chartered in connection with the road show and (x) the fees and expenses associated with listing the Shares on the Nasdaq Capital Market. The fees and disbursements of Agent's counsel pursuant to subsections (vi) and (vii) above shall not exceed (A) \$75,000 in connection with the execution of this Agreement, (B) \$25,000 in connection with each Triggering Event Date (as defined below) involving the filing of a Form 10-K on which the Company is required to provide a certificate pursuant to Section 4(o) and (C) \$15,000 in connection with each other Triggering Event Date on which the Company is required to provide a certificate pursuant to Section 4(o).

#### Section 4. ADDITIONAL COVENANTS

The Company covenants and agrees with the Agent as follows, in addition to any other covenants and agreements made elsewhere in this Agreement:

- (a) Exchange Act Compliance. During the Agency Period, the Company shall (i) file, on a timely basis, with the Commission all reports and documents required to be filed under Section 13, 14 or 15 of the Exchange Act in the manner and within the time periods required by the Exchange Act and (ii) either (A) include in its quarterly reports on Form 10-Q and its annual reports on Form 10-K, a summary detailing, for the relevant reporting period, (1) the number of Shares sold through the Agent pursuant to this Agreement and (2) the net proceeds received by the Company from such sales or (B) prepare a prospectus supplement containing, or include in such other filing permitted by the Securities Act or Exchange Act (each an "Interim Prospectus Supplement") such summary information and, at least once a quarter and subject to this Section 4, file such Interim Prospectus Supplement pursuant to Rule 424(b) under the Securities Act (and within the time periods required by Rule 424(b) and Rule 430B under the Securities Act).
- (b) <u>Securities Act Compliance</u>. After the date of this Agreement, the Company shall promptly advise the Agent in writing (i) of the receipt of any comments of, or requests for additional or supplemental information from, the Commission relating to the Registration Statement or the Prospectus, (ii) of the time and date of any filing of any post-effective amendment to the Registration Statement, any Rule 462(b) Registration Statement or any amendment or

supplement to the Prospectus or any Free Writing Prospectus, (iii) of the time and date that any post-effective amendment to the Registration Statement or any Rule 462(b) Registration Statement becomes effective and (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto, any Rule 462(b) Registration Statement or any amendment or supplement to the Prospectus or of any order preventing or suspending the use of any Free Writing Prospectus or the Prospectus, or of any proceedings to remove, suspend or terminate from listing or quotation the Common Shares from any securities exchange upon which they are listed for trading or included or designated for quotation, or of the threatening or initiation of any proceedings for any of such purposes. If the Commission shall enter any such stop order at any time, the Company will use its reasonable best efforts to obtain the lifting of such order as soon as reasonably practicable. Additionally, the Company agrees that it shall comply with the provisions of Rule 424(b) and Rule 433, as applicable, under the Securities Act and will use its reasonable efforts to confirm that any filings made by the Company under such Rule 424(b) or Rule 433 were received in a timely manner by the Commission.

- (c) Amendments and Supplements to the Prospectus and Other Securities Act Matters. If any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Prospectus so that the Prospectus does not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered to a purchaser, not misleading, or if in the opinion of the Agent or counsel for the Agent it is otherwise necessary to amend or supplement the Prospectus to comply with applicable law, including the Securities Act, the Company agrees (subject to Section 4(d) and Section 4(f)) to promptly prepare, file with the Commission and furnish at its own expense to the Agent, amendments or supplements to the Prospectus so that the statements in the Prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered to a purchaser, be misleading or so that the Prospectus, as amended or supplemented, will comply with applicable law including the Securities Act. Neither the Agent's consent to, or delivery of, any such amendment or supplement shall constitute a waiver of any of the Company's obligations under Section 4(d) and Section 4(f). Notwithstanding the foregoing, the Company shall not be required to file such amendment or supplement if there is no pending Issuance Notice and the Company believes that it is in its best interest not to file such amendment or supplement; provided, however, the Company agrees not to provide an Issuance Notice or otherwise sell under this Agreement until such amendment or supplement is filed or it is determined that such amendment or supplement is no longer required.
- (d) Agent's Review of Proposed Amendments and Supplements. Prior to amending or supplementing the Registration Statement (including any registration statement filed under Rule 462(b) under the Securities Act, but excluding (i) documents incorporated by reference filed under the Exchange Act that either (A) do not name Agent and do not relate to the transactions contemplated by this Agreement or (B) only include disclosure relating to periodic sales pursuant to this Agreement, and (ii) or amendments or supplements that do not name Agent and do not relate to the transactions contemplated by this Agreement) or the Prospectus (excluding documents incorporated by reference filed under the Exchange Act that either (A) do not name Agent and do

not relate to the transactions contemplated by this Agreement or (B) only include disclosure relating to periodic sales pursuant to this Agreement), the Company shall furnish to the Agent for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of each such proposed amendment or supplement, and the Company shall not file or use any such proposed amendment or supplement without the Agent's prior consent, which shall not be unreasonably withheld, conditioned or delayed, and to file with the Commission within the applicable period specified in Rule 424(b) under the Securities Act any prospectus required to be filed pursuant to such Rule.

- (e) <u>Use of Free Writing Prospectus</u>. Neither the Company nor the Agent has prepared, used, referred to or distributed, or will prepare, use, refer to or distribute, without the other party's prior written consent, any "written communication" that constitutes a "free writing prospectus" as such terms are defined in Rule 405 under the Securities Act with respect to the offering contemplated by this Agreement (any such free writing prospectus being referred to herein as a "**Free Writing Prospectus**").
- Free Writing Prospectuses. The Company shall furnish to the Agent for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of each proposed Free Writing Prospectus or any amendment or supplement thereto to be prepared by or on behalf of, used by, or referred to by the Company and the Company shall not file, use or refer to any proposed Free Writing Prospectus or any amendment or supplement thereto without the Agent's consent, which shall not be unreasonably withheld, conditioned or delayed. The Company shall furnish to the Agent, without charge, as many copies of any Free Writing Prospectus prepared by or on behalf of, or used by the Company, as the Agent may reasonably request. If at any time when a prospectus is required by the Securities Act (including, without limitation, pursuant to Rule 173(d)) to be delivered in connection with sales of the Shares (but in any event if at any time through and including the date of this Agreement) there occurred or occurs an event or development as a result of which any Free Writing Prospectus prepared by or on behalf of, used by, or referred to by the Company conflicted or would conflict with the information contained in the Registration Statement or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at that subsequent time, not misleading, the Company shall promptly amend or supplement such Free Writing Prospectus to eliminate or correct such conflict or so that the statements in such Free Writing Prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at such subsequent time, not misleading, as the case may be; provided, however, that prior to amending or supplementing any such Free Writing Prospectus, the Company shall furnish to the Agent for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of such proposed amended or supplemented Free Writing Prospectus and the Company shall not file, use or refer to any such amended or supplemented Free Writing Prospectus without the Agent's consent, which shall not be unreasonably withheld, conditioned or delayed.
- (g) <u>Filing of Agent Free Writing Prospectuses</u>. The Company shall not take any action that would result in the Agent or the Company being required to file with the Commission pursuant

to Rule 433(d) under the Securities Act a Free Writing Prospectus prepared by or on behalf of the Agent that the Agent otherwise would not have been required to file thereunder.

- Copies of Registration Statement and Prospectus. After the date of this Agreement through the last time that a prospectus is required by the Securities Act (including, without limitation, pursuant to Rule 173(d)) to be delivered in connection with sales of the Shares, the Company agrees to furnish the Agent with copies (which may be electronic copies) of the Registration Statement and each amendment thereto, and with copies of the Prospectus and each amendment or supplement thereto in the form in which it is filed with the Commission pursuant to the Securities Act or Rule 424(b) under the Securities Act, both in such quantities as the Agent may reasonably request from time to time; and, if the delivery of a prospectus is required under the Securities Act or under the blue sky or securities laws of any jurisdiction at any time on or prior to the applicable Settlement Date for any Selling Period in connection with the offering or sale of the Shares and if at such time any event has occurred as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made when such Prospectus is delivered, not misleading, or, if for any other reason it is necessary during such same period to amend or supplement the Prospectus or to file under the Exchange Act any document incorporated by reference in the Prospectus in order to comply with the Securities Act or the Exchange Act, to notify the Agent and to request that the Agent suspend offers to sell Shares (and, if so notified, the Agent shall cease such offers as soon as practicable); and if the Company decides to amend or supplement the Registration Statement or the Prospectus as then amended or supplemented, to advise the Agent promptly by telephone (with confirmation in writing) and to prepare and cause to be filed promptly with the Commission an amendment or supplement to the Registration Statement or the Prospectus as then amended or supplemented that will correct such statement or omission or effect such compliance (it being acknowledged that the Company may delay the filing of any amendment or supplement, if, in the judgment of the Company, it is in the best interest of the Company); provided, however, that if during such same period the Agent is required to deliver a prospectus in respect of transactions in the Shares, the Company shall promptly prepare and file with the Commission such an amendment or supplement.
- (i) <u>Blue Sky Compliance</u>. The Company shall cooperate with the Agent and counsel for the Agent to qualify or register the Shares for sale under (or obtain exemptions from the application of) the state securities or blue sky laws or Canadian provincial securities laws of those jurisdictions designated by the Agent, shall comply with such laws and shall continue such qualifications, registrations and exemptions in effect so long as required for the distribution of the Shares. The Company shall not be required to qualify as a foreign corporation or to take any action that would subject it to general service of process in any such jurisdiction where it is not presently qualified or where it would be subject to taxation as a foreign corporation. The Company will advise the Agent promptly of the suspension of the qualification or registration of (or any such exemption relating to) the Shares for offering, sale or trading in any jurisdiction or any initiation or threat of any proceeding for any such purpose, and in the event of the issuance of any order suspending such qualification, registration or exemption, the Company shall use its commercially reasonable efforts to obtain the withdrawal thereof as soon as reasonably practicable.

- (j) <u>Earnings Statement</u>. As soon as reasonably practicable, the Company will make generally available to its security holders and to the Agent an earnings statement (which need not be audited) covering a period of at least twelve months beginning with the first fiscal quarter of the Company occurring after the date of this Agreement which shall satisfy the provisions of Section 11(a) of the Securities Act and Rule 158 under the Securities Act.
- (k) <u>Listing; Reservation of Shares</u>. (a) The Company will use its reasonable best efforts to maintain the listing of the Shares on the Principal Market, and (b) the Company will reserve and keep available at all times, free of preemptive rights, Shares for the purpose of enabling the Company to satisfy its obligations under this Agreement.
- (l) <u>Transfer Agent</u>. The Company shall engage and maintain, at its expense, a registrar and transfer agent for the Shares.
- (m) <u>Due Diligence</u>. During the term of this Agreement, the Company will reasonably cooperate with any reasonable due diligence review conducted by the Agent in connection with the transactions contemplated hereby, including, without limitation, providing information and making available documents and senior corporate officers, during normal business hours and at the Company's principal offices or virtually, as the Agent may reasonably request from time to time.
- (n) Representations and Warranties. The Company acknowledges that each delivery of an Issuance Notice and each delivery of Shares on a Settlement Date shall be deemed to be (i) an affirmation to the Agent that the representations and warranties of the Company contained in or made pursuant to this Agreement are true and correct as of the date of such Issuance Notice or of such Settlement Date, as the case may be, as though made at and as of each such date, except as may be disclosed in the Prospectus (including any documents incorporated by reference therein and any supplements thereto), and (ii) an undertaking that the Company will advise the Agent if any of such representations and warranties will not be true and correct as of the Settlement Date for the Shares relating to such Issuance Notice, as though made at and as of each such date (except that such representations and warranties shall be deemed to relate to the Registration Statement and the Prospectus as amended and supplemented relating to such Shares).
- (o) <u>Deliverables at Triggering Event Dates; Certificates.</u> The Company agrees that on or prior to the date of the first Issuance Notice and, during the term of this Agreement after the date of the first Issuance Notice, upon:
- (i) The filing of the Prospectus or amendment or supplement of any Registration Statement or Prospectus (other than a prospectus supplement relating solely to an offering of securities other than the Shares or a prospectus filed pursuant to Section 4(a)(ii)(B)), by means of a post-effective amendment, sticker or supplement, but not by means of incorporation of documents by reference into the Registration Statement or Prospectus;
- (ii) the filing with the Commission of an annual report on Form 10-K or a quarterly report on Form 10-Q (including any Form 10-K/A or Form 10-Q/A containing amended

financial information or a material amendment to the previously filed annual report on Form 10-K or quarterly report on Form 10-Q), in each case, of the Company; or

(iii) the filing with the Commission of a current report on Form 8-K of the Company containing amended financial information (other than information "furnished" pursuant to Item 2.02 or 7.01 of Form 8-K or to provide disclosure pursuant to Item 8.01 of Form 8-K relating to reclassification of certain properties as discontinued operations in accordance with Statement of Financial Accounting Standards No. 144) that is material to the offering of securities of the Company in the Agent's reasonable discretion;

(any such event, a "Triggering Event Date"), the Company shall furnish the Agent (but in the case of clause (iii) above only if the Agent reasonably determines that the information contained in such current report on Form 8-K of the Company is material) with a certificate as of the Triggering Event Date, in the form and substance satisfactory to the Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel, modified, as necessary, to relate to the Registration Statement and the Prospectus as amended or supplemented, (A) confirming that the representations and warranties of the Company contained in this Agreement are true and correct, (B) confirming that the Company has performed all of its obligations hereunder to be performed on or prior to the date of such certificate and as to the matters set forth in Section 5(a)(i) hereof, and (C) containing any other certification that the Agent shall reasonably request. The requirement to provide a certificate under this Section 4(o) shall be waived for any Triggering Event Date occurring at a time when no Issuance Notice is pending or a suspension is in effect, which waiver shall continue until the earlier to occur of the date the Company delivers an Issuance Notice with instructions for the sale of Shares hereunder (which for such calendar quarter shall be considered a Triggering Event Date) and the next occurring Triggering Event Date. Notwithstanding the foregoing, if the Company subsequently decides to sell Shares following a Triggering Event Date when a suspension was in effect and did not provide the Agent with a certificate under this Section 4(o), then before the Company delivers an Issuance Notice with instructions for the sale of Shares or the Agent sells any Shares pursuant to such instructions, the Company shall provide the Agent with a certificate in conformity with this Section 4(o) dated on or prior to the date that an Issuance Notice with instructions for the sale of Shares is issued.

(p) <u>Legal Opinions.</u> On or prior to the date of the first Issuance Notice and on or prior to each Triggering Event Date with respect to which the Company is obligated to deliver a certificate pursuant to <u>Section 4(o)</u> for which no waiver is applicable and excluding the date of this Agreement, the Company shall cause to be furnished to the Agent (A) a written negative assurances letter and written legal opinion of Wilmer Cutler Pickering Hale and Dorr LLP, counsel to the Company, and (B) the written legal opinion of Morgan, Lewis & Bockius LLP, intellectual property counsel to the Company, each dated the date of delivery, in form and substance reasonably satisfactory to Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel, modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented; *provided* that the Company shall be required to furnish no more than one opinion from each of Company's counsel per each filing of an annual report on Form 10-K or a quarterly report on Form 10-Q. In lieu of such opinions for subsequent periodic filings, in the discretion of the Agent, the Company may caused to be

furnished a reliance letter from such counsel to the Agent, permitting the Agent to rely on a previously delivered opinion letter, modified as appropriate for any passage of time or Triggering Event Date (except that statements in such prior opinion shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented as of such Triggering Event Date).

- (q) Comfort Letter. On or prior to the date of the first Issuance Notice and on or prior to each Triggering Event Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 4(o) for which no waiver is applicable and excluding the date of this Agreement, the Company shall cause Deloitte & Touche LLP, the independent registered public accounting firm who has audited the consolidated financial statements included or incorporated by reference in the Registration Statement, to furnish the Agent a comfort letter, dated the date of delivery, in form and substance reasonably satisfactory to the Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel; provided, however, that any such comfort letter will only be required on the Triggering Event Date specified to the extent that it contains financial statements filed with the Commission under the Exchange Act and incorporated or deemed to be incorporated by reference into a Prospectus and *provided* further that the Company shall be required to furnish no more than one comfort letter per each filing of an annual report on Form 10-K or a quarterly report on Form 10-Q. If requested by the Agent, the Company shall also cause a comfort letter to be furnished to the Agent upon the occurrence of any material transaction or event requiring the filing of a current report on Form 8-K containing material amended financial information of the Company, including the restatement of the Company's financial statements.
- (r) <u>Secretary's Certificate</u>. On or prior to the date of the first Issuance Notice and on or prior to each Triggering Event Date with respect to which the Company is obligated to deliver a certificate pursuant to <u>Section 4(o)</u> for which no waiver is applicable and excluding the date of this Agreement, the Company shall furnish the Agent a certificate executed by the Secretary of the Company, signing in such capacity, dated the date of delivery (i) certifying that attached thereto are true and complete copies of the resolutions duly adopted by the Board of Directors of the Company authorizing the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby (including, without limitation, the issuance of the Shares pursuant to this Agreement), which authorization shall be in full force and effect on and as of the date of such certificate, (ii) certifying and attesting to the office, incumbency, due authority and specimen signatures of each Person who executed this Agreement for or on behalf of the Company, and (iii) containing any other certification that the Agent or its counsel shall reasonably request.

## (s) [Reserved].

- (t) <u>Agent's Own Account; Clients' Account</u>. The Company consents to the Agent trading, in compliance with applicable law, in the Common Shares for the Agent's own account and for the account of its clients at the same time as sales of the Shares occur pursuant to this Agreement.
- (u) <u>Investment Limitation</u>. The Company shall not invest, or otherwise use the proceeds received by the Company from its sale of the Shares in such a manner as would require

the Company or any of its subsidiaries to register as an investment company under the Investment Company Act.

- (v) <u>Market Activities</u>. The Company will not take, directly or indirectly, any action designed to or that might be reasonably expected to cause or result in stabilization or manipulation of the price of the Shares or any other reference security, whether to facilitate the sale or resale of the Shares or otherwise, and the Company will, and shall cause each of its affiliates to, comply with all applicable provisions of Regulation M. If the limitations of Rule 102 of Regulation M ("**Rule 102**") do not apply with respect to the Shares or any other reference security pursuant to any exception set forth in Section (d) of Rule 102, then promptly upon notice from the Agent (or, if later, at the time stated in the notice), the Company will, and shall use commercially reasonable efforts to cause each of its affiliates to, comply with Rule 102 as though such exception were not available but the other provisions of Rule 102 (as interpreted by the Commission) did apply.
- Notice of Other Sale. Without the written consent of the Agent, the Company will not, directly or indirectly, offer to sell, contract to sell, grant any option to sell or otherwise dispose of any Common Shares or securities convertible into or exchangeable for Common Shares (other than Shares hereunder), warrants or any rights to purchase or acquire Common Shares, or effect a reverse stock split, recapitalization, share consolidation, reclassification or similar transaction affecting the outstanding Common Shares, during the period beginning on the third Trading Day immediately prior to the date on which any Issuance Notice is delivered to the Agent hereunder and ending on the earlier of (A) the third Trading Day immediately following the Settlement Date with respect to Shares most recently sold pursuant to such Issuance Notice and (B) the date such Issuance Notice is cancelled if no Shares have been sold pursuant to such Issuance Notice; and will not directly or indirectly enter into any other "at the market" or continuous equity transaction to offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any Common Shares (other than the Shares offered pursuant to this Agreement) or securities convertible into or exchangeable for Common Shares, warrants or any rights to purchase or acquire, Common Shares prior to the termination of this Agreement; provided, however, that such restrictions will not be applicable in connection with (i) issuance or sale of Common Shares issuable upon exchange, conversion or redemption of securities or the exercise or vesting of warrants, options or other equity awards or rights in effect or outstanding and disclosed in the Registration Statement and the Prospectus, (ii) any options and other awards granted under Company Stock Plans described in the Registration Statement, the Prospectus and the Time of Sale Information, (iii) the filing by the Company of a resale registration statement for Common Shares pursuant to a contractual arrangement existing prior to the date of this Agreement and (iv) shares of capital stock or other securities issued in connection with a transaction with an unaffiliated third party that includes a bona fide commercial relationship (including joint ventures, marketing or distribution arrangements, collaboration agreements or intellectual property license agreements) or any acquisition of assets or acquisition of not less than a majority or controlling portion of the equity of another entity, provided that other than Common Shares issued or issuable pursuant to the terms of the Agreement and Plan of Merger, dated as of November 15, 2021, by and among the Company, Ceres Merger Sub, Inc., Combangio, Inc. and, solely in its capacity as Combangio Equityholder Representative, Fortis Advisors LLC, the aggregate number of shares issued pursuant to this clause (iv) shall not exceed ten percent (10%) of the total number of outstanding shares of capital stock at that time.

#### Section 5. CONDITIONS TO DELIVERY OF ISSUANCE NOTICES AND TO SETTLEMENT

- (a) Conditions Precedent to the Right of the Company to Deliver an Issuance Notice and the Obligation of the Agent to Sell Shares During the Selling Period(s). The right of the Company to deliver an Issuance Notice hereunder is subject to the satisfaction, on the date of delivery of such Issuance Notice, and the obligation of the Agent to use its commercially reasonable efforts to place Shares during the applicable Selling Period is subject to the satisfaction, on each Trading Day during the Selling Period, of each of the following conditions:
- (i) Accuracy of the Company's Representations and Warranties; Performance by the Company. The Company shall have delivered the certificate required to be delivered pursuant to Section 4(o) on or before the date on which delivery of such certificate is required pursuant to Section 4(o). The Company shall have performed, satisfied and complied with all covenants, agreements and conditions required by this Agreement to be performed, satisfied or complied with by the Company at or prior to such date, including, but not limited to, the covenants contained in Section 4(p), Section 4(q) and Section 4(r).
- (ii) <u>No Injunction</u>. No statute, rule, regulation, executive order, decree, ruling or injunction shall have been enacted, entered, promulgated or endorsed by any court or governmental authority of competent jurisdiction or any self-regulatory organization having authority over the matters contemplated hereby that prohibits or directly and materially adversely affects any of the transactions contemplated by this Agreement, and no proceeding shall have been commenced that may have the effect of prohibiting or materially adversely affecting any of the transactions contemplated by this Agreement.
- (iii) <u>Material Adverse Changes</u>. Except as disclosed in the Prospectus and the Time of Sale Information, (a) in the judgment of the Agent there shall not have occurred any Material Adverse Change; and (b) there shall not have occurred any downgrading, nor shall any notice have been given of any intended or potential downgrading or of any review for a possible change that does not indicate the direction of the possible change, in the rating accorded any securities of the Company or any of its subsidiaries by any "nationally recognized statistical rating organization" as such term is defined for purposes of Section 3(a)(62) of the Exchange Act.
- (iv) No Suspension of Trading in or Delisting of Common Shares; Other Events. The trading of the Common Shares (including without limitation the Shares) shall not have been suspended by the Commission, the Principal Market or FINRA and the Common Shares (including without limitation the Shares) shall have been approved for listing or quotation on and shall not have been delisted from the Principal Market. There shall not have occurred (and be continuing in the case of occurrences under clauses (i), (ii) and (iii) below) any of the following: (i) trading generally shall have been suspended or materially limited on or by any of the New York Stock Exchange or the Principal Market; (ii) trading of any securities issued or guaranteed by the Company shall have been suspended on any exchange or in any over-the-counter market; (iii) a general moratorium on commercial banking activities shall have been declared by federal or New York State authorities; or (iv) there shall have occurred any outbreak or escalation of hostilities or any change in financial markets or any calamity or crisis, either within or outside the United States,

that, in the judgment of the Agent is material and adverse and makes it impracticable or inadvisable to market the Shares in the manner and on the terms contemplated by this Agreement and described in the Prospectus.

- (b) <u>Documents Required to be Delivered on each Issuance Notice Date</u>. The Agent's obligation to use its commercially reasonable efforts to place Shares hereunder shall additionally be conditioned upon the delivery to the Agent on or before the Issuance Notice Date of a certificate in form and substance reasonably satisfactory to the Agent, executed by the Chief Executive Officer, President or Chief Financial Officer of the Company, to the effect that all conditions to the delivery of such Issuance Notice shall have been satisfied as at the date of such certificate (which certificate shall not be required if the foregoing representations shall be set forth in the Issuance Notice);
- (c) <u>No Misstatement or Material Omission</u>. Agent shall not have advised the Company that the Registration Statement, Prospectus, or the Time of Sale Information, or any amendment or supplement thereto, contains an untrue statement of fact that in the Agent's reasonable opinion is material, or omits to state a fact that in the Agent's reasonable opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.
- (d) <u>Agent Counsel Legal Opinion</u>. Agent shall have received from Cooley LLP, counsel for Agent, such opinion or opinions and negative assurance letters, on or before the date on which the delivery of the Company counsel legal opinion is required pursuant to <u>Section 4(p)</u>, with respect to such matters as Agent may reasonably require, and the Company shall have furnished to such counsel such documents as they request for enabling them to pass upon such matters.

### Section 6. INDEMNIFICATION AND CONTRIBUTION

(a) <u>Indemnification of the Agent.</u> The Company agrees to indemnify and hold harmless the Agent, its officers and employees, and each person, if any, who controls the Agent within the meaning of the Securities Act or the Exchange Act against any loss, claim, damage, liability or expense, as incurred, to which the Agent or such officer, employee or controlling person may become subject, under the Securities Act, the Exchange Act, other federal or state statutory law or regulation, or the laws or regulations of foreign jurisdictions where Shares have been offered or sold or at common law or otherwise (including in settlement of any litigation), insofar as such loss, claim, damage, liability or expense (or actions in respect thereof as contemplated below) arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, including any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading; or (ii) any untrue statement or alleged untrue statement of a material fact contained in any Free Writing Prospectus that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433(d) of the Securities Act or the Prospectus (or any amendment or supplement thereto), or the omission or alleged omission therefrom of a material

fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; and to reimburse the Agent and each such officer, employee and controlling person for any and all reasonable and documented expenses (including the reasonable and documented fees and disbursements of counsel chosen by the Agent) as such expenses are reasonably incurred by the Agent or such officer, employee or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action; provided, however, that the foregoing indemnity agreement shall not apply to any loss, claim, damage, liability or expense to the extent, but only to the extent, arising out of or based upon any untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with written information furnished to the Company by the Agent expressly for use in the Registration Statement, any such Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto), it being understood and agreed that the only such information furnished by the Agent to the Company consists of: (i) the information in the first sentence of the tenth paragraph of the Prospectus under the caption "Plan of Distribution" and (ii) the Agent's name (collectively, the "Agent Information"). The indemnity agreement set forth in this Section 6(a) shall be in addition to any liabilities that the Company may otherwise have.

Indemnification of the Company, its Directors and Officers. The Agent agrees to indemnify and hold harmless the Company, each of its directors, each of its officers who signed the Registration Statement and each person, if any, who controls the Company within the meaning of the Securities Act or the Exchange Act against any loss, claim, damage, liability or expense, as incurred, to which the Company or any such director, officer or controlling person may become subject, under the Securities Act, the Exchange Act, or other federal or state statutory law or regulation, or the laws or regulations of foreign jurisdictions where Shares have been offered or sold or at common law or otherwise (including in settlement of any litigation), insofar as such loss, claim, damage, liability or expense (or actions in respect thereof as contemplated below) arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, including any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading; or (ii) any untrue statement or alleged untrue statement of a material fact contained in any Free Writing Prospectus that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433(d) of the Securities Act or the Prospectus (or any amendment or supplement thereto), or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; but, for each of (i) and (ii) above, only to the extent arising out of or based upon any untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with written information furnished to the Company by the Agent expressly for use in the Registration Statement, any such Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto), it being understood and agreed that the only such information furnished by the Agent to the Company consists of the Agent Information, and to reimburse the Company and each such director, officer and controlling person for any and all reasonable and documented expenses (including the reasonable and documented fees and disbursements of one counsel chosen by the Company) as such expenses are reasonably incurred

by the Company or such officer, director or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action. The indemnity agreement set forth in this Section 6(b) shall be in addition to any liabilities that the Agent or the Company may otherwise have.

- Notifications and Other Indemnification Procedures. Promptly after receipt by an indemnified (c) party under this Section 6 of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against an indemnifying party under this <u>Section 6</u>, notify the indemnifying party in writing of the commencement thereof, but the omission so to notify the indemnifying party will not relieve it from any liability which it may have to any indemnified party for contribution or otherwise than under the indemnity agreement contained in this Section 6 or to the extent it is not prejudiced as a proximate result of such failure. In case any such action is brought against any indemnified party and such indemnified party seeks or intends to seek indemnity from an indemnifying party, the indemnifying party will be entitled to participate in, and, to the extent that it shall elect, jointly with all other indemnifying parties similarly notified, by written notice delivered to the indemnified party promptly after receiving the aforesaid notice from such indemnified party, to assume the defense thereof with counsel reasonably satisfactory to such indemnified party; provided, however, if the defendants in any such action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded that a conflict may arise between the positions of the indemnifying party and the indemnified party in conducting the defense of any such action or that there may be legal defenses available to it and/or other indemnified parties which are different from or additional to those available to the indemnifying party, the indemnified party or parties shall have the right to select separate counsel to assume such legal defenses and to otherwise participate in the defense of such action on behalf of such indemnified party or parties. Upon receipt of notice from the indemnifying party to such indemnified party of such indemnifying party's election so to assume the defense of such action and approval by the indemnified party of counsel, the indemnifying party will not be liable to such indemnified party under this Section 6 for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof unless (i) the indemnified party shall have employed separate counsel in accordance with the proviso to the preceding sentence (it being understood, however, that the indemnifying party shall not be liable for the fees and expenses of more than one separate counsel (together with local counsel), representing the indemnified parties who are parties to such action), which counsel (together with any local counsel) for the indemnified parties shall be selected by the indemnified party (in the case of counsel for the indemnified parties referred to in Section 6(a) and Section 6(b) above), (ii) the indemnifying party shall not have employed counsel reasonably satisfactory to the indemnified party to represent the indemnified party within a reasonable time after notice of commencement of the action or (iii) the indemnifying party has authorized in writing the employment of counsel for the indemnified party at the expense of the indemnifying party, in each of which cases the fees and expenses of counsel shall be at the expense of the indemnifying party and shall be paid as they are incurred.
- (d) <u>Settlements</u>. The indemnifying party under this <u>Section 6</u> shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party against any loss, claim, damage, liability or expense by reason of such settlement

or judgment. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel as contemplated by Section 6(c) hereof, the indemnifying party agrees that it shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 45 days after receipt by such indemnifying party of the aforesaid request and (ii) such indemnifying party shall not have reimbursed the indemnified party in accordance with such request prior to the date of such settlement. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement, compromise or consent to the entry of judgment in any pending or threatened action, suit or proceeding in respect of which any indemnified party is or could have been a party and indemnity was or could have been sought hereunder by such indemnified party, unless such settlement, compromise or consent includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such action, suit or proceeding.

Contribution. If the indemnification provided for in this Section 6 is for any reason held to be unavailable to or otherwise insufficient to hold harmless an indemnified party in respect of any losses, claims, damages, liabilities or expenses referred to therein, then each indemnifying party shall contribute to the aggregate amount paid or payable by such indemnified party, as incurred, as a result of any losses, claims, damages, liabilities or expenses referred to therein (i) in such proportion as is appropriate to reflect the relative benefits received by the Company, on the one hand, and the Agent, on the other hand, from the offering of the Shares pursuant to this Agreement or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and the Agent, on the other hand, in connection with the statements or omissions which resulted in such losses, claims, damages, liabilities or expenses, as well as any other relevant equitable considerations. The relative benefits received by the Company, on the one hand, and the Agent, on the other hand, in connection with the offering of the Shares pursuant to this Agreement shall be deemed to be in the same respective proportions as the total gross proceeds from the offering of the Shares (before deducting expenses) received by the Company bear to the total commissions received by the Agent. The relative fault of the Company, on the one hand, and the Agent, on the other hand, shall be determined by reference to, among other things, whether any such untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company, on the one hand, or the Agent, on the other hand, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

The amount paid or payable by a party as a result of the losses, claims, damages, liabilities and expenses referred to above shall be deemed to include, subject to the limitations set forth in Section 6(c), any reasonable and documented legal or other fees or expenses reasonably incurred by such party in connection with investigating or defending any action or claim. The provisions set forth in Section 6(c) with respect to notice of commencement of any action shall apply if a claim for contribution is to be made under this Section 6(e); provided, however, that no additional notice shall be required with respect to any action for which notice has been given under Section 6(c) for purposes of indemnification.

The Company and the Agent agree that it would not be just and equitable if contribution pursuant to this Section 6(e) were determined by pro rata allocation or by any other method of allocation which does not take account of the equitable considerations referred to in this Section 6(e).

Notwithstanding the provisions of this <u>Section 6(e)</u>, the Agent shall not be required to contribute any amount in excess of the agent fees received by the Agent in connection with the offering contemplated hereby. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this <u>Section 6(e)</u>, each officer and employee of the Agent and each person, if any, who controls the Agent within the meaning of the Securities Act or the Exchange Act shall have the same rights to contribution as the Agent, and each director of the Company, each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of the Securities Act and the Exchange Act shall have the same rights to contribution as the Company.

#### Section 7. TERMINATION & SURVIVAL

- (a) <u>Term.</u> Subject to the provisions of this <u>Section 7</u>, the term of this Agreement shall continue from the date of this Agreement until the end of the Agency Period, unless earlier terminated by the parties to this Agreement pursuant to this <u>Section 7</u>.
- (b) <u>Termination; Survival Following Termination</u>. (i) Either party may terminate this Agreement prior to the end of the Agency Period, by giving written notice as required by this Agreement, upon ten calendar days' notice to the other party; provided that, (A) if the Company terminates this Agreement after the Agent confirms to the Company any sale of Shares, the Company shall remain obligated to comply with <u>Section 3(b)(v)</u> with respect to such Shares and (B) <u>Section 2</u>, <u>Section 3(d)</u>, <u>Section 6</u>, <u>Section 7</u> and <u>Section 8</u> shall survive termination of this Agreement. If termination shall occur prior to the Settlement Date for any sale of Shares, such sale shall nevertheless settle in accordance with the terms of this Agreement. Upon termination of this Agreement, the Company shall not have any liability to the Agent for any discount, commission or other compensation with respect to any Shares not otherwise sold by the Agent under this Agreement.
- (ii) In addition to the survival provision of Section 7(b)(i), the respective indemnities, agreements, representations, warranties and other statements of the Company, of its officers and of the Agent set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation made by or on behalf of the Agent or the Company or any of its or their partners, officers or directors or any controlling person, as the case may be, and, anything herein to the contrary notwithstanding, will survive delivery of and payment for the Shares sold hereunder and any termination of this Agreement.

### **Section 8. MISCELLANEOUS**

(a) <u>Press Releases and Disclosure</u>. The Company may issue a press release describing the material terms of the transactions contemplated hereby as soon as practicable following the

date of this Agreement, and may file with the Commission a Current Report on Form 8 K, with this Agreement attached as an exhibit thereto, describing the material terms of the transactions contemplated hereby, and the Company shall consult with the Agent prior to making such disclosures, and the parties hereto shall use all commercially reasonable efforts, acting in good faith, to agree upon a text for such disclosures that is reasonably satisfactory to all parties hereto. Notwithstanding anything to the contrary herein, the Company shall not issue any press release or make any other public disclosure or public statement (other than disclosure related to periodic sales pursuant to this Agreement) related to this Agreement, or any of the transactions contemplated hereby or naming the Agent without the Agent's prior written approval.

- (b) No Advisory or Fiduciary Relationship. The Company acknowledges and agrees that (i) the transactions contemplated by this Agreement, including the determination of any fees, are arm's-length commercial transactions between the Company and the Agent, (ii) when acting as a principal under this Agreement, the Agent is and has been acting solely as a principal and is not the agent or fiduciary of the Company, or its stockholders, creditors, employees or any other party, (iii) the Agent has not assumed nor will assume an advisory or fiduciary responsibility in favor of the Company with respect to the transactions contemplated hereby or the process leading thereto (irrespective of whether the Agent has advised or is currently advising the Company on other matters) and the Agent does not have any obligation to the Company with respect to the transactions contemplated hereby except the obligations expressly set forth in this Agreement, (iv) the Agent and its respective affiliates may be engaged in a broad range of transactions that involve interests that differ from those of the Company, and (v) the Agent has not provided any legal, accounting, regulatory or tax advice with respect to the transactions contemplated hereby and the Company has consulted its own legal, accounting, regulatory and tax advisors to the extent it deemed appropriate.
- (c) Research Analyst Independence. The Company acknowledges that the Agent's research analysts and research departments are required to and should be independent from their respective investment banking divisions and are subject to certain regulations and internal policies, and as such the Agent's research analysts may hold views and make statements or investment recommendations and/or publish research reports with respect to the Company or the offering that differ from the views of their respective investment banking divisions. The Company understands that the Agent is a full service securities firm and as such from time to time, subject to applicable securities laws, may effect transactions for its own account or the account of its customers and hold long or short positions in debt or equity securities of the companies that may be the subject of the transactions contemplated by this Agreement.
- (d) <u>Notices</u>. All communications hereunder shall be in writing and shall be mailed, hand delivered or telecopied and confirmed to the parties hereto as follows:

If to the Agent:

Jefferies LLC 520 Madison Avenue New York, NY 10022 Attention: General Counsel with a copy to:

Cooley LLP 55 Hudson Yards New York, NY 10001 Facsimile: (212) 479-6722

Attention: Daniel I. Goldberg, Esq.

If to the Company:

Kala Pharmaceuticals, Inc. 1167 Massachusetts Avenue Arlington, MA 02476 Attention: Mark Iwicki

with a copy (which shall not constitute notice) to:

Wilmer Cutler Pickering Hale and Dorr LLP 60 State Street Boston, MA 02109 Attention: Stuart M. Falber Scott Lunin

Any party hereto may change the address for receipt of communications by giving written notice to the others in accordance with this Section  $8(\underline{d})$ .

- (e) <u>Successors</u>. This Agreement will inure to the benefit of and be binding upon the parties hereto, and to the benefit of the employees, officers and directors and controlling persons referred to in <u>Section 6</u>, and in each case their respective successors, and no other person will have any right or obligation hereunder. The term "**successors**" shall not include any purchaser of the Shares as such from the Agent merely by reason of such purchase.
- (f) <u>Partial Unenforceability</u>. The invalidity or unenforceability of any Article, Section, paragraph or provision of this Agreement shall not affect the validity or enforceability of any other Article, Section, paragraph or provision hereof. If any Article, Section, paragraph or provision of this Agreement is for any reason determined to be invalid or unenforceable, there shall be deemed to be made such minor changes (and only such minor changes) as are necessary to make it valid and enforceable.
- (g) <u>Governing Law Provisions</u>. This Agreement, and any claim, controversy or dispute of any kind or nature whatsoever arising out of or in any way relating to this Agreement, shall be governed by and construed in accordance with the internal laws of the State of New York applicable to agreements made and to be performed in such state. Any legal suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated hereby ("**Related Proceedings**") may be instituted in the federal courts of the United States of America

located in the Borough of Manhattan in the City of New York or the courts of the State of New York in each case located in the Borough of Manhattan in the City of New York, and each party irrevocably submits to the exclusive jurisdiction (except for proceedings instituted in regard to the enforcement of a judgment of any such court, as to which such jurisdiction is non-exclusive) of such courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to such party's address set forth above shall be effective service of process for any suit, action or other proceeding brought in any such court. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding in the Specified Courts and irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such suit, action or other proceeding brought in any such court has been brought in an inconvenient forum.

(h) <u>General Provisions</u>. This Agreement constitutes the entire agreement of the parties to this Agreement and supersedes all prior written or oral and all contemporaneous oral agreements, understandings and negotiations with respect to the subject matter hereof, including the Amended and Restated Sales Agreement by and between the Company and the Agent, dated May 7, 2020. This Agreement may be executed in two or more counterparts, each one of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument, and may be delivered by facsimile transmission or by electronic delivery of a portable document format (PDF) file (including any electronic signature covered by the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act, the Electronic Signatures and Records Act or other applicable law, e.g., www.docusign.com). This Agreement may not be amended or modified unless in writing by all of the parties hereto, and no condition herein (express or implied) may be waived unless waived in writing by each party whom the condition is meant to benefit. The Article and Section headings herein are for the convenience of the parties only and shall not affect the construction or interpretation of this Agreement.

[Signature Page Immediately Follows]

If the foregoing is in accordance with your understanding of our agreement, kindly sign and return to the Company the enclosed copies hereof, whereupon this instrument, along with all counterparts hereof, shall become a binding agreement in accordance with its terms

Very truly yours,

### KALA PHARMACEUTICALS, INC.

By: /s/ Mark Iwicki

Name:Mark Iwicki Title:Chief Executive Officer

The foregoing Agreement is hereby confirmed and accepted by the Agent in New York, New York as of the date first above written.

### **JEFFERIES LLC**

By: <u>/s/ Donald Lynaugh</u>

Name: Donald Lynaugh Title: Managing Director

# **EXHIBIT A**

# ISSUANCE NOTICE

[Date]		
Jefferies LLC 520 Madison Avenue New York, New York 10022		
Attn: []		
	19, 2023. The Company	maceuticals, Inc. (the "Company") and Jefferies confirms that all conditions to the delivery of this
Date of Delivery of Issuance Notice (de	etermined pursuant to Sec	<u>stion 3(b)(i)</u> ):
Issuance Amount (equal to the total Sal	les Price for such Shares):	
	\$	_
Number of Days in Selling Period:		
First Date of Selling Period:		_
Last Date of Selling Period:		_
Settlement Date(s) if other than standar	rd T+2 settlement:	
Floor Price Limitation (in no event less may be withheld in the Agent's sole dis		prior written consent of the Agent, which consent
Comments:		
		By: Name: Title:
	A-1	

Schedule A

# **Notice Parties**

The Company		
Mark Iwicki		
Mary Reumuth		
The Agent		
Donald Lynaugh		
Michael Magarro		

# WILMERHALE

+1 212 230 8800 (t) +1 212 230 8888 (f)

January 19, 2023

Kala Pharmaceuticals, Inc. 1167 Massachusetts Avenue Arlington, MA 02476

Re: <u>Prospectus Supplement to Registration Statement on Form S-3</u>

Ladies and Gentlemen:

This opinion is being furnished to you in connection with (i) the Registration Statement on Form S-3 (File No. 333-238087) (the "Registration Statement") filed by Kala Pharmaceuticals, Inc., a Delaware corporation (the "Company"), with the Securities and Exchange Commission (the "Commission") under the Securities Act of 1933, as amended (the "Securities Act"), for the registration of, among other things, an indeterminate number of shares of the Company's common stock, \$0.001 par value per share (the "Common Stock"), which may be issued from time to time on a delayed or continuous basis pursuant to Rule 415 under the Securities Act at an initial aggregate offering price not to exceed \$350,000,000, as set forth in the Registration Statement and the base prospectus contained therein (the "Base Prospectus") and (ii) the prospectus supplement, dated January 19, 2023 (the "Prospectus Supplement" and, together with the Base Prospectus, the "Prospectus") relating to the issuance and sale from time to time by the Company of shares of Common Stock with an aggregate offering price of up to \$40,000,000 (the "Shares").

The Shares are to be issued and sold by the Company pursuant to the Open Market Sale Agreement<sup>SM</sup>, dated as of January 19, 2023, between the Company and Jefferies LLC (the "Agreement"). The Agreement is being filed with the Commission as Exhibit 1.1 to the Company's Current Report on Form 8-K, filed on the date hereof.

We are acting as counsel for the Company in connection with the issue and sale by the Company of the Shares pursuant to the Agreement. We have examined and relied upon copies of the Registration Statement and the Prospectus, as filed with the Commission, including the exhibits thereto. We have also examined and relied upon the Agreement, minutes of meetings of the stockholders and the Board of Directors of the Company (including committees thereof) as provided to us by the Company, stock record books of the Company as provided to us by the Company, the Certificate of Incorporation and By-laws of the Company, each as restated and/or amended to date, and such other documents as we have deemed necessary for purposes of rendering the opinions hereinafter set forth.

In our examination of the foregoing documents, we have assumed the genuineness of all signatures, the authenticity of all documents submitted to us as originals, the conformity to original

Wilmer Cutler Pickering Hale and Dorr LLP, 7 World Trade Center, 250 Greenwich Street, New York, New York 10007

Beijing Berlin Boston Brussels Denver Frankfurt London Los Angeles New York Palo Alto San Francisco Washington

Kala Pharmaceuticals, Inc. January 19, 2023 Page 2

## WILMERHALE

documents of all documents submitted to us as copies, the authenticity of the originals of such latter documents and the legal competence of all signatories to such documents.

We have relied as to certain matters on information obtained from public officials and officers of the Company, and we have assumed that (i) the Shares will be issued and sold in compliance with applicable federal and state securities laws and in the manner stated in the Registration Statement, the Prospectus and any applicable prospectus supplement; (ii) there will be sufficient shares of Common Stock authorized under the Certificate of Incorporation and not otherwise reserved for issuance; and (iii) at the time of the issuance and sale of the Shares, the Company will be validly existing as a corporation and in good standing under the laws of the State of Delaware.

We have assumed that there will not have occurred, prior to the date of issuance of the Shares, any change in law affecting the validity of such Shares and that at the time of the issuance and sale of the Shares, the Board of Directors of the Company (or any committee thereof acting pursuant to authority properly delegated to such committee by the Board of Directors) shall not have taken any action to rescind or otherwise reduce its prior authorization of the issuance of the Shares.

We express no opinion herein as to the laws of any state or jurisdiction other than the General Corporation Law of the State of Delaware. We also express no opinion herein with respect to compliance by the Company with the securities or "blue sky" laws of any state or other jurisdiction of the United States or of any foreign jurisdiction.

Based upon and subject to the foregoing, we are of the opinion that the Shares have been duly authorized for issuance and, when the Shares are issued and paid for in accordance with the terms and conditions of the Agreement, the Shares will be validly issued, fully paid and non-assessable.

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 in effect.

Please note that we are opining only as to the matters expressly set forth herein, and no opinion should be inferred as to any other matters. This opinion is based upon currently existing statutes, rules, regulations and judicial decisions, and we disclaim any obligation to advise you of any change in any of these sources of law or subsequent legal or factual developments which might affect any matters or opinions set forth herein.

We hereby consent to the filing of this opinion with the Commission in accordance with the requirements of Item 601(b)(5) of Regulation S-K under the Securities Act as an exhibit to the Current Report on Form 8-K to be filed by the Company on the date hereof in connection with the issuance and sale of the Shares and to the use of our name therein and in the related Prospectus Supplement under the caption "Legal Matters." In giving such consent, we do not hereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission.

Kala Pharmaceuticals, Inc. January 19, 2023 Page 3

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Very truly yours,

/s/ Wilmer Cutler Pickering Hale and Dorr LLP

WILMER CUTLER PICKERING HALE AND DORR LLP