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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of The Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported)  
July 7, 2020**

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**Otonomy, Inc.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-36591**  
(Commission  
File Number)

**26-2590070**  
(IRS Employer  
Identification No.)

**4796 Executive Drive  
San Diego, CA 92121**  
(Address of principal executive offices, including zip code)

**(619) 323-2200**  
(Registrant's telephone number, including area code)

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

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
<b>Common Stock, par value \$0.001 per share</b>	<b>OTIC</b>	<b>The NASDAQ Stock Market LLC (The Nasdaq Global Select Market)</b>

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 5.03. Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year.**

On July 7, 2020, the Board of Directors of Otonomy, Inc. (the “**Company**”) approved the Company’s amended and restated bylaws (the “**Amended and Restated Bylaws**”) to insert Article XI - Exclusive Forum to provide that unless the Company consents in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended (the “**Securities Act**”).

The Amended and Restated Bylaws are attached hereto as Exhibit 3.1 and are hereby incorporated by reference into this Item 5.03. The foregoing summary description does not purport to be complete and is qualified in its entirety by reference to the full text of the Amended and Restated Bylaws.

**Item 8.01. Other Events.**

On July 8, 2020, the Company issued a press release announcing the commencement of an underwritten public offering of its common stock, par value \$0.001 per share, and, in lieu of common stock to certain investors that so choose, pre-funded warrants to purchase shares of our common stock, pursuant to its shelf registration statement on Form S-3 (File No. 333-227269), which became effective on September 21, 2018 (the “**Registration Statement**”). A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

On July 9, 2020, in connection with the offering, the Company filed a preliminary prospectus supplement (the “**Preliminary Prospectus Supplement**”) to the Registration Statement pursuant to Rule 424(b) under the Securities Act. The Company included updated risk factors in the Preliminary Prospectus Supplement. The revised risk factor disclosure is filed herewith as Exhibit 99.2 and incorporated by reference.

This Current Report on Form 8-K, including the exhibits hereto, shall not constitute an offer to sell or the solicitation of an offer to buy any securities of the Company, which is being made only by means of a written prospectus meeting the requirements of Section 10 of the Securities Act, nor shall there be any sale of the Company’s securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities law of such jurisdiction.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

Exhibit No.	Description
3.1	<a href="#">Amended and Restated Bylaws</a>
99.1	<a href="#">Press Release dated July 8, 2020</a>
99.2	<a href="#">Updated Risk Factors</a>

**SIGNATURES**

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

**OTONOMY, INC.**

By: /s/ Paul E. Cayer

Paul E. Cayer

Chief Financial and Business Officer

Date: July 9, 2020

## AMENDED AND RESTATED BYLAWS OF

## OTONOMY, INC.

(as amended and restated on July 7, 2020)

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ARTICLE I — CORPORATE OFFICES

1.1 REGISTERED OFFICE

The registered office of Otonomy, Inc. shall be fixed in the corporation's certificate of incorporation. References in these bylaws to the certificate of incorporation shall mean the certificate of incorporation of the corporation, as amended from time to time, including the terms of any certificate of designations of any series of Preferred Stock.

1.2 OTHER OFFICES

The corporation's board of directors may at any time establish other offices at any place or places where the corporation is qualified to do business.

ARTICLE II — MEETINGS OF STOCKHOLDERS

2.1 PLACE OF MEETINGS

Meetings of stockholders shall be held at any place, within or outside the State of Delaware, designated by the board of directors. The board of directors may, in its sole discretion, determine that a meeting of stockholders shall not be held at any place, but may instead be held solely by means of remote communication as authorized by Section 211(a)(2) of the General Corporation Law of the State of Delaware (the "DGCL"). In the absence of any such designation or determination, stockholders' meetings shall be held at the corporation's principal executive office.

2.2 ANNUAL MEETING

The annual meeting of stockholders shall be held on such date, at such time, and at such place (if any) within or without the State of Delaware as shall be designated from time to time by the board of directors and stated in the corporation's notice of the meeting. At the annual meeting, directors shall be elected and any other proper business may be transacted.

2.3 SPECIAL MEETING

(i) A special meeting of the stockholders, other than those required by statute, may be called at any time only by (A) the board of directors, (B) the chairperson of the board of directors, (C) the chief executive officer or (D) the president (in the absence of a chief executive officer). A special meeting of the stockholders may not be called by any other person or persons. The board of directors may cancel, postpone or reschedule any previously scheduled special meeting at any time, before or after the notice for such meeting has been sent to the stockholders.

(ii) The notice of a special meeting shall include the purpose for which the meeting is called. Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting by or at the direction of the board of directors, the chairperson of the board of directors, the chief executive officer or the president (in the absence of a chief executive officer). Nothing contained in this Section 2.3(ii) shall be construed as limiting, fixing or affecting the time when a meeting of stockholders called by action of the board of directors may be held.

2.4 ADVANCE NOTICE PROCEDURES

(i) *Advance Notice of Stockholder Business.* At an annual meeting of the stockholders, only such business shall be conducted as shall have been properly brought before the meeting. To be properly brought before an annual meeting, business must be brought: (A) pursuant to the corporation's proxy materials with respect to such meeting, (B) by or at the direction of the board of directors, or (C) by a stockholder of the corporation who (1) is a stockholder of record at the time of the giving of the notice required by this Section 2.4(i) and on the record date for the determination of stockholders entitled to vote at the annual meeting and (2) has timely complied in proper written form with the notice procedures set forth in this Section 2.4(i). In addition, for business to be properly brought before an annual meeting by a stockholder, such business must be a proper matter for stockholder action pursuant to these bylaws and applicable law. Except for proposals properly made in accordance with Rule 14a-8 under the Securities and Exchange Act of 1934, and the rules and regulations thereunder (as so amended and inclusive of such rules and regulations), and included in the notice of meeting given by or at the direction of the board of directors, for

the avoidance of doubt, clause (C) above shall be the exclusive means for a stockholder to bring business before an annual meeting of stockholders.

(a) To comply with clause (C) of Section 2.4(i) above, a stockholder's notice must set forth all information required under this Section 2.4(i) and must be timely received by the secretary of the corporation. To be timely, a stockholder's notice must be received by the secretary at the principal executive offices of the corporation not later than the 45th day nor earlier than the 75th day before the one-year anniversary of the date on which the corporation first mailed its proxy materials or a notice of availability of proxy materials (whichever is earlier) for the preceding year's annual meeting; *provided, however*, that in the event that no annual meeting was held in the previous year or if the date of the annual meeting is advanced by more than 30 days prior to or delayed by more than 60 days after the one-year anniversary of the date of the previous year's annual meeting, then, for notice by the stockholder to be timely, it must be so received by the secretary not earlier than the close of business on the 120th day prior to such annual meeting and not later than the close of business on the later of (i) the 90th day prior to such annual meeting, or (ii) the tenth day following the day on which Public Announcement (as defined below) of the date of such annual meeting is first made. In no event shall any adjournment or postponement of an annual meeting or the announcement thereof commence a new time period for the giving of a stockholder's notice as described in this Section 2.4(i)(a). "Public Announcement" shall mean disclosure in a press release reported by the Dow Jones News Service, Associated Press or a comparable national news service or in a document publicly filed by the corporation with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the Securities Exchange Act of 1934, as amended, or any successor thereto (the "1934 Act").

(b) To be in proper written form, a stockholder's notice to the secretary must set forth as to each matter of business the stockholder intends to bring before the annual meeting: (1) a brief description of the business intended to be brought before the annual meeting and the reasons for conducting such business at the annual meeting, (2) the name and address, as they appear on the corporation's books, of the stockholder proposing such business and any Stockholder Associated Person (as defined below), (3) the class and number of shares of the corporation that are held of record or are beneficially owned by the stockholder or any Stockholder Associated Person and any derivative positions held or beneficially held by the stockholder or any Stockholder Associated Person, (4) whether and the extent to which any hedging or other transaction or series of transactions has been entered into by or on behalf of such stockholder or any Stockholder Associated Person with respect to any securities of the corporation, and a description of any other agreement, arrangement or understanding (including any short position or any borrowing or lending of shares), the effect or intent of which is to mitigate loss to, or to manage the risk or benefit from share price changes for, or to increase or decrease the voting power of, such stockholder or any Stockholder Associated Person with respect to any securities of the corporation, (5) any material interest of the stockholder or a Stockholder Associated Person in such business, and (6) a statement whether either such stockholder or any Stockholder Associated Person will deliver a proxy statement and form of proxy to holders of at least the percentage of the corporation's voting shares required under applicable law to carry the proposal (such information provided and statements made as required by clauses (1) through (6), a "Business Solicitation Statement"). In addition, to be in proper written form, a stockholder's notice to the secretary must be supplemented not later than ten days following the record date for notice of the meeting to disclose the information contained in clauses (3) and (4) above as of the record date for notice of the meeting. For purposes of this Section 2.4, a "Stockholder Associated Person" of any stockholder shall mean (i) any person controlling, directly or indirectly, or acting in concert with, such stockholder, (ii) any beneficial owner of shares of stock of the corporation owned of record or beneficially by such stockholder and on whose behalf the proposal or nomination, as the case may be, is being made, or (iii) any person controlling, controlled by or under common control with such person referred to in the preceding clauses (i) and (ii).

(c) Without exception, no business shall be conducted at any annual meeting except in accordance with the provisions set forth in this Section 2.4(i) and, if applicable, Section 2.4(ii). In addition, business proposed to be brought by a stockholder may not be brought before the annual meeting if such stockholder or a Stockholder Associated Person, as applicable, takes action contrary to the representations made in the Business Solicitation Statement applicable to such business or if the Business Solicitation Statement applicable to such business contains an untrue statement of a material fact or omits to state a material fact necessary to make the statements therein not misleading. The chairperson of the annual meeting shall, if the facts warrant, determine and declare at the annual meeting that business was not properly brought before the annual meeting and in accordance with the provisions of this Section 2.4(i), and, if the chairperson should so determine, he or she shall so declare at the annual meeting that any such business not properly brought before the annual meeting shall not be conducted.

(ii) *Advance Notice of Director Nominations at Annual Meetings.* Notwithstanding anything in these bylaws to the contrary, only persons who are nominated in accordance with the procedures set forth in this Section 2.4(ii) shall be eligible for election or re-election as directors at an annual meeting of stockholders. Nominations of persons for election or re-election to the board of directors of the corporation shall be made at an annual meeting of stockholders only (A) by or at the direction of the board of directors or (B) by a stockholder of the corporation who (1) was a stockholder of record at the time of the giving of the notice required by this Section 2.4(ii) and on the record date for the determination of stockholders entitled to vote at the annual meeting and (2) has complied with the notice procedures set forth in this Section 2.4(ii). In addition to any other applicable requirements, for a nomination to be made by a stockholder, the stockholder must have given timely notice thereof in proper written form to the secretary of the corporation.

(a) To comply with clause (B) of Section 2.4(ii) above, a nomination to be made by a stockholder must set forth all information required under this Section 2.4(ii) and must be received by the secretary of the corporation at the principal executive offices of the corporation at the time set forth in, and in accordance with, the final three sentences of Section 2.4(i)(a) above.

(b) To be in proper written form, such stockholder's notice to the secretary must set forth:

(1) as to each person (a "nominee") whom the stockholder proposes to nominate for election or re-election as a director: (A) the name, age, business address and residence address of the nominee, (B) the principal occupation or employment of the nominee, (C) the class and number of shares of the corporation that are held of record or are beneficially owned by the nominee and any derivative positions held or beneficially held by the nominee, (D) whether and the extent to which any hedging or other transaction or series of transactions has been entered into by or on behalf of the nominee with respect to any securities of the corporation, and a description of any other agreement, arrangement or understanding (including any short position or any borrowing or lending of shares), the effect or intent of which is to mitigate loss to, or to manage the risk or benefit of share price changes for, or to increase or decrease the voting power of the nominee, (E) a description of all arrangements or understandings between the stockholder and each nominee and any other person or persons (naming such person or persons) pursuant to which the nominations are to be made by the stockholder, (F) a written statement executed by the nominee acknowledging that as a director of the corporation, the nominee will owe a fiduciary duty under Delaware law with respect to the corporation and its stockholders, and (G) any other information relating to the nominee that would be required to be disclosed about such nominee if proxies were being solicited for the election or re-election of the nominee as a director, or that is otherwise required, in each case pursuant to Regulation 14A under the 1934 Act (including without limitation the nominee's written consent to being named in the proxy statement, if any, as a nominee and to serving as a director if elected or re-elected, as the case may be); and

(2) as to such stockholder giving notice, (A) the information required to be provided pursuant to clauses (2) through (5) of Section 2.4(i)(b) above, and the supplement referenced in the second sentence of Section 2.4(i)(b) above (except that the references to "business" in such clauses shall instead refer to nominations of directors for purposes of this paragraph), and (B) a statement whether either such stockholder or Stockholder Associated Person will deliver a proxy statement and form of proxy to holders of a number of the corporation's voting shares reasonably believed by such stockholder or Stockholder Associated Person to be necessary to elect or re-elect such nominee(s) (such information provided and statements made as required by clauses (A) and (B) above, a "Nominee Solicitation Statement").

(c) At the request of the board of directors, any person nominated by a stockholder for election or re-election as a director must furnish to the secretary of the corporation (1) that information required to be set forth in the stockholder's notice of nomination of such person as a director as of a date subsequent to the date on which the notice of such person's nomination was given and (2) such other information as may reasonably be required by the corporation to determine the eligibility of such proposed nominee to serve as an independent director or audit committee financial expert of the corporation under applicable law, securities exchange rule or regulation, or any publicly-disclosed corporate governance guideline or committee charter of the corporation and (3) that could be material to a reasonable stockholder's understanding of the independence, or lack thereof, of such nominee; in the absence of the furnishing of such information if requested, such stockholder's nomination shall not be considered in proper form pursuant to this Section 2.4(ii).

(d) Without exception, no person shall be eligible for election or re-election as a director of the corporation at an annual meeting of stockholders unless nominated in accordance with the provisions set forth in this Section 2.4(ii). In addition, a nominee shall not be eligible for election or re-election if a stockholder or Stockholder Associated Person, as applicable, takes action contrary to the representations made in the Nominee Solicitation Statement



applicable to such nominee or if the Nominee Solicitation Statement applicable to such nominee contains an untrue statement of a material fact or omits to state a material fact necessary to make the statements therein not misleading. The chairperson of the annual meeting shall, if the facts warrant, determine and declare at the annual meeting that a nomination was not made in accordance with the provisions prescribed by these bylaws, and if the chairperson should so determine, he or she shall so declare at the annual meeting, and the defective nomination shall be disregarded.

*(iii) Advance Notice of Director Nominations for Special Meetings.*

(a) For a special meeting of stockholders at which directors are to be elected or re-elected, nominations of persons for election or re-election to the board of directors shall be made only (1) by or at the direction of the board of directors or (2) by any stockholder of the corporation who (A) is a stockholder of record at the time of the giving of the notice required by this Section 2.4(iii) and on the record date for the determination of stockholders entitled to vote at the special meeting and (B) delivers a timely written notice of the nomination to the secretary of the corporation that includes the information set forth in Sections 2.4(ii)(b) and (ii)(c) above. To be timely, such notice must be received by the secretary at the principal executive offices of the corporation not later than the close of business on the later of the 90th day prior to such special meeting or the tenth day following the day on which Public Announcement is first made of the date of the special meeting and of the nominees proposed by the board of directors to be elected or re-elected at such meeting. A person shall not be eligible for election or re-election as a director at a special meeting unless the person is nominated (i) by or at the direction of the board of directors or (ii) by a stockholder in accordance with the notice procedures set forth in this Section 2.4(iii). In addition, a nominee shall not be eligible for election or re-election if a stockholder or Stockholder Associated Person, as applicable, takes action contrary to the representations made in the Nominee Solicitation Statement applicable to such nominee or if the Nominee Solicitation Statement applicable to such nominee contains an untrue statement of a material fact or omits to state a material fact necessary to make the statements therein not misleading.

(b) The chairperson of the special meeting shall, if the facts warrant, determine and declare at the meeting that a nomination or business was not made in accordance with the procedures prescribed by these bylaws, and if the chairperson should so determine, he or she shall so declare at the meeting, and the defective nomination or business shall be disregarded.

*(iv) Other Requirements and Rights.* In addition to the foregoing provisions of this Section 2.4, a stockholder must also comply with all applicable requirements of state law and of the 1934 Act and the rules and regulations thereunder with respect to the matters set forth in this Section 2.4. Nothing in this Section 2.4 shall be deemed to affect any rights of:

(a) a stockholder to request inclusion of proposals in the corporation's proxy statement pursuant to Rule 14a-8 (or any successor provision) under the 1934 Act; or

(b) the corporation to omit a proposal from the corporation's proxy statement pursuant to Rule 14a-8 (or any successor provision) under the 1934 Act.

## 2.5 NOTICE OF STOCKHOLDERS' MEETINGS

Whenever stockholders are required or permitted to take any action at a meeting, a written notice of the meeting shall be given which shall state the place, if any, date and hour of the meeting, the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting, the record date for determining the stockholders entitled to vote at the meeting, if such date is different from the record date for determining stockholders entitled to notice of the meeting, and, in the case of a special meeting, the purpose or purposes for which the meeting is called. Except as otherwise provided in the DGCL, the certificate of incorporation or these bylaws, the written notice of any meeting of stockholders shall be given not less than 10 nor more than 60 days before the date of the meeting to each stockholder entitled to vote at such meeting as of the record date for determining the stockholders entitled to notice of the meeting.

## 2.6 QUORUM

The holders of a majority of the stock issued and outstanding and entitled to vote, present in person or represented by proxy, shall constitute a quorum for the transaction of business at all meetings of the stockholders. Where a separate vote by a class or series or classes or series is required, a majority of the outstanding shares of such class or series or classes or series, present in person or represented by proxy, shall constitute a quorum entitled to take action

with respect to that vote on that matter, except as otherwise provided by law, the certificate of incorporation or these bylaws.

If a quorum is not present or represented at any meeting of the stockholders, then either (i) the chairperson of the meeting, or (ii) the stockholders entitled to vote at the meeting, present in person or represented by proxy, shall have power to adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present or represented. At such adjourned meeting at which a quorum is present or represented, any business may be transacted that might have been transacted at the meeting as originally noticed.

## 2.7 ADJOURNED MEETING; NOTICE

When a meeting is adjourned to another time or place, unless these bylaws otherwise require, notice need not be given of the adjourned meeting if the time, place, if any, thereof, and the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such adjourned meeting are announced at the meeting at which the adjournment is taken. At the adjourned meeting, the corporation may transact any business which might have been transacted at the original meeting. If the adjournment is for more than 30 days, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting. If after the adjournment a new record date for stockholders entitled to vote is fixed for the adjourned meeting, the board of directors shall fix a new record date for notice of such adjourned meeting in accordance with Section 213(a) of the DGCL and Section 2.11 of these bylaws, and shall give notice of the adjourned meeting to each stockholder of record entitled to vote at such adjourned meeting as of the record date fixed for notice of such adjourned meeting.

## 2.8 CONDUCT OF BUSINESS

The chairperson of any meeting of stockholders shall determine the order of business and the procedure at the meeting, including such regulation of the manner of voting and the conduct of business. The chairperson of any meeting of stockholders shall be designated by the board of directors; in the absence of such designation, the chairperson of the board, if any, the chief executive officer (in the absence of the chairperson) or the president (in the absence of the chairperson of the board and the chief executive officer), or in their absence any other executive officer of the corporation, shall serve as chairperson of the stockholder meeting.

## 2.9 VOTING

The stockholders entitled to vote at any meeting of stockholders shall be determined in accordance with the provisions of Section 2.11 of these bylaws, subject to Section 217 (relating to voting rights of fiduciaries, pledgors and joint owners of stock) and Section 218 (relating to voting trusts and other voting agreements) of the DGCL.

Except as may be otherwise provided in the certificate of incorporation or these bylaws, each stockholder shall be entitled to one vote for each share of capital stock held by such stockholder.

Except as otherwise required by law, the certificate of incorporation or these bylaws, in all matters other than the election of directors, the affirmative vote of a majority of the voting power of the shares present in person or represented by proxy at the meeting and entitled to vote on the subject matter shall be the act of the stockholders. Except as otherwise required by law, the certificate of incorporation or these bylaws, directors shall be elected by a plurality of the voting power of the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors. Where a separate vote by a class or series or classes or series is required, in all matters other than the election of directors, the affirmative vote of the majority of shares of such class or series or classes or series present in person or represented by proxy at the meeting shall be the act of such class or series or classes or series, except as otherwise provided by law, the certificate of incorporation or these bylaws.

## 2.10 STOCKHOLDER ACTION BY WRITTEN CONSENT WITHOUT A MEETING

Subject to the rights of the holders of the shares of any series of Preferred Stock or any other class of stock or series thereof that have been expressly granted the right to take action by written consent, any action required or permitted to be taken by the stockholders of the corporation must be effected at a duly called annual or special meeting of stockholders of the corporation and may not be effected by any consent in writing by such stockholders.

## 2.11 RECORD DATES

In order that the corporation may determine the stockholders entitled to notice of any meeting of stockholders or any adjournment thereof, the board of directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the board of directors and which record date shall not be more than 60 nor less than 10 days before the date of such meeting. If the board of directors so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the board of directors determines, at the time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination.

If no record date is fixed by the board of directors, the record date for determining stockholders entitled to notice of and to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held.

A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; *provided, however*, that the board of directors may fix a new record date for determination of stockholders entitled to vote at the adjourned meeting, and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote in accordance with the provisions of Section 213 of the DGCL and this Section 2.11 at the adjourned meeting.

In order that the corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights or the stockholders entitled to exercise any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action, the board of directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted, and which record date shall be not more than 60 days prior to such action. If no record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the board of directors adopts the resolution relating thereto.

## 2.12 PROXIES

Each stockholder entitled to vote at a meeting of stockholders may authorize another person or persons to act for such stockholder by proxy authorized by an instrument in writing or by a transmission permitted by law filed in accordance with the procedure established for the meeting, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. The revocability of a proxy that states on its face that it is irrevocable shall be governed by the provisions of Section 212 of the DGCL. A written proxy may be in the form of a telegram, cablegram, or other means of electronic transmission which sets forth or is submitted with information from which it can be determined that the telegram, cablegram, or other means of electronic transmission was authorized by the person.

## 2.13 LIST OF STOCKHOLDERS ENTITLED TO VOTE

The officer who has charge of the stock ledger of the corporation shall prepare and make, at least 10 days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting; *provided, however*, if the record date for determining the stockholders entitled to vote is less than 10 days before the meeting date, the list shall reflect the stockholders entitled to vote as of the tenth day before the meeting date. The stockholder list shall be arranged in alphabetical order and show the address of each stockholder and the number of shares registered in the name of each stockholder. The corporation shall not be required to include electronic mail addresses or other electronic contact information on such list. Such list shall be open to the examination of any stockholder for any purpose germane to the meeting for a period of at least 10 days prior to the meeting (i) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (ii) during ordinary business hours, at the corporation's principal place of business. In the event that the corporation determines to make the list available on an electronic network, the corporation may take reasonable steps to ensure that such information is available only to stockholders of the corporation. If the meeting is to be held at a place, then the list shall be produced and kept at the time and place of the meeting during the whole time thereof, and may be examined by any stockholder who is present. If the meeting is to be held solely by means of remote communication, then the list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall

be provided with the notice of the meeting. Such list shall presumptively determine the identity of the stockholders entitled to vote at the meeting and the number of shares held by each of them.

#### 2.14 INSPECTORS OF ELECTION

Before any meeting of stockholders, the board of directors shall appoint an inspector or inspectors of election to act at the meeting or its adjournment. The number of inspectors shall be either one (1) or three (3). If any person appointed as inspector fails to appear or fails or refuses to act, then the chairperson of the meeting may, and upon the request of any stockholder or a stockholder's proxy shall, appoint a person to fill that vacancy.

Each inspector, before entering upon the discharge of his or her duties, shall take and sign an oath to execute faithfully the duties of inspector with strict impartiality and according to the best of his or her ability. The inspector or inspectors so appointed and designated shall (i) ascertain the number of shares of capital stock of the corporation outstanding and the voting power of each share, (ii) determine the shares of capital stock of the corporation represented at the meeting and the validity of proxies and ballots, (iii) count all votes and ballots, (iv) determine and retain for a reasonable period a record of the disposition of any challenges made to any determination by the inspectors, and (v) certify their determination of the number of shares of capital stock of the corporation represented at the meeting and such inspector or inspectors' count of all votes and ballots.

In determining the validity and counting of proxies and ballots cast at any meeting of stockholders of the corporation, the inspector or inspectors may consider such information as is permitted by applicable law. If there are three (3) inspectors of election, the decision, act or certificate of a majority is effective in all respects as the decision, act or certificate of all.

### ARTICLE III — DIRECTORS

#### 3.1 POWERS

The business and affairs of the corporation shall be managed by or under the direction of the board of directors, except as may be otherwise provided in the DGCL or the certificate of incorporation.

#### 3.2 NUMBER OF DIRECTORS

The board of directors shall consist of one or more members, each of whom shall be a natural person. Unless the certificate of incorporation fixes the number of directors, the number of directors shall be determined from time to time solely by resolution of the board of directors. No reduction of the authorized number of directors shall have the effect of removing any director before that director's term of office expires.

#### 3.3 ELECTION, QUALIFICATION AND TERM OF OFFICE OF DIRECTORS

Except as provided in Section 3.4 of these bylaws, each director, including a director elected to fill a vacancy, shall hold office until the expiration of the term for which elected and until such director's successor is elected and qualified or until such director's earlier death, resignation or removal. Directors need not be stockholders unless so required by the certificate of incorporation or these bylaws. The certificate of incorporation or these bylaws may prescribe other qualifications for directors.

#### 3.4 RESIGNATION AND VACANCIES

Any director may resign at any time upon notice given in writing or by electronic transmission to the corporation; *provided, however*, that if such notice is given by electronic transmission, such electronic transmission must either set forth or be submitted with information from which it can be determined that the electronic transmission was authorized by the director. A resignation is effective when the resignation is delivered unless the resignation specifies a later effective date or an effective date determined upon the happening of an event or events. Acceptance of such resignation shall not be necessary to make it effective. A resignation which is conditioned upon the director failing to receive a specified vote for reelection as a director may provide that it is irrevocable. Unless otherwise provided in the certificate of incorporation or these bylaws, when one or more directors resign from the board of directors, effective at a future date, a majority of the directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective.

Unless otherwise provided in the certificate of incorporation or these bylaws, vacancies and newly created directorships resulting from any increase in the authorized number of directors elected by all of the stockholders having the right to vote as a single class shall be filled only by a majority of the directors then in office, although less than a quorum, or by a sole remaining director. If the directors are divided into classes, a person so elected by the directors then in office to fill a vacancy or newly created directorship shall hold office until the next election of the class for which such director shall have been chosen and until his or her successor shall have been duly elected and qualified.

If, at the time of filling any vacancy or any newly created directorship, the directors then in office constitute less than a majority of the whole board of directors (as constituted immediately prior to any such increase), the Court of Chancery may, upon application of any stockholder or stockholders holding at least 10% of the voting stock at the time outstanding having the right to vote for such directors, summarily order an election to be held to fill any such vacancies or newly created directorships, or to replace the directors chosen by the directors then in office as aforesaid, which election shall be governed by the provisions of Section 211 of the DGCL as far as applicable.

### 3.5 PLACE OF MEETINGS; MEETINGS BY TELEPHONE

The board of directors may hold meetings, both regular and special, either within or outside the State of Delaware.

Unless otherwise restricted by the certificate of incorporation or these bylaws, members of the board of directors, or any committee designated by the board of directors, may participate in a meeting of the board of directors, or any committee, by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and such participation in a meeting shall constitute presence in person at the meeting.

### 3.6 REGULAR MEETINGS

Regular meetings of the board of directors may be held without notice at such time and at such place as shall from time to time be determined by the board of directors.

### 3.7 SPECIAL MEETINGS; NOTICE

Special meetings of the board of directors for any purpose or purposes may be called at any time by the chairperson of the board of directors, the chief executive officer, the president, the secretary or a majority of the authorized number of directors, at such times and places as he or she or they shall designate.

Notice of the time and place of special meetings shall be:

- (i) delivered personally by hand, by courier or by telephone;
- (ii) sent by United States first-class mail, postage prepaid;
- (iii) sent by facsimile; or
- (iv) sent by electronic mail,

directed to each director at that director's address, telephone number, facsimile number or electronic mail address, as the case may be, as shown on the corporation's records.

If the notice is (i) delivered personally by hand, by courier or by telephone, (ii) sent by facsimile or (iii) sent by electronic mail, it shall be delivered or sent at least 24 hours before the time of the holding of the meeting. If the notice is sent by United States mail, it shall be deposited in the United States mail at least four days before the time of the holding of the meeting. Any oral notice may be communicated to the director. The notice need not specify the place of the meeting (if the meeting is to be held at the corporation's principal executive office) nor the purpose of the meeting.

### 3.8 QUORUM; VOTING

At all meetings of the board of directors, a majority of the total authorized number of directors shall constitute a quorum for the transaction of business. If a quorum is not present at any meeting of the board of directors, then the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present. A meeting at which a quorum is initially present may continue to transact

business notwithstanding the withdrawal of directors, if any action taken is approved by at least a majority of the required quorum for that meeting.

The vote of a majority of the directors present at any meeting at which a quorum is present shall be the act of the board of directors, except as may be otherwise specifically provided by statute, the certificate of incorporation or these bylaws.

If the certificate of incorporation provides that one or more directors shall have more or less than one vote per director on any matter, every reference in these bylaws to a majority or other proportion of the directors shall refer to a majority or other proportion of the votes of the directors.

### 3.9 BOARD ACTION BY WRITTEN CONSENT WITHOUT A MEETING

Unless otherwise restricted by the certificate of incorporation or these bylaws, any action required or permitted to be taken at any meeting of the board of directors, or of any committee thereof, may be taken without a meeting if all members of the board of directors or committee, as the case may be, consent thereto in writing or by electronic transmission and the writing or writings or electronic transmission or transmissions are filed with the minutes of proceedings of the board of directors or committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

### 3.10 FEES AND COMPENSATION OF DIRECTORS

Unless otherwise restricted by the certificate of incorporation or these bylaws, the board of directors shall have the authority to fix the compensation of directors.

### 3.11 REMOVAL OF DIRECTORS

A director may be removed from office by the stockholders of the corporation only for cause.

No reduction of the authorized number of directors shall have the effect of removing any director prior to the expiration of such director's term of office.

## ARTICLE IV — COMMITTEES

### 4.1 COMMITTEES OF DIRECTORS

The board of directors may designate one or more committees, each committee to consist of one or more of the directors of the corporation. The board of directors may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the board of directors to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the board of directors or in these bylaws, shall have and may exercise all the powers and authority of the board of directors in the management of the business and affairs of the corporation, and may authorize the seal of the corporation to be affixed to all papers that may require it; but no such committee shall have the power or authority to (i) approve or adopt, or recommend to the stockholders, any action or matter (other than the election or removal of directors) expressly required by the DGCL to be submitted to stockholders for approval, or (ii) adopt, amend or repeal any bylaw of the corporation.

### 4.2 COMMITTEE MINUTES

Each committee shall keep regular minutes of its meetings and report the same to the board of directors when required.

### 4.3 MEETINGS AND ACTION OF COMMITTEES

Meetings and actions of committees shall be governed by, and held and taken in accordance with, the provisions of:

- (i) Section 3.5 (place of meetings and meetings by telephone);
- (ii) Section 3.6 (regular meetings);
- (iii) Section 3.7 (special meetings; notice);

- (iv) Section 3.8 (quorum; voting);
- (v) Section 3.9 (action without a meeting); and
- (vi) Section 7.5 (waiver of notice)

with such changes in the context of those bylaws as are necessary to substitute the committee and its members for the board of directors and its members. *However:*

- (i) the time of regular meetings of committees may be determined by resolution of the committee;
- (ii) special meetings of committees may also be called by resolution of the committee; and
- (iii) notice of special meetings of committees shall also be given to all alternate members, who shall have the right to attend all meetings of the committee. The board of directors may adopt rules for the government of any committee not inconsistent with the provisions of these bylaws.

Any provision in the certificate of incorporation providing that one or more directors shall have more or less than one vote per director on any matter shall apply to voting in any committee or subcommittee, unless otherwise provided in the certificate of incorporation or these bylaws.

#### 4.4 SUBCOMMITTEES

Unless otherwise provided in the certificate of incorporation, these bylaws or the resolutions of the board of directors designating the committee, a committee may create one or more subcommittees, each subcommittee to consist of one or more members of the committee, and delegate to a subcommittee any or all of the powers and authority of the committee.

### ARTICLE V — OFFICERS

#### 5.1 OFFICERS

The officers of the corporation shall be a president and a secretary. The corporation may also have, at the discretion of the board of directors, a chairperson of the board of directors, a vice chairperson of the board of directors, a chief executive officer, a chief financial officer or treasurer, one or more vice presidents, one or more assistant vice presidents, one or more assistant treasurers, one or more assistant secretaries, and any such other officers as may be appointed in accordance with the provisions of these bylaws. Any number of offices may be held by the same person.

#### 5.2 APPOINTMENT OF OFFICERS

The board of directors shall appoint the officers of the corporation, except such officers as may be appointed in accordance with the provisions of Section 5.3 of these bylaws, subject to the rights, if any, of an officer under any contract of employment. A vacancy in any office because of death, resignation, removal, disqualification or any other cause shall be filled in the manner prescribed in this Section 5 for the regular election to such office.

#### 5.3 SUBORDINATE OFFICERS

The board of directors may appoint, or empower the chief executive officer or, in the absence of a chief executive officer, the president, to appoint, such other officers and agents as the business of the corporation may require. Each of such officers and agents shall hold office for such period, have such authority, and perform such duties as are provided in these bylaws or as the board of directors may from time to time determine.

#### 5.4 REMOVAL AND RESIGNATION OF OFFICERS

Subject to the rights, if any, of an officer under any contract of employment, any officer may be removed, either with or without cause, by an affirmative vote of the majority of the board of directors at any regular or special meeting of the board of directors or, except in the case of an officer chosen by the board of directors, by any officer upon whom such power of removal may be conferred by the board of directors.

Any officer may resign at any time by giving written or electronic notice to the corporation; *provided, however,* that if such notice is given by electronic transmission, such electronic transmission must either set forth or be submitted with information from which it can be determined that the electronic transmission was authorized by the officer. Any resignation shall take effect at the date of the receipt of that notice or at any later time specified in that notice.

Unless otherwise specified in the notice of resignation, the acceptance of the resignation shall not be necessary to make it effective. Any resignation is without prejudice to the rights, if any, of the corporation under any contract to which the officer is a party.

#### 5.5 VACANCIES IN OFFICES

Any vacancy occurring in any office of the corporation shall be filled by the board of directors or as provided in Section 5.3.

#### 5.6 REPRESENTATION OF SHARES OF OTHER CORPORATIONS

The chairperson of the board of directors, the president, any vice president, the treasurer, the secretary or assistant secretary of this corporation, or any other person authorized by the board of directors or the president or a vice president, is authorized to vote, represent, and exercise on behalf of this corporation all rights incident to any and all shares of any other corporation or corporations standing in the name of this corporation. The authority granted herein may be exercised either by such person directly or by any other person authorized to do so by proxy or power of attorney duly executed by such person having the authority.

#### 5.7 AUTHORITY AND DUTIES OF OFFICERS

All officers of the corporation shall respectively have such authority and perform such duties in the management of the business of the corporation as may be designated from time to time by the board of directors and, to the extent not so provided, as generally pertain to their respective offices, subject to the control of the board of directors.

### ARTICLE VI — STOCK

#### 6.1 STOCK CERTIFICATES; PARTLY PAID SHARES

The shares of the corporation shall be represented by certificates, provided that the board of directors may provide by resolution or resolutions that some or all of any or all classes or series of its stock shall be uncertificated shares. Any such resolution shall not apply to shares represented by a certificate until such certificate is surrendered to the corporation. Every holder of stock represented by certificates shall be entitled to have a certificate signed by, or in the name of the corporation by the chairperson of the board of directors or vice-chairperson of the board of directors, or the president or a vice-president, and by the treasurer or an assistant treasurer, or the secretary or an assistant secretary of the corporation representing the number of shares registered in certificate form. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate has ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the corporation with the same effect as if such person were such officer, transfer agent or registrar at the date of issue. The corporation shall not have power to issue a certificate in bearer form.

The corporation may issue the whole or any part of its shares as partly paid and subject to call for the remainder of the consideration to be paid therefor. Upon the face or back of each stock certificate issued to represent any such partly-paid shares, or upon the books and records of the corporation in the case of uncertificated partly-paid shares, the total amount of the consideration to be paid therefor and the amount paid thereon shall be stated. Upon the declaration of any dividend on fully-paid shares, the corporation shall declare a dividend upon partly-paid shares of the same class, but only upon the basis of the percentage of the consideration actually paid thereon.

#### 6.2 SPECIAL DESIGNATION ON CERTIFICATES

If the corporation is authorized to issue more than one class of stock or more than one series of any class, then the powers, the designations, the preferences, and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of the certificate that the corporation shall issue to represent such class or series of stock; *provided, however*, that, except as otherwise provided in Section 202 of the DGCL, in lieu of the foregoing requirements there may be set forth on the face or back of the certificate that the corporation shall issue to represent such class or series of stock, a statement that the corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Within a reasonable time after the issuance or transfer of uncertificated stock, the



corporation shall send to the registered owner thereof a written notice containing the information required to be set forth or stated on certificates pursuant to this section 6.2 or Sections 156, 202(a) or 218(a) of the DGCL or with respect to this section 6.2 a statement that the corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Except as otherwise expressly provided by law, the rights and obligations of the holders of uncertificated stock and the rights and obligations of the holders of certificates representing stock of the same class and series shall be identical.

### 6.3 LOST, STOLEN OR DESTROYED CERTIFICATES

Except as provided in this Section 6.3, no new certificates for shares shall be issued to replace a previously issued certificate unless the latter is surrendered to the corporation and cancelled at the same time. The corporation may issue a new certificate of stock or uncertificated shares in the place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the corporation may require the owner of the lost, stolen or destroyed certificate, or such owner's legal representative, to give the corporation a bond sufficient to indemnify it against any claim that may be made against it on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate or uncertificated shares.

### 6.4 DIVIDENDS

The board of directors, subject to any restrictions contained in the certificate of incorporation or applicable law, may declare and pay dividends upon the shares of the corporation's capital stock. Dividends may be paid in cash, in property, or in shares of the corporation's capital stock, subject to the provisions of the certificate of incorporation.

The board of directors may set apart out of any of the funds of the corporation available for dividends a reserve or reserves for any proper purpose and may abolish any such reserve. Such purposes shall include but not be limited to equalizing dividends, repairing or maintaining any property of the corporation, and meeting contingencies.

### 6.5 TRANSFER OF STOCK

Transfers of record of shares of stock of the corporation shall be made only upon its books by the holders thereof, in person or by an attorney duly authorized, and, if such stock is certificated, upon the surrender of a certificate or certificates for a like number of shares, properly endorsed or accompanied by proper evidence of succession, assignment or authority to transfer; *provided, however*, that such succession, assignment or authority to transfer is not prohibited by the certificate of incorporation, these bylaws, applicable law or contract.

### 6.6 STOCK TRANSFER AGREEMENTS

The corporation shall have power to enter into and perform any agreement with any number of stockholders of any one or more classes of stock of the corporation to restrict the transfer of shares of stock of the corporation of any one or more classes owned by such stockholders in any manner not prohibited by the DGCL.

### 6.7 REGISTERED STOCKHOLDERS

The corporation:

- (i) shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends and to vote as such owner;
- (ii) shall be entitled to hold liable for calls and assessments the person registered on its books as the owner of shares; and
- (iii) shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of another person, whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of Delaware.

## ARTICLE VII — MANNER OF GIVING NOTICE AND WAIVER

### 7.1 NOTICE OF STOCKHOLDERS' MEETINGS

Notice of any meeting of stockholders, if mailed, is given when deposited in the United States mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the corporation's records. An affidavit of

the secretary or an assistant secretary of the corporation or of the transfer agent or other agent of the corporation that the notice has been given shall, in the absence of fraud, be *prima facie* evidence of the facts stated therein.

#### 7.2 NOTICE BY ELECTRONIC TRANSMISSION

Without limiting the manner by which notice otherwise may be given effectively to stockholders pursuant to the DGCL, the certificate of incorporation or these bylaws, any notice to stockholders given by the corporation under any provision of the DGCL, the certificate of incorporation or these bylaws shall be effective if given by a form of electronic transmission consented to by the stockholder to whom the notice is given. Any such consent shall be revocable by the stockholder by written notice to the corporation. Any such consent shall be deemed revoked if:

- (i) the corporation is unable to deliver by electronic transmission two consecutive notices given by the corporation in accordance with such consent; and
- (ii) such inability becomes known to the secretary or an assistant secretary of the corporation or to the transfer agent, or other person responsible for the giving of notice.

However, the inadvertent failure to treat such inability as a revocation shall not invalidate any meeting or other action.

Any notice given pursuant to the preceding paragraph shall be deemed given:

- (i) if by facsimile telecommunication, when directed to a number at which the stockholder has consented to receive notice;
- (ii) if by electronic mail, when directed to an electronic mail address at which the stockholder has consented to receive notice;
- (iii) if by a posting on an electronic network together with separate notice to the stockholder of such specific posting, upon the later of (A) such posting and (B) the giving of such separate notice; and
- (iv) if by any other form of electronic transmission, when directed to the stockholder.

An affidavit of the secretary or an assistant secretary or of the transfer agent or other agent of the corporation that the notice has been given by a form of electronic transmission shall, in the absence of fraud, be *prima facie* evidence of the facts stated therein.

An “electronic transmission” means any form of communication, not directly involving the physical transmission of paper, that creates a record that may be retained, retrieved, and reviewed by a recipient thereof, and that may be directly reproduced in paper form by such a recipient through an automated process.

#### 7.3 NOTICE TO STOCKHOLDERS SHARING AN ADDRESS

Except as otherwise prohibited under the DGCL, without limiting the manner by which notice otherwise may be given effectively to stockholders, any notice to stockholders given by the corporation under the provisions of the DGCL, the certificate of incorporation or these bylaws shall be effective if given by a single written notice to stockholders who share an address if consented to by the stockholders at that address to whom such notice is given. Any such consent shall be revocable by the stockholder by written notice to the corporation. Any stockholder who fails to object in writing to the corporation, within 60 days of having been given written notice by the corporation of its intention to send the single notice, shall be deemed to have consented to receiving such single written notice.

#### 7.4 NOTICE TO PERSON WITH WHOM COMMUNICATION IS UNLAWFUL

Whenever notice is required to be given, under the DGCL, the certificate of incorporation or these bylaws, to any person with whom communication is unlawful, the giving of such notice to such person shall not be required and there shall be no duty to apply to any governmental authority or agency for a license or permit to give such notice to such person. Any action or meeting which shall be taken or held without notice to any such person with whom communication is unlawful shall have the same force and effect as if such notice had been duly given. In the event that the action taken by the corporation is such as to require the filing of a certificate under the DGCL, the certificate shall state, if such is the fact and if notice is required, that notice was given to all persons entitled to receive notice except such persons with whom communication is unlawful.

## 7.5 WAIVER OF NOTICE

Whenever notice is required to be given to stockholders, directors or other persons under any provision of the DGCL, the certificate of incorporation or these bylaws, a written waiver, signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether before or after the time of the event for which notice is to be given, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders or the board of directors, as the case may be, need be specified in any written waiver of notice or any waiver by electronic transmission unless so required by the certificate of incorporation or these bylaws.

## ARTICLE VIII — INDEMNIFICATION

### 8.1 INDEMNIFICATION OF DIRECTORS AND OFFICERS IN THIRD PARTY PROCEEDINGS

Subject to the other provisions of this Article VIII, the corporation shall indemnify, to the fullest extent permitted by the DGCL, as now or hereinafter in effect, any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (a “Proceeding”) (other than an action by or in the right of the corporation) by reason of the fact that such person is or was a director of the corporation or an officer of the corporation, or while a director of the corporation or officer of the corporation is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys’ fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such Proceeding if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe such person’s conduct was unlawful. The termination of any Proceeding by judgment, order, settlement, conviction, or upon a plea of *nolo contendere* or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which such person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that such person’s conduct was unlawful.

### 8.2 INDEMNIFICATION OF DIRECTORS AND OFFICERS IN ACTIONS BY OR IN THE RIGHT OF THE CORPORATION

Subject to the other provisions of this Article VIII, the corporation shall indemnify, to the fullest extent permitted by the DGCL, as now or hereinafter in effect, any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that such person is or was a director or officer of the corporation, or while a director or officer of the corporation is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys’ fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation; except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

### 8.3 SUCCESSFUL DEFENSE

To the extent that a present or former director or officer of the corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding described in Section 8.1 or Section 8.2, or in defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys’ fees) actually and reasonably incurred by such person in connection therewith.

#### 8.4 INDEMNIFICATION OF OTHERS

Subject to the other provisions of this Article VIII, the corporation shall have power to indemnify its employees and its agents to the extent not prohibited by the DGCL or other applicable law. The board of directors shall have the power to delegate the determination of whether employees or agents shall be indemnified to such person or persons as the board of determines.

#### 8.5 ADVANCED PAYMENT OF EXPENSES

Expenses (including attorneys' fees) incurred by an officer or director of the corporation in defending any Proceeding shall be paid by the corporation in advance of the final disposition of such Proceeding upon receipt of a written request therefor (together with documentation reasonably evidencing such expenses) and an undertaking by or on behalf of the person to repay such amounts if it shall ultimately be determined that the person is not entitled to be indemnified under this Article VIII or the DGCL. Such expenses (including attorneys' fees) incurred by former directors and officers or other employees and agents may be so paid upon such terms and conditions, if any, as the corporation deems reasonably appropriate and shall be subject to the corporation's expense guidelines. The right to advancement of expenses shall not apply to any claim for which indemnity is excluded pursuant to these bylaws, but shall apply to any Proceeding referenced in Section 8.6(ii) or 8.6(iii) prior to a determination that the person is not entitled to be indemnified by the corporation.

#### 8.6 LIMITATION ON INDEMNIFICATION

Subject to the requirements in Section 8.3 and the DGCL, the corporation shall not be obligated to indemnify any person pursuant to this Article VIII in connection with any Proceeding (or any part of any Proceeding):

- (i) for which payment has actually been made to or on behalf of such person under any statute, insurance policy, indemnity provision, vote or otherwise, except with respect to any excess beyond the amount paid;
- (ii) for an accounting or disgorgement of profits pursuant to Section 16(b) of the 1934 Act, or similar provisions of federal, state or local statutory law or common law, if such person is held liable therefor (including pursuant to any settlement arrangements);
- (iii) for any reimbursement of the corporation by such person of any bonus or other incentive-based or equity-based compensation or of any profits realized by such person from the sale of securities of the corporation, as required in each case under the 1934 Act (including any such reimbursements that arise from an accounting restatement of the corporation pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), or the payment to the corporation of profits arising from the purchase and sale by such person of securities in violation of Section 306 of the Sarbanes-Oxley Act), if such person is held liable therefor (including pursuant to any settlement arrangements);
- (iv) initiated by such person against the corporation or its directors, officers, employees, agents or other indemnitees, unless (a) the board of directors authorized the Proceeding (or the relevant part of the Proceeding) prior to its initiation, (b) the corporation provides the indemnification, in its sole discretion, pursuant to the powers vested in the corporation under applicable law, (c) otherwise required to be made under Section 8.7 or (d) otherwise required by applicable law; or
- (v) if prohibited by applicable law; provided, however, that if any provision or provisions of this Article VIII shall be held to be invalid, illegal or unenforceable for any reason whatsoever: (1) the validity, legality and enforceability of the remaining provisions of this Article VIII (including, without limitation, each portion of any paragraph or clause containing any such provision held to be invalid, illegal or unenforceable, that is not itself held to be invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby; and (2) to the fullest extent possible, the provisions of this Article VIII (including, without limitation, each such portion of any paragraph or clause containing any such provision held to be invalid, illegal or unenforceable) shall be construed so as to give effect to the intent manifested by the provision held invalid, illegal or unenforceable.

#### 8.7 DETERMINATION; CLAIM

If a claim for indemnification or advancement of expenses under this Article VIII is not paid in full within 90 days after receipt by the corporation of the written request therefor, the claimant shall be entitled to an adjudication by a court of competent jurisdiction of his or her entitlement to such indemnification or advancement of expenses. The corporation shall indemnify such person against any and all expenses that are incurred by such person in connection with any action for indemnification or advancement of expenses from the corporation under this Article VIII, to the

extent such person is successful in such action, and to the extent not prohibited by law. In any such suit, the corporation shall, to the fullest extent not prohibited by law, have the burden of proving that the claimant is not entitled to the requested indemnification or advancement of expenses.

#### 8.8 NON-EXCLUSIVITY OF RIGHTS

The indemnification and advancement of expenses provided by, or granted pursuant to, this Article VIII shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under the certificate of incorporation or any statute, bylaw, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in such person's official capacity and as to action in another capacity while holding such office. The corporation is specifically authorized to enter into individual contracts with any or all of its directors, officers, employees or agents respecting indemnification and advancement of expenses, to the fullest extent not prohibited by the DGCL or other applicable law.

#### 8.9 INSURANCE

The corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the corporation would have the power to indemnify such person against such liability under the provisions of the DGCL.

#### 8.10 SURVIVAL

The rights to indemnification and advancement of expenses conferred by this Article VIII shall continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person.

#### 8.11 EFFECT OF REPEAL OR MODIFICATION

Any amendment, alteration or repeal of this Article VIII shall not adversely affect any right or protection hereunder of any person in respect of any act or omission occurring prior to such amendment, alteration or repeal.

#### 8.12 CERTAIN DEFINITIONS

For purposes of this Article VIII, references to the "corporation" shall include, in addition to the resulting corporation, any constituent corporation (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had power and authority to indemnify its directors, officers, employees or agents, so that any person who is or was a director, officer, employee or agent of such constituent corporation, or is or was serving at the request of such constituent corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, shall stand in the same position under the provisions of this Article VIII with respect to the resulting or surviving corporation as such person would have with respect to such constituent corporation if its separate existence had continued. For purposes of this Article VIII, references to "other enterprises" shall include employee benefit plans; references to "finances" shall include any excise taxes assessed on a person with respect to an employee benefit plan (excluding any "parachute payments" within the meanings of Sections 280G and 4999 of the Internal Revenue Code of 1986, as amended); and references to "serving at the request of the corporation" shall include any service as a director, officer, employee or agent of the corporation which imposes duties on, or involves services by, such director, officer, employee or agent with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner such person reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner "not opposed to the best interests of the corporation" as referred to in this Article VIII.

### ARTICLE IX — GENERAL MATTERS

#### 9.1 EXECUTION OF CORPORATE CONTRACTS AND INSTRUMENTS

Except as otherwise provided by law, the certificate of incorporation or these bylaws, the board of directors may authorize any officer or officers, or agent or agents, to enter into any contract or execute any document or instrument in the name of and on behalf of the corporation; such authority may be general or confined to specific instances.

Unless so authorized or ratified by the board of directors or within the agency power of an officer, no officer, agent or employee shall have any power or authority to bind the corporation by any contract or engagement or to pledge its credit or to render it liable for any purpose or for any amount.

#### 9.2 FISCAL YEAR

The fiscal year of the corporation shall be fixed by resolution of the board of directors and may be changed by the board of directors.

#### 9.3 SEAL

The corporation may adopt a corporate seal, which shall be adopted and which may be altered by the board of directors. The corporation may use the corporate seal by causing it or a facsimile thereof to be impressed or affixed or in any other manner reproduced.

#### 9.4 CONSTRUCTION; DEFINITIONS

Unless the context requires otherwise, the general provisions, rules of construction, and definitions in the DGCL shall govern the construction of these bylaws. Without limiting the generality of this provision, the singular number includes the plural, the plural number includes the singular, and the term "person" includes both an entity and a natural person.

### ARTICLE X — AMENDMENTS

These bylaws may be adopted, amended or repealed by the stockholders entitled to vote; *provided, however*, that the affirmative vote of the holders of at least 66 2/3% of the total voting power of outstanding voting securities, voting together as a single class, shall be required for the stockholders of the corporation to alter, amend or repeal, or adopt any bylaw inconsistent with, the following provisions of these bylaws: Article II, Sections 3.1, 3.2, 3.4 and 3.11 of Article III, Article VIII and this Article X (including, without limitation, any such Article or Section as renumbered as a result of any amendment, alteration, change, repeal, or adoption of any other Bylaw). The board of directors shall also have the power to adopt, amend or repeal bylaws; *provided, however*, that a bylaw amendment adopted by stockholders which specifies the votes that shall be necessary for the election of directors shall not be further amended or repealed by the board of directors.

### ARTICLE XI — EXCLUSIVE FORUM

Unless the corporation consents in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. Any person or entity purchasing or otherwise acquiring or holding any interest in any security of the corporation shall be deemed to have notice of and consented to this Article XI.



**FOR IMMEDIATE RELEASE**

**Otonomy Announces Proposed Public Offering**

**SAN DIEGO, July 8, 2020** - Otonomy, Inc. (Nasdaq: OTIC), a biopharmaceutical company dedicated to the development of innovative therapeutics for neurotology, today announced that it has commenced an underwritten public offering of its common stock. All shares of common stock to be sold in the offering will be offered by Otonomy and, in lieu of common stock, to offer and sell to certain investors pre-funded warrants to purchase shares of its common stock in an underwritten public offering. In addition, Otonomy expects to grant the underwriters a 30-day option to purchase up to an additional 15% of the shares of common stock offered in this public offering. The offering is subject to market and other conditions, and there can be no assurance as to whether or when the offering may be completed, or as to the actual size or terms of the offering.

Cowen and Piper Sandler are acting as joint book-running managers in the offering. Cantor Fitzgerald & Co. is acting as a passive bookrunner.

A shelf registration statement (File No. 333-227269) was previously filed with the Securities and Exchange Commission (SEC) on September 9, 2018 and became effective on September 21, 2018. A preliminary prospectus supplement relating to and describing the terms of the offering will be filed with the SEC and will be available on the SEC's website at [www.sec.gov](http://www.sec.gov). When available, copies of the preliminary prospectus supplement and the accompanying prospectus relating to these securities may also be obtained by contacting one of the following: Cowen and Company, LLC, c/o Broadridge Financial Solutions, 1155 Long Island Avenue, Edgewood, NY, 11717, Attn: Prospectus Department, by telephone at (833) 297-2926, or by email at [PostSaleManualRequests@broadridge.com](mailto:PostSaleManualRequests@broadridge.com); or Piper Sandler & Co., by mail at 800 Nicollet Mall, J12S03, Minneapolis, MN 55402, Attn: Prospectus Department, or by telephone at (800) 747-3924, or by email at [prospectus@psc.com](mailto:prospectus@psc.com). The final terms of the offering will be disclosed in a final prospectus supplement to be filed with the SEC.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such state or jurisdiction.

**Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the federal securities laws, including, but not limited to, statements Otonomy makes regarding its intention to conduct an offering and sale of securities, the grant of the option to purchase additional shares and the ability to complete this offering. These statements involve risks and uncertainties that could cause actual results to differ materially, including, but not limited to, whether or not

Otonomy will be able to raise capital through the sale of shares of common stock or consummate the offering, the final terms of the offering, the satisfaction of customary closing conditions, prevailing market conditions, the anticipated use of the proceeds of the offering which could change as a result of market conditions or for other reasons, and the impact of general economic, industry or political conditions in the United States or internationally. Additional risks and uncertainties relating to the offering, Otonomy and its business can be found under the heading "Risk Factors" in Otonomy's most recent current, quarterly and annual reports filed with the SEC and in the preliminary prospectus supplement and accompanying prospectus relating to the offering to be filed with the SEC. Otonomy assumes no duty or obligation to update or revise any forward-looking statements for any reason.

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## RISK FACTORS

*An investment in our securities involves a high degree of risk. Prior to making a decision about investing in our securities, you should carefully consider the specific factors discussed below and discussed under the section entitled "Risk Factors" contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, as updated by our subsequent filings under the Securities Exchange Act of 1934, as amended (the Exchange Act). The risks and uncertainties we have described are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our operations. The occurrence of any of these known or unknown risks might cause you to lose all or part of your investment in the offered securities.*

### **Risks Related to Our Financial Condition and Capital Requirements**

***We have a limited operating history and have incurred significant losses since our inception, and we anticipate that we will continue to incur losses for the foreseeable future, which makes it difficult to assess our future viability.***

We are a commercial-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We are not profitable and have incurred losses in each year since we commenced operations in 2008. In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry. Drug development is a highly speculative undertaking and involves a substantial degree of risk. To date, we have obtained U.S. regulatory approval and launched a single product, OTIPRIO, but have not yet generated significant revenue. We continue to incur significant research and development expenses related to our clinical trials and product development activities and other selling, general and administrative expenses. We have recorded net losses of \$11.8 million and \$12.0 million for the three months ended March 31, 2020 and 2019, respectively. As of March 31, 2020, we had an accumulated deficit of \$471.7 million.

***We have not yet generated significant product revenue and may never become profitable.***

We expect to continue to incur significant losses for the foreseeable future. Our ability to achieve significant revenue and profitability is dependent on our ability to complete the development of our product candidates, obtain necessary regulatory approvals and successfully commercialize our products. We may never succeed in these activities and may never generate revenue that is significant or large enough to achieve profitability. We launched OTIPRIO in March 2016, but we have not generated significant revenue from sales of OTIPRIO, and in November 2017, we announced the discontinuation of our promotional support for OTIPRIO in TTP surgery. In August 2018, we announced the initiation of a partnership with Mission, and in May 2019, we announced the initiation of a partnership with Glenmark, both for the promotion of OTIPRIO to certain end users involved in the treatment of patients for AOE. In July 2019, we were notified by Glenmark of its early discontinuation of OTIPRIO promotional support activities due to the delay in FDA approval of its Ryaltris allergy product, and the impact of such delay on its business operations. In August 2019, Mission informed us of its non-renewal of the co-promotion agreement.

We recently entered into a co-promotion agreement with ALK-Abelló, Inc. (ALK) to support the promotion of OTIPRIO for the treatment of AOE in physician offices in the United States but there are no assurances that such partnership will be successful or that it will not be terminated earlier than we expect. We may also seek other promotional partners for OTIPRIO, but there are no assurances that we can find a new promotional partner or that the terms and timing of any such arrangements would be acceptable to us. Such partnerships may not generate significant revenue, may not be successful, and may be terminated. In addition, we currently have limited sales and marketing capabilities. If we are unable to enter into arrangements on acceptable terms or at all, or if such arrangements are not successful, we may not be

able to successfully commercialize our products or generate product revenue. Any failure or delay in entering promotional partnerships or developing our internal sales, marketing and distribution capabilities could adversely impact the commercialization of our products. If we are not successful in commercializing our products, either on our own or through partnering with one or more third parties, our future product revenue may suffer and we could incur significant additional losses. Even if we achieve profitability in the future, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital and any failure to become and remain profitable may adversely affect the market price of our common stock, our ability to raise capital, and our viability.

***We will require additional financing to obtain regulatory approval for OTIVIDEX, OTO-313, OTO-413 and any other product candidates, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our commercialization efforts, product development, or other operations.***

Since our inception, most of our resources have been dedicated to the development of OTIPRIO and our product candidates, OTIVIDEX, OTO-311 (now OTO-313) and OTO-413. In particular, conducting clinical trials for OTIVIDEX, OTO-313 and OTO-413 will require substantial funds. We have previously funded our operations primarily through the sale and issuance of common stock, convertible preferred stock and convertible notes. Our existing cash, cash equivalents and short-term investments are not sufficient to fund our operations for a period of at least twelve months from the date of this report and as a result we believe there is substantial doubt with respect to our ability to continue as a going concern.

On July 9, 2020, we filed a prospectus supplement in connection with a proposed underwritten public offering with Cowen and Company, LLC and Piper Sandler & Co., as representatives of the underwriters. We believe that our existing cash, cash equivalents and short-term investments together with net proceeds of this proposed offering, if completed, will be sufficient to fund our operations for at least twelve months from the date of this report.

However, we believe that we will continue to expend substantial resources for the foreseeable future for the continued development of OTIVIDEX, OTO-313, OTO-413 and any other product candidates we may choose to pursue. These expenditures will include costs associated with marketing and selling any products approved for sale, manufacturing, preparing regulatory submissions, and conducting nonclinical studies and clinical trials. We cannot estimate with reasonable certainty the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

Our future capital requirements depend on many factors, including:

- the timing of, and the costs involved in, nonclinical and clinical development and obtaining regulatory approvals for OTIVIDEX, OTO-313, OTO-413 or any other product candidates;
- the cost of manufacturing OTIPRIO and our product candidates;
- the revenue generated by OTIPRIO and our product candidates, if approved;
- the cost of commercialization activities for OTIPRIO and any of our product candidates that may be approved for sale, if any, including marketing, sales and distribution costs;
- the number and characteristics of any other product candidates we develop or acquire;
- our ability to establish and maintain strategic collaborations, licensing, development or commercialization arrangements and the terms and timing of such arrangements, including whether we are able to timely find a new promotional partner for OTIPRIO;
- the degree and rate of market acceptance of OTIPRIO and any other approved products;
- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of other products or treatments;
- the expenses needed to attract and retain skilled personnel;

- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, including litigation costs and the outcome of such litigation;
- the extent to which we are required to pay milestone or other payments under our in-license agreements and the timing of such payments; and
- the cost of litigation, including any product liability or other lawsuits related to our products.

Additional capital may not be available when we need it, on terms that are acceptable to us or at all. In addition, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the COVID-19 pandemic. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate our sales and marketing, manufacturing or distribution capabilities or other activities that may be necessary to commercialize our product or product candidates, nonclinical studies, clinical trials or other development activities.

If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product or product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. In addition, we have a sales agreement in place with Cowen and Company, LLC to sell up to \$40.0 million worth of shares of our common stock, from time to time, through an “at the market” equity offering program under which Cowen and Company, LLC will act as sales agent or principal. As of March 31, 2020, \$40.0 million worth of shares of our common stock remained available for sale under the “at the market” equity offering program. If we raise additional capital through our “at the market” equity offering program, or other public or private equity offerings, the ownership interest of our existing stockholders will be diluted and the terms of any new equity securities may have preferential rights over our common stock. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures or specified financial ratios, any of which could restrict our ability to commercialize our product, develop and commercialize our product candidates or operate as a business. Any collaboration agreements we enter into may provide capital in the near-term but limit our potential cash flow and revenue in the future. Any of the foregoing could significantly harm our business, financial condition and prospects.

***A pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, or the perception of its effects, could materially and adversely affect our business, operations and financial condition.***

Outbreaks of epidemic, pandemic or contagious diseases, such as COVID-19, could significantly disrupt our business. Such outbreaks pose the risk that we or our employees, contractors, suppliers, and other partners may be prevented from conducting business activities for an indefinite period of time due to spread of the disease, or due to shutdowns that may be requested or mandated by federal, state and local governmental authorities. Business disruptions could include disruptions or restrictions on our ability to travel, as well as temporary closures of our facility, the facilities of our partners, clinical trial sites, service providers, suppliers or contract manufacturers. While it is not possible at this time to estimate the overall impact that the COVID-19 pandemic could have on our business, the continued rapid spread of COVID-19, both across the United States and through much of the world, and the measures taken by the governments of countries and local authorities affected has disrupted and could delay our ongoing clinical trials, and could disrupt and delay our preclinical activities, the manufacture or shipment of both drug substance and finished drug product for preclinical testing and clinical trials and adversely impact our business, financial condition or operating results.

For example, the state of California, where our corporate offices are located, has issued orders for all residents to remain at home, except as needed for essential activities as a result of the COVID-19 pandemic and we have had to implement work from home policies that may continue for an indefinite

period. We have taken steps to protect the health and safety of our employees and community, while working to ensure the sustainability of our business operations as this unprecedented situation continues to evolve. We continue to evaluate the impact COVID-19 may have on our ability to effectively conduct our business operations as planned, and work with healthcare providers supporting our clinical studies to mitigate risk to patients while taking into account regulatory, institutional, and government guidance and policies, but there can be no assurance that we will be able to avoid part or all of any impact from the spread of COVID-19 or its consequences.

We have clinical trial sites in the United States and Europe, which may be affected by travel or quarantine restrictions imposed by federal, state or local governments due to the COVID-19 pandemic. The enrollment of new patients in our OTIVIDEX trial is being managed on a site-by-site basis according to local conditions. We temporarily paused new patient enrollment in our Phase 1/2 clinical trial of OTO-413 but have resumed enrollment on a site-by-site basis. In light of the significant uncertainty regarding the impact of the COVID-19 pandemic, we had suspended and subsequently updated our guidance regarding timing of trial results. We may in the future need to further update or suspend such guidance as a result of the impact of the COVID-19 pandemic. In addition, we have made and we (and our contract research organizations (CROs)) may need to make certain adjustments to the operation of clinical trials in an effort to ensure the monitoring and safety of patients and minimize risks to trial data integrity during the pandemic in accordance with the guidance issued by the FDA in March 2020 and updated in April 2020.

Third-party manufacturers which we use for the supply of materials for our product candidates or other materials necessary to conduct preclinical studies and clinical trials are located in countries affected by COVID-19. Although we expect no material impact on the clinical supply of our product candidates for our current clinical trials, should our third-party manufacturers experience extended disruptions, we could experience delays in future trials.

Furthermore, the spread of the virus may affect the operations of key governmental agencies, such as the FDA and similar organizations outside the United States, as well as local regulatory agencies and health officials, which may delay the development of our product candidates.

The COVID-19 pandemic continues to rapidly evolve. The extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease and to address its impact, including on financial markets or otherwise. While the extent of the impact of the COVID-19 pandemic on our business and financial results is uncertain, a continued and prolonged public health crisis could have a material negative impact on our business, financial condition and operating results.

#### **Risks Related to Our Product and Product Candidates**

##### ***We are dependent upon the clinical, regulatory and commercial success of OTIVIDEX for Ménière's disease.***

We have invested substantial resources in the development of OTIVIDEX. We have completed two Phase 3 clinical trials for OTIVIDEX in Ménière's disease patients. The AVERTS-2 trial, conducted in Europe, achieved its primary endpoint while the AVERTS-1 trial, conducted in the United States, did not. Based on a Type C meeting with the FDA, we believe that one additional successful pivotal trial is sufficient to support the U.S. registration of OTIVIDEX in Ménière's disease, and we are currently enrolling such trial.

OTIVIDEX is subject to the risks associated with completing such pivotal trial and any future clinical trials required for registration, including risks associated with:

- the successful and timely implementation, enrollment and completion of such clinical trials of OTIVIDEX;
- the potential impacts of the COVID-19 pandemic;
- the use and adequacy of patient reported outcomes in such clinical trials;
- our ability to demonstrate with substantial clinical evidence the safety and efficacy of OTIVIDEX in such clinical trials;
- the successful implementation and completion of any additional clinical safety studies or any additional non-clinical studies that may be required by the FDA; and
- the ability to submit a New Drug Application (NDA) for regulatory approval to the FDA.

If we are able to successfully complete the clinical trials required for OTIVIDEX registration, its success will still remain subject to the risks associated with obtaining regulatory approval from the FDA and being manufactured and commercialized, including risks associated with:

- the successful completion of all non-clinical studies required to support regulatory approval by the FDA;
- the timing of review, as the FDA's grant of Fast Track designation for OTIVIDEX does not guarantee priority review;
- the FDA's acceptance of our NDA submission for OTIVIDEX;
- the successful and timely receipt of necessary marketing approval from the FDA to allow us to begin commercializing OTIVIDEX in the United States;
- the ability to manufacture commercial supplies of OTIVIDEX in compliance with current good manufacturing practices (cGMPs);
- our success in selling OTIVIDEX and achieving broad market acceptance;
- our success in educating physicians and patients about the benefits, administration and use of OTIVIDEX;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of other products or treatments for Ménière's disease;
- patient demand for the treatment of Ménière's disease;
- the availability of coverage and adequate reimbursement for OTIVIDEX;
- our ability to enforce our intellectual property rights in and to OTIVIDEX; and
- a continued acceptable safety profile of OTIVIDEX following approval.

Many of these clinical, regulatory and commercial matters are beyond our control and are subject to other risks described elsewhere in this "Risk Factors" section. Accordingly, we cannot assure you that we will be able to advance OTIVIDEX through final clinical development, or obtain regulatory approval of, manufacture, commercialize or generate significant revenue from OTIVIDEX. If we cannot do so, or are significantly delayed in doing so, our business will be materially harmed.

***In addition to OTIVIDEX, our long-term prospects depend in part upon advancing additional product candidates, such as OTO-313 and OTO-413, through clinical development to regulatory approval and commercialization.***

Although we are focused upon continued development, regulatory approval and commercialization of OTIVIDEX, the development of OTO-313, OTO-413 and other product candidates for the treatment of inner ear disorders is a key element of our long-term strategy. These programs are currently most subject to the risks associated with nonclinical and clinical development, including the risks associated with:

- generating sufficient data to support the initiation or continuation of clinical trials;
- obtaining regulatory approval to commence clinical trials;
- contracting with the necessary parties to conduct clinical trials;
- enrolling sufficient numbers of subjects or patients in clinical trials;
- the use and adequacy of patient reported outcomes in such clinical trials;

- our ability to demonstrate with substantial clinical evidence the safety and efficacy of such product candidates in such clinical trials;
- the timely manufacture of sufficient quantities of the product candidate for use in clinical trials; and
- adverse events in the clinical trials.

Even if we successfully advance OTO-313 or OTO-413 through clinical development, or advance other product candidates from our hearing loss programs or any other future product candidate into clinical development, their success will be subject to all the clinical, regulatory and commercial risks described elsewhere in this “Risk Factors” section. Accordingly, we cannot assure you that we will ever be able to develop, obtain regulatory approval of, commercialize or generate significant revenue from OTO-313, OTO-413, any other product candidate from our hearing loss programs or any other future product candidate.

### **Risks Related to Our Business and Strategy**

***OTIPRIO and our product candidates, OTIVIDEX, OTO-313, OTO-413 or any future product candidates that obtain regulatory approval, may fail to achieve the broad degree of market acceptance and use necessary for commercial success, and market opportunity for these products may be smaller than we estimate.***

OTIPRIO and our product candidates, if approved, may not achieve market acceptance among physicians and patients, and may not be commercially successful. For OTIPRIO, treatment of pediatric patients with bilateral otitis media with effusion undergoing TTP surgery is currently addressed with the off-label use of antibiotic ear drops, but antibiotic ear drops are approved for the AOE indication. We launched OTIPRIO in March 2016, but we have not generated significant revenue from sales of OTIPRIO, and in November 2017, we announced the discontinuation of our promotional support for OTIPRIO in TTP surgery. In August 2018, we announced the initiation of a partnership with Mission, and in May 2019, we announced the initiation of a partnership with Glenmark, both for the promotion of OTIPRIO to certain end users involved in the treatment of patients for AOE. In July 2019, we were notified by Glenmark of its early discontinuation of OTIPRIO promotional support activities due to the delay in FDA approval of its Ryaltris allergy product, and the impact of such delay on its business operations. In August 2019, Mission informed us of its non-renewal of the co-promotion agreement. We recently entered into a co-promotion agreement with ALK to support the promotion of OTIPRIO for the treatment of AOE in physician offices in the United States but there are no assurances that such partnership will be successful or that it will not be terminated earlier than we expect.

There are currently no FDA-approved drug treatments for the indications we are pursuing for our product candidates. Our proposed initial indication for OTIVIDEX is the treatment of vertigo associated with Ménière’s disease. Currently, Ménière’s disease patients are routinely prescribed a low-salt diet and off-label use of diuretics. Physicians may also prescribe the off-label use of antihistamines, anticholinergics, phenothiazines and benzodiazepines as well as corticosteroids. Our proposed indication for OTO-313 is the treatment of tinnitus. Currently, physicians may attempt to treat tinnitus symptoms with the off-label use of steroids, anxiolytics, antidepressants, and antipsychotics. Our target indication for OTO-413 is the treatment of speech-in-noise hearing difficulties. A subset of patients with this condition are currently treated with hearing aids. The commercial success of OTIPRIO and our product candidates, if approved, will depend significantly on the adoption and use of the resulting products by physicians for approved indications. The decision to elect treatment with OTIPRIO for middle ear effusion in pediatric patients requiring TTP surgery and AOE, or to elect to utilize OTIVIDEX for Ménière’s disease, OTO-313 for tinnitus or OTO-413 for speech-in-noise hearing difficulties, rather than other products or treatments, may be influenced by a number of factors, including:

- the cost, safety and effectiveness of our products as compared to other products or treatments;
- physician willingness to adopt our product in lieu of other products or treatments;

- ability to gain utilization in facilities responsible for purchasing our products;
- the extent to which physicians recommend our products to their patients;
- patient or caregiver sentiment about the benefits and risks of our products;
- proper training and administration of our products by physicians and medical staff, such that their patients do not experience excessive discomfort during treatment or adverse side effects;
- the procedural risks of intratympanic (IT) injection;
- overcoming any biases physicians or patients may have in favor of other products or treatments;
- patient preference for non-injectable treatments;
- patient or caregiver satisfaction with the results and administration of our product and overall treatment experience, including relative convenience and ease of administration;
- the effectiveness of our sales and marketing efforts;
- demand for the treatment of the relevant diseases or disorders;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- the prevalence and severity of any adverse events;
- the revenue and profitability that our products will offer a physician as compared to other products or treatments;
- the availability of coverage and adequate reimbursement by third-party payors and government authorities and perceptions regarding such availability; and
- general patient or caregiver confidence, which may be impacted by economic and political conditions.

Our assessment of the potential market opportunity for our product candidates is based on industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties, some of which we commissioned. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. Similarly, although the studies we have commissioned are based on information that we believe to be complete and reliable, we cannot guarantee that such information is accurate or complete. Our estimates of the potential market opportunities for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research and other surveys, which may be based on a small sample size and fail to accurately reflect market opportunities. Further, we have commissioned a number of market studies that are specific to us and to our product candidates and used the results of these studies to help assess our market opportunity. While we believe that our internal assumptions and the bases of our commissioned studies are reasonable, no independent source has verified such assumptions or bases. If any of our assumptions or estimates, or these publications, research, surveys or studies prove to be inaccurate, then the actual market for our product candidates may be smaller than we expect, and as a result our product revenue may be limited and it may be more difficult for us to achieve or maintain profitability.

If our product candidates, if approved for use, fail to achieve the broad degree of market acceptance necessary for commercial success, our operating results and financial condition will be adversely affected. In addition, even if any of our products gain acceptance, the markets for treatment of patients with our target indications may not be as significant as we estimate.

***Clinical drug development involves a lengthy and expensive process with an uncertain outcome, results of earlier studies and trials may not be predictive of future trial results, and our clinical trials may fail to adequately demonstrate the safety and efficacy of our product candidates.***

Clinical testing is expensive, can take many years to complete and its outcome is inherently uncertain. A failure of one or more of our clinical trials can occur at any time during the clinical trial process. The results of nonclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. There is a high failure rate for drugs proceeding through clinical trials, and product candidates in later stages of clinical trials may fail to show the required safety and efficacy

despite having progressed through nonclinical studies and initial clinical trials. For instance, our AVERTS-2 Phase 3 clinical trial for OTIVIDEX in Ménière's disease patients, conducted in Europe, achieved its primary endpoint, while our AVERTS-1 Phase 3 clinical trial, conducted in the United States, did not. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier clinical trials, and we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates or support the indications which we are pursuing.

From time to time, we may publicly disclose preliminary, interim or top-line data from our clinical trials. These interim updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim data and final data could materially affect our business, financial condition, results of operations and growth prospects. If the preliminary or top-line data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize our product candidates may be harmed, which could materially affect our business, financial condition, results of operations and growth prospects.

We have in the past experienced delays in our clinical trials and we may in the future. We do not know whether future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. Clinical trials can be delayed, suspended or terminated for a variety of reasons, including failure to:

- generate sufficient nonclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- obtain regulatory approval, or feedback on trial design, to commence a clinical trial;
- identify, recruit and train suitable clinical investigators;
- reach agreement on acceptable terms with prospective CROs, and clinical trial sites;
- obtain and maintain institutional review board (IRB) approval at each clinical trial site;
- identify, recruit and enroll suitable patients to participate in a clinical trial;
- have a sufficient number of patients complete a clinical trial or return for post-treatment follow-up;
- ensure clinical investigators observe trial protocol and comply with Good Clinical Practices (GCP) or continue to participate in a clinical trial;
- address any patient safety concerns that arise during the course of a clinical trial;
- address any conflicts with new or existing laws or regulations;
- add a sufficient number of clinical trial sites;
- timely manufacture sufficient quantities of product candidate for use in clinical trials; or
- have sufficient capital to fund a clinical trial.

Patient enrollment is a significant factor in the timing of clinical trials. We may not be able to initiate or continue clinical trials for our product candidates on a timely basis if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials. Patient enrollment is affected by many factors, including the size and nature of the patient population, the proximity of and access by patients to



clinical sites, the eligibility criteria for the clinical trial, the design of the clinical trial, competing clinical trials, clinicians' and patients' or caregivers' perceptions as to the potential advantages of the drug candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating, and factors, including quarantine restrictions, due to the COVID-19 pandemic.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board for such clinical trial or by the FDA or any other regulatory authority, or if the IRBs of the institutions in which such clinical trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

For example, OTIVIDEX was previously subject to Full Clinical Hold that was removed in July 2013 and then subject to Partial Clinical Hold that was removed in June 2014. The removal of Full Clinical Hold allowed us to initiate the Phase 2b clinical trial. As a result of OTIVIDEX being placed on Full Clinical Hold, OTIPRIO was also placed on Full Clinical Hold. The OTIPRIO Full Clinical Hold was removed in November 2012. We cannot assure you that our product candidates will not be subject to new clinical holds or significant delay in the future.

We received questions from the FDA regarding use of the Generalized Poisson model to analyze the daily vertigo count data reported by patients in our ongoing OTIVIDEX Phase 3 clinical trial, and we have submitted to the FDA a revised statistical analysis plan that uses a statistical test called the Negative Binomial model for the primary analysis of this ongoing trial. We cannot guarantee that the FDA will agree with this approach, and if not, this could cause future delays. Additionally, we cannot guarantee that our revised statistical analysis plan and associated target enrollment plan will be adequate.

If we experience delays in the initiation or completion of any clinical trial of our product candidates for any reason, or if any clinical trial is terminated, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

***We may be unable to obtain regulatory approval for our product candidates other than OTIPRIO. The denial or delay of any such approval would delay commercialization and have a material adverse effect on our potential to generate revenue, our business and our results of operations.***

The research, development, testing, manufacturing, labeling, packaging, approval, promotion, advertising, storage, recordkeeping, marketing, distribution, post-approval monitoring and reporting, and export and import of drug products are subject to extensive regulation by the FDA and by foreign regulatory authorities in other countries. These regulations differ from country to country. To gain approval to market our product candidates, we must provide clinical data that demonstrates with substantial evidence the safety and efficacy of the product for the intended indication. Other than OTIPRIO in the United States, we have not yet obtained regulatory approval to market any of our other product candidates in the United States or any other country. Our business depends upon obtaining these regulatory approvals.

The FDA can delay, limit or deny approval of our product candidates for many reasons, including:

- our inability to satisfactorily demonstrate that the product candidates are safe and effective for the requested indication;
- the FDA's disagreement with our trial protocol or the interpretation and analysis of data from nonclinical studies or clinical trials;
- the population studied in the clinical trial may not be sufficiently broad or representative to assess safety in the full population for which we seek approval;
- our inability to demonstrate that clinical or other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA's determination that additional nonclinical or clinical trials are required;
- the FDA's non-approval of the formulation, labeling or the specifications of our product candidates;
- the FDA's failure to accept the manufacturing processes or facilities of third-party manufacturers with which we contract, or our inability to manufacture our product candidates pursuant to cGMP; or
- the potential for approval policies or regulations of the FDA to significantly change in a manner rendering our clinical data insufficient for approval.

Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA may grant approval contingent on the performance of costly additional post-approval clinical trials. The FDA may also approve our product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. To the extent we seek regulatory approval in foreign countries, we may face challenges similar to those described above with regulatory authorities in applicable jurisdictions. Any delay in obtaining, or inability to obtain, applicable regulatory approval for any of our product candidates would delay or prevent commercialization of our product candidates and would materially adversely impact our business, results of operations and prospects.

***Use of our product or product candidates could be associated with undesirable side effects or adverse events that could halt their clinical development, delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.***

Our product or product candidates could be associated with side effects or adverse events which can vary in severity and frequency. Side effects or adverse events associated with the use of our product or product candidates may be observed at any time, including in clinical trials or once a product is commercialized, and any such side effects or adverse events may negatively affect our ability to obtain regulatory approval for our product candidates or market our product or product candidates, if approved. Side effects such as toxicity or other safety issues associated with the use of our product or product candidates could affect patient recruitment or the ability of enrolled subjects to complete the trial, require us to perform additional studies, or halt development or sale of our product or product candidates or expose us to product liability lawsuits which will harm our business. We may be required by regulatory agencies to conduct additional nonclinical or clinical trials regarding the safety and efficacy of our product or product candidates which we have not planned or anticipated. We cannot assure you that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any regulatory agency in a timely manner or ever, which could harm our business, prospects and financial condition. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, financial condition and prospects significantly.

Some patients in our clinical trials have reported adverse events after being treated with OTIPRIO, OTIVIDEX and OTO-313. For example, in the Phase 1/2 clinical trial for OTO-313, one patient reported symptoms associated with Grade 2 (moderate) stress cardiomyopathy, a serious adverse event, which was determined not to be treatment related, and five other patients reported Grade 1 (mild) or Grade 2 (moderate) adverse events. If we are successful in commercializing our product or product candidates, the FDA and other foreign regulatory agency regulations will require that we promptly report certain information about adverse medical events if those products may have caused or contributed to those

adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our product or product candidates. If we fail to comply with our reporting obligations, the FDA or other foreign regulatory agencies could take action including criminal prosecution, the imposition of civil monetary penalties, seizure of our products, or delay in approval or clearance of future products.

***OTIPRIO and our product candidates, if approved, will face significant competition in the biopharmaceutical industry, and our failure to effectively compete with competitor drugs, including off-label drug use, and future competitors may prevent us from achieving significant market penetration and expansion.***

The biopharmaceutical industry is intensely competitive and subject to rapid and significant technological change. If approved, our products must compete with off-label drug use by physicians to treat the indications for which we seek approval, such as, in the case of OTIPRIO, the current use of inexpensive generic antibiotic ear drops to treat middle ear effusion in patients requiring TTP surgery. We are also aware that other companies, such as Arbor Pharmaceuticals, LLC, Audion Therapeutics, Auris Medical Holding AG, Autifony Therapeutics Ltd., Decibel Therapeutics, Inc., Fennec Pharmaceuticals Inc., Frequency Therapeutics, KYORIN Pharmaceutical Co. Ltd., Laboratorios SALVAT S.A., Novartis AG, Novus Therapeutics, Inc., Otologic Pharmaceuticals Inc., Pipeline Therapeutics, Sensorion SA, Sound Pharmaceuticals Inc., Spiral Therapeutics, Strekin AG and Synphora AB, are commercializing products or conducting clinical trials for potential products for the treatment of various otic indications, including ear infections, tinnitus, Ménière's disease and hearing loss. Many companies in the biopharmaceutical industry have greater resources to discover, obtain patents, develop, test and obtain regulatory approvals for products, as well as commercialize, market and promote approved products, including communicating the effectiveness, safety and value of products to actual and prospective customers and medical staff. These companies may develop new drugs to treat the diseases and disorders we target or seek to have existing drugs approved for use for new indications that treat the diseases and disorders we target. Mergers and acquisitions in the biopharmaceutical industry may result in even more resources being concentrated in potential competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in this industry. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective, easier to administer or less costly than our product or product candidates.

***We rely on third parties to conduct many of our nonclinical studies and all our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for, or commercialize, our product candidates.***

We do not have the ability to independently conduct many of our nonclinical studies or any of our clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, and other third parties, such as CROs, to conduct clinical trials on our product candidates. Third parties play a significant role in the conduct of our clinical trials and the subsequent collection and analysis of data. These third parties are not our employees, and except for remedies available to us under our agreements, we have limited ability to control the amount or timing of resources that any such third party will devote to our clinical trials. If our CROs or any other third parties upon which we rely for administration and conduct of our clinical trials do not successfully carry out their contractual duties or obligations, comply with applicable laws, including with respect to data privacy, or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements, unauthorized system or data access, or for other reasons, or if they otherwise perform in a substandard manner, our clinical trials may be extended, delayed, suspended or terminated, and we may not be able to complete development of, obtain regulatory approval for, or successfully commercialize our product candidates.

We and the third parties upon whom we rely are required to comply with GCP, which are regulations and guidelines enforced by regulatory authorities around the world for products in clinical development. Regulatory authorities enforce these GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or our third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and our submission of marketing applications may be delayed, or the regulatory authorities may require us to perform additional clinical trials before reviewing or approving our marketing applications. We cannot assure you that, upon inspection, a regulatory authority will determine that any of our clinical trials comply or complied with applicable GCP regulations.

In addition, our clinical trials must be conducted with drug supply produced under cGMP regulations, which are enforced by regulatory authorities. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be impacted if our CROs, clinical investigators or other third parties violate federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. In order for our clinical trials to be carried out effectively and efficiently, it is imperative that our CROs and other third parties communicate and coordinate with one another. Moreover, our CROs and other third parties may also have relationships with other commercial entities, some of which may compete with us. Our CROs and other third parties may terminate their agreements with us upon as few as 30 days' notice under certain circumstances. If our CROs or other third parties conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols or GCPs, or for any other reason, we may need to conduct additional clinical trials or enter into new arrangements with alternative CROs, clinical investigators or other third parties. We may be unable to enter into arrangements with alternative CROs, clinical investigators or other third parties on commercially reasonable terms, or at all. Switching or adding CROs, clinical investigators or other third parties can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Although we carefully manage our relationship with our CROs, clinical investigators and other third parties, there can be no assurance that we will not encounter such challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, prospects, financial condition or results of operations.

***We rely completely on third parties to manufacture our nonclinical, clinical drug supplies and commercial supplies of OTIPRIO and any other approved products.***

We outsource the manufacture of OTIPRIO and our product candidates. We do not currently have the infrastructure or internal capability to manufacture supplies of OTIPRIO or our product candidates for use in development and commercialization. If we were to experience an unexpected loss of supply of OTIPRIO or our product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, our business would be harmed, and we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, we may be required to manufacture additional supplies of our product candidates to the extent our estimates of the amounts required prove inaccurate, we suffer unexpected losses of product candidate supplies, or to the extent that we are required to have fresh product candidate supplies manufactured to satisfy regulatory requirements or specifications. Any significant delay or discontinuation in the supply of OTIPRIO or a product candidate, or the raw material components thereof, due to the need to replace a contract manufacturer or other third-party manufacturer, could considerably harm our business and ability to generate revenue and delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates.

Reliance on third-party manufacturers entails additional risks, including reliance on the third party for regulatory compliance and quality assurance (including compliance with cGMPs), the possible breach of

the manufacturing agreement by the third party, and the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. The facilities used by our third-party manufacturers must be accepted by the FDA pursuant to inspections that will be conducted before approval and after we submit our NDA to the FDA. We do not control the implementation of the manufacturing process of, and are completely dependent on, our third-party manufacturers for compliance with the regulatory requirements, for manufacture of both active drug substances and finished drug products. If our third-party manufacturers cannot successfully manufacture material that conforms to applicable specifications in our regulatory applications and the strict regulatory requirements of the FDA or foreign regulatory authorities, we will not be able to secure and/or maintain regulatory acceptance of our contract manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers or other third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. The failure of our third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of OTIPRIO or our product candidates or any other product candidates or products that we may develop. In addition, if the FDA does not accept these facilities for the manufacture of our product or our product candidates or if it withdraws any such acceptance in the future, we will need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Any failure or refusal to supply the components for our product or our product candidates could delay, prevent or impair our clinical development or commercialization efforts. If our contract manufacturers were to breach or terminate their manufacturing arrangements with us, the development or commercialization of the affected product or product candidates could be delayed, which could have an adverse effect on our business. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

***We may encounter issues with manufacturing as we commercialize OTIPRIO or our product candidates, if approved.***

We have limited experience manufacturing OTIPRIO for commercial use, and our product candidates have never been manufactured for commercial use. There are risks associated with manufacturing for commercial use including, among others, potential problems with forecasting and cost overruns, process reproducibility, storage availability, stability issues, lot consistency and timely availability of materials. We cannot assure you that our contract manufacturers will be able to manufacture any approved product to specifications acceptable to the FDA or foreign regulatory authorities, or to produce it in sufficient quantities to meet the market demand. We have in the past manufactured, and may in the future manufacture, batches of OTIPRIO that do not meet the appropriate specifications and cannot be used. We may also manufacture OTIPRIO or any approved product that remains unused due to obsolescence, expiry or quantities in excess of expected demand. If our contract manufacturers are unable to successfully produce sufficient quantities of any approved product for commercialization, our commercial efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

***We depend on a small number of suppliers for the raw materials necessary to produce OTIPRIO and our product candidates. The loss of these suppliers, or their failure to supply us with these raw materials, would materially and adversely affect our business.***

We depend on the availability of key raw materials, including poloxamer for OTIPRIO and our product candidates, ciprofloxacin for OTIPRIO, dexamethasone for OTIVIDEX, gacyclidine for OTO-313 and BDNF for OTO-413, from a small number of third-party suppliers. Because there are a limited number of suppliers for the raw materials that we use to manufacture our product and product candidates, we may need to engage alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce OTIPRIO for required commercial supplies or our product candidates for our clinical trials. We do not have any control over the availability of raw materials. If we or our manufacturers are

unable to purchase these raw materials on acceptable terms, at sufficient quality levels, or in adequate quantities, if at all, commercial sales of OTIPRIO and the development of OTIVIDEX, OTO-313, OTO-413 or any future product candidates, would be delayed or there would be a shortage in supply, which would impair our ability to meet our development objectives for our product candidates or generate revenues from the sale of any approved products.

***Our ability to market OTIPRIO is limited to its approved indications, and our product candidates, if approved, will be limited to certain indications. If we want to expand the indications for which we may market our products, we will need to obtain additional regulatory approvals, which may not be granted.***

OTIPRIO is currently approved for the treatment of pediatric patients with bilateral otitis media with effusion undergoing TTP surgery and for the treatment of AOE and is in development for acute otitis media with tubes. We are developing OTIVIDEX for the treatment of vertigo associated with Ménière's disease, OTO-313 for the treatment of tinnitus and OTO-413 for the treatment of speech-in-noise hearing difficulties. The FDA and other applicable regulatory agencies will restrict our ability to market and advertise our products to the scope of the approved label for the applicable product and for no other indications, which could limit physician and patient adoption. We may attempt to develop new treatment indications for our product or product candidates in the future, but we cannot predict when or if we will receive the regulatory approvals required to promote our product or product candidates for new treatment indications. Failure to receive such approvals prevents us from promoting and commercializing the new treatment indications. In addition, we would be required to conduct additional clinical trials or studies to support approvals for additional indications, which would be time consuming and expensive, and may produce results that do not support regulatory approvals. If we do not obtain additional regulatory approvals, our ability to expand our business will be limited.

***If our product candidates are approved for marketing, and we are found to have improperly promoted off-label uses, or if physicians misuse our products, we may become subject to prohibitions on the sale or marketing of our products, significant sanctions and product liability claims, and our image and reputation within the industry and marketplace could be harmed.***

The FDA and other regulatory agencies strictly regulate the marketing and promotional claims that are made about drug products. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. For example, OTIPRIO is approved for the treatment of pediatric patients with bilateral otitis media with effusion undergoing TTP surgery and for the treatment of AOE, and we cannot promote the use of our product in a manner that is inconsistent with the approved label. Although physicians are able to, in their independent medical judgment, use OTIPRIO on their patients in an off-label manner, such as for the treatment of other otic indications, if we are found to have promoted such off-label uses, we may receive warning letters and become subject to significant liability, which would materially harm our business. The federal government has levied large administrative, civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred, and our reputation could be damaged. The federal government and regulatory authorities have also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the federal government or regulatory authorities to have engaged in the promotion of our products for off-label use, we could be subject to prohibitions on the sale or marketing of our products or significant fines and penalties, and the imposition of these sanctions could also affect our reputation with physicians, patients and caregivers, and our position within the industry.

Physicians may also misuse our products or use improper techniques, potentially leading to adverse results, side effects or injury, which may lead to product liability claims and costly litigation. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. We currently carry

product liability insurance with policy limits that we believe are customary for similarly situated companies and adequate to provide us with coverage for foreseeable risks. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Furthermore, the use of our products for conditions other than those approved by the FDA may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

***We have limited sales and marketing experience and may be unable to successfully commercialize our products or generate product revenue.***

We have limited experience in the marketing and sale of pharmaceutical products, and there are significant risks involved in managing a sales and marketing organization, including our ability to hire, retain, adequately compensate and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. For example, we discontinued promotional support for OTIPRIO and, as a result, no longer have a sales force. If we decide not to promote our product candidates ourselves, if approved, we may consider promotional partnership arrangements. For instance, in August 2018, we announced the initiation of a partnership with Mission, and in May 2019, we announced the initiation of a partnership with Glenmark, both for the promotion of OTIPRIO to certain end users involved in the treatment of patients for AOE. In July 2019, we were notified by Glenmark of its early discontinuation of OTIPRIO promotional support activities due to the delay in FDA approval of its Ryaltris allergy product, and the impact of such delay on its business operations. In August 2019, Mission informed us of its non-renewal of the co-promotion agreement.

We recently entered into a co-promotion agreement with ALK to support the promotion of OTIPRIO for the treatment of AOE in physician offices in the United States but there are no assurances that such partnership will be successful or that it will not be terminated earlier than we expect. We may also seek other promotional partners for OTIPRIO, but there are no assurances that we can find a new promotional partner or that the terms and timing of any such arrangements would be acceptable to us. Such partnerships may not generate significant revenue, may not be successful, and may be terminated. If we are unable to enter into such arrangements on acceptable terms or at all, or if such arrangements are not successful, we may not be able to successfully commercialize our products or generate product revenue. Any failure or delay in entering promotional partnerships or developing our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our products. If we are not successful in commercializing our products, either on our own or through partnering with one or more third parties, our future product revenue will suffer and we would incur significant additional losses.

***To expand our development and commercial support capabilities in the future, we may need to increase the size of our organization, and we may experience difficulties in managing this growth.***

As we advance our product candidates through the development process and commercialize our product and product candidates, if approved, we may need to expand our development, regulatory, quality, managerial, sales and marketing, operational, finance and other resources to manage our operations and clinical trials, continue our development activities and commercialize our product candidates, if approved. If our operations expand, we expect that we will need to manage additional relationships with various manufacturers and collaborative partners, suppliers and other organizations.

Due to our limited financial resources and our limited experience in managing a company with such growth, we may not be able to effectively manage the expansion of our operations or recruit, train and retain additional qualified personnel. For example, in December 2016, we moved into our current headquarters location in San Diego, California. The physical expansion of our operations has led, and may continue to lead, to significant costs. Any inability to manage growth could delay the execution of our development and strategic objectives, or disrupt our operations, which could materially impact our business, revenue and operating results.

***Coverage and reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. Recent legislative and regulatory activity may exert downward pressure on potential pricing and reimbursement for our products, if approved, that could materially affect the opportunity to commercialize.***

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved drugs. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Therefore, market acceptance and sales of our products, if approved, in both domestic and international markets will depend significantly on the availability of adequate coverage and reimbursement from third-party or government payors for any of our products and may be affected by existing and future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. The Centers for Medicare & Medicaid Services (CMS) has established a unique J Code for OTIPRIO that replaces a previously assigned C Code. We also intend to apply for a unique J Code for OTIVIDEX, OTO-313 and OTO-413. We cannot assure you that J Codes will be issued for OTIVIDEX, OTO-313 and OTO-413, if approved. We also cannot assure you that third-party payors will provide reimbursement according to a J Code. If a J Code is not issued or a J Code is issued but not reimbursed by third-party payors, then the cost of these drugs may be absorbed by healthcare providers or charged to patients. If this is the case, our expectations of the pricing we expect to achieve for OTIPRIO, and OTIVIDEX, OTO-313 and OTO-413, if approved, and the related potential revenue, may be significantly diminished. We cannot be certain that coverage and adequate reimbursement will be available for OTIPRIO or any other products, if approved, or that such coverage and reimbursement will be authorized in a timely fashion, even if a unique J Code is assigned for such products. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, OTIPRIO or any of our product candidates, if approved. If reimbursement is not available or is available on a limited basis for any of our products, if approved, we may not be able to successfully commercialize any such products. Reimbursement by a third-party or government payor may depend upon a number of factors, including, without limitation, the third-party or government payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the medicine is approved by the FDA or other comparable foreign regulatory authorities. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement or to have pricing set at a satisfactory level. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels such as may result where alternative or generic treatments are available, we may be unable to achieve or sustain profitability.

Assuming we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. In some



foreign countries, particularly in Europe, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our products to other available therapies. If reimbursement of any of our products, if approved, is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability of our products in such country.

The United States and several other jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell any of our products profitably, if approved. Among policy-makers and payors in the United States and elsewhere, there has been significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict if or how these or future initiatives may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any of our products, if approved;
- the ability to set a price that we believe is fair for any of our products, if approved;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

In March 2010, the Affordable Care Act (ACA) became law in the United States. One goal of ACA is to reduce the cost of healthcare and substantially change the way healthcare is financed by both governmental and private insurers. While we cannot fully predict what impact on federal reimbursement policies this legislation will continue to have in general or on our business specifically, ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect our ability to generate revenue, achieve market acceptance of our product or future approved products, attain profitability, or commercialize our product or any future approved products. Provisions of ACA relevant to the pharmaceutical industry include the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, not including orphan drug sales;
- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts on negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;

- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report annually certain financial arrangements with physicians and teaching hospitals, as defined in the ACA and its implementing regulations, including reporting any payment or “transfer of value” provided to physicians, as defined by such law, and teaching hospitals and any ownership and investment interests held by physicians and their immediate family members during the preceding calendar year (effective January 1, 2022, these reporting obligations will extend to include payments and transfers of value made during the previous year to certain non-physician providers such as physician assistants and nurse practitioners);
- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research.

There have been judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA and we expect such challenges and amendments to continue. The U.S. Supreme Court is expected to review the constitutionality of the ACA in the fall following a series of federal cases that began with a district court ruling that the ACA is unconstitutional in its entirety because the “individual mandate” provisions of the ACA were repealed by Congress. The U.S. government could repeal or change some or all of the ACA, and complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business. Until the ACA or other healthcare reform measures are fully implemented or there is more certainty concerning the future of the ACA or such healthcare reform measures, it will be difficult to predict its full impact and influence on our business. Healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for our product or future approved products. Any such reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, achieve market acceptance of our product or future approved products, attain profitability, or commercialize future approved products.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products.***

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and face an even greater risk now that OTIPRIO has been commercialized and as other product candidates get approved, if at all. For example, we may be sued if any product we develop allegedly causes or is perceived to cause injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants or cancellation of clinical trials;
- costs to defend the related litigation;

- a diversion of management's time and our resources;
- substantial monetary awards to clinical trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- exhaustion of any available insurance and our capital resources;
- loss of revenue; and
- the inability to commercialize any products we develop.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of our products. We currently carry product liability insurance with policy limits that we believe are customary for similarly situated companies and adequate to provide us with coverage for foreseeable risks. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. If we determine that it is prudent to increase our product liability coverage in the future, we may be unable to obtain such increased coverage on acceptable terms, or at all. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses.

***If we fail to attract and retain senior management and key scientific personnel, we may be unable to successfully develop and commercialize our product candidates.***

Our success depends, in part, on our continued ability to attract, retain and motivate highly qualified management, commercial, clinical and scientific personnel. We believe that our future success is highly dependent upon the contributions of our senior management, particularly our President and Chief Executive Officer, as well as our senior scientists and other members of our senior management team. The loss of services of any of these individuals, who all have at-will employment arrangements with us, could delay or prevent the successful development of our product pipeline, completion of our planned clinical trials or the commercialization of our product candidates, if approved.

We could experience difficulties in attracting, hiring and retaining qualified employees. For example, competition for qualified personnel in the biotechnology and pharmaceuticals field is intense due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all, which may cause our business and operating results to suffer.

***If we are not successful in discovering, developing, acquiring and commercializing additional product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.***

Although a substantial amount of our efforts are focused on the development and regulatory approval of our current product candidates, a key element of our strategy is to identify, develop and commercialize additional product candidates for the treatment of neurology disorders. We are seeking to do so through our internal research programs and may explore strategic collaborations with third parties for the development or acquisition of new product candidates or products. Research programs to identify new product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified or successfully developed.

***Our internal computer systems, or those of our CROs or other contractors or consultants, or our partners, may fail or suffer security breaches, which could result in a material disruption of our drug development programs.***

We rely on information technology systems to keep financial records, maintain laboratory and corporate records, communicate with staff and external parties, collect, store and transmit large amounts of confidential information (including intellectual property, proprietary business information and personal information), and operate other critical functions. Despite the implementation of security measures, our internal computer systems and those of our third-party logistics vendors, CROs and other contractors and consultants, and our partners, are vulnerable to damage from computer viruses, unauthorized access or use resulting from malware, denial-of-service attacks, cyber-attacks or cyber-intrusions over the Internet, hacking, phishing and other social engineering attacks, natural disasters, terrorism, war and telecommunication and electrical failures. To our knowledge, we have not experienced a material system failure, accident or security breach to date, and if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our commercialization activities or drug development programs. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach (whether to our systems or to our CROs or other contractors, consultants, or partners) were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential, proprietary, or other protected information, we could incur liability and penalties and the development and commercialization of our product candidates could be delayed.

***Changes in financial accounting standards or practices may cause adverse, unexpected financial reporting fluctuations and affect our reported operating results.***

Generally accepted accounting principles in the United States are subject to interpretation by the Financial Accounting Standards Board, the SEC and various bodies formed to promulgate and interpret appropriate accounting principles. A change in accounting standards or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and varying interpretations of accounting pronouncements have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business.

***Our employees, independent contractors, clinical investigators, CROs, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.***

We are exposed to the risk that our employees, independent contractors, clinical investigators, CROs, consultants and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, (ii) manufacturing standards, (iii) federal, state and foreign healthcare fraud and abuse laws, (iv) privacy protection laws or (v) laws that require the reporting of financial information or data accurately. Specifically, research, sales, marketing, education and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, education, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, as well as various compliance policies and procedures, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with

such laws. If any such actions are instituted against us, even if we are successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business. Violations of such laws subject us to numerous penalties, including, but not limited to, the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

***We or the third parties upon whom we depend may be adversely affected by earthquakes, wildfires or other natural disasters, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Our corporate headquarters are located in San Diego, which in the past has experienced severe earthquakes. We do not carry earthquake insurance. The San Diego area has also experienced serious wildfires. If a natural disaster or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as product development and research efforts for our current product candidates and finance records, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and may not be adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Furthermore, integral parties in our supply chain and distribution chain are geographically concentrated and operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business.

***Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.***

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn may cause extreme volatility and disruptions in the capital and credit markets and could result in a variety of risks to our business and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers and third-party payors to delay making payments for our services.

Recent events, including the United Kingdom's (UK) 2016 vote in favor of exiting the European Union (EU), or "Brexit," and the UK's withdrawal, and similar geopolitical developments or the perception that any of them could occur, may lead to worldwide economic and legal uncertainty, including significant volatility in global stock markets and currency exchange rates, and increasingly divergent laws and regulations.

Any of the foregoing could harm our business, and we cannot anticipate all the ways in which the current economic climate and financial market conditions could adversely impact our business.

***Our business is subject to economic, political, regulatory, operational and other risks associated with international operations.***

Our business is subject to risks associated with conducting business internationally. Some of our suppliers and collaborative relationships are located outside the United States, and we conduct some of our clinical trials outside the United States. Accordingly, our ability to operate our business and our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in non-U.S. economies and markets;
- differing and changing regulatory or legal requirements in non-U.S. countries;
- challenges enforcing our contractual and intellectual property rights, especially in non-U.S. countries that may not respect and protect intellectual property rights to the same extent as the United States;
- difficulties in compliance with non-U.S. laws and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in currency exchange rates and non-U.S. currency controls;
- changes in a country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty and labor unrest;
- difficulties associated with staffing and managing international operations;
- potential liability under the FCPA, UK Bribery Act or comparable non-U.S. laws; and
- business interruptions resulting from (i) geopolitical actions, including annexation, war and terrorism, (ii) natural disasters, including earthquakes, typhoons, floods and fires or (iii) outbreaks of health epidemics and pandemics.

### **Risks Related to Our Intellectual Property**

***If our efforts to protect the intellectual property related to our product and product candidates are not adequate, we may not be able to compete effectively in our market.***

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product, product candidates and technology. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, eroding our competitive position in the market.

The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and our current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, it is possible that certain patentable aspects of our inventions may not be protected in a manner consistent with the best interests of our business. Defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, etc., although we are unaware of any such defects that we believe are of material import. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. If we or our current licensors, or any future licensors or licensees, fail to file patent applications, or maintain, enforce or protect our patents, such patent rights may be reduced or eliminated. If our current licensors, or any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The strength of patents in the pharmaceutical field involves complex legal and scientific questions and can be uncertain. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law or rules in ways affecting the scope or validity of issued patents. The patent applications that we own or in-license may fail to result in

issued patents in the United States or foreign countries with claims that cover our product or product candidates. Even if patents do successfully issue from the patent applications that we own or in-license, third parties may challenge the validity, enforceability or scope of such patents, which may result in such patents being narrowed, invalidated or held unenforceable. For example, patents granted by the European Patent Office may be challenged, also known as opposed, by any person within nine months from the publication of their grant. Any successful challenge to our patents could deprive us of exclusive rights necessary for the successful commercialization of our product or product candidates. Furthermore, even if they are unchallenged, our patents may not adequately protect our product or product candidates, provide exclusivity for our product or product candidates, or prevent others from designing around our patents. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our product or product candidates is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize our product or product candidates.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its effective filing date. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our product or product candidates, we may be open to competition from generic versions of our product or product candidates. Further, if we encounter delays in our development efforts, including our clinical trials, the period of time during which we could market our product or product candidates under patent protection would be reduced.

Some of our patents and patent applications are entitled to effective filing dates prior to March 16, 2013. For U.S. patent applications for which patent claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party, for example a competitor, or instituted by the U.S. Patent and Trademark Office (USPTO) to determine who was the first to invent any of the subject matter covered by those patent claims. An unfavorable outcome could require us either to cease using the related technology or to attempt to license rights from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our participation in an interference proceeding may fail and, even if successful, may result in substantial costs and distract our management.

In addition to the protection afforded by patents, we also rely on trade secret protection to protect proprietary know-how that may not be patentable or that we elect not to patent, processes for which patents may be difficult to obtain or enforce, and any other elements of our product and product candidates, and our product development processes (such as manufacturing and formulation technologies) that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. If the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secrets. Misappropriation or unauthorized disclosure of our trade secrets could significantly affect our competitive position and may have a material adverse effect on our business. Furthermore, trade secret protection does not prevent competitors from independently developing substantially equivalent information and techniques, and we cannot guarantee that our competitors will not independently develop substantially equivalent information and techniques. The FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all.

In an effort to protect our trade secrets and other confidential information, we require our employees, consultants, advisors, and any other third parties that have access to our proprietary know-how, information or technology, for example, third parties involved in the formulation and manufacture of our product and product candidates, and third parties involved in our clinical trials, to execute confidentiality agreements upon the commencement of their relationships with us. These agreements require that all confidential information developed by such employees, consultants, advisors, etc., or made known to them by us during the course of our relationship with them be kept confidential and not disclosed to third parties. However, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed despite having such confidentiality agreements. Adequate remedies may not exist in the event of unauthorized use or disclosure of our trade secrets. In addition, in some

situations, these confidentiality agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, or advisors have previous employment or consulting relationships. To the extent that our employees, consultants or advisors use any intellectual property owned by third parties in their work for us, disputes may arise as to the rights in any related or resulting know-how and inventions. If we are unable to prevent unauthorized material disclosure of our trade secrets to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

***Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.***

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity, and therefore is costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Further, recent U.S. Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained.

For our U.S. patent and patent applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, or the America Invents Act (AIA), was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. It is not clear what other, if any, impact the AIA will have on the operation of our business. Moreover, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after March 16, 2013 but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product or product candidates or (ii) invent any of the inventions claimed in our patents or patent applications.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and provided opportunities for third parties to challenge any issued patent in the USPTO. This applies to all our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party in a district court action.



Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and any patents that we might obtain in the future.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.***

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent prosecution process. Periodic maintenance fees and various other governmental fees on any issued patent and/or pending patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent or patent application. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees. While an inadvertent lapse may sometimes be cured by payment of a late fee or by other means in accordance with the applicable rules, there are many situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we fail to maintain the patents and patent applications directed to our product or product candidates, our competitors might be able to enter the market earlier than should otherwise have been the case, which would have a material adverse effect on our business.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing and prosecuting patent applications and defending patents on our product and product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries. For example, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement on infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally in those countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, certain countries in Europe and certain other countries, including India and China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

***Third-party claims alleging intellectual property infringement may adversely affect our business.***

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties, for example, patents and proprietary rights of competitors. Our research, development and commercialization activities, including the commercialization of OTIPRIO, may be subject to claims that we infringe or otherwise violate patents owned or controlled by third parties, including our competitors. There are also patent applications, owned by third parties including competitors, that have been filed but not issued that, if issued as patents, may be asserted against us. Numerous U.S. and foreign issued patents and pending patent applications, exist in the otic field in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our activities related to our product or product candidates may give rise to claims of infringement of the patent rights of third parties. We cannot assure you that our product or product candidates will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already issued and that a third party, for example a competitor in the otic market, might assert are infringed by our product or product candidates. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product or product candidates, could be found to be infringed by our product or product candidates.

Third parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop our product candidates and commercialize our product and product candidates, if approved. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. Regardless of the merits of any third-party claims, our defense against such claims, or other related actions we may take, could cause us to incur substantial expenses, and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us by a third party, we may have to (i) pay substantial damages, including treble damages and attorneys' fees if we are found to have willfully infringed the third party's patents; (ii) obtain one or more licenses from the third party; (iii) pay royalties to the third party; and/or (iv) redesign any infringing products. Redesigning any infringing products may be impossible or require substantial time and monetary expenditure. Further, we cannot predict whether any required license would be available at all or whether it would be available on commercially reasonable terms. In the event that we could not obtain a license, we may be unable to further develop our product candidates and commercialize our product and product candidates, if approved, which could harm our business significantly. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

Engaging in litigation is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

***We may become involved in lawsuits to protect or enforce our patents or other intellectual property or the patents of our licensors, which could be expensive and time consuming.***

Third parties may infringe or misappropriate our intellectual property, including our existing patents, patents that may issue to us in the future, or the patents of our licensors to which we have a license. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. Further, we may not be able to prevent, alone or with our licensors, misappropriation of our intellectual

property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Generic drug manufacturers may develop, seek approval for, and launch generic versions of our products. If we file an infringement action against such a generic drug manufacturer, that company may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us and/or our licensors to engage in complex, lengthy and costly litigation or other proceedings. For example, if we or one of our licensors initiated legal proceedings against a third party to enforce a patent covering our product or product candidates, the defendant could counterclaim that the patent covering our product or product candidates is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent.

In addition, within and outside of the United States, there has been a substantial amount of litigation and administrative proceedings, including interference and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in various foreign jurisdictions, regarding patent and other intellectual property rights in the pharmaceutical industry. The AIA introduced procedures including inter partes review and post grant review. The implementation of these procedures brings uncertainty to the possibility of challenges to our patents in the future, including challenges to those patents perceived by our competitors as blocking entry into the market for their products, and the outcome of such challenges.

Such litigation and administrative proceedings could result in revocation of our patents or amendment of our patents such that they do not cover our product or product candidates. They may also put our pending patent applications at risk of not issuing or issuing with limited and potentially inadequate scope to cover our product and product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. Additionally, it is also possible that prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, may, nonetheless, ultimately be found by a court of law or an administrative panel to affect the validity or enforceability of a claim, for example if a priority claim is found to be improper. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product and product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Enforcing our or our licensors' intellectual property rights through litigation is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, during the course of litigation or administrative proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

Although not involving issued U.S. patents covering our product or any of our product candidates, on April 17, 2015, we filed a request for interference between one of our U.S. pending applications and a U.S. pending application controlled by Auris Medical Holding AG (Auris). On July 20, 2015, we received notice from the USPTO that the Patent Trial and Appeal Board (PTAB) declared an interference between our pending application and the Auris patent (issued as U.S. Patent No. 9,066,865 on June 30, 2015). On January 26, 2017, the PTAB determined that all of the Otonomy patent claims and all but one of the Auris

patent claims were not patentable. We filed a Notice of Appeal on March 27, 2017, in which we asked the Federal Circuit to reverse PTAB's decision that our claims are not patentable and that Auris's single claim is. On August 1, 2018, the Federal Circuit agreed with us that the PTAB had erred in its rulings for Auris. The court reversed the PTAB's decision against Otonomy and remanded the case for the PTAB to enter judgment for Otonomy. On March 11, 2019, the PTAB entered the judgment for Otonomy and cancelled the Auris patent. On April 24, 2020, the USPTO issued a Notice of Allowance for our pending application, indicating that all of our claims are allowed.

***If we fail to comply with our obligations in any of the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.***

We are a party to a number of license agreements under which we are granted intellectual property rights that are crucial to our business. A portion of our patent portfolio for our product and certain product candidates was co-developed and is co-owned with UC which licensed its rights to us through an exclusive worldwide license agreement. Under our existing license agreement with UC, we are subject to various obligations, including development and commercialization diligence obligations, and patent prosecution and maintenance obligations, as well as financial obligations such as potential development milestone payments, sublicensing income payments, and royalty payments. If we fail to comply with any of these obligations or otherwise breach other terms of our license agreement, and fail to cure such breach, UC may have the right to terminate the license or, in the instance where we fail to meet our diligence obligations, UC may instead elect to change our exclusive license to a non-exclusive license. The loss of the license from UC would affect a portion of the patent portfolio for OTIPRIO and OTIVIDEX, as well as certain other product candidates we may develop. While we could still proceed with development and, if approved, commercialization of OTIPRIO, OTIVIDEX and other product candidates as co-owner of the licensed patents, third parties, such as our competitors, could enter into the market by obtaining a license from UC under UC's rights to such patents.

In addition, a portion of our patent portfolio for our OTO-313 product candidate is exclusively in-licensed from Durect, which license includes a sublicense to patents jointly owned by Durect and INSERM. Under our existing license agreement with Durect, we are subject to various obligations, including development and commercialization diligence obligations and pre-commercial launch progress reporting obligations, as well as financial obligations such as potential development milestone payments, sublicensing income payments, and royalty payments to both Durect and INSERM. If we fail to comply with the diligence obligations or otherwise materially breach our license agreement and fail to remedy such failure or cure such breach, Durect may have the right to terminate the license or, in the instance of our failure to meet the diligence obligations, Durect may instead elect to convert our exclusive license to a non-exclusive license. In particular, the loss of the license from Durect would affect a portion of the patent portfolio for OTO-313, which would adversely affect our ability to proceed with any development or potential commercialization of OTO-313 and could subject us to claims of patent infringement by Durect if OTO-313 is covered by the licensed patents.

Licensing of intellectual property rights is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property rights subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our right to sublicense intellectual property rights to third parties under collaborative development relationships; and
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product and product candidates, and what activities satisfy those diligence obligations.

While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under the patents licensed to us, we may not be

able to do so in a timely manner, at an acceptable cost or at all. Generally, the loss of any one of our current licenses, or any other license we may acquire in the future, could materially harm our business, prospects, financial condition and results of operations.

***We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.***

We have received confidential and proprietary information from third parties. In addition, we employ individuals, consultants and independent contractors who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed confidential or proprietary information of these third parties or their former employers. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants, independent contractors or others who are involved in developing our product candidates. We may also be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging our right to and use of confidential and proprietary information. If we fail in defending any such claims, in addition to paying monetary damages, we may lose our rights therein. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

## **Risks Related to Government Regulation**

***Our business and products are subject to extensive government regulation.***

We are subject to extensive, complex, costly and evolving regulation by federal and state governmental authorities in the United States, principally by the FDA, the U.S. Drug Enforcement Administration (DEA), the Centers for Disease Control and Prevention (CDC), the U.S. Department of Health and Human Services, and its various agencies, and also from state and foreign regulatory authorities. Failure to comply with all applicable regulatory requirements, including those promulgated under the Federal Food, Drug, and Cosmetic Act (FFDCA), the Public Health Service Act, and the Controlled Substances Act, among others, may subject us to operating restrictions and criminal prosecution, monetary penalties and other disciplinary actions, including, sanctions, warning letters, product seizures, recalls, fines, injunctions, suspension, revocation of approvals, disgorgement, contractual damages, and/or exclusion from future participation in the Medicare and Medicaid programs. After our products receive regulatory approval or clearance, we, and our direct and indirect suppliers, remain subject to the periodic inspection of our plants and facilities, review of production processes, and testing of our products to confirm that we are in compliance with all applicable regulations. Adverse findings during regulatory inspections may result in the implementation of Risk Evaluation and Mitigation Strategies (REMS), programs, completion of government mandated clinical trials, and government enforcement action relating to labeling, advertising, marketing and promotion, as well as regulations governing cGMPs.

***The regulatory approval process is highly uncertain and we may not obtain regulatory approval for the commercialization of OTIVIDEX, OTO-313, OTO-413 or any other product candidates.***

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. We are not permitted to market our product candidates in the United States until we receive approval of an NDA from the FDA. Obtaining regulatory approval of a product can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable United States and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions or other actions, including:

- warning letters and adverse publicity;
- civil and criminal penalties;

- injunctions;
- withdrawal of approved products;
- product seizure or detention;
- product recalls;
- total or partial suspension of production; and
- refusal to approve pending NDAs or supplements to approved NDAs.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we must demonstrate with substantial evidence from well-controlled nonclinical studies and clinical trials, and to the satisfaction of the FDA or other foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways, and insufficient or adverse results from nonclinical studies can affect the ability to conduct clinical trials. For example, following completion of a Phase 1b clinical trial, the OTIVIDEX program was put on Full Clinical Hold due to adverse findings in a nonclinical study evaluating the safety of repeated doses of OTIVIDEX. OTIVIDEX was subsequently removed from Full Clinical Hold in July 2013, allowing for initiation of the Phase 2b single-dose clinical trial, and placed on Partial Clinical Hold prohibiting the initiation of multiple-dose clinical trials in the United States pending the submission and review of additional nonclinical data. We submitted additional nonclinical data to the FDA and OTIVIDEX was removed from Partial Clinical Hold in June 2014. As a result of OTIVIDEX being placed on Full Clinical Hold, OTIPRIO was also placed on Full Clinical Hold. The OTIPRIO Full Clinical Hold was removed in November 2012. We cannot assure you that our product candidates will not be subject to new clinical holds in the future.

Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering product candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials and result in the FDA or other regulatory authorities denying approval of a product candidate for any or all targeted indications.

Regulatory approval is not guaranteed, and the approval process is expensive and may take several years. The FDA also has substantial discretion in the approval process. Despite the time and expense expended, failure can occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical trials, or perform additional nonclinical studies and clinical trials. The number of nonclinical studies and clinical trials that will be required for FDA approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address and the regulations applicable to any particular product candidate. The FDA can delay, limit or deny approval of a product candidate for many reasons, including the following:

- a product candidate may not be deemed safe, effective, pure or potent;
- FDA officials may not find the data from nonclinical studies and clinical trials sufficient;
- the FDA might not accept or approve our third-party manufacturers' processes or facilities; or
- the FDA may change its approval policies or adopt new regulations.

If OTIVIDEX, OTO-313, OTO-413 or any other product candidates fail to demonstrate safety and efficacy in clinical trials or do not gain regulatory approval, our business and results of operations will be materially and adversely harmed.

***For our product, and if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, or the limiting or withdrawal of regulatory approval and subject us to penalties if we fail to comply with applicable regulatory requirements.***

If and when regulatory approval has been granted, our product candidates or any approved product will be subject to continual regulatory review by the FDA and/or non-U.S. regulatory authorities. Additionally, our product and any product candidates, if approved, will be subject to extensive and ongoing regulatory

requirements, including labeling and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indications for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product. In addition, for our product, and if the applicable regulatory agency approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include prompt submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and GCP for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product or our product candidates, including adverse events of unanticipated severity or frequency, or problems with our third-party manufacturers' processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

Our ongoing regulatory requirements may also change from time to time, potentially harming or making costlier our commercialization efforts. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or other countries. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business.

***Our relationships with healthcare professionals, clinical investigators, CROs and third-party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face penalties.***

We are subject to various U.S. federal and state health care laws, including those intended to prevent healthcare fraud and abuse.

The federal Anti-Kickback Statute prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare, and Medicaid. Remuneration has been broadly defined to include anything of value, including, but not limited to, cash, improper discounts, and free or reduced price items and services. Many states have similar laws that apply to their state health care programs as well as private payors.

Federal false claims laws, including the federal False Claims Act (FCA), and civil monetary penalties law impose penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent or making a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government. The FCA has been used to, among other things, prosecute persons and entities

submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. The FCA includes a whistleblower provision that allows individuals to bring actions on behalf of the federal government and share a portion of the recovery of successful claims. Many states also have similar laws that apply to their state health care programs as well as private payors.

Additionally, state and federal authorities have aggressively targeted medical technology and pharmaceutical companies for, among other things, alleged violations of these healthcare fraud and abuse statutes, based on, for example, improper research or consulting contracts and other services agreements with doctors, certain marketing arrangements that rely on volume-based pricing, off-label marketing schemes, and other improper promotional practices.

The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH Act), and their implementing regulations, among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services.

Additionally, U.S. and international laws and regulations could impact our ability to store and process personal data, use certain vendors or service providers, and utilize personal data from certain jurisdictions. Because the global privacy and data protection landscape is rapidly evolving, we may be affected by or subject to new, amended or existing laws and regulations in the future, including as our operations continue to expand or if we operate in foreign jurisdictions.

For example, in the United States, HIPAA imposes certain obligations, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without proper written authorization. Similarly, the California Consumer Privacy Act of 2018 (CCPA) took effect on January 1, 2020. The CCPA gives California residents the right to access and require deletion of their personal information, the right to opt out of certain personal information sharing, and the right to detailed information about how their personal information is collected, used and shared. The CCPA provides civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Although the CCPA includes exemptions for certain clinical trials data, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. The CCPA has prompted a wave of proposals for new federal and state privacy legislation that, if passed, could increase our potential liability, increase our compliance costs and adversely affect our business.

Several foreign jurisdictions, including the European Union, its member states, the United Kingdom, Japan and Australia, among others, have adopted legislation and regulations that increase or change the requirements governing the collection, use, disclosure and transfer of the personal information of individuals in these jurisdictions. Additionally, certain countries have passed or are considering passing laws that require local data residency and/or restrict the international transfer of data. These laws have the potential to increase costs of compliance, risks of noncompliance and penalties for noncompliance.

For example, the collection and use of health data in the EU is governed by the General Data Protection Regulation (GDPR). The GDPR extends the geographical scope of EU data protection law to non-EU entities under certain conditions, tightens existing EU data protection principles and creates new obligations for companies and new rights for individuals. Guidance, interpretation and application under the GDPR are still developing and may change over time. Failure to comply with the GDPR and the applicable national data protection laws of the EU member states may result in substantial fines and other administrative penalties. The GDPR may increase our responsibility and liability in relation to personal data that we control and/or process and we may be required to put in place additional mechanisms ensuring compliance with the GDPR. This may be onerous and if our efforts to comply with GDPR or



other applicable EU laws and regulations are not successful, it could adversely affect our business in the EU.

Since the approval of OTIPRIO, our operations have been subject to the federal transparency requirements under the federal Physician Payment Sunshine Act, created under the ACA, which requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information related to payments and other transfers of value provided to physicians, as defined by law, and teaching hospitals and certain ownership and investment interests held by physicians and their immediate family members. Additionally, in 2018 the "Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act" was enacted which, under the provision entitled "Fighting the Opioid Epidemic with Sunshine," in part, extends the reporting and transparency requirements for physicians under the Physician Payments Sunshine Act to physician assistants, nurse practitioners and other mid-level practitioners, with reporting requirements going into effect in 2022 for payments made in 2021.

If any of our business activities, including but not limited to our relationships with healthcare providers or payors, violate any of the aforementioned laws and analogous state and foreign laws and regulations that may apply to pharmaceutical business practices, we may be subject to significant administrative, civil and/or criminal penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations.

In addition, the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. We cannot assure you that our internal control policies and procedures will protect us from reckless or negligent acts committed by our employees, future distributors, partners, collaborators or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

***Legislative or regulatory healthcare reforms in the United States or abroad may make it more difficult and costly for us to obtain regulatory clearance or approval of our product candidates or any future product candidates and to produce, market, and distribute our products after clearance or approval is obtained.***

From time to time, legislation is drafted and introduced in Congress in the United States or by governments in foreign jurisdictions that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture, and marketing of regulated products or the reimbursement thereof. Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In addition, FDA or foreign regulatory agency regulations and guidance are often revised or reinterpreted by the FDA or the applicable foreign regulatory agency in ways that may significantly affect our business and our product and product candidates. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our product candidates or any future product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- changes to manufacturing methods;
- recall, replacement, or discontinuance of one or more of our products; and

- additional recordkeeping.

Each of these would likely entail substantial time and cost and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any future products would harm our business, financial condition, and results of operations.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries with policy limits that we believe are customary for similarly situated companies and adequate to provide us with coverage for foreseeable risks. Although we maintain such insurance, this insurance may not provide adequate coverage against potential liabilities. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

***We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations which can harm our business.***

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, the UK Bribery Act 2010, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. U.S. economic sanctions and export control laws and regulations prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector.

We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We also have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for any unauthorized exports and reexports of our products and for the corrupt or other illegal activities of our employees, agents, contractors, and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violation of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

## Risks Related to Ownership of Our Securities

***The price of our common stock has been, is, and may continue to be highly volatile, which may make it difficult for stockholders to sell our common stock when desired or at attractive prices.***

Our stock is currently traded on the Nasdaq Global Select Market, but we can provide no assurance that we will be able to maintain an active trading market on the Nasdaq Global Select Market or any other exchange in the future. Moreover, the trading price of our common stock may fluctuate substantially. These price fluctuations may be rapid and severe and may leave investors little time to react. Broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. Sharp drops in the market price of our common stock may also expose us to securities class-action litigation.

On July 9, 2020, we filed a prospectus supplement in connection with a proposed underwritten public offering with Cowen and Company, LLC and Piper Sandler & Co., as representatives of the underwriters. We and the underwriters will determine the offering price of our common stock (and the price of the pre-funded warrant, which will equal the price per share at which the common stock is being sold in the offering minus \$0.001, the exercise price of such warrant) through negotiation. This price will not necessarily reflect the price at which investors in the market will be willing to buy and sell our shares following this proposed offering. The stock market in general and the market for pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price of our common stock has been and is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including:

- regulatory or legal developments;
- results from or delays in clinical trials of our product candidates or product candidates of companies that are perceived to be similar to us;
- announcements of regulatory approval or disapproval of our product candidates;
- commercialization of our products, if approved;
- FDA or other regulatory actions affecting us or our industry;
- introductions and announcements of new products or product candidates by us, any commercialization partners or our competitors, and the timing of these introductions and announcements;
- our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- announcements by us or our competitors of significant acquisitions, licenses, strategic partnerships, joint ventures or capital commitments;
- market conditions in the pharmaceutical and biopharmaceutical sectors and issuance of securities analysts' reports or recommendations;
- actual or anticipated quarterly variations in our results of operations or those of our competitors;
- changes in financial estimates or guidance, including our ability to meet our revenue, operating profit or loss and cash balance estimates or guidance;
- sales of substantial amounts of our stock by insiders and large stockholders, or the expectation that such sales might occur;
- general economic, industry and market conditions;
- the impact of any natural disasters or public health crises, such as the COVID-19 pandemic;
- additions or departures of key personnel;
- intellectual property, product liability or other litigation against us;
- expiration or termination of our potential relationships with strategic partners;
- limited trading volume of our common stock; and
- the other factors described in this "Risk Factors" section.

***If securities or industry analysts do not continue to publish research or publish unfavorable research about our business, our stock price and trading volume could decline.***

The trading market for our common stock will be influenced in part on the research and reports that equity research analysts publish about us and our business. Although certain equity research analysts currently cover us, we do not have any control of the analysts or the content and opinions included in their reports or whether any such analysts will continue to, or whether new analysts will, cover us for any given period of time. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analyst ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

***Sales of substantial amounts of our common stock in the public markets, or the perception that such sales might occur, could cause the market price of our common stock to drop significantly, even if our business is doing well.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly.

In September 2018, the registration statement on Form S-3 (File No. 333-227269) was declared effective by the SEC, pursuant to which we may offer debt securities, preferred stock, common stock and certain other securities from time to time. On August 1, 2019, we filed a prospectus supplement in connection with an “at the market” offering under our Sales Agreement with Cowen and Company, LLC, under which we may sell shares of common stock for up to an aggregate of \$40.0 million. On July 9, 2020, we filed a prospectus supplement in connection with a proposed underwritten public offering with Cowen and Company, LLC and Piper Sandler & Co., as representatives of the underwriters (the July 2020 Offering). If in the future we issue additional shares of common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, the market price of our common stock may decline. We cannot predict the effect that future sales of our common stock would have on the market price of our common stock. Additionally, investors may be further diluted by the exercise of the pre-funded warrants being offered in the July 2020 Offering.

In connection with the proposed offering, we have agreed that for a period of 60 days after the date of the underwriting agreement, and our directors, executive officers and certain affiliates of our directors have agreed that for a period of 60 days after the date of the underwriting agreement, subject to specified exceptions, we or they will not offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, any shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock. Sales of stock by any of our directors, executive officers or principal stockholders could have a material adverse effect on the trading price of our common stock.

As of March 31, 2020, certain holders of approximately 4,192,638 shares of our common stock, including shares issuable upon the exercise of outstanding options, are entitled to certain rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by our affiliates as defined in Rule 144 under the Securities Act.

Any sales of securities by these stockholders could have a material adverse effect on the market price of our common stock.

***We do not anticipate paying dividends on our capital stock.***

We do not intend to pay dividends on our capital stock in the foreseeable future. The declaration of dividends is subject to the discretion of our board of directors and will depend on various factors, including our operating results, financial condition, future prospects and any other factors deemed relevant by our board of directors. You should not rely on an investment in our company if you require dividend income from your investment in our company. The success of your investment will likely depend entirely upon any future appreciation of the market price of our capital stock, which is uncertain and unpredictable. There is no guarantee that our capital stock will appreciate in value or even maintain the price at which you purchased your shares.

***Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.***

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities, or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We are not obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

To the extent that a claim for indemnification is brought by any of our directors or officers, it would reduce the amount of funds available for use in our business.

***Concentration of ownership of our common stock among our existing principal stockholders may effectively limit the voting power of other stockholders.***

As of March 31, 2020, our executive officers, directors and current beneficial owners of 5% or more of our common stock, in aggregate, beneficially owned approximately 32.8% of our outstanding common stock. Accordingly, these stockholders, acting together, may significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transactions. These stockholders may therefore delay or prevent a change of control, even if such a change of control would benefit our other stockholders. The significant concentration of stock ownership may adversely affect the market price of our common stock due to investors' perception that conflicts of interest may exist or arise.

***Anti-takeover provisions in our corporate charter documents and under Delaware law could make an acquisition of us more difficult, which could discourage takeover attempts and lead to management entrenchment, and the market price of our common stock may be lower as a result.***

Certain provisions in our certificate of incorporation and bylaws may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change in control was considered favorable by you and other stockholders. For example, our board of directors has the authority to issue up

to 10,000,000 shares of preferred stock. Our board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change in control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents contain other provisions that could have an anti-takeover effect, including provisions that:

- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three-year terms;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may only be removed for cause;
- eliminate cumulative voting in the election of directors;
- authorize our board of directors to issue shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;
- provide our board of directors with the exclusive right to elect a director to fill a vacancy or newly created directorship;
- permit stockholders to only take actions at a duly called annual or special meeting and not by written consent;
- prohibit stockholders from calling a special meeting of stockholders;
- require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;
- authorize our board of directors, by a majority vote, to amend the bylaws; and
- require the affirmative vote of at least 66 2/3% or more of the outstanding shares of common stock to amend many of the provisions described above.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us. These provisions may also prevent changes in our management or limit the price that certain investors are willing to pay for our stock.

***Our amended and restated certificate of incorporation and our amended and restated bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.***

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the sole and exclusive forum for the following:

- any derivative action or proceeding brought on our behalf;
- any action or proceeding asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of ours to us or our stockholders;
- any action or proceeding asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or our amended- and restated certificate of incorporation or amended and restated bylaws; and
- any action or proceeding asserting a claim governed by the internal-affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Our amended and restated bylaws further provide that the federal district courts of the United States will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings.

It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find either exclusive-forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

***We may be subject to securities litigation, which is expensive and could divert management attention.***

The market price of our common stock has been and will likely continue to be volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

***Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains.***

We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

***Our ability to use our net operating loss carryforwards and certain other tax attributes to offset future taxable income may be subject to certain limitations.***

As of December 31, 2019, we had U.S. federal and state net operating loss carryforwards (NOLs) of approximately \$337.4 million and \$131.7 million, respectively. Of the federal NOLs, approximately \$96.8 million were generated after January 1, 2018, and therefore do not expire. Our U.S. federal and state NOLs will expire in various years beginning in 2030, if not utilized. Under the 2017 legislation commonly referred to as the Tax Cuts and Jobs Act (the Tax Act), as modified by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), the deductibility of our federal NOLs generated in tax years beginning after December 31, 2020 will be limited to 80% of taxable income in such years. As of December 31, 2019, we had federal and California research and development tax credit carryforwards of approximately \$10.9 million and \$5.0 million, respectively. The federal research and development tax credit carryforwards expire in various years beginning in 2030, if not utilized. The California research credit will carry forward indefinitely. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change federal NOLs and other pre-change tax attributes, such as research tax credits, to offset its future post-change income and taxes may be limited. In general, an "ownership change" occurs if there is a cumulative change in our ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. We believe we have experienced certain ownership changes in the past and have reduced our deferred tax assets related to NOLs and research and development tax credit carryforwards accordingly. In the event that it is determined that we have in the past experienced additional ownership changes, or if we experience one or more ownership changes as a result of future transactions in our stock, then we may be further limited in our ability to use our NOLs and other tax assets to reduce taxes owed on the net taxable income that we earn in the event

that we attain profitability. Any such limitations on the ability to use our NOLs and other tax assets could adversely impact our business, financial condition and operating results in the event that we attain profitability.

***The enactment of tax reform policies could adversely affect our business and financial condition.***

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, the CARES Act modified certain provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, and the deductibility of expenses under the Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

***We have incurred and will continue to incur costs as a result of operating as a public company, and our management has been and will continue to be required to devote substantial time to new compliance initiatives and corporate governance practices, including maintaining an effective system of internal control over financial reporting.***

As a public company listed in the United States, we incur and will continue to incur significant legal, accounting and other expenses. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act) and regulations implemented by the SEC, and The Nasdaq Stock Market (Nasdaq) may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

As a public company in the United States, we are required, pursuant to the Sarbanes-Oxley Act, to maintain effective disclosure controls and procedures and internal control over financial reporting. We are also required to provide an annual management report on the effectiveness of our disclosure controls and procedures over financial reporting. We need to disclose any material weaknesses identified by our management in our internal control over financial reporting, and at any time when we are not a non-accelerated filer, we will need to provide a statement that our independent registered public accounting firm has issued an opinion on our internal control over financial reporting. The controls and other procedures are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC, is disclosed accurately and is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms.

Our current controls, and any new controls that we develop may become inadequate because of changes in conditions in our business or the degree of compliance with these policies or procedures may deteriorate and significant deficiencies or material weaknesses in our internal control over financial reporting may be discovered. We may err in the design or operation of our controls, and all internal control systems, no matter how well designed and operated, may provide only reasonable assurance that the objectives of the control system are met. Because there are inherent limitations in all control systems, there can be no absolute assurance that all control issues have been or will be detected. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation could harm our results of operations or cause



us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Any failure to implement and maintain effective internal control over financial reporting also could adversely affect the results of periodic management evaluations regarding the effectiveness of our internal control over financial reporting that are required to be included in our periodic reports that will be filed with the SEC. Ineffective disclosure controls and procedures and internal control over financial reporting could also cause investors to lose confidence in our reported financial information and operating results, which could result in a negative market reaction and effect on the trading price of our common stock.

***We are a “smaller reporting company,” and the reduced disclosure requirements applicable to smaller reporting companies could make our common stock less attractive to investors.***

We are a “smaller reporting company,” as defined in Rule 12b-2 of the Exchange Act. For as long as we remain a “smaller reporting company,” we are permitted and intend to continue to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not “smaller reporting companies.” These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s discussion and analysis of financial condition and results of operations” disclosure; and
- reduced disclosure obligations regarding executive compensation.

We cannot predict whether investors will find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the market price of our common stock may be reduced or more volatile.

***If securities or industry analysts do not continue to publish research or publish unfavorable research about our business, our stock price and trading volume could decline.***

The trading market for our common stock will be influenced in part on the research and reports that equity research analysts publish about us and our business. Although certain equity research analysts currently cover us, we do not have any control of the analysts or the content and opinions included in their reports or whether any such analysts will continue to, or whether new analysts will, cover us for any given period of time. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analyst ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.