Filed Pursuant to Rule 424(b)(5)
Registration No. 333-223669

PROSPECTUS SUPPLEMENT
(to Prospectus dated July 13, 2018)

Up to $40,000,000
Common Stock

We have entered into a common stock sales agreement, or the Sales Agreement, with H.C. Wainwright & Co. LLC and Ladenburg Thalmann & Co. Inc., or the Sales Agents, relating to shares of our common stock offered by this prospectus supplement and the accompanying prospectus. In accordance with the terms of the Sales Agreement, we may offer and sell shares of our common stock having an aggregate offering price of up to $40,000,000 from time to time through the Sales Agents acting as sales agents.

Our common stock is listed on the Nasdaq Capital Market under the symbol "INNT." On October 25, 2018, the last reported sale price for our common stock on the Nasdaq Capital Market was $4.42 per share.

Sales of our common stock, if any, under this prospectus supplement may be made in sales deemed to be "at-the-market offerings" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, or the Securities Act. The Sales Agents are not required to sell any specific number or dollar amount of securities, but will act as the sales agents using their commercially reasonable efforts, consistent with the Sales Agents' normal trading and sales practices, to sell on our behalf all of the shares of common stock requested to be sold by us on mutually agreed terms between the Sales Agents and us. There is no arrangement for funds to be received in any escrow, trust or similar arrangement.

The Sales Agents will be entitled to compensation under the terms of the Sales Agreement at a commission rate of 3.0% of the gross sales price per share sold by such Agent. In connection with the sale of the common stock on our behalf, the Sales Agents will each be deemed to be an "underwriter" within the meaning of the Securities Act and the compensation of the Sales Agents will be deemed to be underwriting commissions or discounts. We have also agreed to provide indemnification and contribution to the Sales Agents against certain civil liabilities, including liabilities under the Securities Act.

We are an "emerging growth company" under the federal securities laws and, as such, we are subject to reduced public company disclosure standards.

Investing in our common stock involves a high degree of risk. Please read "Risk Factors" beginning on page S-6 of this prospectus supplement, page 3 of the accompanying prospectus, and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus for a discussion of the factors you should carefully consider before deciding to purchase our common stock.

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

H.C. Wainwright & Co. **Ladenburg Thalmann**

Prospectus Supplement dated October 26, 2018

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PROSPECTUS SUPPLEMENT

PROSPECTUS

ABOUT THIS PROSPECTUS SUPPLEMENT

This document is in two parts. The first part is this prospectus supplement, which describes the specific terms of this offering of common stock and also adds to and updates information contained in the accompanying prospectus, or the base prospectus, and the documents incorporated by reference in this prospectus supplement and the accompanying prospectus. The second part, the accompanying prospectus, dated July 13, 2018, provides more general information, some of which may not apply to this offering. Generally, when we refer to this prospectus supplement, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement and the information contained in the accompanying prospectus or any document incorporated by reference that was filed with the U.S. Securities and Exchange Commission, or SEC, before the date of this prospectus supplement, you should rely on the information in this prospectus supplement; provided that if any statement in one of these documents is inconsistent with a statement in another document having a later date—for example, a document incorporated by reference in the accompanying prospectus—the statement in the document having the later date modifies or supersedes the earlier statement.

This prospectus supplement and the accompanying prospectus are part of a registration statement on Form S-3 that we filed with the SEC, using a "shelf" registration process. The $40,000,000 of common stock that may be offered, issued and sold under this prospectus is included in the $175,000,000 of securities that may be offered, issued and sold by us pursuant to our shelf registration statement. This prospectus is deemed a prospectus supplement to the accompanying prospectus included in the registration statement of which this prospectus forms a part.

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

We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of the common stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement and the accompanying prospectus must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus supplement and the accompanying prospectus outside the United States. This prospectus supplement and the accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

As permitted by the rules and regulations of the SEC, the registration statement, of which this prospectus supplement and the accompanying prospectus form a part, includes additional information not contained in this prospectus supplement or the accompanying prospectus. You should read this prospectus supplement, the registration statement and the accompanying prospectus together with the documents incorporated by reference into this prospectus supplement and into the accompanying prospectus before buying any shares of our common stock in this offering. See "Where You Can Find Additional Information" on page S-46 of this prospectus supplement.

You should not assume that the information in this prospectus supplement, the accompanying prospectus or any other offering materials is accurate as of any date other than the date on the front of each document, regardless of the time of delivery of this prospectus supplement, the accompanying prospectus or such other offering materials or the time of any sale of securities. Our business, financial condition, results of operations and prospects may have changed since then.

Except where the context otherwise requires or where otherwise indicated, the terms "we," "us," "our," "Innovate" and "the Company" refer to Innovate Biopharmaceuticals, Inc., a Delaware corporation, and its consolidated subsidiaries.

FORWARD-LOOKING STATEMENTS

The information in this prospectus supplement and the accompanying prospectus and the information incorporated herein and therein by reference includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These forward-looking statements are based on current expectations and beliefs and involve numerous risks and uncertainties that could cause actual results to differ materially from expectations. These forward-looking statements should not be relied upon as predictions of future events as we cannot assure you that the events or circumstances reflected in these statements will be achieved or will occur. When used in this report, the words “believe,” “may,” “could,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “indicate,” “seek,” “should,” “would” and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements contain these identifying words. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements.

You should not rely upon forward-looking statements as guarantees of future performance or as predictions of future events. We have based these forward-looking statements largely on our current estimates of our financial results and our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions that may cause our actual results to differ materially from those contained in any forward-looking statements, including those described in “Risk Factors” in this prospectus supplement, the accompanying prospectus and in our most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q and in our other filings with the SEC that are incorporated by reference in this prospectus supplement or the accompanying prospectus. Moreover, we operate in a very competitive and rapidly changing environment and new risks emerge from time to time. In light of these risks, uncertainties and assumptions, the forward-looking statements discussed in this prospectus supplement, the accompanying prospectus and in our most recent Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q and any other filings with the SEC that are incorporated by reference in this prospectus supplement or the accompanying prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

These forward-looking statements include, among other things, statements about:

- the cost, timing and results of the development of our clinical programs, including of INN-202 (for celiac disease), INN-217 (for nonalcoholic steatohepatitis, or NASH), INN-289 (for Crohn’s disease), INN-108 (for ulcerative colitis), and INN-329 (for magnetic resonance cholangiopancreatography, or MRCP);
- the commercial potential of INN-202 and our other clinical programs;
- the timing of, and our ability to obtain and maintain regulatory approvals for INN-202;
- the development of any future product candidates;
- our plans to obtain funding for our operations;
- the development, regulatory approval, efficacy and commercialization of competing products;
- our estimates and expectations, including estimates of the potential market for our product candidates and projected cash needs and timing of the use of cash;
- our liquidity position;
- our intellectual property plans; and
- our anticipated use of the net proceeds in the offering.

If any of these risks or uncertainties materialize or any of these assumptions prove incorrect, our results could differ materially from the forward-looking statements in this prospectus supplement. All forward-looking statements in this prospectus supplement are current only as of the date of this prospectus supplement. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any statement is made or to reflect the occurrence of unanticipated events except as required by law.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus supplement, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information.

PROSPECTUS SUPPLEMENT SUMMARY

This summary description about us and our business highlights selected information contained elsewhere in this prospectus supplement or incorporated by reference in this prospectus supplement and the accompanying prospectus. This summary does not contain all of the information that you should consider before deciding to invest in our common stock. You should carefully read this entire prospectus supplement, the accompanying prospectus and any related free writing prospectus, including each of the documents incorporated herein or therein by reference, before making an investment decision. Investors should carefully consider the information set forth under "Risk Factors" in this prospectus supplement on page S-6, in any related free writing prospectus, and under similar headings in the other documents that are incorporated by reference into this prospectus supplement. You also should carefully read the information incorporated by reference into this prospectus supplement, including our financial statements, other information and the exhibits to the registration statement of which the accompanying prospectus is a part.

Overview

We are a clinical-stage biopharmaceutical company developing novel medicines for autoimmune and inflammatory diseases with unmet needs. Our pipeline includes drug candidates for celiac disease, nonalcoholic steatohepatitis, or NASH, Crohn's and ulcerative colitis. Our lead program, INN-202 (larazotide acetate or larazotide) is entering Phase 3 registration trials in the first half of 2019 and has the potential to be the first-to-market therapeutic for celiac disease, an unmet medical need, which affects an estimated 1% of the North American population or approximately 3 million individuals. Celiac patients have no treatment alternative other than a strict lifelong adherence to a gluten-free diet, which is difficult to maintain and can be deficient in key nutrients. Additionally, current U.S. Food and Drug Administration, or FDA, labeling standards allow up to 20 parts per million of gluten in "gluten-free" labeled foods, which are sufficient to cause celiac symptoms in many patients, including abdominal pain, abdominal cramping, bloating, gas, headaches, ataxia, "brain fog," and fatigue. Long-term consequences of celiac disease include enteropathy associated T-cell lymphoma, osteoporosis and anemia.

Reverse Recapitalization and Merger

On January 29, 2018, Monster Digital, Inc., or Monster, and privately-held Innovate Biopharmaceuticals Inc., or Private Innovate, completed a reverse recapitalization in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated July 3, 2017, as amended, or the Merger Agreement, by and among Monster, Monster Merger Sub, Inc., or Merger Sub, and Private Innovate. In connection with the transaction, Private Innovate changed its name to IB Pharmaceuticals Inc., or IB Pharmaceuticals. Pursuant to the Merger Agreement, Merger Sub merged with and into IB Pharmaceuticals with IB Pharmaceuticals surviving as the wholly-owned subsidiary of Monster, which we refer to as the Merger. Immediately following the Merger, Monster changed its name to Innovate Biopharmaceuticals, Inc. In connection with the closing of the Merger, Innovate's common stock began trading on the Nasdaq Capital Market under the ticker symbol "INNT" on February 1, 2018. Monster was incorporated in Delaware in November 2010 under the name "Monster Digital, Inc."

Prior to the Merger, Monster's primary business focus was the design, development and marketing of premium products under the "Monster Digital" brand for use in high-performance consumer electronics, mobile products and computing applications.

Recent Developments

Exchange of Senior Note

On October 4, 2018, we and Gustavia Capital Partners LLC, or the Holder, entered into an Amendment and Exchange Agreement, exchanging the Holder's existing senior note, or the Existing Note, for a new Senior Convertible Note, or the New Note. Upon issuance of the New Note, the Existing Note and the Company's obligations thereunder were extinguished.

The principal amount outstanding under the New Note is $5,196,667. The New Note bears interest at a rate of 8% per year, payable quarterly, and matures in 24 months. The interest rate shall automatically be increased if there is any event of default to 18% per year.

All amounts then outstanding under the New Note are convertible into shares of our common stock:

- At the Holder's option at a conversion price of $8.02, with such conversion price adjusted down to the price of any future issuances of common stock by us, which may include this offering (which we refer to as the Conversion Price);

- At the Holder's option at a conversion price (which we refer to as the Alternate Conversion Price) equal to the greater of (i) $3.08 (which we refer to as the Floor Price) or (ii) the lower of (A) the Conversion Price, as adjusted, or (B) 93% of the average volume weighted price of the our common stock for the 10 days preceding the conversion. If we default under the New Note, then the Holder is entitled to convert the New Note for 120% of all amounts then outstanding under the New Note at this Alternate Conversion Price;
- At the Holder's option at a conversion price that varies with the market price of our common stock if we issue or enter into an agreement to issue shares of common stock, or securities that convert into shares of common stock, at a price that varies with the market price of our common stock; and
- At our option at the Conversion Price if the volume weighted average price of our common stock for the 10 days preceding the conversion exceeds $10 per share and certain conditions are satisfied.

For example, if the entire principal amount of the New Note converts into shares of our common stock at the Floor Price of $3.08 per share, then we would be required to issue 1,687,229 shares to the Holder upon the conversion of the New Note.

In addition, if the volume weighted average price of our common stock is less than the Floor Price, unless we lower the Floor Price, for 10 consecutive days, the Holder may, at any time at its option, require us to redeem all or any portion of the New Note (including all accrued and unpaid interest thereon), in cash, at a price equal to the 100% of the amount being redeemed. The Holder can also require the Company to redeem the New Note upon a change in control of the Company for 120% of the amount then outstanding. We can redeem the New Note in connection with a merger, strategic partnership and/or a joint venture at 120% of the amount then outstanding under the New Note.

If an event of default occurs, the Holder may require us to redeem all or any portion of the New Note (including all accrued and unpaid interest thereon), in cash, at a price equal to the greater of (i) 125% of the amount being redeemed and (ii) 125% of the intrinsic value of the shares of common stock then issuable upon conversion of the New Note.

Annual Stockholder Meeting Proposals

On October 16, 2018, we filed a definitive proxy statement with the SEC regarding the notice of our annual meeting of stockholders to be held on December 4, 2018, or the Annual Meeting. At the Annual Meeting, we intend for our stockholders to consider and vote upon the matters referred to in the definitive proxy statement, including the election of seven directors, amendments to our 2012 Omnibus Incentive Plan, or the Omnibus Plan, and certain proposed amendments to our certificate of incorporation, which we believe will enhance our board's flexibility to explore alternative strategies for maximizing stockholder value and which we believe are customary for newly public companies in our industry.

Under the proposed amendment to the Omnibus Plan, we will (i) increase the number of shares of common stock authorized for issuance thereunder by 3,000,000 shares and (ii) implement an evergreen provision to automatically increase on January 1st of each year, commencing on January 1, 2019 and ending on (and including) January 1, 2022, the total number of shares of common stock available under the Omnibus Plan by 5% of the total number of shares of common stock outstanding on December 31st of the preceding calendar year. Our board of directors or a designated committee may choose to reduce such planned increase in any given year. We do not intend to issue any additional awards under the Private Innovate 2015 Stock Issuance Plan, or the Private Innovate Plan.

The terms of the proposed amendments to our certificate of incorporation include:

- Our board of directors will be classified;
- Our board of directors will have the exclusive authority to fill vacancies on the board of directors, and, contingent upon this amendment, our certificate of incorporation would prohibit director removal without cause and allow removal with cause only by the vote of the holders of at least two-thirds of all then-outstanding shares of common stock;
- A special meeting of stockholders may be called only by our board of directors, the chairperson of our board of directors, our chief executive officer or our president;
- Our stockholders would be permitted to act only at a duly called annual or special meeting and not by written consent or electronic transmission;
- Our board of directors would have the exclusive authority to increase or decrease the size of our board of directors; and
- Amendments of certain provisions to our certificate of incorporation and bylaws would require a vote of the holders of at least two-thirds of all then-outstanding shares of common stock of our Company.

Estimated Unaudited Cash and Cash Equivalents

The following is a preliminary estimate of our cash and cash equivalents position as of September 30, 2018. This preliminary estimate is based upon our estimates and is subject to completion of our financial closing procedures. Moreover, this preliminary estimate has been prepared solely on the basis of information that is currently available to, and that is the responsibility of, management. Our independent registered public accounting firm has not audited or reviewed, and does not express an opinion with respect to this estimate. This preliminary estimate is not a comprehensive statement of our financial position as of September 30, 2018, and remains subject to, among other things, the completion of our financial closing procedures, final adjustments, and completion of our internal review for the quarter ended September 30, 2018, which may materially impact this preliminary estimate. Our estimated unaudited cash and cash equivalents as of September 30, 2018 were approximately $8.1 million.

Corporate Information

Our principal executive office is currently located at 8480 Honeycutt Road, Suite 120, Raleigh, North Carolina 27615. Our telephone number is (919) 275-1933. Our website address is www.innovatebiopharma.com. Information contained on or that can be accessed through the website is not incorporated by reference into this prospectus supplement or accompanying base prospectus, and should not be considered to be part of this prospectus supplement or the accompanying base prospectus.

Implications of Being an Emerging Growth Company

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups, or JOBS, Act enacted in April 2012, and may remain an “emerging growth company” until December 31, 2021 (the fiscal year-end following the fifth anniversary of the completion of our initial public offering), although, if we have more than $1.07 billion in annual revenue, upon which time we will be deemed to be a large accelerated filer under the rules of the SEC, or we issue more than $1 billion of non-convertible debt over a three-year period before the end of that five-year period, we would cease to be an “emerging growth company” as of the following December 31.

While we are an “emerging growth company,” we will take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not “emerging growth companies” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation and financial statements in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote to approve executive compensation and shareholder approval of any golden parachute payments not previously approved.

For further information regarding us and our financial information, you should refer to our recent filings with the SEC. See “Where You Can Find Additional Information.”

THE OFFERING

Common stock offered by us	Shares of our common stock having an aggregate offering price of up to $40,000,000.
Plan of distribution	"At-the-market" offering that may be made from time to time through our Sales Agents, H.C. Wainwright & Co. LLC and Ladenburg Thalmann & Co. Inc. See "Plan of Distribution."
Use of proceeds	We intend to use the net proceeds from this offering, if any, to fund the Phase 3 registration trials of our lead program, INN-202, as well as for working capital and general corporate purposes. See "Use of Proceeds."
Common stock to be outstanding after this offering(1)	34,745,376 shares
Risk Factors	See "Risk Factors" in this prospectus supplement, the accompanying prospectus and otherwise incorporated by reference into this prospectus supplement and the accompanying prospectus for a discussion of factors you should consider carefully before deciding to invest in shares of our common stock.
Nasdaq Capital Market symbol	"INNT"

(1) The number of shares of our common stock to be outstanding immediately after this offering is based on 25,695,602 shares outstanding as of June 30, 2018, an assumed offering price of $4.42 per share (the closing price on October 25, 2018) and excludes as of that date:

- 1,683 shares of common stock issuable upon the exercise of outstanding stock options under the Omnibus Plan, with a weighted-average exercise price of $45.00 per share;
- 6,428,577 shares of common stock issuable upon the exercise of options outstanding under the Private Innovate Plan;
- 1,698,294 and 349,555 shares of common stock issuable upon the exercise of outstanding warrants, with an exercise price of $3.18 per share and $2.54 per share, respectively;
- 154,403 shares of common stock issuable upon the exercise of warrants issued by Monster with a weighted-average exercise price of $55.31 per share;
- any shares of our common stock issuable upon conversion of the New Note (approximately 1,687,229 shares at a conversion price equal to the floor price of $3.08 per share); and
- 4,505 shares of common stock reserved for future issuance under the Omnibus Plan as of June 30, 2018, as well as any increases in the number of shares of our common stock reserved for issuance under the Omnibus Plan following approval at our Annual Meeting of the amendments described under "Prospectus Supplement Summary—Recent Developments—Annual Stockholder Meeting Proposals," including (i) an increase of the number of shares of common stock authorized for issuance under the Omnibus Plan by 3,000,000 shares and (ii) any future increases pursuant to evergreen provisions thereof, in each case if approved by our stockholders at our Annual Meeting.

In addition, since June 30, 2018, we have made contingent grants of options to purchase up to approximately 1.2 million shares of common stock under the Omnibus Plan to certain of our executive officers, directors, employees and consultants, and such grants would become effective upon approval at our Annual Meeting of the amendments to increase the number of shares available under the Omnibus Plan.

The New Note may convert the note into shares of our common stock at various conversion prices. See "Prospectus Supplement Summary—Recent Developments—Exchange of Senior Note" for additional information on determination of the conversion prices for the New Note. For example, if the entire principal amount of the New Note converts into shares

of our common stock at the Floor Price of $3.08 per share, then we would be required to issue 1,687,229 shares to the Holder upon the conversion of the New Note.

Except as otherwise indicated, all information in this prospectus supplement assumes no exercise of outstanding options or warrants to purchase common stock since June 30, 2018.

RISK FACTORS

Before you invest in our securities, you should be aware that our business faces numerous financial and market risks, including those described below, as well as general economic and business risks. Our securities are speculative, and you should not make an investment in Innovate unless you can afford to bear the loss of your entire investment. Prior to making a decision about investing in our common stock, you should carefully consider the risks, uncertainties and assumptions discussed under Item 1A, "Risk Factors," in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, and under the heading "Risk Factors in our Current Report on Form 8-K, filed as amended with the SEC on April 18, 2018, as updated by our subsequent filings with the Securities and Exchange Commission, or the SEC, under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are incorporated herein by reference, together with the information in this prospectus supplement and the base prospectus and any other information incorporated by reference herein or therein. Before you decide whether to invest in our securities, you should carefully consider these risks and uncertainties, together with all of the other information included in or incorporated by reference into, this prospectus supplement or the base prospectus. The risks and uncertainties identified are not the only risks and uncertainties we face. If any of the material risks or uncertainties that we face were to occur, you could lose part or all of your investment.

Risks Related to this Offering and our Common Stock

The market price of our common stock has been and will likely in the future be volatile.

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. For example, since our stock began trading under the symbol "INNT" on February 1, 2018, through October 25, 2018 the price thereof has ranged from a low of $3.43 per share to a high of $50.50 per share. Companies like us with a lower number of shares comprising their public floats and limited trading activity may experience greater volatility in their stock prices. The market price of our common stock may 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 in the United States and foreign countries;
- results from or delays in clinical trials of our product candidates;
- announcements of regulatory approval or disapproval of, or delays in clinical trials for, INN-202 (for celiac disease), INN-217 (for NASH), INN-289 (for Crohn's disease), INN-108 (for ulcerative colitis) and INN-329 (for magnetic resonance cholangiopancreatography or MRCP) or any future product candidates;
- commercialization of our product candidates;
- FDA or other U.S. or foreign regulatory actions affecting us or our industry;
- introductions and announcements of new products by us, any commercialization partners or our competitors, and the timing of these introductions and announcements;
- variations in 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 future revenue and operating profit or loss estimates or guidance;
- our liquidity position;
- sales of substantial amounts of our stock by insiders and other stockholders, or the expectation that such sales might occur;
- general economic, industry and market conditions;
- 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; and
- the other factors described in this "Risk Factors" section.

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

Equity research analysts do not currently provide research coverage of our common stock. In particular, as a smaller company, it may be difficult for us to attract the interest of equity research analysts. A lack of research coverage may adversely affect the liquidity of and market price of our common stock. To the extent we obtain equity research analyst coverage, we will not have any control of the analysts or the content and opinions included in their reports. The market price of our stock could decline if one or more equity research analysts begin coverage of our common stock and downgrade our common stock or issue other unfavorable commentary or research on us. If one or more equity research analysts ceases coverage of us in the future, or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause the market price of our common stock 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.

If we or our existing stockholders sell, or indicate an intent to sell, substantial amounts of our common stock in the public markets, the trading price of our common stock could decline significantly. On March 14, 2018, we filed a shelf registration statement, or the Shelf Registration Statement, which was declared effective on July 13, 2018. Under the Shelf Registration Statement, we may, from time to time, sell our common stock in one or more offerings, including this offering, up to an aggregate dollar amount of $175.0 million (of which up to an aggregate of $40 million may be sold in an "at-the-market" offering as defined in Rule 415 of the Securities Act). In addition, the selling stockholders included in the Shelf Registration Statement may from time to time sell up to an aggregate amount of approximately 13.99 million shares of our common stock (including up to approximately 2.1 million shares issuable upon exercise of warrants) in one or more offerings. As of October 25, 2018, we had approximately 26.0 million shares of common stock outstanding and exercisable options and warrants to purchase approximately 7.7 million shares of common stock outstanding, in addition to the New Note, which may be converted into shares of our common stock at any time at various conversion prices, as further described under "Prospectus Supplement Summary—Recent Developments—Exchange of Senior Note." Therefore, sales of common stock by us or our stockholders under the Registration Statement or otherwise (including sales pursuant to Rule 144) may represent a significant percentage of our common stock currently outstanding. If we or our stockholders sell, or the market perceives that we or our stockholders intend to sell, substantial amounts of our common stock under the Shelf Registration Statement or otherwise, the market price of our common stock could decline significantly. For example, our closing stock price on July 13, 2018, prior to the Registration Statement being declared effective, was $23.70 per share, and our closing stock price on July 16, 2018, after the Registration Statement was declared effective, was $8.08 per share.

To the extent we raise additional capital by selling and issuing common stock, convertible securities or other equity securities, including pursuant to our current stock option plan and the proposed increase in the number of shares issuable under such plan, it may result in material dilution to our existing stockholders and new investors could gain rights superior to our existing stockholders. Sales by us or by our current stockholders, including sales made pursuant to Rule 144, also could cause the price of our common stock to fall and make it more difficult for you to sell shares of our common stock.

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

To the extent that a third party brings a claim against us and/or any of our officer or directors, whether successful or not, a claim for indemnification brought by any of our directors or officers would reduce the amount of funds available for use in our business.

You will experience immediate and substantial dilution after this offering. The issuance of shares upon exercise of our outstanding options and warrants and the conversion of our convertible note may cause substantial dilution to our existing stockholders and reduce the trading price of our common stock.

Since the price per share of our common stock being offered is substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution with respect to the net tangible book value of the common stock you purchase in this offering. After giving effect to the sale of 9,049,774 shares of our common stock at an assumed public offering price of $4.42 per share, and after deducting discounts, commissions or other Sales Agent compensation, and estimated offering expenses, based on our net tangible book value as of June 30, 2018, if you

purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of $3.21 per share with respect to the net tangible book value of the common stock purchased in this offering. For a further description of the dilution that you will experience immediately after this offering, see "Dilution," below.

In addition, we presently have outstanding options and warrants that if exercised would result in the issuance of approximately 9.5 million shares of our common stock, as well as the New Note, which may be converted into shares of our common stock at any time at various conversion prices. See "Prospectus Supplement Summary—Recent Developments—Exchange of Senior Note." The issuance of shares upon exercise of warrants and options or upon conversion of the New Note may result in dilution to the interests of other stockholders and may reduce the trading price of our common stock.

We may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders or result in downward pressure on the price of our common stock.

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

Prior to this offering, our executive officers, directors and current beneficial owners of 5% or more of our common stock, in aggregate, beneficially own approximately 53% of our outstanding common stock. Accordingly, these stockholders, acting together, will continue to be able to 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 the 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 the 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 organizational documents also contain other provisions that could have an anti-takeover effect, including provisions that:

- 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;
- eliminate cumulative voting in the election of directors;
- authorize the 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;
- 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; and
- authorize the board of directors, by a majority vote, to amend the bylaws.

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 could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that certain investors are willing to pay for our stock.

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

The market price of our common stock may 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.

We will have broad discretion in the use of proceeds we receive in this offering for working capital and general corporate purposes.

The net proceeds of this offering are being allocated to fund the Phase 3 registration trials of our lead program, INN-202, as well as for working capital and general corporate purposes. Our management will have broad discretion over the use and investment of the net proceeds of this offering within those categories, and accordingly investors will need to rely upon the judgment of our management with respect to the use of proceeds, with only limited information concerning management's specific intentions. See "Use of Proceeds" for further details.

We have not paid cash dividends in the past and do not expect to pay dividends in the future. Any return on investment may be limited to the value of our common stock.

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends in the near future. The payment of dividends on our common stock will depend on earnings, financial condition and other business and economic factors affecting us at such time as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on investment will only occur if our stock price appreciates.

If we sell additional equity or debt securities to fund our operations, it may impose restrictions on our business.

In order to raise additional funds to support our operations, we may sell additional equity or debt securities, which may impose restrictive covenants that adversely impact our business. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we are unable to expand our operations or otherwise capitalize on our business opportunities due to such restrictions, our business, financial condition and results of operations could be materially adversely affected.

Risks Related to Our Capital Requirements and Financial Condition

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

We have not been profitable since we commenced operations, and we may never achieve or sustain profitability. As a clinical-stage biopharmaceutical company, we have a limited operating history upon which to evaluate our business and prospects. In addition, we have limited history as an organization 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. We have not yet obtained any regulatory approvals for any of our product candidates, commercialized any of our product candidates, or generated any revenue from sales of products. We have devoted significant resources to research and development and other expenses related to our ongoing clinical trials and operations, in addition to acquiring product candidates.

Since inception, substantial resources have been dedicated to the acquisition and development of our product candidates, INN-202 (larazotide acetate), INN-108 and INN-329 (secretin). We will require significant additional capital to continue operations and to execute on our current business strategy to develop INN-202 through regulatory approval and further develop INN-217, INN-289, INN-108 and INN-329 for eventually seeking regulatory approval. We cannot estimate with reasonable certainty the actual amounts necessary to successfully complete the development and commercialization of our product candidates, and there is no certainty that we will be able to raise the necessary capital on reasonable terms or at all.

Our auditor has expressed substantial doubt about our ability to continue as a going concern.

The audit report on our financial statements for the years ended December 31, 2017 and 2016, included an explanatory paragraph related to recurring losses from operations and dependence on additional financing to continue as a going concern. We have incurred net losses for the three and six months ended June 30, 2018 and 2017, and for the years

ended December 31, 2017 and 2016, and had an accumulated deficit of $39.7 million as of June 30, 2018. In view of these matters, our ability to continue as a going concern is dependent upon our ability to raise additional debt or equity financing or enter into strategic partnerships. On January 29, 2018, we sold approximately $18.1 million of shares of common stock, or $16.5 million, net of approximately $1.6 million in placement agent fees and non-accountable expense costs. In addition, we received approximately $3.0 million in proceeds from a debt financing, and, since that time, we have exchanged the note issued in that debt financing to the New Note with an outstanding principal amount of $5,196,667. See "Prospectus Supplement Summary—Recent Developments—Exchange of Senior Note." We intend to continue to finance our operations through strategic partnerships and/or debt or equity financing. The failure to obtain strategic partnerships or sufficient financing could adversely affect our ability to achieve our business objectives and continue as a going concern.

We will require substantial additional financing to obtain regulatory approval for INN-202 for celiac disease, and for further development of INN-217 (for NASH), INN-108 (for ulcerative colitis), INN-289 (for Crohn's disease) and INN-329 (for magnetic resonance cholangiopancreatography or MRCP), 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 product development efforts and other operations.

We expect to continue to incur substantial operating losses for the next several years as we advance our product candidates through clinical development, U.S. and other regional regulatory approvals, and commercialization. No revenue from operations will likely be available until, and unless, one of our product candidates is approved by the FDA or another regulatory agency and successfully marketed, or we enter into an arrangement that provides for licensing revenue or other partnering-related funding, outcomes which we may not achieve on a timely basis, or at all.

Our capital requirements for the foreseeable future will depend in large part on, and could increase significantly as a result of, our expenditures on our development programs. Future expenditures on our development programs are subject to many uncertainties, and will depend on, and could increase significantly as a result of, many factors, including:

- the number, size, complexity, results and timing of our drug development programs;
- the number of nonclinical and clinical studies necessary to demonstrate acceptable evidence of the safety and efficacy of our product candidates;
- the terms of any collaborative or other strategic arrangement that we may establish;
- changes in standards of care which could increase the size and complexity of clinical studies;
- the ability to locate patients to participate in a study given the limited number of patients available for orphan or ultra-orphan indications;
- the number of patients who participate, the rate of enrollment, and the ratio of randomized to evaluable patients in each clinical study;
- the number and location of sites and the rate of site initiation in each study;
- the duration of patient treatment and follow-up;
- the potential for additional safety monitoring or other post-marketing studies that may be requested by regulatory agencies;
- the time and cost to manufacture clinical trial material and commercial product, including process development and scale-up activities, and to conduct stability studies, which can last several years;
- the degree of difficulty and cost involved in securing alternate manufacturers or suppliers of drug product, components or delivery devices, as necessary to meet FDA requirements and/or commercial demand;
- the costs, requirements, timing of, and the ability to, secure regulatory approvals;
- the extent to which we increase our workforce and the costs involved in recruiting, training and incentivizing new employees;
- the costs related to developing, acquiring and/or contracting for sales, marketing and distribution capabilities, supply chain management capabilities, and regulatory compliance capabilities, if we obtain regulatory approval for a product candidate and commercialize it without a partner;
- the costs involved in evaluating competing technologies and market developments or the loss in sales in case of such competition; and
- the costs involved in establishing, enforcing or defending patent claims and other proprietary rights.

In addition, we are obligated to dedicate a portion of our cash flow to payments on our debt, which reduces the amounts available to fund other corporate initiatives. An event of default on our debt could increase and accelerate the amounts due thereunder.

Additional capital may not be available when we need it, on terms that are acceptable to us or at all. If adequate funds are not available to us on a timely basis, we will be required to delay, limit, reduce or terminate development activities, our establishment of sales and marketing, manufacturing or distribution capabilities, or other activities that may be necessary to commercialize our product candidates, conduct preclinical or clinical studies, 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 be required to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable. If we raise additional capital through public or private equity offerings, or through debt offerings in which the instruments can convert to equity, the ownership interest of our 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 subject to specified financial ratios, any of which could restrict our ability to develop and commercialize our product candidates or operate as a business.

We have not generated any revenue from product sales and may never be profitable.

We have no products approved for commercialization and have never generated any revenue from product sales. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the requisite regulatory approvals necessary to commercialize, one or more of our product candidates.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Risks Related to Our Business Strategy and Operations

We do not have any products that are approved for commercial sale.

We currently do not have any therapeutic products approved for commercial sale. We have not received, and may not receive within the next several years, if at all, any revenues from the commercialization of our product candidates if approved. In the event one or more of our product candidates is approved for commercial sale, we will incur significant costs in connection with commercializing any approved product candidate, and we may not generate significant revenue from sales of such products, which would impact our ability to become profitable and maintain profitability.

We are substantially dependent upon the clinical, regulatory and commercial success of our five product candidates, INN-202, INN-217, INN-108, INN-289 and INN-329. 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 to the satisfaction of regulatory authorities the safety and efficacy of our five product candidates.

The success of our business is dependent on our ability to advance the clinical development of INN-202 for the treatment of celiac disease, INN-217 for NASH, INN-108 for the treatment of mild to moderate ulcerative colitis, INN-289 for Crohn's disease and INN-329 for magnetic resonance cholangiopancreatography, or MRCP. INN-202 has successfully completed Phase 2 trials; however, Phase 3 pivotal studies and open label safety studies remain to be conducted. We will need to prepare for INN-108 to enter Phase 2 efficacy trials for mild to moderate ulcerative colitis. INN-329 requires additional studies to be performed for completion of Phase 3 trials. INN-217 and INN-289 require pre-clinical studies followed by clinical trials.

Clinical testing is expensive and can take many years to complete. The outcome of this testing 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 preclinical studies and early clinical trials of our product candidates may not necessarily 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 preclinical studies and initial clinical trials. Many 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.

Because of the developmental nature of our product candidates, we are subject to risks associated with initiating, completing and achieving positive outcomes from our current and future clinical trials, including:

- inability to enroll enough patients in the clinical trials;
- slow implementation, enrollment and completion of the clinical trials;
- low patient compliance and adherence to dosing and reporting requirements, such as incomplete reporting of patient reported outcomes in the clinical trials or missed doses;
- lack of safety and efficacy in the clinical trials;
- delays in the manufacture of supplies for drug components due to delays in formulation, process development, or manufacturing activities;
- requirements for additional nonclinical or clinical studies based on changes to formulation and/or changes to regulatory requirements; and
- requirements for additional clinical studies based on inconclusive clinical results or changes in market, standard of care, and/or regulatory requirements.

If we successfully complete the necessary clinical trials for our product candidates, our success will be subject to the risks associated with obtaining regulatory approvals, product launch, and commercialization, including:

- delays during regulatory review and/or requirements for additional chemistry, manufacturing and controls, or nonclinical or clinical studies, resulting in increased costs and/or delays in marketing approval and subsequent commercialization of our product candidates in the United States and other markets;
- FDA rejection of our New Drug Application, or NDA, submissions for our product candidates;
- regulatory rejection in the European Union, Japan, and other markets;
- inability to consistently manufacture commercial supplies of drug and delivery devices resulting in slowed market development and lower revenue;
- inability to enforce our intellectual property rights in and to our product candidates;
- reduction in the safety profile of our product candidates following approval; and
- poor commercial sales due to:
  * the ability of our future sales organization or our potential commercialization partners to effectively sell our product candidates;
  * lack of success in educating physicians and patients about the benefits, administration, and use of our product candidates;
  * low patient demand for our product candidates;
  * the availability, perceived advantages, relative cost, relative safety and relative efficacy of other products or treatments for the targeted indications of our product candidates; and
  * poor prescription coverage and inadequate reimbursement for our product candidates.

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 provide any assurances that we will be able to advance our product candidates further through final clinical development or obtain regulatory approval of, commercialize or generate significant revenue from them. If we cannot do so, or are significantly delayed in doing so, our business will be materially harmed.

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.

We have historically operated with a limited number of employees. We currently have eight full-time employees, including two employees engaged full-time and one employee engaged part-time in research and development. Therefore,

institutional knowledge is concentrated within a small number of employees. Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. Our future success is highly dependent upon the contributions of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, completion of our planned clinical trials or the commercialization of our product candidates.

We may have intense competition from other companies and organizations for qualified personnel. Other companies and organizations with which we compete for personnel may have greater financial and other resources and different risk profiles than we do, and a history of successful development and commercialization of their product candidates. Replacing key employees may be difficult and costly; and we may not have other personnel with the capacity to assume all the responsibilities of a key employee upon his or her departure. If we cannot attract and retain skilled personnel, as needed, we may not achieve our development and other goals.

In addition, the success of our business will depend on our ability to develop and maintain relationships with respected service providers and industry-leading consultants and advisers. If we cannot develop and maintain such relationships, as needed, the rate and success at which we can develop and commercialize product candidates may be limited. In addition, our outsourcing strategy, which has included engaging consultants to manage key functional areas, may subject us to scrutiny under labor laws and regulations, which may divert management time and attention and have an adverse effect on our business and financial condition.

Our management team has limited experience managing a public company.

Most members of our management team have limited experience managing a publicly traded company, interacting with public company investors and complying with the increasingly complex laws pertaining to public companies. Our management team may not successfully or efficiently manage our existence as a public company subject to significant regulatory oversight and reporting obligations under the federal securities laws and the continuous scrutiny of securities analysts and investors. These obligations and constituencies require significant attention from our senior management and could divert their attention away from the day-to-day management of our business.

We have identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal control, which may impair our ability to produce accurate financial statements or prevent fraud.

Currently, we have limited resources to address our internal controls and procedures and rely on part-time consultants to assist us with our financial accounting and compliance obligations. In connection with the preparation of our audited financial statements for the years ended December 31, 2017 and 2016, our independent auditors advised management that a material weakness existed in internal controls over financial reporting due to inadequate segregation of duties and appropriate level of review. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the subject company's annual or interim financial statements will not be prevented or detected on a timely basis. Although we are committed to continuing to improve our internal control processes and intend to implement a plan to remediate this material weakness, we cannot be certain of the effectiveness of such plan or that, in the future, additional material weaknesses or significant deficiencies will not exist or otherwise be discovered. If we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements and prevent fraud. In addition, if we are unable to successfully remediate the material weaknesses in our internal controls or if we are unable to produce accurate and timely financial statements, our stock price may be adversely affected, and we may be unable to maintain compliance with applicable stock exchange listing requirements.

Our employees, independent contractors and consultants, principal investigators, clinical research organizations, contract manufacturing organizations and other vendors, and any future commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk that our employees, independent contractors and consultants, principal investigators, clinical research organizations, or CROs, contract manufacturing organizations, or CMOs, and other vendors, and any future commercial partners may engage in fraudulent conduct or other misconduct. This type of misconduct may include intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, to provide accurate information to the FDA or comparable foreign regulatory authorities, to comply with manufacturing standards required by Current Good Manufacturing Practices, or cGMP, or our standards, to comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, and to report financial information or data accurately or disclose unauthorized

activities to them. The misconduct of our employees and other of our service providers could 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 ethics and conduct, but it is not always possible to identify and deter such misconduct, and the precautions we take to detect and prevent this activity, such as the implementation of a quality system which entails vendor audits by quality experts, 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 or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

We do not have, and do not have plans to establish, manufacturing facilities. We completely rely on third parties for the manufacture and supply of our clinical trial drug supplies and, if approved, commercial product materials. The loss of any of these vendors or a vendor's failure to provide us with an adequate supply of clinical trial or commercial product material in a timely manner and on commercially acceptable terms, or at all, could harm our business.

We outsource the manufacture of our product candidates and do not plan to establish our own manufacturing facilities. To manufacture our product candidates, we have made numerous custom modifications at CMOs, making us highly dependent on these CMOs. For clinical and commercial supplies, if approved, we have or plan to have supply agreements with third party CMOs for drug substance and finished drug product. While we have existing supply agreements with third party CMOs, we would need to negotiate agreements for commercial supply with several important CMOs, and we may not be able to reach agreement on acceptable terms. In addition, we rely on these third parties to conduct or assist us in key manufacturing development activities, including qualification of equipment, developing and validating methods, defining critical process parameters, releasing component materials and conducting stability testing, among other things. If these third parties are unable to perform their tasks successfully in a timely manner, whether for technical, financial or other reasons, we may be unable to secure clinical trial material, or commercial supply material if approved, which likely would delay the initiation, conduct or completion of our clinical studies or prevent us from having enough commercial supply material for sale, which would have a material and adverse effect on our business.

Currently, we do not have alternative vendors to back up our primary vendors of clinical trial material or, if approved, commercial supply material. Identification of and discussions with other vendors may be protracted and/or unsuccessful, or these new vendors may be unsuccessful in producing the same results as the current primary vendors producing the material. Therefore, if our primary vendors become unable or unwilling to perform their required activities, we could experience protracted delays or interruptions in the supply of clinical trial material and, ultimately, product for commercial sale, which would materially and adversely affect our development programs, commercial activities, operating results and financial condition. In addition, the FDA or regulatory authorities outside of the United States may require us to have an alternate manufacturer of a drug product before approving it for marketing and sale in the United States or abroad and securing such alternate manufacturer before approval of an NDA could result in considerable additional time and cost prior to approval.

Any new manufacturer or supplier of finished drug product or our component materials, including drug substance and delivery devices, would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing of such product or ingredients required by us. The FDA or foreign regulatory agency may require us to conduct additional clinical studies, collect stability data and provide additional information concerning any new supplier, or change in a validated manufacturing process, including scaling-up production, before we could distribute products from that manufacturer or supplier or revised process. For example, if we were to engage a third party other than our current CMOs to supply the drug substance or drug product for future clinical trial, or commercial product, the FDA or regulatory authorities outside of the United States may require us to conduct additional clinical and nonclinical studies to ensure comparability of the drug substance or drug product manufactured by our current CMOs to that manufactured by the new supplier.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling-up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, and shortages of qualified personnel. Our product candidates have not been manufactured at the scale we believe will be necessary to maximize their commercial value, and accordingly, we may encounter difficulties in attempting to scale-up production and may not succeed in that effort on a timely basis or at all. In addition, the FDA or other regulatory authorities may impose additional requirements as we scale-up initial production capabilities, which may delay our scale-up activities and/or add expense.

All manufacturers of our clinical trial material and, if approved, commercial product, including drug substance manufacturers, must comply with cGMP requirements enforced by the FDA through its facilities inspection program and applicable requirements of foreign regulatory authorities. These requirements include quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our clinical trial material may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. While we or our representatives generally monitor and audit our manufacturers' systems, we do not have full control over their ongoing compliance with these regulations. And while the responsibility to maintain cGMP compliance is shared between the third-party manufacturer and us, we bear ultimate responsibility for our supply chain and compliance with regulatory standards. Failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay or failure to obtain product approval, product seizure or recall, or withdrawal of product approval.

If our manufacturers encounter any of the aforementioned difficulties or otherwise fail to comply with their contractual obligations or there are delays entering commercial supply agreements due to capital constraints, we may have insufficient quantities of material to support ongoing and/or planned clinical studies or to meet commercial demand, if approved. In addition, any delay or interruption in the supply of materials necessary or useful to manufacture our product candidates could delay the completion of our clinical studies, increase the costs associated with our development programs and, depending upon the period of delay, require us to commence new clinical studies at significant additional expense or terminate the studies completely. Delays or interruptions in the supply of commercial product could result in increased cost of goods sold and lost sales. We cannot provide assurance that manufacturing or quality control problems will not arise in connection with the manufacture of our clinical trial material or commercial product, if approved, or that third-party manufacturers will be able to maintain the necessary governmental licenses and approvals to continue manufacturing such clinical trial material or commercial product, as applicable. In addition, if our products are manufactured entirely or partially outside the United States, we may experience interruptions in supply due to shipping or customs difficulties or regional instability. Furthermore, changes in currency exchange rates, shipping costs and import tariffs could adversely affect our cost of goods sold. Any of the above factors could cause us to delay or suspend anticipated or ongoing trials, regulatory submissions or commercialization of our product candidates, entail higher costs or result in us being unable to effectively commercialize our products. Our dependence upon third parties for the manufacture of our clinical trial material may adversely affect our future costs and our ability to develop and commercialize our product candidates on a timely and competitive basis.

We currently rely significantly on third parties to conduct our nonclinical testing and clinical studies and other aspects of our development programs. If those third parties do not satisfactorily perform their contractual obligations or meet anticipated deadlines, the development of our product candidates could be adversely affected.

We do not currently employ personnel or possess the facilities necessary to conduct many of the activities associated with our programs. We engage consultants, advisors, CROs, and others to assist in the design and conduct of nonclinical and clinical studies of our product candidates, with interpretation of the results of those studies and with regulatory activities, and expect to continue to outsource all or a significant amount of such activities. As a result, many important aspects of our development programs are and will continue to be outside our direct control, and our third-party service providers may not perform their activities as required or expected including the maintenance of Good Clinical Practices, or GCP, Good Laboratory Practices, or GLP, and Good Manufacturing Practices, or GMP, compliance, which are ultimately our responsibility to ensure. Further, such third parties may not be as committed to the success of our programs as our own employees and, therefore, may not devote the same time, thoughtfulness or creativity to completing projects or problem-solving as our own employees would. To the extent we are unable to successfully manage the performance of third-party service providers, our business may be adversely affected.

The CROs that we engage or may engage to execute our clinical studies play a significant role in the conduct of the studies, including the collection and analysis of study data, and we likely will depend on CROs and clinical investigators to conduct future clinical studies and to assist in analyzing data from completed studies and developing regulatory strategies for our product candidates. Individuals working at the CROs with which we contract, as well as investigators at the sites at which our studies are conducted, are not our employees, and we have limited control over the amount or timing of resources that they devote to their programs. If our CROs, study investigators, and/or third-party sponsors fail to devote sufficient time and resources to studies of our product candidates, if we and/or our CROs do not comply with all GLP and GCP regulatory and contractual requirements, or if their performance is substandard, it may delay commencement and/or completion of these studies, submission of applications for regulatory approval, regulatory approval, and commercialization of our product candidates. Failure of CROs to meet their obligations to us could adversely affect the development of our product candidates.

In addition, the CROs we engage may have relationships with other commercial entities, some of which may compete with us. Through intentional or unintentional means, our competitors may benefit from lessons learned on the project

that could ultimately harm our competitive position. Moreover, if a CRO fails to properly, or at all, perform our activities during a clinical study, we may not be able to enter into arrangements with alternative CROs on acceptable terms or in a timely manner, or at all. Switching CROs may increase costs and divert management time and attention. In addition, there likely would be a transition period before a new CRO commences work. These challenges could result in delays in the commencement or completion of our clinical studies, which could materially impact our ability to meet our desired and/or announced development timelines and have a material adverse impact on our business and financial condition.

We may not achieve our projected development goals within the time frames that we have announced.

We have set goals for accomplishing certain objectives material to the successful development of our product candidates. The actual timing of these events may vary due to many factors, including delays or failures in our nonclinical testing, clinical studies and manufacturing and regulatory activities and the uncertainties inherent in the regulatory approval process. From time to time, we create estimates for the completion of enrollment of or announcement of data from clinical studies of our product candidates. However, predicting the rate of enrollment or the time from completion of enrollment to announcement of data for any clinical study requires us to make significant assumptions that may prove to be incorrect. As discussed in other risk factors above, our estimated enrollment rates and the actual rates may differ materially, and the time required to complete enrollment of any clinical study may be considerably longer than we estimate. Such delays may adversely affect our business, financial condition and results of operations.

Even if we complete a clinical study with successful results, we may not achieve our projected development goals within the periods we initially anticipate or announce. If a development plan for a product candidate becomes more extensive and costly than anticipated, we may determine that the associated time and cost are not financially justifiable and, as a result, may discontinue development in a particular indication or of the product candidate as a whole. In addition, even if a study did complete with successful results, changes may occur in regulatory requirements or policy during the period of product development and/or regulatory review of an NDA that relate to the data required to be included in NDAs which may require additional studies that may be costly and time consuming. Any of these actions may be viewed negatively, which could adversely impact our business, financial condition and results of operations.

Further, throughout development, we must provide adequate assurance to the FDA and other regulatory authorities that we can consistently develop and produce our product candidates in conformance with GLP, GCP, cGMP, and other regulatory standards. As discussed above, we rely on CMOs for the manufacture of clinical, and future commercial, quantities of our product candidates. If future FDA or other regulatory authority inspections identify cGMP compliance deficiencies at these third-party facilities, production of our clinical trial material or, in the future, commercial product, could be disrupted, causing potentially substantial delay in or failure of development or commercialization of our product candidates.

We currently have limited marketing capabilities and no sales organization. If we are unable to establish sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize our products, if approved, or generate product revenue.

To commercialize our products, if approved, in the United States and other jurisdictions we seek approvals, we must build our marketing, sales, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If our products receive regulatory approval, we expect to market such products in the United States through a focused, specialized sales force, which will be costly and time consuming. We have no prior experience in the marketing and sale of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain 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. Outside of the United States, we may consider collaboration arrangements. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our products in certain markets. Any failure or delay in the development of 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 collaborations with one or more third parties, our future product revenue will suffer, and we would incur significant additional losses.

To establish a sales and marketing infrastructure and expand our manufacturing capabilities, we will need to increase the size of our organization, and we may experience difficulties in managing this growth.

We currently have eight full-time employees, including two employees engaged full-time and one employee engaged part-time in research and development. As we advance our product candidates through the development process and to commercialization, we will need to continue 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. As 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 anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. In addition, the physical expansion of our operations may lead to significant costs and may divert our management and resources. 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.

Our product candidates may cause undesirable side effects or adverse events, or have other properties that could delay or prevent their clinical development, regulatory approval or commercialization.

As with many pharmaceutical products, undesirable side effects or adverse events caused by our product candidates could interrupt, delay or halt clinical studies and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all indications, and in turn prevent us from commercializing our product candidates. If undesirable side effects occur, they could possibly prevent approval, which would have a material and adverse effect on our business.

If any of our product candidates receive marketing approval, and we or others later identify undesirable side effects caused by the product:

- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we may be required to change the way the product is administered, conduct additional clinical studies or change the labeling of the product;
- regulatory authorities may withdraw approval of the product; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating significant revenue from its sale.

Our business and operations would suffer in the event of third-party computer system failures, cyber-attacks on third-party systems or deficiency in our cyber security.

We rely on information technology, or IT, systems, including third-party “cloud based” service providers, to keep financial records, maintain laboratory data, clinical data and corporate records, to communicate with staff and external parties, and to operate other critical functions. This includes critical systems such as email, other communication tools, electronic document repositories, and archives. If any of these third-party information technology providers are compromised due to computer viruses, unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication failures, electrical failures, cyber-attacks or cyber-intrusions over the internet, then sensitive emails or documents could be exposed or deleted. Similarly, we could incur business disruption if our access to the internet is compromised and we are unable to connect with third-party IT providers. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, we rely on those third parties to safeguard important confidential personal data regarding our employees and patients enrolled in our clinical trials. If a disruption event were to occur and cause interruptions in a third-party IT provider’s operations, it could result in a disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned 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 results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and development of our product candidates could be delayed, or could fail.

Risks Related to Drug Development and Commercialization

We depend on the successful completion of clinical studies of our product candidates, and any positive results in prior clinical studies do not ensure that ongoing or future clinical studies will be successful.

Pharmaceutical products are subject to stringent regulatory requirements covering quality, safety and efficacy. The burden of proof is on the manufacturer, such as us, to show with substantial clinical data that the risk/benefit profile for any new drug is favorable. Only after successfully completing extensive pharmaceutical development, nonclinical testing and clinical studies may a product be considered for regulatory approval.

If we license rights to develop our product candidates to independent third parties or otherwise permit such third parties to evaluate our product candidates in clinical studies, we may have limited control over those clinical studies. Any safety or efficacy concern identified in a third-party sponsored study could adversely affect our or another licensee's development of our product candidate and prospects for our regulatory approval, even if the data from that study are subject to varying interpretations and analyses.

There is significant risk that ongoing and future clinical studies of our product candidates are or will be unsuccessful. Negative or inconclusive results could cause the FDA and other regulatory authorities to require us to repeat or conduct additional clinical studies, which could significantly increase the time and expense associated with development of that product candidate or cause us to elect to discontinue one or more clinical programs. Failure to complete a clinical study of a product candidate or an unsuccessful result of a clinical study could have a material adverse effect on our business.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug candidates.

Clinical studies are expensive, difficult to design and implement, may take many years to complete, and outcomes are inherently uncertain. A drug product may fail to demonstrate positive results at any stage of testing despite having progressed satisfactorily through nonclinical testing and initial clinical studies. There is significant risk in clinical development where later stage clinical studies are designed and powered based on the analysis of data from earlier studies, with these earlier studies involving a smaller number of patients, and the results of the earlier studies being driven primarily by a subset of responsive patients. In addition, interim results of a clinical study do not necessarily predict final results. Further, clinical study data frequently are susceptible to varying interpretations. Medical professionals and/or regulatory authorities may analyze or weigh study data differently than the sponsor company, resulting in delay or failure to obtain marketing approval for a product candidate. Additionally, the possible lack of standardization across multiple investigative sites may induce variability in the results, which can interfere with the evaluation of treatment effects.

Delays in commencement and completion of clinical studies are common and have many causes. Delays in clinical studies of our product candidates could increase overall development costs and jeopardize our ability to obtain regulatory approval and successfully commercialize any approved products.

Clinical studies may not commence on time or be completed on schedule, if at all. The commencement and completion of clinical studies can be delayed for a variety of reasons, including:

- inability to raise sufficient funding to initiate or to continue a clinical study;
- delays in obtaining regulatory approval to commence a clinical study;
- delays in identifying and reaching agreement on acceptable terms with prospective CROs and clinical study sites and investigators, which agreements can be subject to extensive negotiation and may vary significantly among study sites;
- delays in obtaining regulatory approval in a prospective country;
- delays in obtaining ethics committee approval to conduct a clinical study at a prospective site;
- delays in reaching agreements on acceptable terms with prospective CMOs or other vendors for the production and supply of clinical trial material and, if necessary, drug administration devices, which agreements can be subject to extensive negotiation;
- delays in the production or delivery of sufficient quantities of clinical trial material from our CMOs and other vendors to initiate or continue a clinical study;
- delays due to product candidate recalls as a result of stability failure, excessive product complaints or other failures of the product candidate during its use or testing;
- invalidation of clinical data caused by premature unblinding or integrity issues;

- invalidation of clinical data caused by mixing up of the active drug and placebo through randomization or manufacturing errors;
- delays on the part of our CROs, CMOs and other third-party contractors in developing procedures and protocols or otherwise conducting activities in accordance with applicable policies and procedures and in accordance with agreed upon timelines;
- delays in identifying and hiring or engaging, as applicable, additional employees or consultants to assist in managing clinical study-related activities;
- delays in recruiting and enrolling individuals to participate in a clinical study, which historically can be challenging in orphan diseases;
- delays caused by patients dropping out of a clinical study due to side effects, concurrent disorders, difficulties in adhering to the study protocol, unknown issues related to different patient profiles than in previous studies, or otherwise;
- delays in having patients complete participation in a clinical study, including returning for post-treatment follow-up;
- delays resulting from study sites dropping out of a trial, providing inadequate staff support for the study, problems with shipment of study supplies to clinical sites, or focusing our staff's efforts on enrolling studies that compete for the same patient population;
- suspension of enrollment at a study site or the imposition of a clinical hold by the FDA or other regulatory authority following an inspection of clinical study operations at study sites or finding of a drug-related serious adverse event; and
- delays in quality control/quality assurance procedures necessary for study database lock and analysis of unblinded data.

We may experience difficulties in the enrollment of patients in our clinical trials, which may delay or prevent us from obtaining regulatory approval.

We may not be able to continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In particular, some of our competitors have ongoing clinical trials for drug candidates that treat the same indications as our drug candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' drug candidates.

Patient enrollment, a critical component to successful completion of a clinical study, is affected by many factors, including:

- the size of the target patient population;
- other ongoing studies competing for the same patient population;
- the eligibility criteria for the clinical trial;
- the design of the clinical study;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the proximity and availability of clinical trial sites for prospective patients; and
- the ability to monitor patients adequately during and after treatment.

Clinical studies may not begin on time or be completed in the time frames we anticipate. The length of time necessary to successfully complete clinical studies varies significantly and is difficult to predict accurately. We may make statements regarding anticipated timing for completion of enrollment in and/or availability of results from our clinical studies, but such predictions are subject to a number of significant assumptions and actual timing may differ materially for a variety of reasons, including patient enrollment rates, length of time needed to prepare raw study data for analysis and then to review and analyze it, and other factors described above. If we experience delays in the completion of a clinical study, if a clinical study is terminated, or if failure to conduct a study in accordance with regulatory requirements or the study's protocol leads to deficient safety and/or efficacy data, the regulatory approval and/or commercial prospects for our product candidates may be harmed and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical studies likely will increase our development costs. Further, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical studies may ultimately lead to the denial of regulatory approval of a product candidate. Even if we ultimately commercialize our product candidates, the standard of care may have changed or other therapies for the same indications may have been introduced to the market in the interim and may establish a competitive threat to us or may diminish the need for our products.

Clinical studies are very expensive, difficult to design and implement, often take many years to complete, and the outcome is inherently uncertain.

Clinical development of pharmaceutical products for humans is generally very expensive and takes many years to complete. Failures can occur at any stage of clinical testing. We estimate that clinical development of our product candidates will take several additional years to complete, but because of the variety of factors that can affect the design, timing, and outcome of clinical studies, we are unable to estimate the exact funds required to complete research and development, to obtain regulatory approval and to commercialize all of our product candidates. We will need significant additional capital to continue to advance our product candidates pursuant to our current development and commercialization plans.

Failure at any stage of clinical testing is not uncommon, and we may encounter problems that would require additional, unplanned studies or cause us to abandon a clinical development program.

In addition, a clinical study may be suspended or terminated by us, an institutional review board, or IRB, a data safety monitoring board, the FDA or other regulatory authorities due to a number of factors, including:

- lack of adequate funding to continue the study;
- failure to conduct the study in accordance with regulatory requirements or the study's protocol;
- inspection of clinical study operations or sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues, including adverse side effects; or
- changes in governmental regulations or administrative actions.

Changes in governmental regulations and guidance relating to clinical studies may occur, and we may need to amend study protocols to reflect these changes, or we may amend study protocols for other reasons. Amendments may require us to resubmit protocols to IRBs for reexamination and approval or renegotiate terms with CROs, study sites and investigators, all of which may adversely impact the costs or timing of or our ability to successfully complete a trial.

Use of our proprietary patient-reported outcome measure, CeD PRO, in our Phase 3 clinical trials of larazotide acetate for the treatment of celiac disease may adversely impact our ability to achieve a positive result from these clinical trials.

Patient-reported outcome assessments, or PROs, involve patients' subjective assessments of efficacy, and this subjectivity can increase the uncertainty of clinical trial outcomes. Such assessments can be influenced by a number of factors and can vary widely from day to day for a particular patient, and from patient to patient and site to site within a clinical trial, leading to high variability in PRO measurements.

The variability of PRO measures and high placebo response rates could adversely impact our Phase 3 clinical trials of larazotide acetate for celiac disease. The variability of a PRO measure can complicate clinical trial design, adversely impact the ability of a study to show a statistically significant improvement, and generally adversely impact a clinical development program by introducing additional uncertainties.

There is significant uncertainty regarding the regulatory approval process for any investigational new drug, substantial further testing and validation of our product candidates and related manufacturing processes may be required, and regulatory approval may be conditioned, delayed or denied, any of which could delay or prevent us from successfully marketing our product candidates and substantially harm our business.

Pharmaceutical products generally are subject to rigorous nonclinical testing and clinical studies and other approval procedures mandated by the FDA and foreign regulatory authorities. Various federal and foreign statutes and regulations also govern or materially influence the manufacturing, safety, labeling, storage, record keeping and marketing of pharmaceutical products. The process of obtaining these approvals and the subsequent compliance with appropriate U.S. and foreign statutes and regulations is time-consuming and requires the expenditure of substantial resources.

We are preparing INN-202, larazotide acetate, for Phase 3 clinical trials, the success of which will be needed for FDA approval to market INN-202 in the United States to treat celiac disease in patients with persistent symptoms while adhering to a gluten free diet. While significant communication with the FDA on the Phase 3 study design has occurred, even if the Phase 3 clinical study meets all of its statistical goals and protocol end points, the FDA may not view the results as robust and convincing and may require additional clinical studies and/or other costly studies, which could require us to expend substantial additional resources and could significantly extend the timeline for clinical development prior to market approval. Additionally, we are required by the FDA to conduct a long-term safety study on INN-202. The results of this study will not be known until a short time prior to potential submission of an NDA for INN-202. If the

safety study cannot be completed for technical or other reasons, or provides results that the FDA determines to be concerning, this may cause a delay or failure in obtaining approval for INN-202. We are conducting pre-clinical work for INN-217 in NASH and INN-289 in Crohn's disease to prepare for future clinical proof-of-concept trials.

We may make formulation changes to INN-108 that would simplify the dosing in pediatric patients. While this change is expected by us to reduce studies and/or other documentation requirements, the regulatory agencies may require additional clinical or nonclinical studies prior to approval, even if current clinical studies are deemed successful, which could require us to expend substantial additional resources and significantly extend the timeline for clinical development of INN-108.

We intend to prepare INN-329, secretin, for additional testing in its Phase 3 clinical trial, the success of which will be needed for FDA approval to market INN-329 in the United States for MRCP procedures. While significant communication with the FDA on the Phase 3 study design has occurred in the past, we will be required to initiate communication with the FDA to finalize the study design and to seek its approval for the additional Phase 3 trial design. Even if the Phase 3 clinical study meets all of its statistical goals and protocol end points, the FDA may not view the results as robust and convincing. The FDA may require additional clinical studies and/or other costly studies, which could require us to expend substantial additional resources and could significantly extend the timeline for clinical development prior to market approval. Additionally, we are required by the FDA to conduct a long-term safety study on INN-329. The results of this study will not be known until a short time prior to potential submission of an NDA for INN-329. If the safety study cannot be completed for technical or other reasons, or provides results that the FDA determines to be concerning, this may cause a delay or failure in obtaining approval for INN-329.

Significant uncertainty exists with respect to the regulatory approval process for any investigational new drug, including INN-202, INN-217, INN-108, INN-289 and INN-329. Regardless of any guidance the FDA or foreign regulatory agencies may provide a drug's sponsor during its development, the FDA or foreign regulatory agencies retain complete discretion in deciding whether to accept an NDA or the equivalent foreign regulatory approval submission for filing or, if accepted, approve an NDA. There are many components to an NDA or marketing authorization application submission in addition to clinical study data. For example, the FDA or foreign regulatory agencies will review the sponsor's internal systems and processes, as well as those of its CROs, CMOs and other vendors, related to development of its product candidates, including those pertaining to its clinical studies and manufacturing processes. Before accepting an NDA for review or before approving the NDA, the FDA or foreign regulatory agencies may request that we provide additional information that may require significant resources and time to generate and there is no guarantee that its product candidates will be approved for any indication for which we may apply. The FDA or foreign regulatory agencies may choose not to approve an NDA for any of a variety of reasons, including a decision related to the safety or efficacy data, manufacturing controls or systems, or for any other issues that the agency may identify related to the development of its product candidates. Even if one or more Phase 3 clinical studies are successful in providing statistically significant evidence of the efficacy and safety of the investigational drug, the FDA or foreign regulatory agencies may not consider efficacy and safety data from the submitted studies adequate scientific support for a conclusion of effectiveness and/or safety and may require one or more additional Phase 3 or other studies prior to granting marketing approval. If this were to occur, the overall development cost for the product candidate would be substantially greater and our competitors may bring products to market before we do, which could impair our ability to generate revenues from the product candidates, or even seek approval, if blocked by a competitor's Orphan Drug exclusivity, which would have a material adverse effect on our business, financial condition and results of operations.

Further, development of our product candidates and/or regulatory approval may be delayed for reasons beyond our control. For example, a U.S. federal government shut-down or budget sequestration, such as ones that occurred during 2013 and 2018, may result in significant reductions to the FDA's budget, employees and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates.

Even if the FDA or foreign regulatory agencies grant approvals for our product candidates, the conditions or scope of the approval(s) may limit successful commercialization of the product candidates and impair our ability to generate substantial sales revenue. The FDA or foreign regulatory agencies may also only grant marketing approval contingent on the performance of costly post-approval nonclinical or clinical studies, or subject to warnings or contraindications that limit commercialization. Additionally, even after granting approval, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for our products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, and continued compliance with cGMP, good clinical practices, regulations of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use and good laboratory practices, which are regulations and guidelines that are enforced by the FDA or foreign regulatory

agencies for all of our clinical development and for any clinical studies that we conduct post-approval. The FDA or foreign regulatory agencies may decide to withdraw approval, add warnings or narrow the approved indications in the product label, or establish risk management programs that could restrict distribution of our products. These actions could result from, among other things, safety concerns, including unexpected side effects or drug-drug interaction problems, or concerns over misuse of a product. If any of these actions were to occur following approval, we may have to discontinue commercialization of the product, limit our sales and marketing efforts, implement risk minimization procedures, and/or conduct post-approval studies, which in turn could result in significant expense and delay or limit our ability to generate sales revenues.

Regulations may be changed prior to submission of an NDA that require higher hurdles than currently anticipated. These may occur as a result of drug scandals, recalls, or a political environment unrelated to our products.

Even if we receive regulatory approval for a product candidate, we may face regulatory difficulties that could materially and adversely affect our business, financial condition and results of operations.

Even if initial regulatory approval is obtained, as a condition to the initial approval the FDA or a foreign regulatory agency may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or marketing surveillance programs, any of which would limit the commercial potential of the product. Our product candidates also will be subject to ongoing FDA requirements related to the manufacturing processes, labeling, packaging, storage, distribution, advertising, promotion, record-keeping and submission of safety and other post-market information regarding the product. For instance, the FDA may require changes to approved drug labels, require post-approval clinical studies and impose distribution and use restrictions on certain drug products. In addition, approved products, manufacturers and manufacturers' facilities are subject to continuing regulatory review and periodic inspections. If previously unknown problems with a product are discovered, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, the FDA may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If one of our CMOs or we fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- impose civil or criminal penalties;
- suspend or terminate any ongoing clinical studies;
- close the facilities of a CMO;
- refuse to approve pending applications or supplements to approved applications;
- suspend or withdraw regulatory approval;
- exclude our product from reimbursement under government healthcare programs, including Medicaid or Medicare;
- impose restrictions or affirmative obligations on our or our CMOs' operations, including costly new manufacturing requirements; or
- seize or detain products or require a product recall.

If any of our product candidates for which we receive regulatory approval fails to achieve significant market acceptance among the medical community, patients or third-party payers, the revenue we generate from our sales will be limited and our business may not be profitable.

Our success will depend in substantial part on the extent to which our product candidates, if approved, are accepted by the medical community and patients and reimbursed by third-party payers, including government payers. We cannot predict with reasonable accuracy whether physicians, patients, healthcare insurers or health maintenance organizations, or the medical community in general, will accept or utilize any of our products, if approved. If our product candidates are approved but do not achieve an adequate level of acceptance by these parties, we may not generate sufficient revenue to become or to remain profitable. In addition, our efforts to educate the medical community and third-party payers regarding the benefits of our products may require significant resources and may never be successful.

The degree of market acceptance with respect to each of our approved products, if any, will depend upon a number of factors, including:

- the safety and efficacy of our product as demonstrated in clinical studies;
- acceptance in the medical and patient communities of our product as a safe and effective treatment;
- the perceived advantages of our product over alternative treatments, including with respect to the incidence and severity of any adverse side effects and the cost of treatment;

- the indications for which our product is approved;
- claims or other information (including limitations or warnings) in our product's approved labeling;
- reimbursement and coverage policies of government and other third-party payers;
- smaller than expected market size due to lack of disease awareness of a rare disease, or the patient population with a specific rare disease being smaller than anticipated;
- availability of alternative treatments;
- pricing and cost-effectiveness of our product relative to alternative treatments;
- inappropriate diagnostic efforts due to limited knowledge and/or resources among clinicians;
- the prevalence of off-label substitution of chemically equivalent products or alternative treatments; and
- the resources we devote to marketing our product and restrictions on promotional claims we can make with respect to the product.

If we determine that a product candidate may not achieve adequate market acceptance or that the potential market size does not justify additional expenditure on the program, we may reduce our expenditures on the development and/or the process of seeking regulatory approval of the product candidate while we evaluate whether and on what timeline to move the program forward.

Even if we receive regulatory approval to market one or more of our product candidates in the United States, we may never receive approval or commercialize our products outside of the United States, which would limit our ability to realize the full commercial potential of our product candidates.

In order to market products outside of the United States, we must establish and comply with the numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. The time required to obtain approval in other countries generally differs from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States, as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the United States. As described above, such effects include the risks that our product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and have an adverse effect on product sales, and that such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

Conversely, even if our product candidates receive approval outside the United States in the future, we may still be unable to meet the FDA requirements necessary for approval in the United States.

We must comply with the U.S. Foreign Corrupt Practices Act and similar foreign anti-corruption laws.

The U.S. Foreign Corrupt Practices Act, to which we are subject, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. Other countries, such as the United Kingdom, have similar laws with which we must comply. We face the risk that an employee or agent could be accused of violating one or more of these laws, particularly in geographies where significant overlap exists between local government and healthcare industries. Such an accusation, even if unwarranted, could prove disruptive to our developmental and commercialization efforts.

We may expend our limited resources to pursue a particular product candidate or indication in lieu of other opportunities and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we intend to focus on developing product candidates for specific indications that we identify as most likely to succeed, in terms of their potential both to gain regulatory approval and to achieve commercialization. As a result, we may forego or delay pursuit of opportunities with other product candidates or in other indications with greater commercial potential. We currently intend to focus our limited financial and managerial resources on developing our lead program, INN-202, for the treatment of celiac disease and INN-217 for the treatment of NASH and intend to use the net proceeds from this offering to, among other things, fund the Phase 3 registration trials of INN-202. As a result, we may allocate fewer resources to the other product candidates in our

pipeline, including INN-108, and we may be required to seek additional sources of financing to pursue further development of such other product candidates.

Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the product candidate.

Risks Related to Our Intellectual Property

Our success will depend in part on obtaining and maintaining effective patent and other intellectual property protection for our product candidates and proprietary technology.

We rely on patents and other intellectual property to maintain exclusivity for our product candidates. INN-202 and INN-108 are covered by several issued patents in the U.S., issued patents outside the U.S., and with patent applications pending in several jurisdictions. INN-329 is not protected by patents. Intellectual property relating to the INN-202 program is exclusively licensed from Alba Therapeutics Corp. Intellectual property relating to INN-108 program is exclusively licensed from Seachaid Pharmaceuticals Inc. There are two pending patent applications relating to INN-217 based on Innovate's internal developments.

Our success will depend in part on our ability to:

- obtain and maintain patents and other exclusivity with respect to our products;
- prevent third parties from infringing upon our proprietary rights;
- maintain proprietary know-how and trade secrets;
- operate without infringing upon the patents and proprietary rights of others; and
- obtain and maintain appropriate licenses to patents or proprietary rights held by third parties if infringement would otherwise occur or if necessary to secure exclusive rights to them, both in the United States and in foreign countries.

The patent and intellectual property positions of biopharmaceutical companies generally are highly uncertain, involve complex legal and factual questions, and have been and continue to be the subject of much litigation. There is no guarantee that we have or will develop or obtain the rights to products or processes that are patentable, that patents will issue from any pending applications or that claims issued will be sufficient to protect the technology we develop or have developed or that is used by us, our CMOs or our other service providers. In addition, any patents that are issued and/or licensed to us may be limited in scope or challenged, invalidated, infringed or circumvented, including by our competitors, and any rights we have under issued and/or licensed patents may not provide competitive advantages to us. If competitors can develop and commercialize technology and products similar to ours, our ability to successfully commercialize our technology and products may be impaired.

Patent applications in the United States are confidential for a period of time until they are published, and publication of discoveries in scientific or patent literature typically lags actual discoveries by several months. As a result, we cannot be certain that the inventors listed in any patent or patent application owned or licensed by us were the first to conceive of the inventions covered by such patents and patent applications (for U.S. patent applications filed before March 16, 2013), or that such inventors were the first to file patent applications for such inventions outside the United States and, after March 15, 2013, in the United States. In addition, changes in or different interpretations of patent laws in the United States and foreign countries may affect our patent rights and limit the patents we can obtain, which could permit others to use our discoveries or to develop and to commercialize our technology and products without any compensation to us.

We also rely on unpatented know-how and trade secrets and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, through confidentiality agreements with employees, consultants, collaborators and others. We also have invention or patent assignment agreements with our employees and certain consultants. The steps we have taken to protect our proprietary rights, however, may not be adequate to preclude misappropriation of or otherwise protect our proprietary information or prevent infringement of our intellectual property rights, and we may not have adequate remedies for any such misappropriation or infringement. In addition, it is possible that inventions relevant to our business could be developed by a person not bound by an invention assignment agreement with us or independently discovered by a competitor.

We also intend to rely on regulatory exclusivity for protection of our product candidates, if approved for commercial sale. Implementation and enforcement of regulatory exclusivity, which may consist of regulatory data protection and market protection, varies widely from country to country. Failure to qualify for regulatory exclusivity, or failure to obtain or to maintain the extent or duration of such protections that we expect for our product candidates, if approved, could affect our decision on whether to market the products in a particular country or countries or could otherwise have an adverse impact on our revenue or results of operations.

We may rely on trademarks, trade names and brand names to distinguish our products, if approved for commercial sale, from the products of our competitors. However, our trademark applications may not be approved. Third parties may also oppose our trademark applications or otherwise challenge our use of the trademarks, in which case we may expend substantial resources to defend our proposed or approved trademarks and may enter into agreements with third parties that may limit our use of our trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote significant resources to advertising and marketing these new brands. Further, our competitors may infringe our trademarks or we may not have adequate resources to enforce our trademarks.

If we fail to comply with our obligations under any license, collaboration or other agreements, we could lose intellectual property rights that are necessary for developing and commercializing our product candidates.

Our intellectual property relating to the INN-202 program is licensed from Alba Therapeutics Corp. Our intellectual property relating to the INN-108 program is licensed from Seachaid Pharmaceuticals Inc. Our license agreements with Alba and Seachaid impose, and any future licenses or collaboration agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, patent prosecution and enforcement, and other obligations on us. These type of agreements and related obligations are complex and subject to contractual disputes. If we breach any of these imposed obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages or the licensor may have the right to terminate the license, which could result in our loss of the intellectual property rights and us being unable to develop, manufacture and sell drugs that are covered by the licensed technology.

Our success depends on our ability to prevent competitors from duplicating or developing and commercializing equivalent versions of our product candidates, and intellectual property protection may not be sufficient or effective to exclude this competition.

We have patent protection in the United States and other countries to cover the composition of matter, formulation and method of use for INN-202 and INN-108. However, these patents may not provide us with significant competitive advantages, because the validity, scope, term, or enforceability of the patents may be challenged and, if instituted, one or more of the challenges may be successful. Patents may be challenged in the United States under post-grant review proceedings, inter partes reexamination, ex parte reexamination, or challenged in district court. Any patents issued in foreign jurisdictions may be subjected to comparable proceedings lodged in various foreign patent offices or courts. These proceedings could result in either loss of the patent or loss or reduction in the scope of one or more of the claims of the patent. Even if a patent issues, and is held valid and enforceable, competitors may be able to design around our patent rights, such as by using pre-existing or newly developed technology, in which case competitors may not infringe our issued claims and may be able to market and sell products that compete directly with ours before and after our patents expire.

Further, the INN-202 primary end point is a proprietary patient reported outcome measure (CeD PRO) that is protected by copyright until 2106. However, copyright protection may not be sufficient to exclude others from developing products that compete with INN-202.

The patent prosecution process is expensive and time-consuming. We, and any future licensors and licensees, may not apply for or prosecute patents on certain aspects of our product candidates at a reasonable cost, in a timely fashion, or at all. We may not have the right to control the preparation, filing and prosecution of some patent applications related to our product candidates or technologies. As a result, these patents and patent applications may not be prosecuted and enforced in a manner consistent with our best interests. It is also possible that we or any future or present 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. Further, it is possible that defects of form in the preparation or filing of our patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, assignment, term or claim scope. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid or unenforceable. In addition, one or more parties may independently develop similar technologies or methods, duplicate our technologies or methods, or design around the patented aspects of our products, technologies or methods. Any of these circumstances could impair our

ability to protect our products, if approved, in ways which may have an adverse impact on our business, financial condition and operating results.

Furthermore, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in and outside of the United States. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to use our patents to stop others from using or commercializing similar or identical products or technology, or to limit the duration of the patent protection of our technology and drugs. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar to or identical to ours.

Enforcement of intellectual property rights in certain countries outside the United States, including China in particular, has been limited or non-existent. Future enforcement of patents and proprietary rights in many other countries will likely be problematic or unpredictable. Moreover, the issuance of a patent in one country does not assure the issuance of a similar patent in another country. Claim interpretation and infringement laws vary by nation, so the extent of any patent protection is uncertain and may vary in different jurisdictions.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the United States Patent and Trademark Office, or the USPTO, and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non-compliance can result in decreased patent term or in abandonment or lapse of the patent or patent application, leading to partial or complete loss of patent rights in the relevant jurisdiction.

Third parties may claim that our products, if approved, infringe on their proprietary rights and may challenge the approved use or uses of a product or our patent rights through litigation or administrative proceedings, and defending such actions may be costly and time consuming, divert management attention away from our business, and result in an unfavorable outcome that could have an adverse effect on our business.

Our commercial success depends on our ability and the ability of our CMOs and component suppliers to develop, manufacture, market and sell our products and product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are or may be developing products. Because patent applications can take many years to publish and issue, there currently may be pending applications, unknown to us, that may later result in issued patents that our products, product candidates or technologies infringe, or that the process of manufacturing our products or any of our respective component materials, or the component materials themselves, infringe, or that the use of our products, product candidates or technologies infringe.

We, our CMOs and/or our component material suppliers may be exposed to, or threatened with, litigation by third parties alleging that our products, product candidates and/or technologies infringe our patents and/or other intellectual property rights, or that one or more of the processes for manufacturing our products or any of our respective component materials, or the component materials themselves, or the use of our products, product candidates or technologies, infringe our patents and/or other intellectual property rights. If a third-party patent or other intellectual property right is found to cover our products, product candidates, technologies or uses, or any of the underlying manufacturing processes or components, we could be required to pay damages and could be unable to commercialize our products or to use our technologies or methods unless we are able to obtain a license to the patent or intellectual property right. A license may not be available to us in a timely manner or on acceptable terms, or at all. In addition, during litigation, the third-party alleging infringement could obtain a preliminary injunction or other equitable remedy that could prohibit us from making, using, selling or importing our products, technologies or methods.

There generally is a substantial amount of litigation involving patent and other intellectual property rights in the industries in which we operate and the cost of such litigation may be considerable. We can provide no assurance that our product candidates or technologies will not infringe patents or rights owned by others, licenses to which may not be available to us in a timely manner or on acceptable terms, or at all. If a third party claims that we or our CMOs or

component material suppliers infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, with or without merit, may be expensive and time consuming to litigate and may divert management's time and attention from our core business;
- substantial damages for infringement, including the potential for treble damages and attorneys' fees, which we may have to pay if it is determined that the product and/or its use at issue infringes or violates the third party's rights;
- a court prohibiting us from selling or licensing the product unless the third-party licenses its intellectual property rights to us, which it may not be required to do;
- if a license is available from the third party, we may have to pay substantial royalties, fees and/or grant cross-licenses to the third party; and
- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial expense and time.

No assurance can be given that patents do not exist, have not been filed, or could not be filed or issued, which contain claims covering our products, product candidates or technology or those of our CMOs or component material suppliers or the use of our products, product candidates or technologies. Because of the large number of patents issued and patent applications filed in the industries in which we operate, there is a risk that third parties may allege they have patent rights encompassing our products, product candidates or technologies, or those of our CMOs or component material suppliers, or uses of our products, product candidates or technologies.

In the future, it may be necessary for us to enforce our proprietary rights, or to determine the scope, validity and unenforceability of other parties' proprietary rights, through litigation or other dispute proceedings, which may be costly and, to the extent we are unsuccessful, adversely affect our rights. In these proceedings, a court or administrative body could determine that our claims, including those related to enforcing patent rights, are not valid or that an alleged infringer has not infringed our rights. The uncertainty resulting from the mere institution and continuation of any patent- or other proprietary rights-related litigation or interference proceeding could have a material and adverse effect on our business prospects, operating results and financial condition.

Risks Related to Our Industry

We are subject to uncertainty relating to healthcare reform measures and reimbursement policies that, if not favorable to our products, could hinder or prevent our products' commercial success, if any of our product candidates are approved.

The unavailability or inadequacy of third-party payer coverage and reimbursement could negatively affect the market acceptance of our product candidates and the future revenues we may expect to receive from our products. The commercial success of our product candidates, if approved, will depend in part on the extent to which the costs of such products will be covered by third-party payers, such as government health programs, commercial insurance and other organizations. Third-party payers are increasingly challenging the prices and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. If these third-party payers do not consider our products to be cost-effective compared to other therapies, we may not obtain coverage for our products after approval as a benefit under the third-party payers' plans or, even if we do, the level of coverage or payment may not be sufficient to allow us to sell our products on a profitable basis.

Significant uncertainty exists as to the reimbursement status for newly approved drug products, including coding, coverage and payment. There is no uniform policy requirement for coverage and reimbursement for drug products among third-party payers in the United States; therefore coverage and reimbursement for drug products can differ significantly from payer to payer. 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 payer separately, with no assurance that coverage and adequate payment will be applied consistently or obtained. The process for determining whether a payer will cover and how much it will reimburse a product may be separate from the process of seeking approval of the product or for setting the price of the product. Even if reimbursement is provided, market acceptance of our products may be adversely affected if the amount of payment for our products proves to be unprofitable for healthcare providers or less profitable than alternative treatments or if administrative burdens make our products less desirable to use. Third-party payer reimbursement to providers of our products, if approved, may be subject to a bundled payment that also includes the procedure of administering our products or third-party payers may require providers to perform additional patient testing to justify the use of our products. To the extent there is no separate payment for our product(s), there may be further uncertainty as to the adequacy of reimbursement amounts.

The continuing efforts of governments, private insurance companies, and other organizations to contain or to reduce costs of healthcare may adversely affect:

- our ability to set an appropriate price for our products;
- the rate and scope of adoption of our products by healthcare providers;
- our ability to generate revenue or achieve or maintain profitability;
- the future revenue and profitability of our potential customers, suppliers and collaborators; and
- our access to additional capital.

Our ability to successfully commercialize our products will depend in part on the extent to which governmental authorities, private health insurers and other organizations establish what we believe are appropriate coverage and reimbursement for our products. The containment of healthcare costs has become a priority of federal, state and foreign governments and the prices of drug products have been a focus in this effort. For example, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs, and the Trump administration has stated that reducing drug pricing is a priority. We expect that federal, state and local governments in the United States, as well as governments in other countries, will continue to consider legislation directed at lowering the total cost of healthcare. In addition, in certain foreign markets, the pricing of drug products is subject to government control and reimbursement may in some cases be unavailable or insufficient. It is uncertain whether and how future legislation, whether domestic or abroad, could affect prospects for our product candidates or what actions governmental or private payers for healthcare treatment and services may take in response to any such healthcare reform proposals or legislation. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, may prevent or limit our ability to generate revenue, attain profitability or commercialize our product candidates, especially in light of our plans to price our product candidates at a high level.

Furthermore, we expect that the U.S. Congress will again attempt to pass reform measures that may be adopted in the future, including the possible repeal and replacement of the Patient Protection and Affordable Care Act, which the Trump administration has stated is a priority. These potential courses of action are unpredictable, and the potential impact of new legislation on our operations and financial position is uncertain, but may result in more rigorous coverage criteria, lower reimbursement, and additional downward pressure on the price we may receive for an approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products, if approved.

We expect competition in the marketplace for our product candidates, should any of them receive regulatory approval.

Larazotide acetate has issued patents for composition of matter, method of use and its formulation in the United States, our primary targeted market. INN-202 has either been issued patents or is prosecuting patent applications in numerous countries outside the United States. The barrier to entry for any company developing larazotide acetate for celiac disease is very high. We believe that INN-202 is the first drug entering into Phase 3 clinical trials for celiac disease. Additionally, if larazotide acetate is the first drug granted FDA approval for celiac disease, competitors may need to license or to seek approval from us for the usage of our CeD PRO as an endpoint in subsequent celiac disease trials.

We have received Orphan Drug Designation from the FDA for INN-108 for pediatric ulcerative colitis. Orphan Drug Designation may provide market exclusivity in the U.S. for seven years if (1) INN-108 receives market approval before a competitor using the same active compound for the same indication, (2) we are able to produce sufficient supply to meet demand in the marketplace, and (3) another product with the same active ingredient(s) is not deemed clinically superior.

INN-329, secretin, has received Orphan Drug Designation from the FDA. Orphan Drug Designation may provide market exclusivity in the U.S. for seven years if (1) INN-329 receives market approval before a competitor using a similar peptide for the same indication, (2) we are able to produce sufficient supply to meet demand in the marketplace, and (3) another product with the same active ingredient is not deemed clinically superior.

The industries in which we operate are highly competitive and subject to rapid and significant changes. Developments by others may render potential application of any of our product candidates in a particular indication obsolete or noncompetitive, even prior to completion of our development and approval for that indication.

If successfully developed and approved, we expect our product candidates will face competition. We may not be able to compete successfully against organizations with competitive products, particularly large pharmaceutical companies.

Many of our potential competitors have significantly greater financial, technical and human resources than we do, and may be better equipped to develop, manufacture, market and distribute products. Many of these companies operate large, well-funded research, development and commercialization programs, have extensive experience in nonclinical and clinical studies, obtaining FDA and other regulatory approvals and manufacturing and marketing products, and have multiple products that have been approved or are in late-stage development. These advantages may enable them to receive approval from the FDA or any foreign regulatory agency before us and prevent us from competing due to their orphan drug protections. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and biotechnology companies. Furthermore, heightened awareness on the part of academic institutions, government agencies and other public and private research organizations of the potential commercial value of their inventions have led them to actively seek to commercialize the technologies they develop, which increases competition for investment in our programs. Competitive products may be more effective, easier to dose, or more effectively marketed and sold, which would have a material adverse effect on our ability to generate revenue.

We face potential product liability exposures, and if successful claims are brought against us, we may incur substantial liability for a product or product candidate and may have to limit its commercialization. In the future, we anticipate that we will need to obtain additional or increased product liability insurance coverage, and we are uncertain whether such increased or additional insurance coverage can be obtained on commercially reasonable terms, if at all.

Our business (in particular, the use of our product candidates in clinical studies and the sale of any products for which we obtain marketing approval) will expose us to product liability risks. Product liability claims may be brought against us by patients, healthcare providers, pharmaceutical companies or others selling or involved in the use of our products. If we cannot successfully defend ourselves against any such claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- significant costs of related litigation;
- decreased demand for our products and loss of revenue;
- impairment of our business reputation;
- a “clinical hold,” suspension or termination of a clinical study or amendments to a study design;
- delays in enrolling patients to participate in our clinical studies;
- withdrawal of clinical study participants;
- substantial monetary awards to patients or other claimants; and
- the inability to commercialize our products and product candidates.

We maintain limited product liability insurance for our clinical studies, and our insurance coverage may not reimburse us or may not be sufficient to reimburse us for all expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and 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.

We expect that we will expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates, but we may be unable to obtain product liability insurance on commercially acceptable terms or may not be able to maintain such insurance at a reasonable cost or in sufficient amounts to protect us against potential losses. Large judgments have been awarded in class action lawsuits based on drug products that had unanticipated side effects. A successful product liability claim or series of claims brought against us, if judgments exceed our insurance coverage, could materially decrease our cash and adversely affect our business.

Our relationships with investigators, healthcare professionals, institutional providers, consultants, third-party payors and customers are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties, including without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations.

Healthcare providers, physicians and others play a primary role in the recommendation and prescribing of any product candidates for which we may obtain marketing approval. In the United States, our current business operations and future arrangements with investigators, healthcare professionals, institutional providers, consultants, third-party payors and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our products that obtain marketing approval. Restrictions under applicable federal, state and foreign healthcare laws and regulations, include, but are not limited to, the following:

- the federal healthcare program 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 in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, service or item for which payment is made, in whole or in part, under a federal healthcare program;
- the federal civil and criminal false claims laws and civil monetary penalties laws, including civil whistleblower or qui tam actions, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent or from knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, and as amended again by the final HIPAA omnibus rule, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to HIPAA, published in January 2013, imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the omnibus rule, such as health plans, clearinghouses and healthcare providers, and their associates;
- HIPAA, imposes criminal liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program regardless of the payor (e.g., public or private) and knowingly or willfully falsifying, concealing, or covering up by any trick, scheme or device a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- the federal transparency law, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA), and its implementing regulations, require manufacturers of drugs, devices, biologicals and medical supplies to report to the U.S. Department of Health and Human Services information related to payments and other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- analogous state laws and regulations, including but not limited to: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by state governmental and non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; and state laws and regulations that require manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and
- European Union, or EU, data protection regulations, which may require member states of the EU to impose minimum restrictions on the collection and use of personal data that, in many respects, are more stringent, and impose more significant burdens on subject businesses, than current privacy standards in the United States.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these or any other health regulatory laws or any other governmental regulations that may apply to us, we may be subject to penalties, including without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, enhanced government reporting and oversight under a corporate integrity agreement or other similar arrangement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses or divert our management's attention from the operation of our business. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable healthcare laws, they also may be subject to similar penalties.

USE OF PROCEEDS

We may issue and sell shares of our common stock having aggregate gross sales proceeds of up to $40.0 million from time to time. Because there is no minimum offering amount required as a condition to close this offering, the actual total public offering amount, commissions and proceeds to us, if any, are not determinable at this time.

We intend to use the net proceeds from this offering to fund the Phase 3 registration trials of our lead program, INN-202, as well as for working capital and general corporate purposes.

This expected use of net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. As a result, we cannot specify with certainty all of the particular uses of the proceeds from this offering. Accordingly, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Pending use of the proceeds as described above or otherwise, we intend to invest the net proceeds of this offering in short- to medium-term, investment-grade, interest-bearing securities, certificates of deposit or government securities.

DIVIDEND POLICY

We have never declared or paid any dividends on our capital stock. We currently intend to retain all future earnings for the operation and expansion of our business and, therefore, we do not anticipate declaring or paying cash dividends for the foreseeable future. The payment of dividends, if any, will be at the discretion of our board of directors and will depend on our results of operations, capital requirements, financial condition, prospects, contractual arrangements, any limitations on payment of dividends in our debt agreements, and other factors that our board of directors may deem relevant.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the price per share of our common stock in this offering and the as adjusted net tangible book value per share of our common stock immediately after this offering.

As of June 30, 2018, our net tangible book value was $3.5 million, or $0.13 per share of our common stock, based upon 25,695,602 shares of common stock outstanding as of that date. Historical net tangible book value per share is equal to our total tangible assets, less total liabilities, divided by the number of outstanding shares of our common stock. Dilution in net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the net tangible book value per share of common stock immediately after this offering.

On a pro forma basis, after giving effect to our receipt of $38.6 million of estimated net proceeds (after deducting commissions and estimated offering expenses payable by us) from our sale of $40.0 million of common stock in this offering at an assumed public offering price of $4.42 per share (the last reported sale price of our common stock on the Nasdaq on October 25, 2018), our as adjusted net tangible book value as of June 30, 2018 would have been $42.1 million, or $1.21 per share. This amount would represent an immediate increase in net tangible book value of $1.08 per share of our common stock to existing stockholders and an immediate and substantial dilution in net tangible book value of $3.21 per share of our common stock to new investors purchasing shares of common stock in this offering at the assumed public offering price.

The following table illustrates this hypothetical dilution on a per share basis:

Public offering price per share		$ 4.42
Historical net tangible book value per share as of June 30, 2018	$ 0.13	
Increase in net tangible book value per share attributable to new investors in this offering	1.08	
As adjusted net tangible book value per share after giving effect to this offering		1.21
Dilution per share to new investors participating in this offering		$ 3.21

The foregoing table assumes for illustrative purposes that an aggregate of 9,049,774 shares of our common stock are sold at a price of $4.42 per share, the last reported sale price of our common stock on the Nasdaq on October 25, 2018, for aggregate gross proceeds of $40.0 million. The shares sold in this offering, if any, will be sold from time to time at various prices.

The information discussed above is illustrative only and will adjust based on the actual public offering price and other terms of this offering determined at pricing and will also be affected by any securities sold by us, if any, pursuant the accompanying base prospectus. An increase of $1.00 per share in the price at which the shares are sold from the assumed offering price of $4.42 per share shown in the table above, assuming all of our common stock in the aggregate amount of $40.0 million is sold at that price, would increase our as adjusted net tangible book value per share after the offering to $1.27 per share and would increase the dilution in net tangible book value per share to new investors to $4.15 per share, after deducting commissions and estimated aggregate offering expenses payable by us. A decrease of $1.00 per share in the price at which the shares are sold from the assumed offering price of $4.42 per share shown in the table above, assuming all of our common stock in the aggregate amount of $40.0 million is sold at that price, would decrease our as adjusted net tangible book value per share after the offering to $1.12 per share and would decrease the dilution in net tangible book value per share to new investors to $2.30 per share, after deducting commissions and estimated aggregate offering expenses payable by us.

The foregoing table and discussion is based on 25,695,602 shares of our common stock outstanding as of June 30, 2018, an assumed offering price of $4.42 per share (the closing price on October 25, 2018) and excludes the following as of that date:

- 1,683 shares of common stock issuable upon the exercise of outstanding stock options under the Omnibus Plan, with a weighted-average exercise price of $45.00 per share;

- 6,428,577 shares of common stock issuable upon the exercise of options outstanding under the Private Innovate Plan;
- 1,698,294 and 349,555 shares of common stock issuable upon the exercise of outstanding warrants, with an exercise price of $3.18 per share and $2.54 per share, respectively;
- 154,403 shares of common stock issuable upon the exercise of warrants issued by Monster with a weighted-average exercise price of $55.31 per share;
- any shares of our common stock issuable upon conversion of the New Note (approximately 1,687,229 shares at a conversion price equal to the floor price of $3.08 per share); and
- 4,505 shares of common stock reserved for future issuance under the Omnibus Plan as of June 30, 2018, as well as any increases in the number of shares of our common stock reserved for issuance under the Omnibus Plan following approval at our Annual Meeting of the amendments described under "Prospectus Supplement Summary—Recent Developments—Annual Stockholder Meeting Proposals," including (i) an increase of the number of shares of common stock authorized for issuance under the Omnibus Plan by 3,000,000 shares and (ii) any future increases pursuant to evergreen provisions, if approved by our stockholders at our Annual Meeting.

In addition, since June 30, 2018, we have made contingent grants of options to purchase up to approximately 1.2 million shares of common stock under the Omnibus Plan to certain of our executive officers, directors, employees and consultants, and such grants would become effective upon approval at our Annual Meeting of the amendments to increase the number of shares available under the Omnibus Plan.

The New Note may convert the note into shares of our common stock at various conversion prices. See "Prospectus Supplement Summary—Recent Developments—Exchange of Senior Note" for additional information on determination of the conversion prices for the New Note. For example, if the entire principal amount of the New Note converts into shares of our common stock at the Floor Price of $3.08 per share, then we would be required to issue 1,687,229 shares to the Holder upon the conversion of the New Note.

To the extent that any outstanding stock options or warrants are exercised, new stock options or warrants are issued, or we otherwise issue additional shares of common stock in the future at a price less than the public offering price, there will be further dilution to new investors.

In addition, we may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

MATERIAL U.S. FEDERAL INCOME AND ESTATE TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK

The following is a summary of the material U.S. federal income and estate tax consequences to non-U.S. holders (as defined below) of the ownership and disposition of our common stock but does not purport to be a complete analysis of all the potential tax considerations relating thereto. This summary is based upon the provisions of the Internal Revenue Code of 1986, as amended, or the Code, U.S. Treasury regulations promulgated thereunder, administrative rulings and judicial decisions, all as of the date hereof. These authorities may be changed, possibly retroactively, or be subject to differing interpretations so as to result in U.S. federal income and estate tax consequences different from those set forth below. We have not sought and will not seek any ruling from the Internal Revenue Service, or the IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will not take a position contrary to such statements and conclusions.

This summary applies only to common stock acquired in this offering. It does not address the tax considerations arising under the laws of any non-U.S., state or local jurisdiction or under U.S. federal non-income tax laws, except to the limited extent set forth below. In addition, this discussion does not address the potential application of the Medicare surtax on net investment income or any tax considerations applicable to an investor's particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

- banks, insurance companies or other financial institutions;
- persons subject to the alternative minimum tax;
- tax-exempt organizations;
- qualified foreign pension funds;
- "controlled foreign corporations," "passive foreign investment companies" and corporations that accumulate earnings to avoid U.S. federal income tax;
- brokers or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- persons that own, or are deemed to own, more than 5% of our capital stock (except to the extent specifically set forth below);
- certain former citizens or long-term residents of the United States;
- entities or arrangements treated as partnerships for U.S. federal income tax purposes and other pass-through entities (and investors therein);
- persons who hold our common stock as a position in a "straddle," "conversion transaction" or other risk reduction transaction or integrated transaction;
- persons who do not hold our common stock as a capital asset within the meaning of Code Section 1221 (generally, property held for investment);
- persons subject to special tax accounting rules as a result of any item of gross income with respect to our common stock being taken into account in an applicable financial statement; or
- persons deemed to sell our common stock under the constructive sale provisions of the Code.

If a partnership or entity or arrangement classified as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner generally will depend on the status of the partner and upon the activities of the partnership. Accordingly, partnerships that hold our common stock, and partners in such partnerships, should consult their tax advisors regarding the tax consequences of the purchase, ownership and disposition of our common stock.

You are urged to consult your tax advisor with respect to the application of the U.S. federal income tax laws to your particular situation, as well as any tax consequences of the purchase, ownership and disposition of our common stock arising under the U.S. federal non-income tax laws or under the laws of any state, local, non-U.S. or other taxing jurisdiction or under any applicable tax treaty.

Non-U.S. Holder Defined

For purposes of this discussion, except as modified for estate tax purposes, you are a non-U.S. holder if you are a beneficial owner of shares of our common stock, other than a partnership or entity or arrangement classified as a partnership for U.S. federal income tax purposes, or:

- an individual who is a citizen or resident of the United States (for U.S. federal income tax purposes);

- a corporation or other entity taxable as a corporation created or organized in the United States or under the laws of the United States or any political subdivision thereof or entity treated as such for U.S. federal income tax purposes;
- an estate whose income is subject to U.S. federal income tax regardless of its source; or
- a trust (x) whose administration is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust or (y) which has made a valid election to be treated as a U.S. person.

Distributions

We have never paid cash distributions on our common stock and do not anticipate doing so in the foreseeable future. However, if we do make distributions on our common stock, those payments will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed both our current and our accumulated earnings and profits, they will constitute a return of capital and will first reduce your basis in our common stock, but not below zero, and then will be treated as gain from the sale of stock.

Subject to the discussion below on effectively connected income, any dividend paid to a non-U.S. holder generally will be subject to U.S. withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty. In order to receive a reduced treaty rate, a non-U.S. holder must provide us with an IRS Form W-8BEN, IRS Form W-8BEN-E or other appropriate version of IRS Form W-8, including a U.S. taxpayer identification number, if required, certifying qualification for the reduced rate. A non-U.S. holder of shares of our common stock eligible for a reduced rate of U.S. withholding tax pursuant to an income tax treaty may obtain a refund of any excess amounts withheld by filing an appropriate claim for refund with the IRS. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the non-U.S. holder's behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which may then be required to provide certification to the relevant paying agent, either directly or through other intermediaries.

Dividends received by a non-U.S. holder that are effectively connected with such holder's conduct of a U.S. trade or business (and, if required by an applicable tax treaty, that are attributable to a permanent establishment maintained in the U.S.), are generally exempt from such withholding tax. In order to obtain this exemption, a non-U.S. holder must provide us with an IRS Form W-8ECI properly certifying such exemption. Such effectively connected dividends, although not subject to withholding tax, generally are taxed at the same graduated rates applicable to U.S. persons, net of certain deductions and credits. In addition, if you are a corporate non-U.S. holder, dividends you receive that are effectively connected with your conduct of a U.S. trade or business may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty. You should consult your tax advisor regarding any applicable tax treaties that may provide for different rules.

Gain on Disposition of Common Stock

Subject to discussions below regarding backup withholding and foreign accounts, a non-U.S. holder generally will not be required to pay U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

- the gain is effectively connected with such holder's conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, the gain is attributable to a permanent establishment maintained in the United States);
- the non-U.S. holder is an individual who is present in the United States for a period or periods aggregating 183 days or more during the taxable year in which the sale or disposition occurs and certain other conditions are met; or
- our common stock constitutes a U.S. real property interest by reason of our status as a "United States real property holding corporation," or USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five year period preceding such holder's disposition of, or the holder's holding period for, our common stock.

We believe that we are not currently and will not become a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, however, as long as our common stock is regularly traded on an established securities market, such common stock will be treated as U.S. real property interests only if a non-U.S. holder actually or constructively holds more than

5% of such regularly traded common stock at any time during the shorter of the five year period preceding the holder's disposition of, or the holder's holding period for, our common stock.

If you are a non-U.S. holder described in the first bullet above, you will be required to pay U.S. federal income tax on the net gain derived from the sale under regular graduated U.S. federal income tax rates, and a corporate non-U.S. holder described in the first bullet above also may be subject to the branch profits tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty. If you are an individual non-U.S. holder described in the second bullet above, you will be required to pay a flat 30% U.S. federal income tax (or such lower rate specified by an applicable income tax treaty) on the gain derived from the sale, which gain may be offset by U.S.-source capital losses for the year, provided you have timely filed U.S. federal income tax returns with respect to such losses. You should consult any applicable income tax or other treaties that may provide for different rules.

Federal Estate Tax

Our common stock beneficially owned by an individual who is not a citizen or resident of the United States (as defined for U.S. federal estate tax purposes) at the time of death will generally be includable in the decedent's gross estate for U.S. federal estate tax purposes, unless an applicable estate tax treaty provides otherwise.

Backup Withholding and Information Reporting

Generally, we must report annually to the IRS the amount of dividends paid to a non-U.S. holder, such holder's name and address, and the amount of tax withheld, if any. A similar report will be sent to such non-U.S. holder. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in the non-U.S. holder's country of residence.

Payments of dividends on or of proceeds from the disposition of our common stock made to a non-U.S. holder may be subject to additional information reporting and backup withholding at a current rate of 24% unless such holder establishes an exemption, for example, by properly certifying such holder's non-U.S. status on a Form W-8BEN, IRS Form W-8BEN-E or another appropriate version of IRS Form W-8. Notwithstanding the foregoing, backup withholding and information reporting may apply if either we or our paying agent has actual knowledge, or reason to know, that such holder is a U.S. person.

Backup withholding is not an additional tax; rather, the U.S. federal income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of taxes, a refund or credit may generally be obtained from the IRS, provided that the required information is furnished to the IRS in a timely manner.

Foreign Account Tax Compliance Act

Provisions commonly referred to as "FATCA" impose a U.S. federal withholding tax of 30% on dividends on, and the gross proceeds from a disposition of, our common stock paid to a "foreign financial institution" (as specifically defined under the FATCA rules) unless such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or otherwise establishes an exemption. FATCA also imposes a U.S. federal withholding tax of 30% to dividends on, and the gross proceeds from a disposition of, our common stock paid to a "non-financial foreign entity" (as specifically defined under the FATCA rules) unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect U.S. owners or provides information regarding direct and indirect U.S. owners of the entity or otherwise establishes an exception. The withholding provisions described above generally apply to payments of dividends on our common stock and will apply to payments of gross proceeds from a sale or other disposition of our common stock on or after January 1, 2019. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. You should consult your personal tax advisor regarding these withholding provisions.

The preceding discussion of U.S. federal tax considerations is for general information only. It is not tax advice. Each prospective investor should consult its own tax advisor regarding the particular U.S. federal, state and local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, including the consequences of any proposed change in applicable laws.

PLAN OF DISTRIBUTION

We have entered into a common stock sales agreement, or Sales Agreement, with H.C. Wainwright & Co., LLC and Ladenburg Thalmann & Co. Inc., or the Sales Agents, under which we may issue and sell shares of our common stock from time to time through the Sales Agents acting as the sales agents. We may issue and sell shares through this prospectus supplement having an aggregate gross sales price of up to $40,000,000. The following summary of the material provisions of the Sales Agreement does not purport to be a complete statement of its terms and conditions. The Sales Agreement has been incorporated by reference as an exhibit to our Registration Statement on Form S-3 of which this prospectus forms a part.

Upon delivery of a placement notice and subject to the terms and conditions of the Sales Agreement, the Sales Agents may sell our common stock by any method permitted by law deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act, including sales made directly on The Nasdaq Capital Market, on any other existing trading market for our common stock or to or through a market maker. The Sales Agents may also sell our common stock by any other method permitted by law, including in privately negotiated transactions. If we and the Sales Agents agree on any method of distribution other than sales of shares of our common stock into the Nasdaq Capital Market or another existing trading market in the United States at market prices, we will file a further prospectus supplement providing all information about such offering as required by Rule 424(b) under the Securities Act. We may instruct the Sales Agents not to sell common stock if the sales cannot be effected at or above the price designated by us from time to time. We and the Sales Agents may suspend the offering of common stock upon notice and subject to other conditions.

We will pay the Sales Agents commissions, in cash, for their services in acting as Sales Agents in the sale of our common stock. The Sales Agents will be entitled to compensation at a commission rate of 3.0% of the gross sales price per share sold. Because there is no minimum offering amount required as a condition to close this offering, the actual total public offering amount, commissions and proceeds to us, if any, are not determinable at this time. We have also agreed to reimburse each of the Sales Agents for certain specified expenses, including the fees and disbursements of their legal counsel in an amount not to exceed $50,000 in aggregate to the Sales Agents. Additionally, we agreed to reimburse Sales Agents for the fees of their legal counsel reasonably incurred in connection with the ongoing diligence, drafting and other filing requirements arising under the Sales Agreement in an amount not to exceed $2,500 in the aggregate per calendar quarter. We estimate that the total expenses for the offering, excluding compensation and reimbursements payable to the Sales Agents under the terms of the Sales Agreement, will be approximately $200,000.

Settlement for sales of common stock will occur on the second business day following the date on which any sales are made, or on some other date that is agreed upon by us and the Sales Agents in connection with a particular transaction, in return for payment of the net proceeds to us. Sales of our common stock as contemplated in this prospectus will be settled through the facilities of The Depository Trust Company or by such other means as we and the Sales Agents may agree upon. There is no arrangement for funds to be received in an escrow, trust or similar arrangement.

The Sales Agents will use their respective commercially reasonable efforts, consistent with their sales and trading practices, to solicit offers to purchase the shares of common stock under the terms and subject to the conditions set forth in the Sales Agreement. In connection with the sale of the common stock on our behalf, the Sales Agents will be deemed to be "underwriters" within the meaning of the Securities Act and the compensation of the Sales Agents will be deemed to be underwriting commissions or discounts. We have agreed to provide indemnification and contribution to the Sales Agents against certain civil liabilities, including liabilities under the Securities Act.

The offering of our common stock pursuant to the Sales Agreement will terminate upon the earlier of (i) the sale of all shares of our common stock subject to the Sales Agreement or (ii) termination of the Sales Agreement as permitted therein. We and the Sales Agents may each terminate the Sales Agreement at any time upon five (5) days' prior notice.

Any portion of the $40,000,000 included in this prospectus supplement that is not previously sold or included in an active placement notice pursuant to the Sales Agreement is available for sale in other offerings pursuant to the base prospectus, and if no shares are sold under the Sales Agreement, the full $40,000,000 of securities may be sold in other offerings pursuant to the base prospectus and a corresponding prospectus supplement.

The Sales Agents and their affiliates may in the future provide various investment banking, commercial banking and other financial services for us and our affiliates, for which services they may in the future receive customary fees. To the extent required by Regulation M, the Sales Agents will not engage in any market making activities involving our common stock while the offering is ongoing under this prospectus.

This prospectus in electronic format may be made available on websites maintained by the Sales Agents, and the Sales Agents may distribute this prospectus and the accompanying base prospectus electronically.

LEGAL MATTERS

The validity of the common stock offered by this prospectus supplement and the accompanying prospectus will be passed upon for us by Wilson Sonsini Goodrich & Rosati, Professional Corporation, San Diego, California. The Sales Agents are being represented in connection with this offering by Ellenoff Grossman & Schole LLP, New York, New York.

EXPERTS

The consolidated financial statements of Monster Digital, Inc., as of December 31, 2017 and 2016, and for the years then ended, have been incorporated by reference herein and in the registration statement, which includes an explanatory paragraph relating to the Company's ability to continue as a going concern, in reliance upon the report of CohnReznick LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

Mayer Hoffman McCann P.C., our independent registered public accounting firm, has audited our balance sheets as of December 31, 2017 and 2016, and the related statements of operations and comprehensive loss, stockholders' deficit and cash flows for each of the two years in the period ended December 31, 2017, as set forth in their report, which report expresses an unqualified opinion and includes an explanatory paragraph relating to our ability to continue as a going concern. We have incorporated by reference the financial statements in this registration statement in reliance on the report of Mayer Hoffman McCann P.C. given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We file annual, quarterly and other reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at http://www.sec.gov. You may also read and copy any document we file at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the Public Reference Room.

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K, including any amendments to those reports, and other information we file with or furnish to the SEC pursuant to Section 13(a) or 15(d) of the Exchange Act can also be accessed free of charge at our website at http://www.innovatebiopharma.com. Such information is made available on our website as soon as reasonably practicable after we electronically file it with or furnish it to the SEC. Information contained on, or accessible through, our website is not part of this prospectus supplement.

INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference into this prospectus supplement the information we file with the SEC, which means we may disclose important information to you by referring you to other documents we file separately with the SEC. The information we incorporate by reference is considered a part of this prospectus supplement. We hereby incorporate by reference the following documents:

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 filed on March 14, 2018, as amended on June 29, 2018;
- our Quarterly Reports on Form 10-Q for the quarters ended June 30, 2018, filed on August 14, 2018, and March 31, 2018, filed on May 15, 2018;
- our Current Reports on Form 8-K filed on January 5, 2018, January 11, 2018, February 2, 2018 (as amended on March 29, 2018, and April 18, 2018), February 22, 2018, February 23, 2018, March 14, 2018, April 20, 2018, May 15, 2018, June 18, 2018, June 29, 2018, August 23, 2018 (other than Item 7.01 and Exhibit 99.1 thereto) and October 5, 2018;
- our definitive proxy statement on Schedule 14A filed on October 16, 2018; and
- the description of our common stock contained in our Registration Statement on Form 8-A as filed with the SEC on June 7, 2016 pursuant to Section 12(b) of the Exchange Act.

Any information in the foregoing documents will automatically be deemed to be modified or superseded to the extent that information in this prospectus supplement modifies or replaces such information. We also incorporate by reference any future filings (other than information furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items) made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act until the termination of the offering of the shares of common stock covered by this prospectus supplement. Information in such future filings shall be deemed to update and supplement the information provided in this prospectus supplement, and any statements in such future filings will automatically be deemed to modify and supersede any information in any document we previously filed with the SEC that is incorporated or deemed to be incorporated herein by reference to the extent that the statements in the later filed document modify or replace such earlier statements.

You may obtain from us copies of the documents incorporated by reference in this prospectus supplement, at no cost, by requesting them in writing or by telephone at:

Innovate Biopharmaceuticals, Inc.
8480 Honeycutt Road, Suite 120
Raleigh, NC 27615
(919) 275-1933

SUBJECT TO COMPLETION, DATED JULY 13, 2018

PROSPECTUS

Common Stock

Up to $175,000,000 of
Shares of Common Stock
13,990,403 Shares of Common Stock
Offered by Selling Stockholders

We may offer and sell from time to time, in one or more series or issuances and on terms that we will determine at the time of the offering, any of the securities described in this prospectus, up to an aggregate maximum amount of $175,000,000.

This prospectus also relates to the disposition from time to time of up to 13,990,403 shares of our common stock (including up to 2,051,771 shares issuable upon exercise of warrants), which are held by the selling stockholders named in this prospectus. We will not receive any of the proceeds from the sale of our common stock by the selling stockholders.

The selling stockholders identified in this prospectus, or their permitted transferees or other successors-in-interest, may offer the shares from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices, or at privately negotiated prices. We provide additional information about how the selling stockholders may sell their shares of common stock in the section entitled "Plan of Distribution" beginning on page 16 of this prospectus. We will not be paying any underwriting discounts or selling commissions in connection with any offering of common stock under this prospectus.

Our common stock is quoted on the Nasdaq Capital Market ("Nasdaq") under the symbol "INNT." The last reported sale price of our common stock as reported on Nasdaq on July 5, 2018 was $22.71 per share.

Investing in our common stock involves a high degree of risk. Please see the section entitled "Risk Factors" beginning on page 3 of this prospectus.

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

The date of this prospectus is July 13, 2018.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the United States Securities and Exchange Commission, or the SEC, using a "shelf" registration process. Under this shelf process, we may, from time to time, sell any of the securities described in this prospectus in one or more offerings up to an aggregate dollar amount of $175,000,000 (of which up to an aggregate of $40 million may be sold in an "at-the-market" offering as defined in Rule 415 of the Securities Act). In addition, the selling stockholders may from time to time sell up to an aggregate amount of 13,990,403 shares of our common stock (including up to 2,051,771 shares issuable upon exercise of warrants) in one or more offerings.

This prospectus provides you with a general description of the securities we or the selling stockholders may offer. Each time we or the selling stockholders sell securities, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add to, update or change information contained in the prospectus and, accordingly, to the extent inconsistent, information in this prospectus is superseded by the information in the prospectus supplement. If there is any inconsistency between the information in this prospectus and any prospectus supplement, you should rely on the information in that prospectus supplement. You should carefully read both this prospectus and any prospectus supplement together with the additional information described under the heading "Information Incorporated by Reference."

The prospectus supplement to be attached to the front of this prospectus may describe, as applicable, the terms of the securities offered; the price paid for the securities; net proceeds; and the other specific terms related to the offering of the securities.

THIS PROSPECTUS MAY NOT BE USED TO OFFER AND SELL SECURITIES UNLESS IT IS ACCOMPANIED BY A PROSPECTUS SUPPLEMENT.

You should only rely on the information contained or incorporated by reference in this prospectus and any prospectus supplement or issuer free writing prospectus relating to a particular offering. No person has been authorized to give any information or make any representations in connection with this offering other than those contained or incorporated by reference in this prospectus, any accompanying prospectus supplement and any related issuer free writing prospectus in connection with the offering described herein and therein, and, if given or made, such information or representations must not be relied upon as having been authorized by us. Neither this prospectus nor any prospectus supplement nor any related issuer free writing prospectus shall constitute an offer to sell or a solicitation of an offer to buy offered securities in any jurisdiction in which it is unlawful for such person to make such an offering or solicitation. This prospectus does not contain all of the information included in the registration statement. For a more complete understanding of the offering of the securities, you should refer to the registration statement, including its exhibits.

You should read the entire prospectus and any prospectus supplement and any related issuer free writing prospectus, as well as the documents incorporated by reference into this prospectus or any prospectus supplement or any related issuer free writing prospectus, before making an investment decision. Neither the delivery of this prospectus or any prospectus supplement or any issuer free writing prospectus nor any sale made hereunder shall under any circumstances imply that the information contained or incorporated by reference herein or in any prospectus supplement or issuer free writing prospectus is correct as of any date subsequent to the date hereof or of such prospectus supplement or issuer free writing prospectus, as applicable. You should assume that the information appearing in this prospectus, any prospectus supplement or any document incorporated by reference is accurate only as of the date of the applicable documents, regardless of the time of delivery of this prospectus or any sale of securities. Our business, financial condition, results of operations and prospects may have changed since that date.

Except where the context otherwise requires or where otherwise indicated, the terms "we," "us," "our," "Innovate" and "the Company" refer to Innovate Biopharmaceuticals, Inc., a Delaware corporation, and its consolidated subsidiaries. References to the "selling stockholders" refer to the stockholders listed herein under the heading "Selling Stockholders" and their donees, pledgees, transferees or other successors-in-interest.

FORWARD-LOOKING STATEMENTS

The information in this Registration Statement on Form S-3, particularly in the sections entitled “Innovate Business,” and “Innovate Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and the information incorporated herein by reference, include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements are based on current expectations and beliefs and involve numerous risks and uncertainties that could cause actual results to differ materially from expectations. These forward-looking statements should not be relied upon as predictions of future events as we cannot assure you that the events or circumstances reflected in these statements will be achieved or will occur. When used in this report, the words “believe,” “may,” “could,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “indicate,” “seek,” “should,” “would” and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements contain these identifying words. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements.

If any of these risks or uncertainties materializes or any of these assumptions proves incorrect, our results could differ materially from the forward-looking statements in this report. All forward-looking statements in this report are current only as of the date of this report. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any statement is made or to reflect the occurrence of unanticipated events except as required by law.

PROSPECTUS SUMMARY

This summary highlights the information contained elsewhere in or incorporated by reference into this prospectus. Because this is only a summary, it does not contain all of the information that you should consider before deciding whether to invest in our securities. For a more complete understanding of our company's business and the risks and uncertainties facing it, you should read this entire prospectus, including but not limited to the information incorporated by reference herein and under the caption "Risk Factors," beginning on page 3.

Overview

On January 29, 2018, Monster Digital, Inc. ("Monster") and privately held Innovate Biopharmaceuticals Inc. ("Private Innovate") completed a reverse recapitalization in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated July 3, 2017, as amended (the "Merger Agreement"), by and among Monster, Monster Merger Sub, Inc. ("Merger Sub") and Private Innovate, which changed its name in connection with the transaction to IB Pharmaceuticals Inc. ("IB Pharmaceuticals"). Pursuant to the Merger Agreement, Merger Sub merged with and into IB Pharmaceuticals with IB Pharmaceuticals surviving as the wholly owned subsidiary of Monster (the "Merger"). Immediately following the Merger, Monster changed its name to Innovate Biopharmaceuticals, Inc. ("Innovate"). In connection with the closing of the Merger, Innovate's common stock began trading on the Nasdaq Capital Market under the ticker symbol "INNT" on February 1, 2018. Prior to the Merger, Monster was incorporated in Delaware in November 2010 under the name "Monster Digital, Inc."

Prior to the Merger, Monster's primary business focus was the design, development and marketing of premium products under the "Monster Digital" brand for use in high-performance consumer electronics, mobile products and computing applications.

After the Merger, we are a clinical-stage biopharmaceutical company developing novel medicines for autoimmune and inflammatory diseases with unmet needs. Our pipeline includes drug candidates for celiac disease, nonalcoholic steatohepatitis (NASH), Crohn's and ulcerative colitis. Our lead program, INN-202 (larazotide acetate or larazotide) is entering Phase 3 registration trials in the second half of 2018 and has the potential to be the first-to-market therapeutic for celiac disease, an unmet medical need, which affects an estimated 1% of the North American population or approximately 3 million individuals. Celiac patients have no treatment alternative other than a strict lifelong adherence to a gluten-free diet, which is difficult to maintain and can be deficient in key nutrients. Additionally, current FDA labeling standards allow up to 20 parts per million (ppm) of gluten in "gluten-free" labeled foods, which are sufficient to cause celiac symptoms in many patients, including abdominal pain, abdominal cramping, bloating, gas, headaches, ataxia, ‘‘brain fog,’’ and fatigue. Long-term sequelae of celiac disease include enteropathy associated T-cell lymphoma (EATL), osteoporosis and anemia.

Our principal executive office is currently located at 8480 Honeycutt Road, Suite 120, Raleigh, North Carolina 27615.

THE OFFERING	
Common stock offered by the selling stockholders	13,990,403 shares of our common stock (including up to 2,051,771 shares issuable upon exercise of warrants)
Common stock offered by Innovate	Shares of our common stock having an aggregate offering price of up to $175,000,000.
Use of proceeds	Unless otherwise set forth in a prospectus supplement, we currently intend to use the net proceeds of any offering of securities for working capital and other general corporate purposes. Accordingly, we will have significant discretion in the use of any net proceeds. The specific allocations of the proceeds we receive from the sale of our securities will be described in the applicable prospectus supplement. We will not receive any proceeds from the sale of shares of our common stock by the selling stockholders. See “Selling Stockholders” and “Plan of Distribution.”
Risk Factors	See “Risk Factors” and other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in shares of our common stock.
Nasdaq symbol	INNT

RISK FACTORS

Before you invest in our securities, you should be aware that our business faces numerous financial and market risks, including those described below, as well as general economic and business risks. Our securities are speculative, and you should not make an investment in Innovate unless you can afford to bear the loss of your entire investment. Prior to making a decision about investing in our common stock, you should carefully consider the risks, uncertainties and assumptions discussed under Item 1A, "Risk Factors," in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, as updated by our subsequent filings with the Securities and Exchange Commission, or the SEC, under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are incorporated herein by reference, together with the information in this prospectus and any other information incorporated by reference into this prospectus. Before you decide whether to invest in our securities, you should carefully consider these risks and uncertainties, together with all of the other information included in or incorporated by reference into this prospectus. The risks and uncertainties identified are not the only risks and uncertainties we face. If any of the material risks or uncertainties that we face were to occur, you could lose part or all of your investment.

USE OF PROCEEDS

Unless otherwise set forth in a prospectus supplement, we currently intend to use the net proceeds of any offering of securities for working capital and other general corporate purposes. Accordingly, we will have significant discretion in the use of any net proceeds. The specific allocations of the proceeds we receive from the sale of our securities will be described in the applicable prospectus supplement.

We will not receive any proceeds from the sale of shares of our common stock by the selling stockholders.

SELLING STOCKHOLDERS

The shares may be offered by the selling stockholders or by pledges, donees, transferees or other successors in interest that receive such shares as a gift or through a private sale or transfer. We may amend or supplement this prospectus from time to time to update information provided in the table.

On January 29, 2018, prior to the closing of the Merger, Private Innovate issued to the selling stockholders 31,678,964 shares of common stock at $0.9609 per share and five-year warrants to purchase 3,774,039 shares of common stock at an exercise price of $1.201125 for aggregate gross proceeds of $18,132,660.50 (the "Equity Issuance"). Certain of the warrants were issued to affiliates of H.C. Wainwright & Co., LLC and GP Nurmenkari Inc., the placement agents for the Equity Issuance. The shares were exchanged in connection with the Merger for 11,938,632 shares of common stock. The warrants were exchanged in connection with the Merger for warrants to purchase 2,051,771 shares of common stock.

On January 29, 2018, Monster and Private Innovate completed a reverse recapitalization in accordance with the terms of the Merger Agreement, by and among Monster, Merger Sub and Private Innovate, which changed its name in connection with the transaction to IB Pharmaceuticals Inc. Pursuant to the Merger Agreement, Merger Sub merged with and into IB Pharmaceuticals with IB Pharmaceuticals surviving as the wholly owned subsidiary of Monster. Immediately following the Merger, Monster changed its name to Innovate Biopharmaceuticals, Inc. In connection with the closing of the Merger, Innovate's common stock began trading on the Nasdaq Capital Market under the ticker symbol "INNT" on February 1, 2018.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. The Registrant believes these transactions were exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or Regulation D promulgated under the Securities Act as transactions by an issuer not involving any public offering. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates issued in these transactions. All recipients had adequate access, through their relationships with Monster or Private Innovate (as applicable) or otherwise, to information about Monster or Private Innovate (as applicable).

Selling Stockholder	Shares beneficially owned prior to offering	Number of shares being offered	Shares beneficially owned after offering	Percentage of outstanding shares beneficially owned after offering(1)
Adolfo & Donna Carmona(2)	52,635	52,635	—	*
Alan McIntyre(3)	23,561	23,561	—	*
Alexander J. Brown Trust(4)	34,200	34,200	—	*
Alexandra Koeppel(5)	23,532	23,532	—	*
Andrew and Melissa Fisher(6)	47,064	47,064	—	*
Argjent Mena & Lara Sabani(7)	9,413	9,413	—	*
B3 Group LLC(8)	470,642	470,642	—	*
Barry Shemaria(9)	14,120	14,120	—	*
Basil Palmeri(10)	14,120	14,120	—	*
Bozarth LLC(11)	23,532	23,532	—	*
Brenda & Dave Rickey Family Foundation(12)	16,473	16,473	—	*
Brian & Andrea Fischhoff(13)	11,765	11,765	—	*
Brian Eliot Peierls(14)	56,477	56,477	—	*
Bruce & Mitsie Levy(15)	23,532	23,532	—	*
Carl J. Domino(16)	47,064	47,064	—	*

Selling Stockholder	Shares beneficially owned prior to offering	Number of shares being offered	Shares beneficially owned after offering	Percentage of outstanding shares beneficially owned after offering(1)
Casimir S. Skrzypczak(17)	16,473	16,473	—	*
Charmi Vijapura(18)	47,064	47,064	—	*
Chirag Shah(19)	7,059	7,059	—	*
Christopher Washburn(20)	14,120	14,120	—	*
Clay Lebhar(21)	23,531	23,531	—	*
Dennis R. DeLoach, Jr. & Faye M. DeLoach(22)	11,766	11,766	—	*
Donald Sesterhenn(23)	11,765	11,765	—	*
Douglas Rivers(24)	235,321	235,321	—	*
Dyke Rogers(25)	94,128	94,128	—	*
E. Jeffrey Peierls(26)	70,596	70,596	—	*
Edward O'Connell(27)	9,413	9,413	—	*
Edward P. Swyer LLC(28)	235,321	235,321	—	*
Foster Family Trust(29)	23,532	23,532	—	*
FourJr Investments LTD(30)	23,532	23,532	—	*
Frederick B. Epstein(31)	11,766	11,766	—	*
GSB Holdings, Inc.(32)	235,321	235,321	—	*
Gubbay Investments, LLC(33)	16,507	16,507	—	*
Gwen Swenson-Hale(34)	11,765	11,765	—	*
Howard & Susan Kalka(35)	35,328	35,328	—	*
Howard Stringer(36)	11,766	11,766	—	*
Intracoastal Capital, LLC(37)	47,064	47,064	—	*
Iroquois Capital Investment Group LLC(38)	28,238	28,238	—	*
Iroquois Master Fund Ltd(39)	89,422	89,422	—	*
Irwin Gruverman(40)	11,765	11,765	—	*
Jai V. Desai(41)	14,119	14,119	—	*
James H. Wiesenberg(42)	11,765	11,765	—	*
James J. Watson(43)	23,532	23,532	—	*
James L. Dritz(44)	18,826	18,826	—	*
Jan Arnett(45)	47,064	47,064	—	*
Jay M. Haft(46)	11,766	11,766	—	*
Jayesh K. Patel & Bela J. Patel(47)	47,064	47,064	—	*
Jesal Kothari(48)	7,059	7,059	—	*
Jimmy R. Hasley(49)	14,120	14,120	—	*
Joan L Bonanno TTE U/A DTD 12/05/2002 By Joan L Bonanno(50)	47,064	47,064	—	*
John Q Joubert & Terri L Joubert(51)	47,064	47,064	—	*
John E. Kyees(52)	11,766	11,766	—	*

Selling Stockholder	Shares beneficially owned prior to offering	Number of shares being offered	Shares beneficially owned after offering	Percentage of outstanding shares beneficially owned after offering(1)
John V. Wagner, Jr.(53)	35,298	35,298	—	*
Juli-Ann Cialone(54)	4,707	4,707	—	*
Kara Lynn Hart(55)	11,765	11,765	—	*
Keith J. Gelles(56)	23,532	23,532	—	*
Lars Bader(57)	470,642	470,642	—	*
Lee J. Seidler Revocable Trust DTD 4/12/1990(58)	23,561	23,561	—	*
Mackie Klingbeil(59)	23,561	23,561	—	*
Mahendra Doobay(60)	4,706	4,706	—	*
Meryle Evans Family Trust(61)	11,766	11,766	—	*
Michael J. Pierce(62)	94,128	94,128	—	*
Michael M. Mainero(63)	11,766	11,766	—	*
Michael Stark(64)	11,765	11,765	—	*
MITZ ZHU YAN,LP(65)	23,532	23,532	—	*
N. Michael Wolsonovich, Jr.(66)	7,060	7,060	—	*
Nomis Bay LTD(67)	1,411,924	1,411,924	—	*
Northlea Partners LLLP(68)	11,765	11,765	—	*
OHB Family Trust(69)	23,532	23,532	—	*
Pamela M. Baker & Russell S. Baker(70)	23,532	23,532	—	*
Peter S. Kastner(71)	23,532	23,532	—	*
Provident Trust Group LLC FBO Universal Technology Inc. 401K Plan FBO Robert G. Curtin(72)	135,671	135,671	—	*
Rameshchandra Dabhi(73)	23,531	23,531	—	*
Raphael Tshibangu(74)	18,826	18,826	—	*
Raymond J Bonanno TTE U/A DTD 12/05/2002 By Raymond J Bonanno(75)	47,064	47,064	—	*
Renald J. & Catherine C. Anelle(76)	23,561	23,561	—	*
Richard A Brown Trust(77)	81,403	81,403	—	*
Richard David(78)	23,532	23,532	—	*
Rickey Family Trust dtd 3/22/16(79)	30,592	30,592	—	*
Robert Caione(80)	23,532	23,532	—	*
Robert G. Curtin(81)	4,975	4,975	—	*
Robert Harrigan(82)	26,316	26,316	—	*
RS & VS LTD(83)	11,765	11,765	—	*
RS Irrevocable Trust(84)	235,321	235,321	—	*
Russell S. Dritz(85)	7,060	7,060	—	*
Saha Living LLC(86)	47,064	47,064	—	*
Sal DeStefano(87)	11,765	11,765	—	*

Selling Stockholder	Shares beneficially owned prior to offering	Number of shares being offered	Shares beneficially owned after offering	Percentage of outstanding shares beneficially owned after offering(1)
Satterfield Vintage Investments, LP(88)	117,673	117,673	—	*
SDL Ventures, LLC(89)	141,192	141,192	—	*
Sphera Global Healthcare Master Fund(90)	1,142,717	1,142,717	—	*
HFR HE Sphera Global Healthcare Master Trust (91)	33,886	33,886	—	*
Stephen A. DiChiara(92)	7,059	7,059	—	*
Steven M. Cohen(93)	18,826	18,826	—	*
Suresh Patel(94)	11,765	11,765	—	*
The Fourys Co. LTD(95)	37,652	37,652	—	*
The Peierls Bypass Trust(96)	6,588	6,588	—	*
The Peierls Foundation, Inc.(97)	316,271	316,271	—	*
UD E.F. Peierls for Brian E. Peierls(98)	24,473	24,473	—	*
UD E.F. Peierls for E. Jeffrey Peierls(99)	24,473	24,473	—	*
UD E.S. Peierls for E.F. Peierls et al(100)	16,943	16,943	—	*
UD Ethel F. Peierls Charitable Lead Trust(101)	37,651	37,651	—	*
UD J.N. Peierls for Brian Eliot Peierls(102)	31,063	31,063	—	*
UD J.N. Peierls for E. Jeffrey Peierls(103)	31,063	31,063	—	*
UKR Partners LLC(104)	1,579,559	1,579,559	—	*
UW E.S. Peierls for Brian E. Peierls - Accumulation(105)	22,590	22,590	—	*
UW E.S. Peierls for E. Jeffrey Peierls - Accumulation(106)	13,177	13,177	—	*
UW J.N. Peierls for Brian E. Peierls(107)	27,297	27,297	—	*
UW J.N. Peierls for E. Jeffrey Peierls(108)	27,297	27,297	—	*
Vijay & Tejal Patel(109)	117,659	117,659	—	*
Valley Forge Investments LLC(110)	94,128	94,128	—	*
Walter G. Gans(111)	7,060	7,060	—	*
Yisroel Brauner & Chana Brauner(112)	23,532	23,532	—	*
Amit Patel	69,267	69,267	—	*
Anthony Barrett	58,869	58,869	—	*
Ashit Vijapura	80,298	80,298	—	*
Ashwin N. Patel & Achala A. Patel	107,065	107,065	—	*
Atul and Namrata Wadhwa	41,346	41,346	—	*
Bearing Circle Capital LLC	109,242	109,242	—	*
Bhavesh Patel	14,229	14,229	—	*
Bhikabhai Nayi	13,104	13,104	—	*
Bijal Patel	15,728	15,728	—	*
Bindu Sangani	80,344	80,344	—	*

Selling Stockholder	Shares beneficially owned prior to offering	Number of shares being offered	Shares beneficially owned after offering	Percentage of outstanding shares beneficially owned after offering(1)
Charles Mosseri-Marlio	153,442	153,442	—	*
David Cassimus	13,836	13,836	—	*
David Purdy	74,800	74,800	—	*
Deepen R. Patel	5,423	5,423	—	*
Himanshu M. Patel	51,511	51,511	—	*
Hiren K. Patel	27,784	27,784	—	*
Howard Yee	20,578	20,578	—	*
Nailesh Sangani	132,051	132,051	—	*
Janet League Katzin	222,555	222,555	—	*
Jay Madan	6,839	6,839	—	*
Jigar J. Patel	7,939	7,939	—	*
Jonathan Barrett	162,065	162,065	—	*
JRK Inc.	27,419	27,419	—	*
Juan Vallarino	60,044	60,044	—	*
Justin Prior	15,554	15,554	—	*
Karl Pinto	14,972	14,972	—	*
Kumar Patel	68,500	68,500	—	*
Malika Sangani	53,002	53,002	—	*
Malur R. Balaji	53,522	53,522	—	*
Marilyn Hemani	40,276	40,276	—	*
Mary Cheeran	53,532	53,532	—	*
Michael Mindlin	60,297	60,297	—	*
Nalini Krishnankutty	13,385	13,385	—	*
Niranjana Patel	8,135	8,135	—	*
ONE by NP	26,358	26,358	—	*
Parul T. Patel	53,532	53,532	—	*
Piyush Patel	26,761	26,761	—	*
Praful Patel	106,507	106,507	—	*
Prentice Lending II LLC	695,562	695,562	—	*
Raj S. Shah	13,104	13,104	—	*
Rajesh and Suny Patel	27,799	27,799	—	*
Rajesh B. Patel	68,460	68,460	—	*
Rakesh Shah	80,621	80,621	—	*
Rameschchandra Dabhi	105,951	105,951	—	*
Ramesh Donthamsetty	30,689	30,689	—	*
Rathin Patel	13,906	13,906	—	*
Saurabh Shah	14,214	14,214	—	*

Selling Stockholder	Shares beneficially owned prior to offering	Number of shares being offered	Shares beneficially owned after offering	Percentage of outstanding shares beneficially owned after offering(1)
SDS Capital Partners II, LLC	262,924	262,924	—	*
Sebastian Prior	15,554	15,554	—	*
Shuchin Bajaj	5,693	5,693	—	*
Sireesh Appajosyula	30,689	30,689	—	*
Subhashini Chandran	5,692	5,692	—	*
Sujata Shah	53,522	53,522	—	*
Sunil and Prity Vaidya	80,298	80,298	—	*
Sunil Kumar S. Reddy	26,761	26,761	—	*
Todd Gallinek	8,536	8,536	—	*
Vijay Patel & Mrs. Tejal Patel	106,312	106,312	—	*
Vijay Taunk	53,522	53,522	—	*
Vikram Patel	80,750	80,750	—	*
Wallace R. Nelms	22,768	22,768	—	*
Aaron Segal(113)	115,501	115,501	—	*
David Landskowsky(114)	74,158	74,158	—	*
Eric Rubenstein(115)	74,158	74,158	—	*
Todd Harrigan(116)	60,419	60,419	—	*
Tim Herrmann(117)	30,387	30,387	—	*
Scott Cardone(118)	18,612	18,612	—	*
Albert Pezone(119)	29,363	29,363	—	*
Steven Nicholson(120)	8,471	8,471	—	*
Kimberly Bechtle(121)	3,677	3,677	—	*
Lindsey McGrandy(122)	2,680	2,680	—	*
Richard Mish(123)	2,038	2,038	—	*
Michael Vasinkevich(124)	141,718	141,718	—	*
Sean Hagerty(125)	39,891	39,891	—	*
Noam Rubinstein(126)	26,244	26,244	—	*
Charles Worthman(127)	2,100	2,100	—	*
Total	13,990,403			

* Less than 1%

(1) Based upon 25,695,602 shares of common stock outstanding as of the close of business on July 5, 2018 (the “Measurement Date”) in accordance with Rule 13d-3 under the Securities Exchange Act of 1934.

(2) Shares beneficially owned includes a warrant to purchase 8,773 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(3) Shares beneficially owned includes a warrant to purchase 3,927 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(4) Shares beneficially owned includes a warrant to purchase 5,700 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(5) Shares beneficially owned includes a warrant to purchase 3,922 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(6) Shares beneficially owned includes a warrant to purchase 7,844 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(7) Shares beneficially owned includes a warrant to purchase 1,569 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(8) Shares beneficially owned includes a warrant to purchase 78,441 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(9) Shares beneficially owned includes a warrant to purchase 2,354 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(10) Shares beneficially owned includes a warrant to purchase 2,354 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(11) Shares beneficially owned includes a warrant to purchase 3,922 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(12) Shares beneficially owned includes a warrant to purchase 2,746 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(13) Shares beneficially owned includes a warrant to purchase 1,961 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(14) Shares beneficially owned includes a warrant to purchase 9,413 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(15) Shares beneficially owned includes a warrant to purchase 3,922 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(16) Shares beneficially owned includes a warrant to purchase 7,844 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(17) Shares beneficially owned includes a warrant to purchase 2,746 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(18) Shares beneficially owned includes a warrant to purchase 7,844 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(19) Shares beneficially owned includes a warrant to purchase 1,177 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(20) Shares beneficially owned includes a warrant to purchase 2,354 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(21) Shares beneficially owned includes a warrant to purchase 3,922 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(22) Shares beneficially owned includes a warrant to purchase 1,961 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(23) Shares beneficially owned includes a warrant to purchase 1,961 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(24) Shares beneficially owned includes a warrant to purchase 39,221 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(25) Shares beneficially owned includes a warrant to purchase 15,688 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(26) Shares beneficially owned includes a warrant to purchase 11,766 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(27) Shares beneficially owned includes a warrant to purchase 1,569 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(28) Shares beneficially owned includes a warrant to purchase 39,221 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(29) Shares beneficially owned includes a warrant to purchase 3,922 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(30) Shares beneficially owned includes a warrant to purchase 3,922 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(31) Shares beneficially owned includes a warrant to purchase 1,961 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(32) Shares beneficially owned includes a warrant to purchase 39,221 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(33) Shares beneficially owned includes a warrant to purchase 2,752 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(34) Shares beneficially owned includes a warrant to purchase 1,961 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(35) Shares beneficially owned includes a warrant to purchase 5,888 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(36) Shares beneficially owned includes a warrant to purchase 1,961 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(37) Shares beneficially owned includes a warrant to purchase 7,844 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase. Mitchell P. Kopin ("Mr. Kopin") and Daniel B. Asher ("Mr. Asher"), each of whom are managers of Intracoastal Capital LLC ("Intracoastal"), have shared voting control and investment discretion over the securities reported herein that are held by Intracoastal. As a result, each of Mr. Kopin and Mr. Asher may be deemed to have beneficial ownership (as determined under Section 13(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) of the securities reported herein that are held by Intracoastal.

(38) Shares beneficially owned includes a warrant to purchase 4,707 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(39) Shares beneficially owned includes a warrant to purchase 14,904 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(40) Shares beneficially owned includes a warrant to purchase 1,961 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(41) Shares beneficially owned includes a warrant to purchase 2,354 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(42) Shares beneficially owned includes a warrant to purchase 1,961 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(43) Shares beneficially owned includes a warrant to purchase 3,922 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(44) Shares beneficially owned includes a warrant to purchase 3,138 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(45) Shares beneficially owned includes a warrant to purchase 7,844 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(46) Shares beneficially owned includes a warrant to purchase 1,961 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(47) Shares beneficially owned includes a warrant to purchase 7,844 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(48) Shares beneficially owned includes a warrant to purchase 1,177 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(49) Shares beneficially owned includes a warrant to purchase 2,354 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(50) Shares beneficially owned includes a warrant to purchase 7,844 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(51) Shares beneficially owned includes a warrant to purchase 7,844 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(52) Shares beneficially owned includes a warrant to purchase 1,961 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(53) Shares beneficially owned includes a warrant to purchase 5,883 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(54) Shares beneficially owned includes a warrant to purchase 785 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(55) Shares beneficially owned includes a warrant to purchase 1,961 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(56) Shares beneficially owned includes a warrant to purchase 3,922 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(57) Shares beneficially owned includes a warrant to purchase 78,441 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(58) Shares beneficially owned includes a warrant to purchase 3,927 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(59) Shares beneficially owned includes a warrant to purchase 3,927 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(60) Shares beneficially owned includes a warrant to purchase 785 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(61) Shares beneficially owned includes a warrant to purchase 1,961 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(62) Shares beneficially owned includes a warrant to purchase 15,688 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(63) Shares beneficially owned includes a warrant to purchase 1,961 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(64) Shares beneficially owned includes a warrant to purchase 1,961 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(65) Shares beneficially owned includes a warrant to purchase 3,922 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(66) Shares beneficially owned includes a warrant to purchase 1,177 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(67) Shares beneficially owned includes a warrant to purchase 235,321 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(68) Shares beneficially owned includes a warrant to purchase 1,961 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(69) Shares beneficially owned includes a warrant to purchase 3,922 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(70) Shares beneficially owned includes a warrant to purchase 3,922 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(71) Shares beneficially owned includes a warrant to purchase 3,922 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(72) Shares beneficially owned includes a warrant to purchase 22,612 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(73) Shares beneficially owned includes a warrant to purchase 3,922 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(74) Shares beneficially owned includes a warrant to purchase 3,138 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(75) Shares beneficially owned includes a warrant to purchase 7,844 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(76) Shares beneficially owned includes a warrant to purchase 3,927 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(77) Shares beneficially owned includes a warrant to purchase 13,568 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(78) Shares beneficially owned includes a warrant to purchase 3,922 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(79) Shares beneficially owned includes a warrant to purchase 5,099 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(80) Shares beneficially owned includes a warrant to purchase 3,922 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(81) Shares beneficially owned includes a warrant to purchase 830 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(82) Shares beneficially owned includes a warrant to purchase 4,386 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(83) Shares beneficially owned includes a warrant to purchase 1,961 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(84) Shares beneficially owned includes a warrant to purchase 39,221 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(85) Shares beneficially owned includes a warrant to purchase 1,177 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(86) Shares beneficially owned includes a warrant to purchase 7,844 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(87) Shares beneficially owned includes a warrant to purchase 1,961 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(88) Shares beneficially owned includes a warrant to purchase 19,613 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(89) Shares beneficially owned includes a warrant to purchase 23,532 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(90) Shares beneficially owned includes a warrant to purchase 190,453 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(91) Shares beneficially owned includes a warrant to purchase 5,648 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(92) Shares beneficially owned includes a warrant to purchase 1,177 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(93) Shares beneficially owned includes a warrant to purchase 3,138 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(94) Shares beneficially owned includes a warrant to purchase 1,961 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(95) Shares beneficially owned includes a warrant to purchase 6,276 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(96) Shares beneficially owned includes a warrant to purchase 1,098 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(97) Shares beneficially owned includes a warrant to purchase 52,712 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(98) Shares beneficially owned includes a warrant to purchase 4,079 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(99) Shares beneficially owned includes a warrant to purchase 4,079 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(100) Shares beneficially owned includes a warrant to purchase 2,824 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(101) Shares beneficially owned includes a warrant to purchase 6,276 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(102) Shares beneficially owned includes a warrant to purchase 5,178 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(103) Shares beneficially owned includes a warrant to purchase 5,178 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(104) Shares beneficially owned includes a warrant to purchase 117,661 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(105) Shares beneficially owned includes a warrant to purchase 3,765 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(106) Shares beneficially owned includes a warrant to purchase 2,196 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(107) Shares beneficially owned includes a warrant to purchase 4,550 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(108) Shares beneficially owned includes a warrant to purchase 4,550 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(109) Shares beneficially owned includes a warrant to purchase 19,610 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(110) Shares beneficially owned includes a warrant to purchase 15,688 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(111) Shares beneficially owned includes a warrant to purchase 1,177 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(112) Shares beneficially owned includes a warrant to purchase 3,922 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(113) Shares beneficially owned includes a warrant to purchase 115,501 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(114) Shares beneficially owned includes a warrant to purchase 74,158 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(115) Shares beneficially owned includes a warrant to purchase 74,158 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(116) Shares beneficially owned includes a warrant to purchase 60,419 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(117) Shares beneficially owned includes a warrant to purchase 30,387 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(118) Shares beneficially owned includes a warrant to purchase 18,612 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(119) Shares beneficially owned includes a warrant to purchase 29,363 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(120) Shares beneficially owned includes a warrant to purchase 8,471 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(121) Shares beneficially owned includes a warrant to purchase 3,677 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(122) Shares beneficially owned includes a warrant to purchase 2,680 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(123) Shares beneficially owned includes a warrant to purchase 2,038 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(124) Shares beneficially owned includes a warrant to purchase 141,718 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(125) Shares beneficially owned includes a warrant to purchase 39,891 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(126) Shares beneficially owned includes a warrant to purchase 26,244 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

(127) Shares beneficially owned includes a warrant to purchase 2,100 shares of our common stock, which is fully exercisable for up to five (5) years from the date of purchase.

PLAN OF DISTRIBUTION

We and/or the selling stockholders, if applicable, may sell the securities offered through this prospectus (1) to or through underwriters or dealers, (2) directly to purchasers, including our affiliates, (3) through agents, or (4) through a combination of any these methods. The securities may be distributed at a fixed price or prices, which may be changed, market prices prevailing at the time of sale, prices related to the prevailing market prices, or negotiated prices.

The prospectus supplement relating to any offering will include the following information:

- the terms of the offering;
- the names of any underwriters or agents;
- the name or names of any managing underwriter or underwriters;
- the purchase price of the securities;
- the net proceeds from the sale of the securities;
- any delayed delivery arrangements;
- any underwriting discounts, commissions and other items constituting underwriters' compensation;
- any discounts or concessions allowed or reallowed or paid to dealers; and
- any commissions paid to agents.

Sale through Underwriters or Dealers

If underwriters are used in the sale, the underwriters will acquire the securities for their own account, including through underwriting, purchase, security lending or repurchase agreements with us. The underwriters may resell the securities from time to time in one or more transactions, including negotiated transactions. Underwriters may sell the securities in order to facilitate transactions in any of our other securities (described in this prospectus or otherwise), including other public or private transactions and short sales. Underwriters may offer securities to the public either through underwriting syndicates represented by one or more managing underwriters or directly by one or more firms acting as underwriters. Unless otherwise indicated in the prospectus supplement, the obligations of the underwriters to purchase the securities will be subject to certain conditions, and the underwriters will be obligated to purchase all the offered securities if they purchase any of them. The underwriters may change from time to time any price and any discounts or concessions allowed or reallowed or paid to dealers. The prospectus supplement will include the names of the principal underwriters the respective amount of securities underwritten, the nature of the obligation of the underwriters to take the securities and the nature of any material relationship between an underwriter and us.

Some or all of the securities that we offer through this prospectus may be new issues of securities with no established trading market. Any underwriters to whom we sell securities for public offering and sale may make a market in those securities, but they will not be obligated to do so and they may discontinue any market making at any time without notice. Accordingly, we cannot assure you of the liquidity of, or continued trading markets for, any securities offered pursuant to this prospectus.

If dealers are used in the sale of securities offered through this prospectus, we or the selling stockholders will sell the securities to them as principals. They may then resell those securities to the public at varying prices determined by the dealers at the time of resale. The prospectus supplement will include the names of the dealers and the terms of the transaction.

Direct Sales and Sales through Agents

We or the selling stockholders may sell the securities offered through this prospectus directly. In this case, no underwriters or agents would be involved. Such securities may also be sold through agents designated from time to time. The prospectus supplement will name any agent involved in the offer or sale of the offered securities and will describe any commissions payable to the agent by us or the selling stockholders. Unless otherwise indicated in the prospectus supplement, any agent will agree to use its reasonable best efforts to solicit purchases for the period of its appointment.

We or the selling stockholders may sell the securities directly to institutional investors or others who may be deemed to be underwriters within the meaning of the Securities Act with respect to any sale of those securities. The terms of any such sales will be described in the prospectus supplement.

At-the-Market Offerings

To the extent that we make sales through one or more underwriters or agents in at-the-market offerings, we will do so pursuant to the terms of a sales agency financing agreement or other at-the-market offering arrangement between us, on one hand, and the underwriters or agents, on the other. If we engage in at-the-market sales pursuant to any such agreement, we will issue and sell our securities through one or more underwriters or agents, which may act on an agency basis or a principal basis. During the term of any such agreement, we may sell securities on a daily basis in exchange transactions or otherwise as we agree with the underwriters or agents. Any such agreement will provide that any securities sold will be sold at prices related to the then prevailing market prices for our securities. Therefore, exact figures regarding proceeds that will be raised or commissions to be paid cannot be determined at this time. Pursuant to the terms of the agreement, we may agree to sell, and the relevant underwriters or agents may agree to solicit offers to purchase blocks of our common stock or other securities. The terms of any such agreement will be set forth in more detail in the applicable prospectus or prospectus supplement.

Delayed Delivery Contracts

If the prospectus supplement indicates, we or the selling stockholders may authorize agents, underwriters or dealers to solicit offers from certain types of institutions to purchase securities at the public offering price under delayed delivery contracts. These contracts would provide for payment and delivery on a specified date in the future. The contracts would be subject only to those conditions described in the prospectus supplement. The applicable prospectus supplement will describe the commission payable for solicitation of those contracts.

Derivative Transactions and Hedging

We, the underwriters or other agents may engage in derivative transactions involving the securities. These derivatives may consist of short sale transactions and other hedging activities. The underwriters or agents may acquire a long or short position in the securities, hold or resell securities acquired and purchase options or futures on the securities and other derivative instruments with returns linked to or related to changes in the price of the securities. In order to facilitate these derivative transactions, we may enter into security lending or repurchase agreements with the underwriters or agents. The underwriters or agents may effect the derivative transactions through sales of the securities to the public, including short sales, or by lending the securities in order to facilitate short sale transactions by others. The underwriters or agents may also use the securities purchased or borrowed from us or others (or, in the case of derivatives, securities received from us in settlement of those derivatives) to directly or indirectly settle sales of the securities or close out any related open borrowings of the securities.

Electronic Auctions

We or the selling stockholders may also make sales through the Internet or through other electronic means. Since we or the selling stockholders may from time to time elect to offer securities directly to the public, with or without the involvement of agents, underwriters or dealers, utilizing the Internet or other forms of electronic bidding or ordering systems for the pricing and allocation of such securities, you should pay particular attention to the description of that system we will provide in a prospectus supplement. Such electronic system may allow bidders to directly participate, through electronic access to an auction site, by submitting conditional offers to buy that are subject to acceptance by us, and which may directly affect the price or other terms and conditions at which such securities are sold. These bidding or ordering systems may present to each bidder, on a so-called “real-time” basis, relevant information to assist in making a bid, such as the clearing spread at which the offering would be sold, based on the bids submitted, and whether a bidder’s individual bids would be accepted, prorated or rejected. For example, in the case of a debt security, the clearing spread could be indicated as a number of “basis points” above an index treasury note. Of course, many pricing methods can and may also be used.

Upon completion of such an electronic auction process, securities will be allocated based on prices bid, terms of bid or other factors. The final offering price at which securities would be sold and the allocation of securities among bidders would be based in whole or in part on the results of the Internet or other electronic bidding process or auction.

Rule 144

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act of 1933, provided that it meets the criteria and conforms to the requirements of that rule.

The selling stockholders and any broker-dealers that act in connection with the sale of securities may be deemed to be “underwriters” within the meaning of Section 2(11) of the Securities Act in connection with such sales, and any commissions received by such broker-dealers and any profit on the resale of the securities sold by them while acting as principals may be deemed to be underwriting discounts or commissions under the Securities Act. In the event that any selling stockholder is deemed to be an “underwriter” within the meaning of Section 2(11) of the Securities Act, such selling stockholder will be subject to the prospectus delivery requirements of the Securities Act. We and the selling stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

General Information

Agents, underwriters, and dealers may be entitled, under agreements entered into with us, to indemnification by us or the selling stockholders against certain liabilities, including liabilities under the Securities Act. Agents, dealers, and underwriters may engage in transactions with or perform services for us in the ordinary course of their businesses.

DESCRIPTION OF CAPITAL STOCK

This section summarizes our authorized and outstanding securities and certain of the provisions of our amended and restated certificate of incorporation and our amended and restated bylaws.

General

The Company's authorized capital stock consists of 360,000,000 shares of capital stock, par value $0.0001 per share, of which 350,000,000 shares are common stock, par value $0.0001 per share and 10,000,000 of preferred stock, par value $0.0001. As of July 5, 2018, the Company had 25,695,602 shares of common stock outstanding held by approximately 341 shareholders of record, and no shares of preferred stock outstanding.

Common Stock

The holders of our common stock (i) have equal ratable rights to dividends from funds legally available, therefore, when, as and if declared by our Board; (ii) are entitled to share in all of our assets available for distribution to holders of common stock upon liquidation, dissolution or winding up of our affairs; (iii) do not have preemptive, subscription or conversion rights and there are no redemption or sinking fund provisions or rights; and (iv) are entitled to one non-cumulative vote per share on all matters on which stockholders may vote. Reference is made to the Company's Amended and Restated Certificate of Incorporation, Amended and Restated Bylaws, and the applicable statutes of the State of Delaware for a more complete description of the rights and liabilities of holders of the Company's securities.

Preferred Stock

The Company has authorized 10,000,000 shares of preferred stock. There is no preferred stock outstanding.

Non-cumulative Voting

Holders of shares of our common stock do not have cumulative voting rights; meaning that the holders of 50.1% of the outstanding shares, voting for the election of directors, can elect all of the directors to be elected, and, in such event, the holders of the remaining shares will not be able to elect any of our directors.

Dividends

We have not paid any cash dividends to stockholders. The declaration of any future cash dividend will be at the discretion of our Board and will depend upon our earnings, if any, our capital requirements and financial position, our general economic conditions, and other pertinent conditions. It is our present intention not to pay any cash dividends in the foreseeable future, but rather to reinvest earnings, if any, in our business operations.

Warrants

As of the date of this registration statement, the Company has warrants outstanding, which entitle their holders to purchase (i) 1,702,216 shares of common stock, with a term of five years and an exercise price of $3.18 per share, and (ii) 349,555 shares of common stock, with a term of five years and an exercise price of $2.54 per share. Such warrants contain certain customary exceptions, as well as customary provisions for adjustment in the event of stock splits, subdivision or combination, mergers, and similar business combinations.

Anti-Takeover Effects of Certain Provisions of Delaware Law and Charter and Bylaw Provisions

Certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws could discourage potential acquisition proposals and could delay or prevent a change in control. These provisions are intended to enhance the likelihood of continuity and stability in the composition of our board of directors and in the policies formulated by our board of directors and to discourage certain types of transactions that may involve an actual or threatened change of control. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal. The provisions also are intended to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they also may inhibit fluctuations in the market price of our Common Stock that could result from actual or rumored takeover attempts. Such provisions also may have the effect of preventing changes in our management or delaying or preventing a transaction that might benefit you or other minority stockholders.

Certain Limitations on Stockholder Actions. Our bylaws will also impose some procedural requirements on stockholders who wish to:

- make nominations in the election of directors;

- propose that a director be removed;
- propose any repeal or change in our bylaws; or
- propose any other business to be brought before an annual or special meeting of stockholders.

Under these procedural requirements, in order to bring a proposal before a meeting of stockholders, a stockholder must deliver timely notice of a proposal pertaining to a proper subject for presentation at the meeting to our corporate secretary along with the following:

- a description of the business or nomination to be brought before the meeting and the reasons for conducting such business at the meeting;
- the stockholder's name and address;
- any material interest of the stockholder in the proposal;
- the number of shares beneficially owned by the stockholder and evidence of such ownership; and
- the names and addresses of all persons with whom the stockholder is acting in concert and a description of all arrangements and understandings with those persons, and the number of shares such persons beneficially own.

To be timely, a stockholder must generally deliver notice not less than 90 days prior the anniversary date of the immediately preceding annual meeting of stockholders.

In order to submit a nomination for our board of directors, a stockholder must also submit any information with respect to the nominee that we would be required to include in a proxy statement, as well as some other information. If a stockholder fails to follow the required procedures, the stockholder's proposal or nominee will be ineligible and will not be voted on by our stockholders.

LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus and other legal matters will be passed upon for us by Wilson Sonsini Goodrich & Rosati, PC, San Diego, California. Additional legal matters may be passed upon for us, or any underwriters, dealers or agents, by counsel that we will name in the applicable prospectus supplement.

EXPERTS

The consolidated financial statements of Monster Digital, Inc., as of December 31, 2017 and 2016, and for the years then ended, have been incorporated by reference herein and in the registration statement, which includes an explanatory paragraph relating to the Company's ability to continue as a going concern, in reliance upon the report of CohnReznick LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

Mayer Hoffman McCann P.C., our independent registered public accounting firm, has audited our balance sheets as of December 31, 2017 and 2016, and the related statements of operations and comprehensive loss, stockholders' deficit and cash flows for each of the two years in the period ended December 31, 2017, as set forth in their report, which report expresses an unqualified opinion and includes an explanatory paragraph relating to our ability to continue as a going concern. We have incorporated by reference the financial statements in this registration statement in reliance on the report of Mayer Hoffman McCann P.C. given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We file annual, quarterly and other reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at http://www.sec.gov. You may also read and copy any document we file at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the Public Reference Room. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K, including any amendments to those reports, and other information we file with or furnish to the SEC pursuant to Section 13(a) or 15(d) of the Exchange Act can also be accessed free of charge at our website at http://www.innovatebiopharma.com. Such information is made available on our website as soon as reasonably practicable after we electronically file it with or furnish it to the SEC. Information contained on our website is not part of this prospectus.

INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" into this prospectus the information we file with the SEC, which means we may disclose important information to you by referring you to other documents we file separately with the SEC. The information we incorporate by reference is considered a part of this prospectus. We hereby incorporate by reference the following documents:

- Innovate's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 filed on March 14, 2018, as amended on June 29, 2018;
- Innovate's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, filed on May 15, 2018; and
- Innovate's Current Reports on Form 8-K filed on January 5, January 11, February 2 (as amended on March 29, 2018, and April 18, 2018), February 22, February 23, March 14, April 20, May 15, June 18, and June 29, 2018.

Any information in the foregoing documents will automatically be deemed to be modified or superseded to the extent that information in this prospectus modifies or replaces such information. We also incorporate by reference any future filings (other than information furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items) made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act until we file a post-effective amendment which indicates that all securities offered hereby have been sold or which deregisters all securities then remaining unsold. All filings made with the SEC pursuant to the Exchange Act after the date of this Registration Statement and prior to effectiveness of the Registration Statement are incorporated by reference. Information in such future filings shall be deemed to update and supplement the information provided in this prospectus, and any statements in such future filings will automatically be deemed to modify and supersede any information in any document we previously filed with the SEC that is incorporated or deemed to be incorporated herein by reference to the extent that the statements in the later filed document modify or replace such earlier statements.

You may obtain from us copies of the documents incorporated by reference in this prospectus, at no cost, by requesting them in writing or by telephone at:

Innovate Biopharmaceuticals, Inc.
8480 Honeycutt Road, Suite 120
Raleigh, NC 27615
(919) 275-1933

Up to $40,000,000

Common Stock

PROSPECTUS SUPPLEMENT

H.C. Wainwright & Co. **Ladenburg Thalmann**

October 26, 2018