UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

☑ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended June 30, 2018
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number **001-37797**

INNOVATE BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**27-3948465**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

8480 Honeycutt Road, Suite 120
Raleigh, North Carolina 27615
(Address of principal executive offices, including zip code)

(919) 275-1933
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "non-accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☑
(Do not check if smaller reporting company)		Emerging growth company	☑

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

As of August 7, 2018, the registrant had 25,787,437 shares of common stock, par value $0.0001 per share, issued and outstanding.

TABLE OF CONTENTS

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

INNOVATE BIOPHARMACEUTICALS, INC.

Condensed Balance Sheets

	(Unaudited) June 30, 2018	December 31, 2017
Assets		
Current Assets:		
Cash and cash equivalents	$ 10,663,434	$ 355,563
Prepaid expenses	244,390	161,844
Deferred offering costs	—	159,795
Due from related party	—	75,000
Total current assets	10,907,824	752,202
Property and equipment, net	45,371	40,707
Other assets	5,580	5,580
Total assets	$ 10,958,775	$ 798,489
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 3,347,614	$ 2,658,637
Accrued expenses	—	1,180,225
Note payable, net of debt discount	4,151,985	—
Convertible promissory notes, net	—	8,329,045
Convertible promissory notes, related party, net	—	244,816
Accrued interest	—	560,380
Total current liabilities	7,499,599	12,973,103
Commitments and contingencies (Note 8)		
Stockholders' equity (deficit)		
Common stock* - $0.0001 par value, 350,000,000 and 250,000,000 shares authorized; 25,695,602 and 11,888,240 shares issued and outstanding as of June 30, 2018 and December 31, 2017, respectively	2,570	11,888
Additional paid-in-capital	43,181,593	7,167,189
Accumulated deficit	(39,724,987)	(19,353,691)
Total stockholders' equity (deficit)	3,459,176	(12,174,614)
Total liabilities and stockholders' equity (deficit)	$ 10,958,775	$ 798,489

* Common shares adjusted for the exchange ratio from the reverse recapitalization

See accompanying notes to these condensed financial statements.

INNOVATE BIOPHARMACEUTICALS, INC.

Condensed Statements of Operations and Comprehensive Loss

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Operating expenses:				
Research and development	$ 1,243,221	$ 1,129,733	$ 7,601,225	$ 2,465,236
General and administrative	2,132,850	1,561,106	8,299,463	4,141,832
Total operating expenses	3,376,071	2,690,839	15,900,688	6,607,068
Loss from operations	(3,376,071)	(2,690,839)	(15,900,688)	(6,607,068)
Other income (expense):				
Interest income	54,637	—	85,129	—
Interest expense	(894,118)	(99,483)	(4,555,737)	(171,130)
Total other income (expense), net	(839,481)	(99,483)	(4,470,608)	(171,130)
Loss before income taxes	(4,215,552)	(2,790,322)	(20,371,296)	(6,778,198)
Benefit from (provision for) income taxes	—	—	—	—
Net loss	$ (4,215,552)	$ (2,790,322)	$ (20,371,296)	$ (6,778,198)
Net loss per common share, basic and diluted*	$ (0.16)	$ (0.23)	$ (0.87)	$ (0.57)
Weighted-average common shares, basic and diluted*	25,695,171	11,888,240	23,481,834	11,888,240

* Common shares adjusted for the exchange ratio from the reverse recapitalization

See accompanying notes to these condensed financial statements.

INNOVATE BIOPHARMACEUTICALS, INC.

Condensed Statements of Stockholders' Equity (Deficit)

	Common Stock*					
	Shares	Amount	Additional Paid-in-Capital	Accumulated Deficit	Stock Subscription Receivable	Total
Balance as of December 31, 2016	11,888,240	$ 11,888	$ 1,148,457	$ (7,747,874)	$ (25)	$ (6,587,554)
Payment of stock subscription receivable	—	—	—	—	25	25
Share-based compensation	—	—	6,018,732	—	—	6,018,732
Net loss	—	—	—	(11,605,817)	—	(11,605,817)
Balance as of December 31, 2017	11,888,240	11,888	7,167,189	(19,353,691)	—	(12,174,614)
Change in par value from $0.001 to $0.0001	—	(10,699)	10,699	—	—	—
Issuance of shares as a result of reverse recapitalization	1,864,808	186	(978,860)	—	—	(978,674)
Issuance of common stock	7,111,631	711	16,136,950	—	—	16,137,661
Warrants issued with common stock	—	—	1,995,000	—	—	1,995,000
Warrants issued to placement agents	—	—	913,000	—	—	913,000
Stock issuance costs	—	—	(2,568,079)	—	—	(2,568,079)
Conversion of convertible debt and accrued interest	4,827,001	483	9,229,336	—	—	9,229,819
Beneficial conversion feature	—	—	3,077,887	—	—	3,077,887
Share-based compensation	—	—	8,186,000	—	—	8,186,000
Exercise of warrants	3,922	1	12,471	—		12,472
Net loss	—	—	—	(20,371,296)	—	(20,371,296)
Balance as of June 30, 2018 (unaudited)	25,695,602	$ 2,570	$ 43,181,593	$ (39,724,987)	$ —	$ 3,459,176

* Common shares adjusted for the exchange ratio from the reverse recapitalization

See accompanying notes to these condensed financial statements.

INNOVATE BIOPHARMACEUTICALS, INC.
Condensed Statements of Cash Flows

	Six Months Ended June 30,	
	2018	**2017**
	(Unaudited)	**(Unaudited)**
Cash flows from operating activities		
Net loss	$ (20,371,296)	$ (6,778,198)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	8,186,000	3,472,900
Accrued interest on convertible promissory notes	25,578	150,988
Amortization of debt discount	1,171,985	20,142
Depreciation	9,279	1,674
Beneficial conversion feature	3,077,887	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(70,074)	(10,220)
Accounts payable	(289,697)	564,255
Accrued expenses	(1,020,430)	524,246
Net cash used in operating activities	(9,280,768)	(2,054,213)
Cash flows from investing activities		
Purchase of property and equipment	(13,943)	(1,600)
Loan payments from related party	75,000	—
Net cash provided by (used in) investing activities	61,057	(1,600)
Cash flows from financing activities		
Borrowings from note payable	3,000,000	—
Payments of note payable issuance costs	(20,000)	—
Borrowings from convertible promissory notes	345,000	1,700,000
Principal payments of convertible promissory notes	(275,000)	—
Proceeds from issuance of common stock and warrants	18,132,661	—
Payment of stock issuance costs	(1,495,284)	—
Payment of deferred offering costs	(159,795)	—
Payment of stock subscription receivable	—	25
Net cash provided by financing activities	19,527,582	1,700,025
Net increase (decrease) in cash and cash equivalents	10,307,871	(355,788)
Cash and cash equivalents as of beginning of period	355,563	360,811
Cash and cash equivalents as of end of period	$ 10,663,434	$ 5,023
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	$ 280,287	$ —
Supplemental disclosure of noncash financing activities		
Conversion of convertible notes and accrued interest to common stock	$ 9,229,336	$ —
Assumption of liabilities from reverse recapitalization transaction	$ 978,674	$ —

Warrants issued to placement agents	$ 913,000	$ —
Receivable for warrants exercised	$ 12,472	$ —

See accompanying notes to these condensed financial statements.

NOTE 1: SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Business Description

Innovate Biopharmaceuticals, Inc. (the "Company" or "Innovate") is a clinical-stage biopharmaceutical company developing novel medicines for autoimmune and inflammatory diseases with unmet medical needs. The Company's pipeline includes drug candidates for celiac disease, nonalcoholic steatohepatitis (NASH), Crohn's, and ulcerative colitis.

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. In connection with the transaction, Private Innovate changed its name 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"). On March 29, 2018, IB Pharmaceuticals was merged into Innovate and ceased to exist.

Monster, a Delaware corporation (formed in November 2010), and its subsidiary SDJ Technologies, Inc. ("SDJ"), was an importer of high-end memory storage products, flash memory and action sports cameras marketed and sold under the Monster Digital brand name acquired under a long-term licensing agreement with Monster, Inc. In September 2017, Monster incorporated MD Holding Co, Inc. ("MDH"), a Delaware corporation, and transferred all of the businesses and assets of Monster, including all shares of SDJ and those liabilities of Monster not assumed by Innovate pursuant to the Merger to MDH. In January 2018, the name of MDH was changed to NLM Holding Co., Inc.

On January 29, 2018, prior to the Merger, Private Innovate completed an equity financing (the "Equity Issuance"). See Note 3.

Basis of Presentation

The unaudited condensed interim financial statements as of June 30, 2018 and for the three and six months then ended, have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial reporting. These financial statements are unaudited and, in the opinion of management, include all adjustments (consisting of normal recurring adjustments and accruals) necessary for a fair statement of the balance sheets, operating results, and cash flows for the periods presented in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Operating results for the three and six months ended June 30, 2018, are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2018. Certain information and footnote disclosure normally included in the annual financial statements prepared in accordance with GAAP have been omitted in accordance with the SEC's rules and regulations for interim reporting. The Company's financial position, results of operations and cash flows are presented in U.S. Dollars.

Upon the closing of the Merger, the outstanding shares of Private Innovate were exchanged for shares of common stock of Monster at an exchange ratio of one share of Private Innovate common stock to 0.37686604 shares of Monster common stock (the "Exchange Ratio"). All common share amounts and per share amounts have been adjusted to reflect this Exchange Ratio, which was effected upon the Merger.

The Merger has been accounted for as a reverse recapitalization. Prior to the Merger, Monster spun-out all of its pre-merger business assets and liabilities before it acquired Private Innovate. The owners and management of Private Innovate have actual or effective voting and operating control of the combined company. In the Merger transaction, Monster is the accounting acquiree and Private Innovate is the accounting acquirer. A reverse recapitalization is equivalent to the issuance of stock by the private operating company for the net monetary assets of the accounting acquiree accompanied by a recapitalization with accounting similar to that resulting from a reverse acquisition, except that no goodwill or intangible assets are recorded.

Immediately prior to the effective time of the Merger, Monster effected a reverse stock split at a ratio of one new share for every ten shares of its common stock outstanding. In connection with the Merger, 1,864,808 shares of the Company's common stock were transferred to the existing Monster stockholders and the Company assumed approximately $1.0 million in liabilities from Monster for certain transaction costs and tail insurance coverage for its directors and officers, which were recorded as a reduction of additional paid-in-capital.

The accompanying unaudited financial statements and related notes reflect the historical results of Private Innovate prior to the Merger and of the combined company following the Merger, and do not include the historical results of Monster prior to the completion of the Merger. These financial statements and related notes should be read in conjunction with the audited financial statements of Private Innovate for the year ended December 31, 2017, included in the Company's Form 8-K/A filed with the SEC on April 18, 2018, and Monster's audited consolidated financial statements and related notes thereto for the year ended December 31, 2017, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 14, 2018, as amended.

There have been no material changes to the Company's significant accounting policies during the three and six months ended June 30, 2018 and 2017, as compared to the significant accounting policies disclosed in Note 1 of the financial statements of Private Innovate for the years ended December 31, 2017 and 2016. However, the following accounting policies are the most critical in fully understanding the Company's financial condition and results of operations.

Business Risks

The Company faces risks associated with biopharmaceutical companies whose products are in the early stages of development. These risks include, among others, the Company's need for additional financing to achieve key development milestones, the need to defend intellectual property rights, and the dependence on key members of management.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and disclosures made in the accompanying notes to the financial statements. Areas of the financial statements where estimates may have the most significant effect include accrued expenses, share-based compensation, deferred compensation, valuation allowance for income tax assets and management's assessment of the Company's ability to continue as a going concern. Changes in the facts or circumstances underlying these estimates could result in material changes and actual results could differ from these estimates.

Accrued Expenses

The Company incurs periodic expenses such as research and development, salaries, and professional fees. An adjusting entry to accrue expenses is necessary when expenses have been incurred by the Company prior to them being invoiced. When a vendor's invoice is not received, the Company is required to estimate its accrued expenses. This process involves reviewing quotations and contracts, identifying services that have been performed on the Company's behalf and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of the actual cost. The majority of the Company's service providers invoice monthly in arrears for services performed or when contractual milestones are met. The Company estimates accrued expenses as of each balance sheet date based on facts and circumstances known at that time.

Accrued expenses consisted of the following:

	June 30, 2018	December 31, 2017
Compensation and benefits	$ —	$ 1,065,225
Other	—	115,000
Total	$ —	$ 1,180,225

Research and Development

Research and development expenses consist of costs incurred to further the Company's research and development activities and include salaries and related employee benefits, manufacturing of pharmaceutical active ingredients and drug products, costs associated with clinical trials, nonclinical activities, regulatory activities, research-related overhead expenses and fees paid to expert consultants, external service providers and contract research organizations which conduct certain research and development activities on behalf of the Company. Costs incurred in the research and development of products are charged to research and development expense as incurred.

Costs for preclinical studies and clinical trial activities are recognized based on an evaluation of vendors' progress towards completion of specific tasks, using data such as patient enrollment, clinical site activations or information provided by vendors regarding their actual costs incurred. Payments for these activities are based on the terms of individual contracts and payment timing may differ significantly from the period in which the services were performed. The Company determines accrual estimates through reports from and discussions with applicable personnel and outside service providers as to the progress or state of completion of trials, or the services completed. The estimates of accrued expenses as of each balance sheet date are based on the facts and circumstances known at the time.

Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity is performed or when the goods have been received, rather than when payment is made.

Share-Based Compensation

The Company measures compensation cost for share-based payment awards granted to employees and non-employee directors at fair value using the Black-Scholes option-pricing model. Compensation expense is recognized on a straight-line basis over the service period for awards expected to vest. Share-based compensation cost related to share-based payment awards granted to non-employees is adjusted each reporting period for changes in the fair value of the Company's stock until the measurement date. The measurement date is generally considered to be the date when all services have been rendered or the date that options are fully vested.

Patent Costs

Costs associated with the submission of patent applications are expensed as incurred given the uncertainty of the future economic benefits of the patents. Patent and patent related legal and administrative costs included in general and administrative expenses were approximately $161,000 and $92,000 for the three months ended June 30, 2018 and 2017, and $309,000 and $235,000 for the six months ended June 30, 2018 and 2017, respectively.

Net Loss Per Share

The Company calculates net loss per share as a measurement of the Company's performance while giving effect to all dilutive potential common shares that were outstanding during the reporting period. As the Company had a net loss for all periods presented, the inclusion of common stock options or other similar instruments would be anti-dilutive. Therefore, the weighted average shares used to calculate both basic and diluted earnings per share are the same. For the three and six months ended June 30, 2018 and 2017, 8.5 million and 6.5 million potentially dilutive securities related to warrants and stock options issued and outstanding have been excluded from the computation of diluted weighted shares outstanding because the effect would be anti-dilutive. The potentially dilutive securities consisted of the following:

	Three Months Ended June 30, 2018		Six Months Ended June 30, 2018	
	2018	2017	2018	2017
Options outstanding under the Private Innovate 2015 Stock Incentive Plan	6,428,577	6,509,824	6,428,577	6,509,824
Warrants issued at an exercise price of $2.54	349,555	—	349,555	—
Warrants issued at an exercise price of $3.18	1,698,245	—	1,698,245	—
Total	8,476,377	6,509,824	8,476,377	6,509,824

Segments

Operating segments are defined as components of an enterprise engaging in business activities for which discrete financial information is available and regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company operates and manages its business as one operating segment and all of the Company's operations are in North America.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-2, Leases (Topic 842) ("ASU 2016-2"). The provisions of ASU 2016-2 set out the principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for in a similar manner as under existing guidance for operating leases. ASU 2016-2 supersedes the previous lease standard, Topic 840, *Leases*. The guidance is effective for public companies with annual periods and interim periods within those annual periods beginning after December 15, 2018, and is expected to be effective for the Company for the year ending December 31, 2019. The Company is currently evaluating the impact that the implementation of this standard will have on the Company's financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230) - Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"). The provisions of ASU 2016-15 address eight specific cash flow issues and how those certain cash receipts and cash payments are presented and classified in the statement of cash flows under Topic 230, *Statement of Cash Flows*, and other Topics. The guidance is effective for public companies with annual periods and interim periods within those annual periods beginning after December 15, 2017, with early adoption permitted. The Company adopted this standard effective January 1, 2018 and the adoption of this standard did not have a material impact on the Company's financial statements.

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation* (Topic 718): Scope of Modification Accounting, which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The standard is effective for interim and annual reporting periods beginning after December 15, 2017, with early adoption permitted. The Company adopted this standard effective January 1, 2018, and the adoption of this standard did not have a material impact on the Company's financial statements.

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation* (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting. ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The standard is effective for the Company beginning with the first quarter of 2019 with early adoption permitted. The Company is currently evaluating the impact that the implementation of this standard will have on the Company's financial statements.

NOTE 2: LIQUIDITY AND GOING CONCERN

The accompanying financial statements have been prepared on a basis which assumes that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. There is substantial doubt that the Company will continue as a going concern for at least 12 months following the date these financial statements are issued without additional financing, based on the Company's limited operating history and recurring operating losses. As we continue to progress our research programs, we will need substantial additional funding to support our planned and future operating activities. Management's plans with regard to these matters include entering into strategic partnerships or seeking additional debt or equity financing arrangements or a combination of these activities. The failure to obtain sufficient financing or strategic partnerships could adversely affect the Company's ability to achieve its business objectives and continue as a going concern. The accompanying financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern.

NOTE 3: MERGER AND FINANCING

As noted above, on January 29, 2018, Private Innovate and Monster completed the Merger in accordance with the terms of the Merger Agreement. 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. On March 29, 2018, IB Pharmaceuticals was merged into Innovate and ceased to exist.

Immediately prior to the closing of the Merger, accredited investors purchased shares of common stock of Private Innovate in a private placement for gross proceeds of approximately $18.1 million, or $16.5 million, net of approximately $1.6 million in placement agent fees and expenses (the "Equity Issuance"). Additionally, Private Innovate issued five-year warrants to each cash purchaser of common stock, or an aggregate of approximately 1.4 million warrants, with an exercise price of $3.18 after giving effect to the Exchange Ratio. The Company calculated the fair value of the warrants issued utilizing the Black-Scholes option pricing model with the following assumptions; expected dividend yield of 0.0%, expected stock price volatility of 84.8%, risk free rate of 2.5%, and term of 5.0 years. The proceeds were allocated between common stock and warrants utilizing the relative fair value method with the allocated warrant value of approximately $2.0 million recorded as additional paid-in-capital.

Private Innovate also issued 349,555 five-year warrants with an exercise price of $2.54 and 279,862 five-year warrants with an exercise price of $3.18 (after giving effect to the Exchange Ratio) to the respective placement agents and their affiliates. The Company calculated the fair value of the warrants issued utilizing the Black-Scholes option pricing model with the following assumptions; expected dividend yield of 0.0%, expected stock price volatility of 84.8%, risk free rate of 2.5%, and term of 5.0 years. The total value for these warrants approximated $913,000 and was recorded as stock issuance costs and additional paid-in-capital.

Concurrently with the Equity Issuance, convertible promissory notes issued by Private Innovate in the aggregate principal amount of approximately $8.6 million plus accrued interest of $582,000 were converted into shares of Private Innovate common stock at a price per share of $0.72, prior to the Exchange Ratio (the "Conversion"), which reflected a 25% discount relative to the shares issued pursuant to the Equity Issuance (the "Conversion Discount"). The Conversion Discount represented a beneficial conversion feature of approximately $3.1 million which was recorded as a charge to interest expense and a credit to additional paid-in capital.

NOTE 4: NOTE PAYABLE

On January 29, 2018, the Company entered into a Note Purchase Agreement and Senior Note Payable ("Note") with a lender. The principal amount of the Note is $4.8 million ("Principal"). The Note was issued at a discount of $1.8 million and net of $20,000 for financing costs, for total proceeds of $2.98 million. The Note matures on September 30, 2018 ("Maturity Date"); however, the Maturity Date may be extended at the option of the lender under certain circumstances as outlined in the Note. Interest on the Note accrues from January 29, 2018, at a rate of 12.5% per annum and quarterly payments of interest only are due beginning on March 30, 2018, and compound quarterly. Upon the Maturity Date of the Note, the Company is required to pay the lender an amount representing 105% of all outstanding Principal, accrued and unpaid interest, and any unpaid late charges, if applicable. The Note contains redemption features and certain non-financial covenants and penalties to the Company in the case of certain events of default, as defined in the Note. The Company is currently in compliance with the covenants of the Note.

The Note payable consists of the following:

	June 30, 2018
Note payable	$ 4,800,000
Less debt discount	(648,015)
Total	$ 4,151,985

Amortization of debt discount recorded as interest expense was approximately $0.7 million and $1.2 million for the three and six months ended June 30, 2018, respectively.

NOTE 5: LICENSE AGREEMENTS

During 2016 the Company entered into a license agreement (the "Alba License") with Alba Therapeutics Corporation ("Alba") to obtain the rights to certain intellectual property relating to larazotide acetate and related compounds. The Company's initial area of focus for these assets relates to the treatment of celiac disease. These assets are now referred to as INN-202 by the Company.

Upon execution of the Alba License, the Company paid Alba a non-refundable license fee of $0.5 million. In addition, the Company is required to make milestone payments to Alba upon the achievement of certain clinical and regulatory

milestones totaling up to $1.5 million and payments upon regulatory approval and commercial sales of a licensed product totaling up to $150 million, which is based on sales ranging from $100 million to $1.5 billion.

Upon the Company paying Alba $2.5 million for the first commercial sale of a licensed product, the Alba License becomes perpetual and irrevocable. Upon the achievement of net sales in a year exceeding $1.5 billion, the Alba License also becomes milestone fee free. The Alba License provides Alba with certain termination rights; including failure of the Company to use Commercially Reasonable Efforts to develop the licensed products.

During 2013, the Company entered into an exclusive license agreement with Seachaid Pharmaceuticals, Inc. (the "Seachaid Agreement") to further develop and commercialize the licensed product, the compound known as APAZA. This product is now referred to as INN-108 by the Company. The agreement shall continue in effect on a country-by-country basis, unless terminated sooner in accordance with the termination provisions of the agreement, until the expiration of the royalty term for such product and such country. The royalty term for each such product and such country shall continue until the earlier of the expiration of certain patent rights (as defined in the agreement) or the date that the sales for one or more generic equivalents makes up a certain percentage of sales in an applicable country during a calendar year.

The Company was required to make an initial, non-refundable payment under the Seachaid Agreement in the amount of $0.2 million. The agreement also calls for milestone payments totaling up to $6.0 million to be paid when certain clinical and regulatory milestones are met. There are also commercialization milestone payments ranging from $1.0 million to $2.5 million depending on net sales of the products in a single calendar year, followed by royalty payments in the single digits based on net product sales.

During 2014, the Company entered into an Asset Purchase Agreement with Repligen Corporation ("Repligen") to acquire Repligen's RG-1068 program for the development of Secretin for the Pancreatic Imaging Market and Magnetic Resonance Cholangiopancreatography. This program is now referred to as INN-329 by the Company. As consideration for the Asset Purchase Agreement, the Company agreed to make a non-refundable cash payment on the date of the agreement and future royalty payments consisting of a percentage between five and fifteen of annual net sales, with the royalty payment percentage increasing as annual net sales increase. The royalty payments are made on a product-by-product and country-by-country basis and the obligation to make the payments expires with respect to each country upon the later of (i) the expiration of regulatory exclusivity for the product in that country or (ii) ten years after the first commercial sale in that country. The royalty amount is subject to reduction in certain situations, such as the entry of generic competition in the market.

NOTE 6: STOCKHOLDERS' EQUITY

The Company's authorized capital stock consists of 360 million shares of capital stock, par value $0.0001 per share, of which 350 million shares are designated as common stock and 10 million shares are designated as preferred stock.

The holders of the Company's common stock (i) have equal ratable rights to dividends from funds legally available, therefore, when, as and if declared by the Company's board of directors; (ii) are entitled to share in all the Company's assets available for distribution to holders of common stock upon liquidation, dissolution or winding up of the Company's 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.

NOTE 7: SHARE-BASED COMPENSATION

Upon consummation of the Merger, the Company has two stock option plans in existence. The Monster Digital, Inc. 2012 Omnibus Incentive Plan ("Omnibus Plan") and the Innovate 2015 Stock Incentive Plan ("Private Innovate Plan").

As of June 30, 2018, there were options to purchase 1,683 shares of Innovate common stock outstanding under the Omnibus Plan and 4,505 shares available for future grants under the Omnibus Plan. As of June 30, 2018, all of the options outstanding were fully vested and the weighted average exercise price was $45.00 per share. There was no unrecognized compensation expense related to the Omnibus Plan as of June 30, 2018.

As of June 30, 2018, there were options to purchase 6,428,577 shares of Innovate common stock outstanding under the Private Innovate Plan and 1,108,744 shares available for issuance under the Private Innovate Plan; however, the Company does not intend to issue any additional awards from the Private Innovate Plan.

The terms of the option agreements are determined by the Company's board of directors. The Company's awards vest based on the terms in the agreements with some awards vesting immediately and others vesting typically over a period of three to four years with options typically having a term of ten years.

The Company utilizes the Black-Scholes option pricing model to value awards under the option plans. Key valuation assumptions include:

- *Expected dividend yield.* The expected dividend is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on the Company's common stock.
- *Expected stock-price volatility.* As the Company's common stock has a limited trading history as a public company, the expected volatility is derived from the average historical volatilities of publicly traded companies within the Company's industry that the Company considers to be comparable to the Company's business over a period approximately equal to the expected term.
- *Risk-free interest rate.* The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero coupon U.S. Treasury notes with maturities approximately equal to the expected term.
- *Expected term.* The expected term represents the period that the stock-based awards are expected to be outstanding. The Company's historical share option exercise experience does not provide a reasonable basis upon which to estimate an expected term for employees because of a lack of sufficient data. Therefore, the Company estimates the expected term by using the simplified method provided by the Securities and Exchange Commission. The simplified method calculates the expected term as the average of the time-to-vesting and the contractual life of the options. The expected term for non-employees is the contractual life of the option.

The material factors incorporated in the Black-Scholes model in estimating the fair value of the options granted or re-measured for the periods presented were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Expected dividend yield	0%	0%	0%	0%
Expected stock-price volatility	67% – 68%	76%	67% – 72%	69% –76%
Risk-free interest rate	2.8% – 2.9%	2.2% – 2.3%	2.7% – 2.9%	2.0% – 2.4%
Term of options	8.7 – 9.3	9.7 – 10.0	8.7 – 9.5	5.0 – 10.0

The following table summarizes stock option activity under the Private Innovate Plan:

	Number of Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value	Weighted-Average Remaining Contractual Life (in years)
Outstanding at December 31, 2017	6,843,296	$ 1.56	$ 6,617,433	9.04
Options granted	—	—	—	—
Options forfeited	(414,719)	2.08	—	—
Options exercised	—	—	—	—
Outstanding at June 30, 2018	6,428,577	1.53	141,694,679	8.24
Exercisable at June 30, 2018	5,396,755	1.44	119,438,461	8.14
Vested and expected to vest at June 30, 2018	6,366,229	$ 1.52	$ 140,355,814	8.23

The weighted average grant date fair value of options granted was $1.79 and $1.60 during the three and six months ended June 30, 2017. There were no options granted during the three and six months ended June 30, 2018.

Share-based compensation expense recognized in the Company's financial statements was as follows:

	Three Months Ended June 30, 2018		Six Months Ended June 30, 2018	
	2018	2017	2018	2017
Research and development	$ (334,000)	$ 367,600	$ 5,417,000	$ 1,313,400
General and administrative	150,000	718,100	2,769,000	2,159,500
Total share-based compensation	$ (184,000)	$ 1,085,700	$ 8,186,000	$ 3,472,900

The adjustment to research and development expense for the three months ended June 30, 2018, resulted from the remeasurement of non-employee options during the period.

As of June 30, 2018, there was approximately $8.5 million of total unrecognized compensation cost related to unvested stock-based compensation arrangements. This cost is expected to be recognized over a weighted average period of 2.7 years.

The Private Innovate Plan provides for accelerated vesting under certain change-of-control transactions.

NOTE 8: COMMITMENTS AND CONTINGENCIES

Employment Agreements

Prior to March 11, 2018, the Company was party to employment agreements with certain executives of the Company. Under the terms of these agreements, the Company agreed to pay the executives certain payments upon the achievement of financial milestone events. These milestone events were based on total debt or equity funding received by the Company. During the three and six months ended June 30, 2017, the initial funding milestone was reached and the executives in the aggregate were paid $145,000 in accordance with the terms of these agreements. During January 2018, additional financial milestone events were achieved through the Merger and Equity Issuance events and the Company paid these executives approximately $1.1 million in accordance with the agreements, which was included in accrued expenses as of December 31, 2017.

On March 11, 2018, the Company entered into amended and restated executive employment agreements with the executives and new executive employment agreements with certain new executives (the "Executive Agreements"). The Executive Agreements provide an annual base salary and the opportunity to participate in the Company's equity compensation, employee benefit and bonus plans once they are established and approved by the Company's board of directors. The Executive Agreements contain severance provisions if the executives are terminated under certain conditions that would provide the executive with 12 months of their base salary and up to 12 months of continuation of health insurance benefits.

Office Lease

In October 2017, the Company entered into a three-year lease for office space that expires on September 30, 2020. Base annual rent is $60,000, or $5,000 per month. The first two months of rent were paid in advance upon lease signing and the next ten months of rent were paid in advance on November 30, 2017. Beginning with month thirteen, monthly payments of $5,000 will be paid in advance of the one day of each month of the remaining term. A security deposit of $5,000 was paid in October 2017. The lease contains a two-year renewal option.

Legal

The Company is not currently involved in any legal matters arising in the normal course of business. From time to time, the Company could become involved in disputes and various litigation matters that arise in the normal course of business. These may include disputes and lawsuits related to intellectual property, licensing, contract law and employee relations matters. Periodically, the Company reviews the status of significant matters, if any exist, and assesses its potential financial exposure. If the potential loss from any claim or legal claim is considered probable and the amount can be estimated, the Company accrues a liability for the estimated loss. Legal proceedings are subject to uncertainties, and the outcomes are difficult to predict; therefore, accruals are based on the best information available at the time. As additional information becomes available, the Company reassesses the potential liability related to pending claims and litigation.

NOTE 9: SUBSEQUENT EVENTS

The Company has evaluated subsequent events through August 14, 2018, the date these financial statements were available for issuance, and has determined that there were no events which have occurred that would require adjustment to or disclosure in these financial statements.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). When used in this report, the words "believe," "may," "could," "will," "estimate," "continue," "anticipate," "intend," "expect," "plan," "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.

These forward-looking statements are based on our current expectations and beliefs and necessarily involve significant risks and uncertainties that may cause our actual results, performance, prospects and opportunities in the future to differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties include, among other things, risks related to our limited operating history; our need for substantial additional funding; the lengthy, expensive and uncertain nature of the clinical trial process; results of earlier studies and trials not being predictive of future trial results; our need to attract and retain senior management and key scientific personnel; our reliance on third parties; our ability to manage our growth; potential delays in commencement and completion of clinical studies; our ability to obtain and maintain effective intellectual property protection; and other risks described with these in greater detail in the "Risk Factors" section of this Quarterly Report on Form 10-Q. These forward-looking statements are made as of the date of this Quarterly Report on Form 10-Q, and we assume no obligation to update or revise them to reflect new events or circumstances except as required by law.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Except as otherwise noted or where the context otherwise requires, as used in this report, the words "we," "us," "our," the "Company" and "Innovate" refer to Innovate Biopharmaceuticals, Inc. as of and following the closing of the Merger on January 29, 2018, and, where applicable, the business of Private Innovate prior to the Merger. All references to "Monster" refer to Monster Digital, Inc. prior to the closing of the Merger.

The following analysis reflects the historical financial results of Private Innovate prior to the Merger and that of Innovate following the Merger and does not include the historical financial results of Monster. All share and per share disclosures have been retroactively adjusted to reflect the exchange of shares in the Merger.

The following discussion of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and the related notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q, the audited financial statements of Private Innovate for the year ended December 31, 2017, included in our Form 8-K/A filed with the SEC on April 18, 2018, and Monster's audited consolidated financial statements and related notes thereto for the year ended December 31, 2017, included in our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 14, 2018, as amended.

Company Overview

We are a clinical-stage biopharmaceutical company developing novel medicines for autoimmune and inflammatory diseases with unmet medical needs, including drug candidates for celiac disease, nonalcoholic steatohepatitis (NASH), Crohn's disease and ulcerative colitis (UC). The lead program, INN-202 (larazotide acetate or larazotide is entering Phase 3 registration trials, targeted for 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. Another indication for which larazotide is currently being developed is NASH. NASH is an unmet medical need disease affecting approximately 5%-6% of the U.S. adult population. We are developing a proprietary formulation of larazotide for NASH, INN-217, for efficient delivery to the intestine. INN-217 has the potential to reduce the transport of bacterial toxins and immunogenic antigens, including lipopolysaccharide (LPS). There are currently a number of drugs in drugs in development for NASH; however, to our knowledge, none have larazotide's mechanism of action (MoA).

Since our inception, we have focused our efforts and resources on identifying and developing our programs. We have not had any products approved for commercial sale and have incurred operating losses in each year since inception. Substantially all of our operating losses resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to continue to incur significant expenses and increase our operating losses for the foreseeable future, which may fluctuate significantly between periods. We anticipate that our expenses will increase substantially as we:

- continue research and development, including preclinical and clinical development of our existing product candidates;
- potentially seek regulatory approval for our product candidates;
- commercialize any product candidates for which we obtain regulatory approval;
- maintain and protect our intellectual property rights;
- add operational, financial and management information systems and personnel; and
- incur additional legal, accounting and other expenses in operating as a public company.

Recent Developments

Merger and Financing

On January 29, 2018, Monster Digital, Inc., a Delaware corporation now known as Innovate Biopharmaceuticals, Inc. (the "Company") completed its merger with privately-held Innovate Biopharmaceuticals Inc. ("IB Pharmaceuticals" or "Private Innovate") in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated July 3, 2017, whereby Monster Merger Sub., Inc. ("Merger Sub"), a wholly owned subsidiary of the Company merged with and into IB Pharmaceuticals, with IB Pharmaceuticals surviving as the Company's wholly owned subsidiary (the "Merger"). In connection with the Merger, we changed our name from Monster Digital, Inc. to Innovate Biopharmaceuticals, Inc. On March 29, 2018, IB Pharmaceuticals was merged into Innovate and ceased to exist.

Immediately prior to the closing of the Merger, accredited investors purchased shares of common stock of IB Pharmaceuticals in a private placement for gross proceeds of approximately $18.1 million (the "Equity Issuance"). IB Pharmaceuticals issued five-year warrants to each purchaser of common stock with an exercise price of $3.18 per share after giving effect to the Exchange Ratio. Concurrently with the Equity Issuance, convertible promissory notes issued by IB Pharmaceuticals in the aggregate principal amount of approximately $8.65 million, plus accrued interest of $0.6 million, were converted into shares of IB Pharmaceuticals common stock at a price per share of $0.7206 (the "Conversion").

H.C. Wainwright & Co., LLC ("HCW") and GP Nurmenkari Inc. ("GPN") were retained as the placement agents for the Equity Issuance. HCW was paid a flat fee of $250,000, a cash fee of $285,000 (equal to 10% of the gross proceeds of the Equity Issuance up to a certain cap), a cash fee of $9,018 (equal to 3.5% of the gross proceeds in excess of a certain cap), and non-accountable expense allowance of $50,000. GPN was paid a cash fee of $891,266 (equal to 10% of the gross proceeds of certain investors in the Equity Issuance) and non-accountable expense allowance of $50,000. IB Pharmaceuticals issued to affiliates of HCW five-year warrants to purchase 209,951 shares of common stock with an exercise price per share equal to $3.18 (after giving effect to the Exchange Ratio). IB Pharmaceuticals issued to GPN five-year warrants to purchase 349,555 shares of common stock with an exercise price per share equal to $2.54 and five-year warrants to purchase 69,911 shares of common stock with an exercise price of $3.18 (after giving effect to Exchange Ratio). Upon the closing of the Merger, the outstanding shares of IB Pharmaceuticals' common stock were exchanged for shares of common stock of Monster at an exchange ratio of one share of IB Pharmaceuticals common stock to 0.37686604 shares of Monster common stock (the "Exchange Ratio"). Immediately following the closing of the Merger, after giving effect to the Equity Issuance and applying the Exchange Ratio, Monster's securityholders owned approximately 5.8% of the outstanding common stock of the Company on a fully-diluted basis and IB Pharmaceuticals' securityholders owned approximately 94.2% of the outstanding common stock of the Company.

On January 29, 2018, we entered into a Note Purchase Agreement and Senior Note Payable ("Note") with a lender. The principal amount of the Note is $4,800,000 ("Principal"). The Note was issued at a discount of $1,800,000 and net of $20,000 for financing costs, for total proceeds of $2,980,000. The Note matures on September 30, 2018 ("Maturity Date"), however, the Maturity Date may be extended at the option of the lender under certain circumstances as outlined in the Note. Interest on the Note accrues starting on January 29, 2018, at a rate of 12.5% per annum and payments of interest only are due beginning on March 30, 2018 and compound quarterly. Upon the Maturity Date of the Note, we are required to pay the lender an amount representing 105% of all outstanding Principal, accrued and unpaid interest, and any unpaid late charges, if applicable ("Outstanding Amount"). The Note contains redemption features and certain non-financial covenants and penalties to us in the case of certain events of default, as defined in the Note.

Research and Development

As we move towards initiating the Phase 3 registration trials for INN-202, we are performing key study start up activities, including study site identification. We anticipate that our first Phase 3 trial will have approximately 925 subjects, with three treatment groups (two different doses of larazotide and a placebo group).

Recent research and development milestones include:

- creation of a Scientific Advisory Board for NASH;
- acceptance of two abstracts at the Digestive Disease Week conference in June 2018; This work was performed in collaboration with Dr. Anthony Blikslager of North Carolina State University. We continue to collaborate with Dr. Blikslager to further understand and characterize the mechanism of action of larazotide; and
- initiation of a collaboration with Dr. O. Colin Stine of the University of Maryland, Baltimore to study larazotide's corrective effect on the dysfunctional intestinal barrier and the dysfunctional microbiome in various diseases.

Critical Accounting Policies

Use of Estimates. While our significant accounting policies are more fully described in the notes to our financial statements appearing elsewhere in this Form 10-Q and in our Form 8-K/A filed with the SEC on April 18, 2018, as amended, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements and understanding and evaluating our reported financial results.

Areas of the financial statements where estimates may have the most significant effect include accrued expenses, share-based compensation, deferred compensation, valuation allowance for income tax assets, and management's assessment of our ability to continue as a going concern. Changes in the facts or circumstances underlying these estimates could result in material changes and actual results could differ from these estimates.

Accrued Expenses. We incur periodic expenses such as research and development, salaries, taxes, and professional fees. An adjusting entry to accrue expenses is necessary when expenses have been incurred by us prior to them being invoiced. When a vendor's invoice is not received, we are required to estimate its accrued expenses. This process involves reviewing quotations and contracts, identifying services that have been performed on our behalf when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice monthly in arrears for services performed or when contractual milestones are met. We estimate accrued expenses as of each balance sheet date based on facts and circumstances known at that time. We periodically confirm the accuracy of its estimates with the service providers and make adjustments if necessary.

Research and Development. Research and development expenses consist of costs incurred to further our research and development activities and include salaries and related employee benefits, manufacturing of pharmaceutical active ingredients and drug products, costs associated with clinical trials, nonclinical activities, regulatory activities, research-related overhead expenses and fees paid to expert consultants, external service providers, and contract research organizations which conduct certain research and development activities on our behalf. Costs incurred in the research and development of products are charged to research and development expense as incurred.

Costs for preclinical studies and clinical trial activities are recognized based on an evaluation of vendors' progress towards completion of specific tasks, using data such as patient enrollment, clinical site activations or information provided by vendors regarding their actual costs incurred. Payments for these activities are based on the terms of individual contracts and payment timing may differ significantly from the period in which the services were performed. We determine accrual estimates through reports from and discussions with applicable personnel and outside service providers as to the progress or state of completion of trials, or the services completed. The estimates of accrued expenses as of each balance sheet date are based on the facts and circumstances known at the time.

Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity is performed or when the goods have been received, rather than when payment is made.

Share-Based Compensation. We account for share-based compensation using the fair value method of accounting which requires all such compensation to employees, including the grant of employee stock options, to be recognized in the statements of operations based on its fair value at the grant date. The expense associated with share-based compensation is recognized on a

straight-line basis over the requisite service period of each award. Share-based compensation cost related to share-based payment awards granted to non-employees is adjusted each reporting period for changes in the fair value of our stock until the measurement date. The measurement date is generally considered to be the date when all services have been rendered or the date that options are fully vested.

Recently Issued Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-02, Leases (Topic 842) ("ASU 2016-02"). The provisions of ASU 2016-02 set out the principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for in a similar manner as under existing guidance for operating leases. ASU 2016-02 supersedes the previous lease standard, Topic 840, *Leases*. The guidance is effective for public companies with annual periods and interim periods within those annual periods beginning after December 15, 2018, and is expected to be effective for us for the year ending December 31, 2019. We are currently evaluating the impact that the implementation of this standard will have on our financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230) - Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"). The provisions of ASU 2016-15 address eight specific cash flow issues and how those certain cash receipts and cash payments are presented and classified in the statement of cash flows under Topic 230, *Statement of Cash Flows*, and other Topics. The guidance is effective for public companies with annual periods and interim periods within those annual periods beginning after December 15, 2017, with early adoption permitted. We adopted this standard effective January 1, 2018, and the adoption of this standard did not have a material impact on our financial statements.

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation* (Topic 718): Scope of Modification Accounting, which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The standard is effective for interim and annual reporting periods beginning after December 15, 2017, with early adoption permitted. We adopted this standard effective January 1, 2018, and the adoption of this standard did not have a material impact on our financial statements.

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation* (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting. ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The standard is effective for the Company beginning with the first quarter of 2019 with early adoption permitted. We are currently evaluating the impact that the implementation of this standard will have on our financial statements.

Results of Operations

Comparison of the Three Months Ended June 30, 2018 and 2017

The following table sets forth the key components of our results of operations for the three months ended June 30, 2018 and 2017:

	Three Months Ended June 30,			
	2018	2017	$ Change	% Change
Operating expenses:				
Research and development	$ 1,243,221	$ 1,129,733	$ 113,488	10%
General and administrative	2,132,850	1,561,106	571,744	37%
Total operating expenses	3,376,071	2,690,839	685,232	25%
Loss from operations	(3,376,071)	(2,690,839)	685,232	25%
Other income (expense), net	(839,481)	(99,483)	739,998	744%
Net loss	$ (4,215,552)	$ (2,790,322)	$ 1,425,230	51%

Research and Development Expense

Research and development expense for the three months ended June 30, 2018, increased approximately $0.1 million, or 10%, as compared to the three months ended June 30, 2017. The increase was driven primarily by:

- an increase of approximately $1.0 million in clinical trial costs associated with preparation for our Phase III clinical trials;
- an increase of approximately $0.1 million primarily related to additional employees performing research and development services or oversight;
- an increase of approximately $0.1 million in research and development costs for INN-217;
- a decrease of approximately $0.7 million in share-based compensation, non-cash expense primarily due to the decrease in the market value of our common stock between March 31, 2018, and June 30, 2018; and
- a decrease of approximately $0.4 million in manufacturing costs for INN-202;

General and Administrative Expense

General and administrative expense for the three months ended June 30, 2018, increased approximately $0.6 million, or 37%, as compared to the three months ended June 30, 2017. The increase was driven primarily by:

- an increase of approximately $0.7 million in accounting and legal fees associated with SEC filings, an increase in the utilization of outsourced accounting personnel, and additional insurance and other costs associated with operating as a public company;
- an increase of approximately $0.2 million in travel and conference costs for investor and industry conferences;
- an increase of approximately $0.3 million for patent costs, compensation costs and consulting fees for business development and investor relations; and
- a decrease of approximately $0.6 million in share-based compensation, non-cash expense primarily due to the decrease in the market value of our common stock between March 31, 2018, and June 30, 2018.

Other income (expense), net

Other income (expense), net for the three months ended June 30, 2018, increased by approximately $0.7 million, or 744%, as compared to the three months ended June 30, 2017. The increase was primarily due to an increase of approximately $0.7 million in amortization of debt discount and $0.1 million in interest expense associated with our $4.8 million Senior Note Payable issued on January 29, 2018, offset by a decrease of $0.1 million in interest expense from convertible debt that was outstanding during the three months ended June 30, 2017.

Comparison of the Six Months Ended June 30, 2018 and 2017

The following table sets forth the key components of our results of operations for the six months ended June 30, 2018 and 2017:

	Six Months Ended June 30,			
	2018	**2017**	**$ Change**	**% Change**
Operating expenses:				
Research and development	$ 7,601,225	$ 2,465,236	$ 5,135,989	208%
General and administrative	8,299,463	4,141,832	4,157,631	100%
Total operating expenses	15,900,688	6,607,068	9,293,620	141%
Loss from operations	(15,900,688)	(6,607,068)	9,293,620	141%
Other income (expense), net	(4,470,608)	(171,130)	4,299,478	2,512%
Net loss	$ (20,371,296)	$ (6,778,198)	$ 13,593,098	201%

Research and Development Expense

Research and development expense for the six months ended June 30, 2018, increased approximately $5.1 million, or 208%, as compared to the six months ended June 30, 2017. The increase was driven primarily by:

- an increase of approximately $4.1 million in share-based compensation, non-cash expense primarily due to the increase in the market value of our common stock between June 30, 2017 and June 30, 2018. Share-based compensation, non-cash expense for the six months ended June 30, 2018 and 2017 was $5.4 million and $1.3 million, respectively;
- an increase of approximately $1.0 million in clinical trial costs associated with preparation for our Phase III clinical trials;
- an increase of approximately $0.2 million in compensation costs primarily related to additional employees performing research and development services or oversight; and
- a decrease of approximately $0.2 million in manufacturing costs for INN-202.

General and Administrative Expense

General and administrative expense for the six months ended June 30, 2018, increased approximately $4.2 million, or 100%, as compared to the six months ended June 30, 2017. The increase was driven primarily by:

- an increase of approximately $1.2 million in accounting and legal fees associated with the Merger, SEC filings, and an increase in the utilization of outsourced accounting personnel;
- an increase of approximately $1.0 million in transaction advisory fees associated with the Merger;
- an increase of approximately $0.6 million in share-based compensation, non-cash expense primarily due to the increase in the market value of our common stock. Share-based compensation, non-cash expense for the six months ended June 30, 2018 and 2017 was $2.8 million and $2.2 million, respectively;
- an increase of approximately $0.6 million for increased insurance costs, Nasdaq listing fees and other additional costs associated with operating as a public company; and
- an increase of approximately $0.6 for patent costs, compensation costs and consulting fees and travel expenses for business development, industry conferences and investor relations.

Other income (expense), net

Other income (expense), net, for the six months ended June 30, 2018, increased by approximately $4.3 million, or 2,512%, as compared to the six months ended June 30, 2017. The increase was primarily due to a non-cash charge of $3.1 million for the beneficial conversion feature that was triggered when our convertible debt and accrued interest were converted to common stock at a 25% discount on January 29, 2018. The additional increase was due to non-cash interest expense of approximately $1.2 million for the amortization of debt discount and $0.3 million in cash interest expense associated with our $4.8 million Senior Note Payable issued on January 29, 2018, offset by $0.1 million of interest income and a decrease of $0.2 million in interest expense from convertible debt.

Liquidity and Capital Resources

Going Concern

The accompanying financial statements have been prepared on a basis which assumes that we will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Based on our operating history and recurring operating losses, there is substantial doubt that we will continue as a going concern for at least 12 months following the date of this Quarterly Report on Form 10-Q, without additional financing based on our limited operating history and recurring operating losses. Management's plans with regard to these matters include entering into strategic partnerships or seeking additional debt or equity financing arrangements or a combination of these activities. The failure to obtain sufficient financing or strategic partnerships could adversely affect our ability to achieve our business objectives and continue as a going concern. The accompanying financial statements do not include any adjustments that might be necessary should we be unable to continue as a going concern.

Sources of Liquidity

As of June 30, 2018, we had cash and cash equivalents of approximately $10.7 million, compared to approximately $0.4 million as of December 31, 2017. We expect to incur substantial expenditures in the foreseeable future for the development and clinical trials of our product candidates. We will continue to require additional financing to develop our product candidates and fund operations for the foreseeable future. We will continue to seek funds through debt or equity financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements, or other sources of financing. If we are unable to raise additional funds when needed, our ability to develop our product candidates may be impaired. We may also be required to delay, reduce, or terminate some or all of our development programs and clinical trials.

On January 29, 2018 we completed the Merger, which was accounted for as a reverse recapitalization. Immediately prior to the closing of the Merger, accredited investors purchased shares of Private Innovate common stock in a private placement for gross proceeds of approximately $18.1 million, or $16.5 million, net of approximately $1.5 million in placement agent fees and $80,000 in non-accountable expense costs. Additionally, Private Innovate issued five-year warrants to each cash purchaser of common stock, or an aggregate of approximately 1.4 million warrants, with an exercise price of $3.18 per share after giving effect to the Exchange Ratio. Private Innovate also issued 349,555 five-year warrants with an exercise price of $2.54 per share and 279,862 five-year warrants with an exercise price of $3.18 per share (after giving effect of the Exchange Ratio) to the respective placement agents and their affiliates.

Concurrently with the Equity Issuance, convertible promissory notes issued by Private Innovate in the aggregate principal amount of approximately $8.6 million plus accrued interest of $582,000 were converted into shares of Private Innovate common stock at an exercise price per share of $0.72, prior to the Exchange Ratio (the "Conversion"), which reflected a 25% discount relative to the shares issued pursuant to the Equity Issuance (the "Conversion Discount"). The Conversion Discount represented a beneficial conversion feature of approximately $3.1 million which was recorded as a charge to interest expense and a credit to additional paid-in capital.

On January 29, 2018, Private Innovate entered into a Note Purchase Agreement and Senior Note Payable ("Note") with a lender. The principal amount of the Note is $4.8 million. The Note was issued at a discount of $1.8 million and net of $20,000 for financing costs, for total proceeds of $2.98 million. The Note matures on September 30, 2018 ("Maturity Date"); however, the Maturity Date may be extended at the option of the lender under certain circumstances as outlined in the Note. Interest on the Note accrues starting on the closing date at a rate of 12.5% per annum and payments of interest only are due beginning on June 30, 2018, and compound quarterly.

Cash Flows

The following table sets forth the primary sources and uses of cash for the six months ended June 30, 2018 and 2017:

	Six Months Ended June 30,	
	2018	**2017**
Net cash (used in) provided by:		
Operating activities	$ (9,280,768)	$ (2,054,213)
Investing activities	61,057	(1,600)
Financing activities	19,527,582	1,700,025
Net increase (decrease) in cash and cash equivalents	$ 10,307,871	$ (355,788)

Operating Activities

For the six months ended June 30, 2018, our net cash used in operating activities of approximately $9.3 million primarily consisted of a net loss of $20.4 million, offset by adjustments for share-based compensation of approximately $8.2 million, non-cash interest expense of approximately $4.2 million, and decreases in accounts payable and accrued expenses of approximately $1.3 million.

For the six months ended June 30, 2017, our net cash used in operating activities of approximately $2.1 million primarily consisted of a net loss of $6.8 million, offset by adjustments for share-based compensation of approximately $3.5 million and an increase in accounts payable and accrued expenses of approximately $1.1 million.

Investing Activities

Net cash provided by investing activities for the six months ended June 30, 2018, primarily represented loan payments received from a related party of $75,000 offset by the purchase of office furniture and computer equipment. Net cash used in investing activities for the six months ended June 30, 2017, represented the purchase of computer equipment.

Financing Activities

For the six months ended June 30, 2018, net cash provided by financing activities of approximately $19.5 million primarily consisted of the proceeds of $18.1 million received from the sale of our common stock and warrants and $3.0 million from the issuance of a note payable offset by approximately $1.6 million in stock issuance and deferred offering costs.

For the six months ended June 30, 2017, net cash provided by financing activities of approximately $1.7 million primarily consisted of borrowings from convertible debt.

Future Funding Requirements

We have not generated any revenue from product sales or any other activities. We do not expect to generate significant revenue unless and until we obtain regulatory approval of and commercialize, or out license, one or more of our product candidates and do not know when, or if, these will occur. In addition, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our product candidates. In addition, subject to obtaining regulatory approval of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations, including increased costs associated with being a public company.

Contractual Obligations and Commitments

In October 2017, we entered into a new three-year lease for office space that expires on September 30, 2020. Base annual rent is $60,000, or $5,000 per month. The first two months of rent were paid in advance upon lease signing and the next ten months of rent was paid in advance on November 30, 2017. Beginning with month thirteen, monthly payments of $5,000 will be paid in advance of the first day of each month of the remaining term. A security deposit of $5,000 was paid in October 2017. The lease contains a two-year renewal option.

We are obligated to make future payments to third parties under in-license agreements, including sublicense fees, royalties, and payments that become due and payable on the achievement of certain development and commercialization milestones. As the amount and timing of sublicense fees and the achievement and timing of these milestones are not probable and estimable, such commitments have not been included on our balance sheet.

Off-Balance Sheet Arrangements

As of June 30, 2018, we had no off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K as promulgated by the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2018. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure. Based on such evaluation, our principal executive officer and principal financial officer concluded that, as of June 30, 2018, our disclosure controls and procedures were not effective as a result of the material weakness in our internal control over financial reporting due to our limited resources available to address our internal controls and procedures and our reliance on part-time consultants to assist us with our financial accounting and compliance obligations. In connection with the preparation of Private Innovate's audited financial statements for the year ended December 31, 2017, its independent auditors advised management that a material weakness existed in internal control over financial reporting due to its inability to adequately segregate duties as a result of its limited number of accounting personnel, and this material weakness has not been remediated in the Company's internal control over financial reporting as of June 30, 2018.

Changes in Internal Control Over Financial Reporting

In connection with the Merger, the internal control structure of Monster was replaced by the internal control structure of Private Innovate. As of June 30, 2018, there were no other material changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II -OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently a party to any legal or governmental regulatory proceedings, nor is our management currently aware of any pending or threatened legal or governmental regulatory proceedings proposed to be initiated against us that would have a material adverse effect on our business, financial condition or operating results. Our industry is characterized by frequent claims and litigation including securities litigation, claims regarding patent and other intellectual property rights and claims for product liability. As a result, in the future, we may be involved in various legal proceedings from time to time.

Item 1A. Risk Factors.

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 to 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. 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.

For the six months ended June 30, 2018 and 2017, and for the years ended December 31, 2017 and 2016, we incurred losses from operations of $20.4 million, $6.8 million, $11.2 million and $5.4 million, respectively, and net cash used in operating activities was $9.3 million, $2.1 million, $5.1 million and $2.2 million, respectively. At June 30, 2018, we had an accumulated deficit of $39.7 million and cash and cash equivalents of $10.7 million. 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 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;
- 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 CMC, 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 ("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;
- 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;
    - poor prescription coverage and inadequate reimbursement for our product candidates;
- inability to enforce our intellectual property rights in and to our product candidates; and

- reduction in the safety profile of our product candidates following approval.

Many of these clinical, regulatory and commercial matters are beyond our control and are subject to other risks described elsewhere in this "Risk Factors" section. Accordingly, we cannot 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.

Innovate has identified a material weakness in its 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 its 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, CROs, CMOs 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 ("CROs"), contract manufacturing organizations ("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 Food and Drug Administration ("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 ("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 ("GCP"), Good Laboratory Practices ("GLP") and Good Manufacturing Practices ("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 (“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, because we are focused on diseases in genomically defined patient populations, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. In addition, 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 independent review board (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.

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 are preparing INN-108 to enter Phase 2 clinical trials for mild-to-moderate ulcerative colitis. Concurrently, 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, international conference on harmonization regulations 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 us 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 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.

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* re-examination, 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 ("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 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 will provide market exclusivity in the U.S. for seven years, but only 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 will provide market exclusivity in the U.S. for seven years, but only 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.

Risks Related to Our Common Stock

The market price of our common stock is likely to 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 January 29, 2018, through August 7, 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 INN-202 (for celiac disease), INN-217 (NASH), INN-329 (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;
- 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 section entitled "Risk Factors."

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 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 August 7, 2018, we had approximately 25.8 million shares of common stock outstanding and exercisable warrants to purchase approximately 2.0 million shares of common stock outstanding, and therefore sales of common stock by us or our stockholders under the Registration Statement 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.

The issuance of shares upon exercise of our outstanding options and warrants may cause substantial dilution to our existing stockholders and reduce the trading price of our common stock.

We presently have outstanding and exercisable options and warrants that if exercised would result in the issuance of approximately 8.5 million shares of our common stock. The issuance of shares upon exercise of warrants and options may result in dilution to the interests of other stockholders and may reduce the trading price 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 claim for indemnification is brought by any of our directors or officers, it would reduce the amount of funds available for use in our business.

If we sell our common stock in the future, stockholders may experience immediate dilution and, as a result, the market price of our common stock may decline.

We may from time to time issue additional shares of our common stock at a discount from the then-current trading price. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of such common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, the market price of our common stock may decline.

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

Our executive officers, directors and current beneficial owners of 5% or more of our common stock, in aggregate, beneficially own approximately 52.0% 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, the Board has the authority to issue up to 10,000,000 shares of preferred stock. The Board 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 the Board 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 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, 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 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.

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

We have U.S. federal net operating loss carryforwards, or NOLs, which expire in various years if not utilized. In addition, we have federal research and development credit carryforwards. The federal research and development credit carryforwards expire in various years if not utilized. Under Sections 382 and 383 of Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change NOLs and other pre-change tax attributes, such as research tax credits, to offset its future post-change income and taxes may be limited. In general, an "ownership change" occurs if there is a cumulative change in our ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. We have not performed a formal study to determine whether any of our NOLs are subject to these limitations. We have recorded deferred tax assets for our NOLs and research and development credits and have recorded a full valuation allowance against these deferred tax assets. In the event that it is determined that we have in the past experienced additional ownership changes, or if we experience one or more ownership changes as a result of future transactions in our stock, then we may be further limited in our ability to use our NOLs and other tax assets to reduce taxes owed on the net taxable income that we earn in the event that we attain profitability. Any such limitations on the ability to use our NOLs and other tax assets could adversely impact our business, financial condition and operating results in the event that we attain profitability.

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

As a public company in the United States, and increasingly after we are no longer an "emerging growth company," we may incur significant additional legal, accounting and other expenses that Innovate did not incur as a private company. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act and regulations implemented by the SEC and Nasdaq, may increase our legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If notwithstanding our efforts to comply with applicable laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

As a public company in the United States, we are required, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. We are required to disclose any material weaknesses identified by our management in our internal control over financial reporting, and, when we are no longer an "emerging growth company," we may need to provide a statement that our independent registered public accounting firm has issued an opinion on our internal control over financial reporting.

The controls and other procedures are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is disclosed accurately and is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. We are in the early stages of conforming our internal control procedures to the requirements of Section 404 and we may not be able to complete our evaluation, testing and any required remediation needed to comply with Section 404 in a timely fashion. Our independent registered public accounting firm was not engaged to perform an audit of our internal control over financial reporting for the year ended December 31, 2017, or for any other period. Accordingly, no such opinion will be expressed.

Even after we develop these new procedures, these new controls may become inadequate because of changes in conditions or the degree of compliance with these policies or procedures may deteriorate and material weaknesses in our internal control over financial reporting may be discovered. We may err in the design or operation of our controls, and all internal control systems, no matter how well designed and operated, can provide only reasonable assurance that the objectives of the control

system are met. Because there are inherent limitations in all control systems, there can be no absolute assurance that all control issues have been or will be detected. If we are unable, or are perceived as unable, to produce reliable financial reports due to internal control deficiencies, investors could lose confidence in our reported financial information and operating results, which could result in a negative market reaction.

To fully comply with Section 404, we will need to retain additional employees to supplement our current finance staff, and we may not be able to do so in a timely manner, or at all. In addition, in the process of evaluating our internal control over financial reporting, we expect that certain of our internal control practices will need to be updated to comply with the requirements of Section 404 and the regulations promulgated thereunder, and we may not be able to do so on a timely basis, or at all. In the event that we are not able to demonstrate compliance with Section 404 in a timely manner, or are unable to produce timely or accurate financial statements, we may be subject to sanctions or investigations by regulatory authorities, such as the SEC or the stock exchange on which our stock is listed, and investors may lose confidence in our operating results and the price of our common stock could decline. Furthermore, if we are unable to certify that our internal control over financial reporting is effective and in compliance with Section 404, we may be subject to sanctions or investigations by regulatory authorities, such as the SEC or stock exchanges, and we could lose investor confidence in the accuracy and completeness of our financial reports, which could hurt our business, the price of our common stock and our ability to access the capital markets.

Being a public company makes it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to maintain coverage. These factors could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

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" for up to five years following the completion of our initial public offering, although, if we have more than $1.07 billion in annual revenue, we are deemed to be a large accelerated filer under the rules of the SEC, or we issue more than $1.0 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. For as long as we remain an "emerging growth company," we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not "emerging growth companies." These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "management's discussion and analysis of financial condition and results of operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have irrevocably elected not to avail ourselves of this exemption. We cannot predict whether investors will find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the market price of our common stock may be reduced or more volatile.

Item 2. Recent Sales of Unregistered Securities

Not applicable.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6.

Exhibit Index

EXHIBIT NO.		DESCRIPTION	FILED HEREWITH	INCORPORATED BY REFERENCE			
				FORM	FILE NO.	EXHIBIT	FILING DATE
10.1	†	Sublicense Agreement, dated February 19, 2016, between the Company and Alba Therapeutics Corporation		10-K/A	001-37797	10.1	June 29, 2018
10.2	†	License Agreement, dated February 26, 2016, between the Company and Alba Therapeutics Corporation		10-K/A	001-37797	10.2	June 29, 2018
31.1		Certification of Principal Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X				
31.2		Certification of Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X				
32.1		Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X				
32.2		Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X				
101.INS		XBRL Instance Document	X				
101.SCH		XBRL Taxonomy Extension Schema Document	X				
101.CAL		XBRL Taxonomy Extension Calculation Linkbase Document	X				
101.DEF		XBRL Taxonomy Extension Definition Document	X				
101.LAB		XBRL Taxonomy Extension Label Linkbase Document	X				
101.PRE		XBRL Taxonomy Extension Presentation Linkbase Document	X				

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 under the Securities Exchange Act of 1934.

SIGNATURES

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

INNOVATE BIOPHARMACEUTICALS, INC.
a Delaware corporation

Date: August 14, 2018 By: /s/ Jay P. Madan

Jay P. Madan
President, Chief Business Officer and Interim Principal Financial Officer

Exhibit 31.1

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Christopher Prior, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Innovate Biopharmaceuticals, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ Christopher Prior

Date: August 14, 2018

Christopher Prior
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Jay Madan, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Innovate Biopharmaceuticals, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ Jay Madan

Date: August 14, 2018

Jay Madan
President, Chief Business Officer and Interim Principal Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

I, Christopher Prior, Chief Executive Officer of Innovate Biopharmaceuticals, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2018 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

By: /s/ Christopher Prior

Date: August 14, 2018

Christopher Prior
Chief Executive Officer
(Principal Executive Officer)

This certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Report, irrespective of any general incorporation language contained in such filing.

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

I, Jay Madan, President, Chief Business Officer and Interim Principal Financial Officer of Innovate Biopharmaceuticals, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2018 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

By: /s/ Jay Madan

Date: August 14, 2018

Jay Madan

President, Chief Business Officer and Interim Principal Financial Officer

(Principal Financial Officer)

This certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Report, irrespective of any general incorporation language contained in such filing.

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.