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, 2019
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)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock $0.0001 Par Value	INNT	The Nasdaq Stock Market LLC

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 every Interactive Data File required to be submitted 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 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	☑
		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 6, 2019, the registrant had 35,883,953 shares of common stock, par value $0.0001 per share, issued and outstanding.

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

INNOVATE BIOPHARMACEUTICALS, INC.

Condensed Balance Sheets

	(Unaudited) June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 13,337,898	$ 5,728,900
Restricted deposit	75,000	75,000
Prepaid expenses and other current assets	1,117,628	504,907
Deferred offering costs	—	104,706
Total current assets	14,530,526	6,413,513
Property and equipment, net	34,157	35,095
Right-of-use asset	69,325	—
Other assets	5,580	5,580
Total assets	$ 14,639,588	$ 6,454,188
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,712,285	$ 3,618,634
Accrued expenses	974,091	826,327
Convertible note payable, net	4,044,212	5,196,667
Derivative liability	999,000	370,000
Warrant liabilities	660,200	—
Accrued interest	174,166	101,624
Lease liability, current portion	54,620	—
Total current liabilities	9,618,574	10,113,252
Lease liability, net of current portion	14,705	—
Total liabilities	9,633,279	10,113,252
Commitments and contingencies (Note 8)		
Stockholders' equity (deficit):		
Preferred stock $0.0001 par value, 10,000,000 shares authorized; 0 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	—	—
Common stock - $0.0001 par value, 350,000,000 shares authorized; 35,883,953 and 26,088,820 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	3,589	2,609
Additional paid-in capital	57,441,695	39,854,297
Accumulated deficit	(52,438,975)	(43,515,970)
Total stockholders' equity (deficit)	5,006,309	(3,659,064)
Total liabilities and stockholders' equity (deficit)	$ 14,639,588	$ 6,454,188

See accompanying notes to these condensed financial statements.

INNOVATE BIOPHARMACEUTICALS, INC.

Condensed Statements of Operations and Comprehensive Loss
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development	$ 3,073,344	$ 1,243,221	$ 4,271,659	$ 7,601,225
General and administrative	3,049,711	2,132,850	6,164,206	7,103,463
Total operating expenses	6,123,055	3,376,071	10,435,865	14,704,688
Loss from operations	(6,123,055)	(3,376,071)	(10,435,865)	(14,704,688)
Other income (expense):				
Interest income	72,641	54,637	99,097	85,129
Interest expense	(431,626)	(894,118)	(858,871)	(4,555,737)
Loss on extinguishment of convertible note payable	—	—	(1,049,166)	—
Change in fair value of derivative liability and extinguishment of derivative liability	181,000	—	652,000	—
Change in fair value of warrant liabilities	1,812,800	—	2,669,800	—
Total other income (expense), net	1,634,815	(839,481)	1,512,860	(4,470,608)
Loss before income taxes	(4,488,240)	(4,215,552)	(8,923,005)	(19,175,296)
Benefit from income taxes	—	—	—	—
Net loss	$ (4,488,240)	$ (4,215,552)	$ (8,923,005)	$ (19,175,296)
Net loss per common share, basic and diluted	$ (0.13)	$ (0.16)	$ (0.29)	$ (0.82)
Weighted-average common shares, basic and diluted	33,973,788	25,695,171	30,631,601	23,481,834

See accompanying notes to these condensed financial statements.

INNOVATE BIOPHARMACEUTICALS, INC.
Unaudited Condensed Statements of Stockholders' Equity (Deficit)

	Six Months Ended June 30, 2019				
	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Total
Balance as of December 31, 2018	26,088,820	$ 2,609	$ 39,854,297	$ (43,515,970)	$ (3,659,064)
Issuance of common stock and warrants	4,886,782	489	11,474,766	—	11,475,255
Allocation of warrants to liabilities	—	—	(1,970,000)	—	(1,970,000)
Stock issuance costs	—	—	(319,819)	—	(319,819)
Share-based compensation	—	—	526,000	—	526,000
Issuance of RSUs	90,000	9	(9)	—	—
Net loss	—	—	—	(4,434,765)	(4,434,765)
Balance as of March 31, 2019	31,065,602	3,107	49,565,235	(47,950,735)	1,617,607
Issuance of common stock and warrants	4,318,272	432	8,744,069	—	8,744,501
Allocation of warrants to liabilities	—	—	(1,360,000)	—	(1,360,000)
Stock issuance costs	—	—	(389,623)	—	(389,623)
Exercise of stock options	100,079	10	30,054	—	30,064
Issuance of RSUs	400,000	40	(40)	—	—
Share-based compensation	—	—	852,000	—	852,000
Net loss	—	—	—	(4,488,240)	(4,488,240)
Balance as of June 30, 2019	35,883,953	$ 3,589	$ 57,441,695	$ (52,438,975)	$ 5,006,309

	Six Months Ended June 30, 2018				
	Common Stock Shares*	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Total
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	—	—	7,174,000	—	7,174,000
Net loss	—	—	—	(14,959,744)	(14,959,744)
Balance as of March 31, 2018	25,691,680	$ 2,569	$ 42,157,122	$ (34,313,435)	$ 7,846,256
Exercise of warrants	3,922	1	12,471	—	12,472
Share-based compensation	—	—	(184,000)	—	(184,000)
Net loss	—	—	—	(4,215,552)	(4,215,552)
Balance as of June 30, 2018	25,695,602	$ 2,570	$ 41,985,593	$ (38,528,987)	$ 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.
Unaudited Condensed Statements of Cash Flows

	Six Months Ended June 30,	
	2019	**2018**
Cash flows from operating activities		
Net loss	$ (8,923,005)	$ (19,175,296)
Adjustments to reconcile net loss to net cash used in operating activities:		—
Share-based compensation	1,378,000	6,990,000
Write-off of deferred offering costs	100,056	—
Accrued interest on convertible notes	174,166	25,578
Amortization of debt discount	382,212	1,171,985
Depreciation	10,413	9,279
Beneficial conversion feature	—	3,077,887
Change in fair value of derivative liability	(282,000)	—
Change in fair value of warrant liability	(2,669,800)	—
Extinguishment of derivative liability	(370,000)	—
Loss on extinguishment of debt	1,049,166	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(592,375)	(70,074)
Accounts payable	(1,058,692)	(289,697)
Accrued expenses	147,764	(1,020,430)
Accrued interest	(101,624)	—
Net cash used in operating activities	(10,755,719)	(9,280,768)
Cash flows from investing activities		
Purchase of property and equipment	(9,475)	(13,943)
Loan payments from related party	—	75,000
Net cash (used in) provided by investing activities	(9,475)	61,057
Cash flows from financing activities		
Borrowings from convertible notes	5,000,000	3,345,000
Payments of convertible notes	(6,245,833)	(275,000)
Payments of debt issuance costs	(57,000)	(20,000)
Proceeds from the exercise of stock options	15,574	—
Proceeds from issuance of common stock and warrants	20,706,919	18,132,661
Payment of deferred offering costs	(1,045,468)	(1,655,079)
Net cash provided by financing activities	18,374,192	19,527,582
Net increase in cash and cash equivalents	7,608,998	10,307,871
Cash and cash equivalents as of beginning of period	5,728,900	355,563
Cash and cash equivalents as of end of period	$ 13,337,898	$ 10,663,434
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	$ 418,927	$ 280,287
Supplemental disclosure of non-cash 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
Non-cash addition of derivative liability	$ 1,281,000	$ —
Non-cash addition of deferred offering costs	$ 151,137	$ —
Receivable for stock options and warrants exercised	$ 14,490	$ 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), alcoholic steatohepatitis (ASH), Crohn's disease, 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—Merger and Financing.

Basis of Presentation

The unaudited condensed interim financial statements 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 ("U.S. GAAP"). Operating results for the three and six months ended June 30, 2019 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2019. Certain information and footnote disclosure normally included in the annual financial statements prepared in accordance with U.S. 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. In addition, warrants to purchase up to 154,403 shares of the Company's common stock remained outstanding after completion of the Merger. These warrants have a weighted-average exercise price of $55.31 per share and expire in 2021 and 2022.

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 and related notes thereto for the year ended December 31, 2018, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on March 18, 2019.

Except as noted below under the section entitled "Recently Issued Accounting Standards—Accounting Pronouncements Adopted", there have been no material changes to the Company's significant accounting policies during the three and six months ended June 30, 2019, as compared to the significant accounting policies disclosed in Note 1 of the Company's financial statements for the years ended December 31, 2018 and 2017. However, the following accounting policies are the most critical in fully understanding the Company's financial condition and results of operations.

Shelf Registration Filing

On March 15, 2018, the Company filed a shelf registration statement that was declared effective on July 13, 2018. Under the shelf registration statement, the Company may, from time to time, sell its common stock in one or more offerings up to an aggregate dollar amount of $175 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; the use of this facility was suspended on June 24, 2019). In addition, the selling stockholders included in the shelf registration statement may from time to time sell up to an aggregate amount of 13,990,403 shares of the Company's common stock (including up to 2,051,771 shares issuable upon exercise of warrants) in one or more offerings.

March 2019 Offering

On March 17, 2019, the Company entered into a securities purchase agreement (the "Purchase Agreement") with SDS Capital Partners II, LLC and certain other accredited investors, pursuant to which the Company sold, on March 18, 2019, 4,181,068 shares of common stock and issued short-term warrants (the "Short-Term Warrants") to purchase up to 4,181,068 shares of common stock, and long-term warrants (the "March Long-Term Warrants") to purchase up to 2,508,634 shares of common stock. Pursuant to the Purchase Agreement, the Company issued the common stock and warrants at a purchase price of $2.33 per share for aggregate proceeds of approximately $9.7 million.

The March Long-Term Warrants issued will be exercisable for five years commencing on the six-month anniversary of March 18, 2019, have an initial exercise price of $2.56, subject to certain adjustments, and have an expiration date of March 18, 2024. Any March Long-Term Warrant that has not been exercised by the expiration date shall be automatically exercised via cashless exercise. The Short-Term Warrants are exercisable for a period of one year from March 18, 2019, have an expiration date of March 18, 2020 and have an initial exercise price of $4.00, subject to certain adjustments. If at any time after March 18, 2019, the weighted-average price of the Company's common stock exceeds $5.25 for ten consecutive trading days, the Company may call the outstanding Short-Term Warrants and require that they be exercised in cash, except to the extent that such exercise would surpass the beneficial ownership limitations, as specified in the Purchase Agreement. If not previously exercised in full, at the expiration of their applicable terms, the warrants shall be automatically exercised via cashless exercise. The Short-Term Warrants and March Long-Term Warrants are classified as warrant liabilities on the accompanying condensed balance sheet.

Additional Issuance of Warrants

On April 25, 2019, the Company entered into an amendment (the "Amendment") to the Purchase Agreement dated as of March 17, 2019, between the Company and each purchaser party thereto. The Amendment (i) deleted Section 4.12 of the Purchase Agreement, which generally prohibited the Company from issuing, entering into agreements to issue, announcing proposed issuances, selling or granting certain securities between the date of the Purchase Agreement and the date that was 45 days following the closing date thereunder and (ii) gave each purchaser the right to purchase, for $0.125 per underlying share, an additional warrant to purchase shares of the Company's common stock having an exercise price per share of $2.13 and otherwise having the terms of the March Long-Term Warrants (collectively, the "New Warrants") pursuant to a securities purchase agreement to be entered into among the Company and each purchaser that desires to purchase the New Warrants. On May 17, 2019, the Company and each purchaser entered into such Securities Purchase Agreement (the "New Agreement"), and the Company issued New Warrants exercisable for an aggregate of 3,897,010 shares of the Company's common stock.

The New Warrants are exercisable for five years beginning on the six months anniversary of the date of issuance until the five-year anniversary of their date of issuance. The New Warrants have an initial exercise price equal to $2.13 per share, subject to certain adjustments. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon notice to the Company, provided that any increase in such percentage shall not be effective until 61 days after such notice. If not previously exercised in full, at the expiration of their applicable terms, the New Warrants will be automatically exercised via cashless exercise, in which case the holder would receive upon such exercise the net number of shares, if any, of common stock determined according to the formula set forth in the New Warrants. The New Warrants are classified as warrant liabilities on the accompanying condensed balance sheet.

April 2019 Offering

On April 29, 2019, the Company entered into a Securities Purchase Agreement (the "April Purchase Agreement") with certain institutional and accredited investors providing for the sale by the Company of up to 4,318,272 shares of its common stock at a purchase price of $2.025 per share.

Pursuant to the April Purchase Agreement, the Company agreed to issue unregistered warrants (the "April Warrants") to purchase up to 4,318,272 shares of common stock. Subject to certain ownership limitations, the April Warrants are exercisable beginning on the date of their issuance until the five-and-a-half-year anniversary of their date of issuance at an initial exercise price of $2.13. The exercise price of the April Warrants is subject to adjustment for stock splits, reverse splits, and similar capital transactions as described in the April Warrants. Upon a fundamental transaction, the holder shall have the right to receive payment in cash, or under certain circumstances in other consideration, from the Company at the Black-Scholes value as described in the April Warrants. The April Warrants may be exercisable on a "cashless" basis while there is no effective registration statement or current prospectus available for the shares of common stock issuable upon exercise of the April Warrants. A holder will not have the right to exercise any portion of the April Warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or, at the election of the holder, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the April Warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon notice to the Company, provided that any increase in such percentage shall not be effective until 61 days after such notice. If not previously exercised in full, at the expiration of their terms, the April Warrants will be automatically exercised via cashless exercise.

The net proceeds from the offering and the private placement were approximately $7.9 million, after deducting commissions and estimated offering costs. The Company granted the placement agent warrants to purchase up to 215,914 shares of common stock (the "Placement Agent Warrants"). The Placement Agent Warrants have substantially the same terms as the April Warrants, except that the Placement Agent Warrants have an exercise price of $2.53 and have a term of 5 years from the effective date of the offering. The Company also paid the placement agent a reimbursement for non-accountable expenses in the amount of $35,000 and a reimbursement for legal fees and expenses of the placement agent in the amount of $25,000. The April Warrants and Placement Agent Warrants are classified as warrant liabilities on the accompanying condensed balance sheet.

Business Risks

The Company faces risks associated with biopharmaceutical companies whose products are in the various 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 U.S. 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, valuation of the derivative liability and warrant liabilities, 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, licensing fees, salaries and benefits, and professional fees. The Company is required to estimate its expenses resulting from obligations under contracts with clinical

research organizations, vendors and consulting agreements that have been incurred by the Company prior to being invoiced. 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, 2019	December 31, 2018
Accrued compensation and benefits	$ 621,905	$ 697,334
Other accrued expenses	352,186	128,993
Total	$ 974,091	$ 826,327

Derivative Liability

The Company accounts for derivative instruments in accordance with Accounting Standards Codification ("ASC") 815, *Derivative and Hedging,* which establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other financial instruments or contracts and requires recognition of all derivatives on the balance sheet at fair value. The Company's derivative financial instrument consists of an embedded option in the Company's convertible debt. The embedded derivative includes provisions that provide the noteholder with certain conversion and put rights at various conversion or redemption values as well as certain call options for the Company. See Note 4—Debt for further details.

Warrant Liabilities

The warrants the Company issued during 2019 are freestanding financial instruments that contain net settlement options and may require the Company to settle these warrants in cash under certain circumstances. As such, the Company has classified these warrants as liabilities on the accompanying condensed balance sheets. The warrant liabilities are initially recorded at fair value on the date of issuance and will be subsequently re-measured to fair value at each balance sheet date until the warrant liabilities are settled. Changes in the fair value of the warrants are recognized as a non-cash component of other income and expense in the accompanying condensed statements of operations and comprehensive loss.

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 the 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. Although the Company does not expect its estimates to be materially different from amounts incurred, the Company's estimates and assumptions for clinical trial costs could differ significantly from actual costs incurred, which could result in increases or decreases in research and development expenses in future periods when actual results are known.

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

Share-Based Compensation

The Company recognizes share-based compensation expense for grants of stock options to employees and non-employee members of the Company's board of directors based on the grant-date fair value of those awards using the Black-Scholes option-pricing model. Share-based compensation expense is generally recognized on a straight-line basis over the requisite service period for awards expected to vest.

Prior to adoption of Accounting Standards Update ("ASU") 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Non-employee Share-Based Payment Accounting*, share-based compensation expense related to stock options granted to non-employees, other than non-employee directors, was adjusted each reporting period for changes in the fair value of the Company's stock until the measurement date. The measurement date was generally considered to be the date when all services had been rendered or the date that options were fully vested. Effective January 1, 2019, the Company adopted ASU 2018-07, which no longer requires the re-measurement of the fair value for stock options awarded to non-employees. ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees.

Share-based compensation expense for both employees and non-employees includes an estimate, which is made at the time of grant, of the number of awards that are expected to be forfeited. This estimate is revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Under the Black-Scholes option-pricing model, fair value is calculated based on assumptions with respect to:

- *Expected dividend yield.* The expected dividend yield 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.* Due to 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. In evaluating comparable companies, the Company considers factors such as industry, stage of life cycle, financial leverage, size and risk profile.
- *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. Due to limited history of stock option exercises, the Company estimates the expected term of employee stock options based on the simplified method, which calculates the expected term as the average of the time-to-vesting and the contractual life of the options. Pursuant to ASU-2018-07, the Company has elected to use the contractual life of the option as the expected term for non-employee options.

Periodically, the board may approve the grant of restricted stock units ("RSUs") pursuant to the Innovate Biopharmaceuticals, Inc. 2012 Omnibus Incentive Plan, as amended, which represent the right to receive shares of the Company's common stock based on terms of the agreement. The fair value of RSUs is recognized as share-based compensation expense generally on a straight-line basis over the service period, net of estimated forfeitures. The grant date fair value of an RSU represents the closing price of the Company's common stock on the date of grant.

Share-based Compensation Adjustment to Prior Period Results

In preparing the Company's financial statements for the year ended December 31, 2018, the Company determined that an immaterial error was made in the amount of share-based compensation expense recorded in the Company's Quarterly Report on Form 10-Q for March 31, 2018, which was filed with the SEC on May 15, 2018. The error resulted in an overstatement of share-based compensation expense of approximately $1.2 million for the first quarter of 2018 and the subsequent year-to-date periods through September 30, 2018. The Company disclosed this error in its Annual Report on Form 10-K for the year ended December 31, 2018, which was filed with the SEC on March 18, 2019. The Company has revised its previously reported financial results for the six months ending June 30, 2018 to correct the error. The Company concluded that this correction did not have a material impact on its previously issued quarterly financial statements or the audited financial statements for the year ended December 31, 2018. The financial results for the six months ended June 30, 2018 included within this Quarterly Report on Form 10-Q reflect the adjustment to the prior period.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received for sale of an asset or paid for transfer of a liability, in an orderly transaction between market participants at the measurement date. U.S. GAAP establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). Financial instruments recorded in the accompanying condensed balance sheets are categorized based on the inputs to valuation techniques as follows:

- Level 1 - defined as observable inputs based on unadjusted quoted prices for identical instruments in active markets;
- Level 2 - defined as inputs other than Level 1 that are either directly or indirectly observable in the marketplace for identical or similar instruments in markets that are not active; and
- Level 3 - defined as unobservable inputs in which little or no market data exists where valuations are derived from techniques in which one or more significant inputs are unobservable.

The fair value of the embedded derivative issued in connection with the Senior Convertible Note and the Unsecured Convertible Note, further described in Note 4—Debt, was determined by using a Monte Carlo simulation technique ("MCS") to value the embedded derivative associated with each note. As part of the MCS valuation, a discounted cash flow ("DCF") model is used to value the debt on a stand-alone basis and determine the discount rate to utilize in both the DCF and MCS models. The significant estimates used in the DCF model include the time to maturity of the convertible debt and calculated discount rate, which includes an estimate of the Company's specific risk premium. The MCS methodology calculates the theoretical value of an option based on certain parameters, including: (i) the threshold of exercising the option, (ii) the price of the underlying security, (iii) the time to expiration, or expected term, (iv) the expected volatility of the underlying security, (v) the risk-free rate and (vi) the number of paths.

These valuation techniques involve management's estimates and judgment based on unobservable inputs and are classified in Level 3. The table below summarizes the valuation inputs into the MCS model for the derivative liability associated with the Senior Convertible Note as of December 31, 2018 and for the derivative liability associated with the Unsecured Convertible Note as of March 8, 2019 and June 30, 2019.

	Derivative Liability		
	June 30, 2019	March 8, 2019	December 31, 2018
Expected dividend yield			
Discount rate	29.1%	29.3%	13.6%
Expected stock price volatility	105.6%	101.1%	105.6%
Risk-free interest rate	1.8%	2.5%	2.5%
Expected term	20 months	24 months	21 months
Price of the underlying common stock	$ 1.16	$ 1.99	$ 2.31

The fair value of the warrants issued pursuant to the Purchase Agreements further described above in the sections entitled "March 2019 Offering," "Additional Issuance of Warrants," and "April 2019 Offering" were determined through the use of an MCS model. The MCS methodology calculates the theoretical value of an option based on certain parameters, including (i) the threshold of exercising the option, (ii) the price of the underlying security, (iii) the time to expiration, or expected term, (iv) the expected volatility of the underlying security, (v) the risk-free interest rate and (vi) the number of paths. Given the high level of the selected volatilities, the methodology selected simulates the Company's market value of invested capital ("MVIC") through the maturity date of the respective warrants (ranging from one year to five-and-a-half years). Further, the estimated future stock price of the Company is calculated by subtracting the debt plus accrued interest from the MVIC. The significant estimates used in the MCS model include management's estimated probability of future financing and liquidation events.

These valuation techniques involve management's estimates and judgment based on unobservable inputs and are classified in Level 3. The March Long-term Warrants, the New Warrants, the April Warrants and the Placement Agent Warrants are referred to collectively as the "Long-term Warrants."

The table below summarizes the valuation inputs into the MCS model for the warrant liabilities at their respective dates of issuance.

	Short-Term Warrants	Long-Term Warrants		
	March 18, 2019	March 18, 2019	May 1, 2019	May 17, 2019
Conversion price	$ 4.00	$ 2.56	$ 2.13 - $ 2.53	$ 2.13
Expected stock price volatility	122.0%	85.2%	84.1%	83.4%
Risk-free interest rate	2.5%	2.2%	2.2%	2.2%
Expected term	1 year	5 years	5 - 5.5 years	5 years
Price of the underlying common stock	$ 2.48	$ 2.48	$ 1.54	$ 1.58

The table below summarizes the range of valuation inputs into the MCS model for the warrant liabilities as of June 30, 2019.

	Short-Term Warrants	Long-Term Warrants
	June 30, 2019	
Conversion price	$ 4.00	$2.13 - $2.56
Expected stock price volatility	85.3%	83% - 83.5%
Risk-free interest rate	2.0%	1.8% - 2.0%
Expected term	1 year	5 - 5.5 years
Price of the underlying common stock	$ 1.16	1.16

The following table summarizes the fair value hierarchy of financial liabilities measured at fair value as of June 30, 2019 and December 31, 2018.

	June 30, 2019			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Derivative liability	$ —	$ —	$ 999,000	$ 999,000
Warrant liabilities	—	—	660,200	660,200
Total liabilities at fair value	$ —	$ —	$ 1,659,200	$ 1,659,200

	December 31, 2018			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Derivative liability	$ —	$ —	$ 370,000	$ 370,000
Warrant liabilities	—	—	—	—
Total liabilities at fair value	$ —	$ —	$ 370,000	$ 370,000

The following table summarizes the changes in fair value of the derivative liability and warrant liabilities classified in Level 3. Gains and losses reported in this table include changes in fair value that are attributable to unobservable inputs.

	Six Months Ended June 30, 2019
Beginning balance as of December 31, 2018	$ 370,000
Issuance of warrant liabilities	3,330,000
Extinguishment of derivative liability (the Senior Convertible Note)	(370,000)
Issuance of derivative liability (the Unsecured Convertible Note)	1,281,000
Change in fair value of warrant liabilities	(2,669,800)
Change in fair value of derivative liability	(282,000)
Ending balance as of June 30, 2019	$ 1,659,200
The amount of total gain for the period included in earnings attributable to the change in unrealized gains relating to the fair value liabilities still held at the reporting date	$ 2,951,800

There were no gains or losses included in earnings attributable to changes in unrealized gains or losses for fair value assets or liabilities during the three and six months ended June 30, 2018.

The cumulative unrealized gain relating to the change in fair value of the derivative liability and warrant liabilities of $2,951,800 and the extinguishment of derivative liability of $370,000 for the six months ended June 30, 2019 is included in other income (expense) in the condensed statements of operations and comprehensive loss.

ASC 820, *Fair Value Measurement and Disclosures* requires all entities to disclose the fair value of financial instruments, both assets and liabilities, for which it is practicable to estimate fair value. As of June 30, 2019 and December 31, 2018, the recorded values of cash and cash equivalents, restricted deposit, accounts payable, accrued expenses and convertible promissory notes approximate their fair values due to the short-term nature of the instruments.

Deferred Offering Costs

Deferred offering costs consist principally of legal, accounting and underwriters' fees related to offerings or the Company's shelf registration. Offering costs incurred prior to an offering are initially capitalized and then subsequently reclassified to additional paid-in capital upon completion of the offering. Deferred offering costs associated with the shelf registration will be charged to additional paid-in capital on a pro-rata basis in the event the Company completes an offering under the shelf registration. Due to the voluntary suspension of the "at-the-market" ("ATM") facility effective June 24, 2019, deferred offering costs associated with the ATM facility were written off during the three and six months ended June 30, 2019.

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 $126,000 and $161,000 for the three months ended June 30, 2019 and 2018, respectively, and $287,000 and $309,000 for the six months ended June 30, 2019 and 2018, 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 potentially dilutive shares that were outstanding during the reporting period. Because 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 outstanding used to calculate both basic and diluted net loss per share are the same. For the three and six months ended June 30, 2019 and 2018, 24.5 million and 8.6 million potentially dilutive securities related to warrants and stock options issued and outstanding have been excluded from the computation of diluted weighted average shares outstanding because the effect would be anti-dilutive. The potentially dilutive securities consisted of the following:

	Six Months Ended June 30,	
	2019	2018
Options outstanding under the Private Innovate Plan	6,240,792	6,428,577
Options outstanding under the Amended Omnibus Plan	1,266,546	1,683
Warrants issued at a weighted-average exercise price of $55.31	154,403	154,403
Warrants issued at an exercise price of $2.54	349,555	349,555
Warrants issued at an exercise price of $3.18	1,410,358	1,702,216
Short-term warrants issued at an exercise price of $4.00	4,181,068	—
Long-term warrants issued at a weighted-average exercise price of $2.24	10,939,830	—
Total	24,542,552	8,636,434

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.

Recently Issued Accounting Standards

Accounting Pronouncements Adopted

The Company adopted ASU No. 2016-02, *Leases (Topic 842)*, as amended, as of January 1, 2019 using the modified retrospective approach at the beginning of the period of adoption. Under this approach, the reporting for comparative periods presented in the financial statements are presented in accordance with the legacy lease standard. In addition, the Company elected the available practical expedients permitted under the transition guidance within the new lease standard.

Under the new leases standard, the Company recognizes a right-of-use ("ROU") asset and lease liability upon commencement of a lease. The ROU asset represents the Company's right to use an underlying asset for the lease term and is included in right-of-use asset on the accompanying condensed balance sheet. Lease liabilities represent the Company's obligation to make lease payments arising from the lease and are included in current and non-current lease liability on the accompanying condensed balance sheet. Operating lease ROU assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. In the absence of an implicit rate, the Company uses their incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. All leases with a term of less than 12 months are not recognized on the balance sheet. Adoption of the new leases standard resulted in the Company recognizing a ROU asset and lease liability of less than $0.1 million as of January 1, 2019. The adoption of ASU 2016-02 did not result in a cumulative adjustment to accumulated deficit.

In June 2018, the Financial Accounting Standards Board ("FASB") issued ASU 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Non-employee 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 non-employees. The Company adopted this standard effective January 1, 2019. Effective January 1, 2019, the date of adoption, the Company changed its expense recognition for share-based payments to non-employees to an amount determined at the grant or modification date instead of a variable amount to be re-measured each reporting period. The Company calculated the fair value of its non-employee grants as of the adoption date and determined that there was no impact to the Company's accumulated deficit or other components of equity upon adoption of ASU 2018-07. The unamortized expense for non-employee grants will be recognized on a straight-line basis over the remaining contractual term of the respective non-employee option agreements. The adoption of ASU 2018-07 did not have a material impact on the Company's financial statements.

Accounting Pronouncements Being Evaluated

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement.* This standard no longer requires public companies to disclose transfers between level 1 and 2 of the fair value hierarchy and adds additional disclosure requirements about the range and

weighted average used to develop significant unobservable inputs for Level 3 fair value measurements. The guidance is effective for fiscal years beginning after December 15, 2019, and for interim periods within those fiscal years. Early adoption is permitted and the Company is currently evaluating the impact this standard will have on the Company's financial statements.

NOTE 2: LIQUIDITY AND GOING CONCERN

The accompanying financial statements have been prepared assuming 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. The Company has concluded that the prevailing conditions and ongoing liquidity risks faced by the Company raise substantial doubt about the Company's ability to continue as a going concern for at least 12 months following the date these financial statements are issued. Based on the Company's limited operating history and recurring operating losses, the Company will need substantial additional funding to support its planned and future operating activities, including progression of research and development programs. Management's plans with regard to these matters may include entering into strategic partnerships or licensing arrangements or seeking additional debt or equity financing arrangements or a combination of these activities. There can be no assurance that the Company will be able to obtain additional capital on terms acceptable to the Company, on a timely basis or at all. The failure to obtain additional funding or strategic partnerships could adversely affect the Company's ability to achieve its business objectives and product development timelines and could have a material adverse effect on the Company's results of operations. 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: DEBT

Senior Convertible Note

On January 29, 2018, the Company entered into a Note Purchase Agreement and Senior Note Payable (the "Note") with a lender. The principal amount of the Note was $4.8 million ("Original Principal"). The Note was issued at a discount of $1.8 million and net of $20,000 for financing costs, for total proceeds of $3.0 million. The discount and additional repayment premium were amortized to interest expense using the effective interest method through the scheduled maturity date of September 30, 2018 (the "Maturity Date"). Interest on the Note accrued from January 29, 2018, at a rate of 12.5% per annum and quarterly payments of interest only were due beginning on March 30, 2018 and compounded quarterly. The Company entered into a Waiver Agreement with the noteholder that extended the Maturity Date until October 4, 2018. On October 4, 2018, the Company entered into an Amendment and Exchange Agreement ("Exchange Agreement") with the noteholder exchanging the Note for a new Senior Convertible Note (the "Senior Convertible Note").

The principal amount of the Senior Convertible Note was $5.2 million and bore interest at a rate of eight percent (8%) per annum payable quarterly in cash, with a scheduled maturity date of October 4, 2020. The interest rate would automatically increase to 18% per annum if there was an event of default during the period. The Company evaluated the Exchange Agreement and the Senior Convertible Note and determined that the amendment to the Note constituted an extinguishment of debt, in accordance with authoritative guidance. The Company determined that there was no difference between the reacquisition price of the new debt and the net carrying amount of the extinguished debt and thus there was no gain or loss from the extinguishment. The Company incurred approximately $30,000 of legal fees associated with the Senior Convertible Note, which were recorded as debt issuance costs and are included in the amortization of debt discount discussed below.

The various conversion and redemption features contained in the Senior Convertible Note are embedded derivative instruments, which were recorded as a debt discount and derivative liability at their estimated fair value. See Note 1—Summary of Significant Accounting Policies for details regarding the fair value of derivative liability. During 2018, the VWAP of the Company's common stock was lower than the Floor Price for more than ten consecutive days. As such, the noteholder had the right to require the Company to redeem the Senior Convertible Note prior to December 31, 2018, at its option. Therefore, the Company has amortized the entire debt discount to interest expense through the triggering of the redemption option, which occurred in 2018. Based on the conversion features, redemption features and subjective acceleration clauses contained in the Senior Convertible Note, the Company recorded the Senior Convertible Note as a short-term obligation as of December 31, 2018.

During January 2019, the noteholder issued a redemption notice to the Company requiring the Company to repay the noteholder $1,049,167 of principal and $1,399 of accrued interest. On January 7, 2019, the Company entered into an Option to Purchase Senior Convertible Note (the "Option Agreement") with the noteholder. The Company paid the noteholder $250,000 in consideration for the noteholder entering into the Option Agreement with the Company, which was recorded as interest expense in the accompanying statements of operations and comprehensive loss. The Option Agreement provided the Company with the ability to repay (purchase) the outstanding principal and accrued interest of the Senior Convertible Note any time from January 7, 2019 until March 31, 2019 (the "Option Period").

During March 2019, the Company exercised its repurchase rights from the Option Agreement and paid the noteholder of the Senior Convertible Note approximately $5,200,000 in principal and $60,000 in interest, which was the full purchase amount of the Senior Convertible Note pursuant to the terms of the Option Agreement. There are no further amounts outstanding under the Senior Convertible Note and the Senior Convertible Note has been canceled. The Company accounted for the repayment of the Senior Convertible Note as a liability extinguishment in accordance with ASC 405, *Extinguishments of Liabilities,* which resulted in the Company recording a loss on extinguishment of debt of approximately $1.0 million in the accompanying statements of operations and comprehensive loss for the six months ended June 30, 2019.

Amortization of debt discount for the Note and Senior Convertible Note recorded as interest expense was approximately $0.7 million and $1.2 million for the three and six months ended June 30, 2018, respectively. There was no such expense for the Note and Senior Convertible Note during the three and six months ended June 30, 2019.

Unsecured Convertible Promissory Note

On March 8, 2019, the Company entered into a Securities Purchase Agreement (the "Note Purchase Agreement") with a purchaser (the "Convertible Noteholder"). Pursuant to the Note Purchase Agreement, the Company issued the Convertible Noteholder an unsecured Convertible Promissory Note (the "Unsecured Convertible Note") in the principal amount of $5,500,000. The Convertible Noteholder may elect to convert all or a portion of the Unsecured Convertible Note at any time and from time to time into the Company's common stock at a conversion price of $3.25 per share, subject to adjustment for stock splits, dividends, combinations and similar events. The Company may prepay all or a portion of the Unsecured Convertible Note at any time for an amount equal to 115% of then outstanding obligations or the portion of the obligations the Company is prepaying. The purchase price of the Unsecured Convertible Note was $5,000,000, and the Unsecured Convertible

Note carries an original issuance discount ("OID") of $500,000, which is included in the principal amount of the Unsecured Convertible Note. In addition, the Company agreed to pay $20,000 of transaction expenses, which were netted out of the purchase price of the Unsecured Convertible Note. The Company also incurred additional transaction costs of approximately $37,000, which were recorded as debt issuance costs. As a result of the redemption features of the Unsecured Convertible Note, further described below, the Company is amortizing the debt issuance costs and accreting the OID to interest expense over the estimated redemption period of 15 months, using the effective interest method.

The various conversion and redemption features contained in the Unsecured Convertible Note are embedded derivative instruments, which were recorded as a debt discount and derivative liability at the issuance date at their estimated fair value of $1.3 million. Amortization of debt discount and accretion of the OID for the Unsecured Convertible Note recorded as interest expense was approximately $0.3 million and $0.4 million for the three and six months ended June 30, 2019, respectively.

The Unsecured Convertible Note consists of the following:

	June 30, 2019
Convertible Note	$ 5,500,000
Less: unamortized debt discount and OID accretion	(1,455,788)
Total	$ 4,044,212

The Unsecured Convertible Note bears interest at the rate of 10% (which will increase to 18% upon and during the continuance of an event of default) per annum, compounding on a daily basis. All principal and accrued interest on the Unsecured Convertible Note is due on the second-year anniversary of the Unsecured Convertible Note's issuance.

At any time after the six month anniversary of the issuance of the Unsecured Convertible Note, (i) if the average volume weighted average price over twenty trading dates exceeds $10.00 per share, the Company may generally require that the Unsecured Convertible Note convert into shares of its common stock at the $3.25 (as adjusted) conversion price, and (ii) the Convertible Noteholder may elect to require all or a portion of the Unsecured Convertible Note be redeemed by the Company. If the Convertible Noteholder requires a redemption, the Company, at its discretion, may pay the redeemed portion of the Unsecured Convertible Note in cash or in the Company's common stock at a conversion rate equal to the lesser of (i) the $3.25 (as adjusted) conversion rate or (ii) 80% of the average of the five lowest volume weighted average price of the Company's Common Stock over the preceding twenty trading days. The Convertible Noteholder may not redeem more than $500,000 per calendar month during the period between the six months anniversary of the date of issuance until the first-year anniversary of the date of issuance and $750,000 per calendar month thereafter. The obligation or right of the Company to deliver its shares upon the conversion or redemption of the Unsecured Convertible Note is subject to a 19.99% cap and subject to a floor price trading price of $3.25 (unless waived by the Company). Any amounts redeemed or converted once the cap is reached or if the market price is less than the $3.25 floor price must be paid in cash.

If there is an Event of Default under the Unsecured Convertible Note, the Convertible Noteholder may accelerate the Company's obligations or elect to increase the outstanding obligations under the Unsecured Convertible Note. The amount of the increase ranges from 5% to 15% depending on the type of default (as defined in the Unsecured Convertible Note). In addition, the Unsecured Convertible Note obligations will be increased if there are delays in the Company's delivery requirements for the shares or cash issuable upon the conversion or redemption of the Unsecured Convertible Note in certain circumstances.

If the Company issues convertible debt in the future with any terms, including conversion terms, that are more favorable to the terms of the Unsecured Convertible Note, the Convertible Noteholder may elect to incorporate the more favorable terms into the Unsecured Convertible Note.

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 free of milestone fees. 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) 10 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.

There were no milestone or royalty fees incurred during the three and six months ended June 30, 2019 and 2018.

NOTE 6: STOCKHOLDERS' EQUITY (DEFICIT)

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.

The Company had reserved shares of common stock for future issuance as follows:

	June 30, 2019	December 31, 2018
Outstanding stock options	7,507,338	7,117,002
Warrants to purchase common stock	17,035,214	1,914,316
Shares issuable upon conversion of convertible debt	1,745,897	1,720,224
For possible future issuance under the Amended Omnibus Plan	2,554,083	2,230,057
Total common shares reserved for future issuance	28,842,532	12,981,599

During the six months ended June 30, 2019, the Company sold 8,499,340 shares of common stock and issued Short-Term Warrants and Long-Term Warrants to purchase up to 15,120,898 shares of common stock. For further details, see Note 1—Summary of Significant Accounting Policies.

On October 26, 2018, the Company entered into a common stock sales agreement with H.C. Wainwright & Co., LLC and Ladenburg Thalmann & Co., Inc. and filed a prospectus with the SEC to such offering. The Company previously filed a Form S-3 that became effective July 13, 2018 that included the registration of $40 million of its shares of common stock in connection with a potential ATM offering. Pursuant to the sales agreement, the Company may issue and sell shares having an aggregate gross sales price of up to $40 million. The Company is required to pay the sales agents commissions of 3% of the gross sales price per share sold. During the six months ended June 30, 2019, the Company sold 705,714 shares under the ATM for total net proceeds of approximately $1,675,000. All proceeds were received as of June 30, 2019. The ATM facility was voluntarily suspended as of June 24, 2019. Due to suspension of the ATM facility, deferred offering costs of approximately $0.1 million were written off during the three months ended June 30, 2019.

NOTE 7: SHARE-BASED COMPENSATION

Upon consummation of the Merger, the Company had two stock option plans in existence: the Monster Digital, Inc. 2012 Omnibus Incentive Plan (the "Omnibus Plan") and the Innovate 2015 Stock Incentive Plan (the "Private Innovate Plan"). During 2018, the Company's board of directors approved an amendment to the Omnibus Plan to, among other things, formally change the name of the Omnibus Plan to the Innovate Biopharmaceuticals, Inc. 2012 Omnibus Incentive Plan (the "Amended Omnibus Plan") and increase the number of shares authorized for issuance under the Amended Omnibus Plan to provide for an additional 3,000,000 shares. In addition, the shares reserved for issuance under the Amended Omnibus Plan will automatically increase on the first day of each calendar year beginning in 2019 and ending in 2022 by an amount equal to the lesser of (i) five percent of the number of shares of common stock outstanding as of December 31st of the immediately preceding calendar year or (ii) such lesser number of shares of common stock as determined by the board of directors (the "Evergreen Provision"). On January 1, 2019, the number of shares of common stock available under the Amended Omnibus Plan automatically increased by 1,304,441 shares pursuant to the Evergreen Provision.

The terms of the option agreements are determined by the Company's board of directors. The Company's stock options vest based on the terms in the stock option agreements and typically vest over a period of three to four years. These stock options typically have a maximum term of ten years.

Private Innovate Plan

As of June 30, 2019, there were 6,240,792 stock options outstanding under the Private Innovate Plan. Following completion of the Merger, the Company does not intend to issue any additional awards from the Private Innovate Plan.

The range of assumptions used in estimating the fair value of the options granted or re-measured under the Private Innovate Plan using the Black-Scholes option pricing model for the periods presented were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Expected dividend yield	0%	0%	0%	0%
Expected stock-price volatility	—%	67% - 68%	67%	67% - 72%
Risk-free interest rate	—%	2.8% - 2.9%	2.6%	2.7% - 2.9%
Expected term of options	0	8.7 - 9.3	8.2 - 8.7	8.7 - 9.5

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, 2018	6,340,871	$ 1.53	$ 4,978,205	7.7
Options granted	—	—	—	
Options forfeited	—	—	—	
Options exercised	(100,079)	0.30	—	
Outstanding at June 30, 2019	6,240,792	1.55	1,662,932	5.9
Exercisable at June 30, 2019	5,659,872	1.49	1,662,932	5.7
Vested and expected to vest at June 30, 2019	6,217,132	$ 1.54	$ 1,662,932	5.9

There were no options granted under the Private Innovate Plan during the three and six months ended June 30, 2019 and 2018. The total intrinsic value of options exercised was approximately $81,000 during the three and six months ended June 30, 2019.

The total fair value of stock option awards vested during the six months ended June 30, 2019 under the Private Innovate Plan was approximately $289,000. As of June 30, 2019, there was approximately $0.8 million of total unrecognized compensation cost related to unvested stock-based compensation arrangements under the Private Innovate Plan, which is expected to be recognized over a weighted average period of 1.8 years.

The Private Innovate Plan provides for accelerated vesting under certain change-of-control transactions, if approved by the Company's board of directors.

Amended Omnibus Plan

As of June 30, 2019, there were options to purchase 1,266,546 shares of Innovate common stock outstanding under the Amended Omnibus Plan and 2,554,083 shares available for future grants under the Amended Omnibus Plan.

The range of assumptions used in estimating the fair value of the options granted or re-measured under the Amended Omnibus Plan using the Black-Scholes option pricing model for the periods presented were as follows:

	Three Months Ended June 30,	Six Months Ended June 30,
	2019	2019
Expected dividend yield	0%	0%
Expected stock-price volatility	70%	68% – 72%
Risk-free interest rate	2.0% – 2.2%	2.0% – 2.7%
Expected term of options	5.7	5.4 – 10.0

The following table summarizes stock option activity under the Amended Omnibus Plan:

	Number of Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value	Weighted-Average Remaining Contractual Life (in years)
Outstanding at December 31, 2018	776,131	$ 5.79	$ —	7.4
Options granted	665,000	1.63	—	
Options forfeited	(174,585)	6.02	—	
Options exercised	—	—	—	
Outstanding at June 30, 2019	1,266,546	3.58	—	9.5
Exercisable at June 30, 2019	418,741	4.25	—	9.2
Vested and expected to vest at June 30, 2019	1,201,929	$ 3.61	$ —	9.5

The weighted-average grant date fair value of options granted under the Amended Omnibus Plan was $0.99 and $1.02 during the three and six months ended June 30, 2019, respectively. There were no options granted under the Amended Omnibus Plan during the three and six months ended June 30, 2018.

The total fair value of stock option awards vested under the Amended Omnibus Plan was approximately $371,000 during the six months ended June 30, 2019. As of June 30, 2019, there was approximately $1.2 million of total unrecognized compensation cost related to unvested stock-based compensation arrangements under the Amended Omnibus Plan. This cost is expected to be recognized over a weighted average period of 2.9 years.

The Amended Omnibus Plan provides for accelerated vesting under certain change-of-control transactions, if approved by the Company's board of directors.

During the six months ended June 30, 2019, the board approved grants of 490,000 RSUs. 390,000 of the RSUs vested immediately on the date of grant; the remaining 100,000 RSUs vest 50% on the date of grant and the remainder pro-rata over six months following the date of grant. The weighted-average fair value of RSUs granted during the six months ended June 30, 2019 was $1.44 and the Company recognized share-based compensation expense for the RSUs of approximately $449,000 and $639,000 during the three and six months ended June 30, 2019. There were no RSUs granted during the three and six months ended June 30, 2018.

Total share-based compensation expense recognized in the accompanying statements of operations was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Research and development	$ 351,000	$ (334,000)	$ 443,000	$ 5,417,000
General and administrative	501,000	150,000	935,000	1,573,000
Total share-based compensation	$ 852,000	$ (184,000)	$ 1,378,000	$ 6,990,000

NOTE 8: COMMITMENTS AND CONTINGENCIES

Clinical Trial Agreement

From time to time, the Company enters into agreements with contract research organizations and other service providers. In August 2018, the Company entered into such an agreement for its planned Phase 3 trial for the treatment of celiac disease. Under this agreement, the Company expects to pay approximately $1.1 million for data management over the course of the Phase 3 celiac disease trial for data management and biostatistics services.

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 six months ended June 30, 2018, 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.

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.

In November 2018 and February 2019, the Company entered into separation and general release agreements with two former executives of the Company that included separation benefits consistent with each former executives' employment agreement. The Company recognized severance expense totaling $300,000 during the six months ended June 30, 2019, which is being paid in equal installments over 12 months beginning February 2019. There was no severance expense recognized during the three months ended June 30, 2019. The remaining accrued severance obligation in respect of the two former executives is $0.3 million as of June 30, 2019, which is included in accrued expenses on the accompanying condensed balance sheet.

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. Monthly payments of $5,000 are due and payable over the 24-month term. A security deposit of $5,000 was paid in October 2017. The lease contains a two-year renewal option.

Effective January 1, 2019, the Company adopted ASC 842 using the transition approach described in Note 1—Summary of Significant Accounting Policies. On the adoption date, the Company estimated the present value of the lease payments over the remaining term of the lease using a discount rate of 12%, which represented the Company's estimated incremental borrowing rate. The two-year renewal option was excluded from the lease payments as the Company concluded the exercise of this option was not considered reasonably certain.

Operating lease cost under ASC 842 was approximately $15,000 and $30,000 for the three and six months ended June 30, 2019 and is included in general and administrative expenses on the accompanying condensed statement of operations and comprehensive loss. Lease expense under ASC 840 was $15,000 and $30,000 for the three and six months ended June 30, 2018 and is included in general and administrative expenses on the accompanying condensed statements of operations and comprehensive loss. The total cash paid for amounts included in the measurement of the operating lease liability and reported within operating activities was less than $0.1 million during the six months ended June 30, 2019.

Future minimum payments under the Company's lease liability were as follows:

Year ended December 31,	**Operating Leases**
2019	$ 30,000
2020	45,000
Total lease payment	75,000
Less: imputed interest	(5,675)
Total	$ 69,325

Legal

In November 2018, the Company received a letter and draft complaint regarding a former consultant of the Company who was compensated in cash and stock options for his services, demanding damages of up to approximately $3.6 million plus punitive damages in connection with a delay in such consultant's ability and timing to exercise options and sell shares of the Company's common stock related to past consulting services. On January 8, 2019, M. Scott Harris and Middleburg Consultants, Inc. (collectively, "Harris") filed the claim in the Superior Court of the State of Delaware (the "Delaware Action"). As previously disclosed, the Company strongly denies any wrongdoing alleged in the threatened litigation and firmly believes the allegations in the complaint are entirely without merit and intends to defend against them vigorously. On February 25, 2019, the Company filed a motion to dismiss the Delaware Action. The motion to dismiss was heard by the Delaware court on June 26, 2019 and the Company is awaiting the Court's decision. If the motion is not granted, the Company intends to dispute

the factual basis of Harris' claims and also intends to assert affirmative defenses and counterclaims against Harris. The Company is unable to estimate the amount of a potential loss or range of potential loss, if any.

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.

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 trials 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 "Item 1A. Risk Factors" of the Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on March 18, 2019. 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 of Monster and Private Innovate (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 included elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements and related notes thereto for the year ended December 31, 2018, included in our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on March 18, 2019.

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), alcoholic steatohepatitis (ASH), Crohn's disease and ulcerative colitis (UC). We started the Phase 3 clinical trial for our lead drug candidate, larazotide acetate or larazotide (INN-202), for the treatment of celiac disease in June 2019. We will provide updates from time to time as the trial gets further along. Larazotide has the potential to be the first-to-market therapeutic for celiac disease, an unmet medical need affecting an estimated 1% of the U.S. population or more than 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. In celiac disease, larazotide is the only drug which has successfully met its primary endpoint with statistical significance in a Phase 2b efficacy trial, which was comprised of 342 patients. Innovate completed the End of Phase 2 meeting with the FDA for the treatment of celiac disease with larazotide and received Fast Track designation. Larazotide has been shown to be safe and effective after being tested in several clinical trials involving nearly 600 patients, most recently in the Phase 2b trial for celiac disease.

We are also developing larazotide for the treatment of NASH, a type of liver disease stemming from the most common liver disorder in the world, fatty liver disease. NASH is an unmet medical need affecting approximately 5% to 6% of the U.S. adult population, or more than 15 million individuals. We are developing a proprietary formulation of larazotide for NASH for efficient delivery to the intestine. Larazotide has the potential to reduce the transport of bacterial toxins and immunogenic antigens, including lipopolysaccharide (LPS). Larazotide may be the first drug with this novel mechanism to potentially show improvements in validated NASH biomarkers and endpoints. In a 12-week preclinical study of larazotide combined with obeticholic acid (OCA), data demonstrated statistically significant reductions in plasma total cholesterol, absolute and relative

liver weights, relative and total liver cholesterol, and relative and absolute liver triglycerides. These data suggest a synergistic effect between larazotide and OCA.

Intestinal permeability is compromised in numerous diseases where a disruption of the epithelial barrier that separates the lumen from the host's immune system may contribute to uncontrolled inflammation. Larazotide is a gut-restricted peptide which has been shown to re-normalize intestinal permeability in various inflammatory and metabolic preclinical models. During 2019, we initiated a research collaboration with Institut Gustave Roussy's Laurence Zitovogel, MD, Ph.D., Department of Immuno-oncology. Through this collaboration, we seek to understand how the therapeutic effect of immune checkpoint inhibitors, such as antibodies to CTLA-4 and PD-1, are modulated by blocking translocation of certain metabolites and bacterial antigens and toxins from interacting with the host immune system in pre-clinical oncology models. Building on previous research that showed a type of permeability known as "leaky gut" that may cause microbial translocation of toxic products into circulation of the bloodstream, we are expanding our work in liver disease. Initial *in vitro* data suggests the potential use of larazotide in alcoholic liver diseases. We entered into a research collaboration with Massachusetts General Hospital to explore larazotide in animal models for the treatment of ASH.

INN-108 is a novel oral small molecule therapeutic for UC, which plagues up to 1.4 million individuals in the U.S. alone. With the combination of an immunomodulator, INN-108 could lead to a more efficacious drug than the current 5-ASA/mesalamine formations being used to treat UC. A Phase 1 trial was successfully completed in the U.S. with 24 subjects. We expect to enter Phase 2 trials for mild to moderate UC and an adult orphan indication, subject to the receipt of additional financing.

Financial Overview

Since our inception, we have focused our efforts and resources on identifying and developing our research and development 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.

As of June 30, 2019, we had an accumulated deficit of $52.4 million. We incurred net losses of $4.5 million and $4.2 million for the three months ended June 30, 2019 and 2018, respectively, and $8.9 million and $19.2 million for the six months ended June 30, 2019 and 2018, respectively. 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 future and existing product candidates, including INN-202;
- 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
- continue to incur additional legal, accounting, regulatory, tax-related and other expenses required to operate as a public company.

As such, we will need substantial additional funding to support our operating activities. Adequate funding may not be available to us on acceptable terms, or at all. We currently anticipate that we will seek to fund our operations through equity or debt financings, strategic alliances or licensing arrangements, or other sources of financing. Our failure to obtain sufficient funds on acceptable terms could have a material adverse effect on our business, results of operations and financial condition.

Recent Developments

March 2019 Offering

On March 17, 2019, we entered into a securities purchase agreement (the "Purchase Agreement") with SDS Capital Partners II, LLC and certain other accredited investors, pursuant to which we sold, on March 18, 2019, 4,181,068 shares of our common stock and issued short-term warrants (the "Short-Term Warrants") to purchase up to 4,181,068 shares of common stock, and long-term warrants (the "March Long-Term Warrants") to purchase up to 2,508,634 shares of common stock.

Pursuant to the Purchase Agreement, we issued the common stock and warrants at a purchase price of $2.33 per share for aggregate proceeds of approximately $9.7 million.

The March Long-Term Warrants issued will be exercisable commencing on the six-month anniversary of March 18, 2019, have an initial exercise price of $2.56, subject to certain adjustments, and have an expiration date of March 18, 2024. Any March Long-Term Warrant that has not been exercised by the expiration date will be automatically exercised via cashless exercise. The Short-Term Warrants are exercisable from the date of issuance, have an expiration date of March 18, 2020 and have an initial exercise price of $4.00, subject to certain adjustments. If at any time after March 18, 2019, the weighted-average price of our common stock exceeds $5.25 for ten consecutive trading days, we may call the outstanding Short-Term Warrants and require that they be exercised in cash, except to the extent that such exercise would surpass the beneficial ownership limitations, as specified in the Purchase Agreement. If exercised in full, the Short-Term Warrants and March Long-Term Warrants could result in aggregate gross proceeds of $23.1 million; however, there can be no guarantee that any or all of the Short-Term Warrants and March Long-Term Warrants will be exercised, that the market price of our common stock will exceed the exercise price of the Short-Term Warrants or March Long-Term Warrants or that the exercise price will not be subject to certain adjustments. In addition, in certain circumstances, the Short-Term Warrants and March Long-Term Warrants may also be exercised via cashless exercise pursuant to their respective terms.

Additional Warrant Issuance

On April 25, 2019, we entered into an amendment (the "Amendment") to the Purchase Agreement dated as of March 17, 2019, further described in Note 1 —Summary of Significant Accounting Policies, between us and each purchaser. The Amendment (i) deleted Section 4.12 of the Purchase Agreement, which generally prohibited us from issuing, entering into agreements to issue, announcing proposed issuances, selling or granting certain securities between the date of the Purchase Agreement and the date that was 45 days following the closing date thereunder and (ii) gave each purchaser the right to purchase, for $0.125 per underlying share, an additional warrant to purchase shares of our common stock having an exercise price per share of $2.13 and otherwise having the terms of the March Long-Term Warrants (collectively, the "New Warrants") pursuant to a securities purchase agreement (the "New Securities Purchase Agreement") entered into among us and each purchaser on May 17, 2019.

We issued New Warrants exercisable for an aggregate of 3,897,010 shares of our common stock and the New Warrants are exercisable for five years beginning on the six-month anniversary of the date of issuance. The New Warrants have an initial exercise price equal to $2.13 per share, subject to certain adjustments. If not previously exercised in full, at the expiration of their applicable terms, the New Warrants will be automatically exercised via cashless exercise, in which case the holder would receive upon such exercise the net number of shares, if any, of common stock determined according to the formula set forth in the New Warrant. If exercised in full, the New Warrants could result in aggregate gross proceeds of $8.3 million; however, there can be no guarantee that any or all of the New Warrants will be exercised, that the market price of our common stock will exceed the exercise price of the New Warrants or that the exercise price will not be subject to certain adjustments. In addition, in certain circumstances, the New Warrants may also be exercised via cashless exercise pursuant to the terms of the New Warrants.

April 2019 Offering

On April 29, 2019, we entered into a Securities Purchase Agreement (the "April Purchase Agreement") with certain institutional and accredited investors providing for the sale of up to 4,318,272 shares of our common stock at a purchase price of $2.025 per share.

Pursuant to the April Purchase Agreement, we agreed to issue unregistered warrants (the "April Warrants") to purchase up to 4,318,272 shares of our common stock. Subject to certain ownership limitations, the April Warrants are exercisable beginning on the date of their issuance until the five-and-a-half-year anniversary of their date of issuance at an initial exercise price of $2.13. The exercise price of the April Warrants is subject to adjustment for stock splits, reverse splits, and similar capital transactions as described in the April Warrants. Upon a fundamental transaction, the holder shall have the right to receive payment in cash, or under certain circumstances in other consideration, from us at the Black-Scholes value as described in the April Warrants. The April Warrants may be exercisable on a "cashless" basis while there is no effective registration statement or current prospectus available for the shares of common stock issuable upon exercise of the April Warrants. A holder will not have the right to exercise any portion of the April Warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or, at the election of the holder, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the April Warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon notice to us, provided that any increase in such percentage shall not be effective until 61 days after such notice. If not

previously exercised in full, at the expiration of their terms, the April Warrants will be automatically exercised via cashless exercise.

The net proceeds from the offering and the private placement are approximately $7.9 million, after deducting commissions and estimated offering costs. We also granted the placement agent warrants to purchase up to 215,914 shares of our common stock (the "Placement Agent Warrants"). The Placement Agent Warrants have substantially the same terms as the April Warrants, except that the Placement Agent Warrants have an exercise price equal to 125% of the per share purchase price and will have a term of 5 years from the effective date of the offering. We will also pay the placement agent a reimbursement for non-accountable expenses in the amount of $35,000 and a reimbursement for legal fees and expenses of the placement agent in the amount of $25,000. If exercised in full, the warrants issued in the April 2019 Offering, including the Placement Agent Warrants, could result in aggregate gross proceeds of $9.8 million; however, there can be no guarantee that any or all of the April Warrants and Placement Agent Warrants will be exercised, that the market price of our common stock will exceed the exercise price of the April Warrants or Placement Agent Warrants or that the exercise price will not be subject to certain adjustments. In addition, in certain circumstances, the April Warrants and Placement Agent Warrants may also be exercised via cashless exercise pursuant to their respective terms.

Corporate Updates

In June 2019, we expanded our senior management team by appointing Edward J. Sitar, CPA, to Chief Financial Officer. Mr. Sitar has extensive experience in finance and the life sciences industry. Mr. Sitar will be responsible for developing and implementing our financial strategy and growth plans.

Senior Convertible Note

On October 4, 2018, we entered into an Amendment and Exchange Agreement and Senior Convertible Note ("Senior Convertible Note"). The Senior Convertible Note was convertible into shares of our common stock at certain conversion prices depending on certain factors, which include the volume weighted average price ("VWAP") of our common stock for a period of time prior to conversion. In addition, the Senior Convertible Note was redeemable by the noteholder or by us under certain qualifying conditions. The principal balance of the Senior Convertible Note was $5.2 million with a stated interest rate of 8.0% per annum and a maturity date of October 4, 2020. In January 2019, the noteholder issued a redemption notice and we repaid the noteholder $1.1 million of principal and accrued interest. During January 2019, we entered into an Option to Purchase Senior Convertible Note ("Option Agreement") with the noteholder. The Option Agreement provided us with the ability to repay the Senior Convertible Note prior to March 31, 2019, which we exercised in March 2019. We paid the noteholder of the Senior Convertible Note approximately $5.3 million, which was the full purchase amount, including interest, of the Senior Convertible Note pursuant to the terms of the Option Agreement. There are no further amounts outstanding under the Senior Convertible Note and the Senior Convertible Note has been canceled.

Unsecured Convertible Promissory Note

On March 8, 2019, we entered into a Securities Purchase Agreement and an unsecured Convertible Promissory Note, or the Unsecured Convertible Note, in the principal amount of $5.5 million. The holder of the Unsecured Convertible Note, or the Convertible Noteholder, may elect to convert all or a portion of the Unsecured Convertible Note at any time and from time to time into our common stock at a conversion price of $3.25 per share, subject to adjustment for stock splits, dividends, combinations and similar events. We may prepay all or a portion of the Unsecured Convertible Note at any time for an amount equal to 115% of then outstanding obligations or the portion of the obligations we are prepaying. The purchase price of the Unsecured Convertible Note was $5.0 million and the Unsecured Convertible Note carries an original issuance discount of $0.5 million, which is included in the principal amount of the Unsecured Convertible Note. See "Liquidity and Capital Resources" below and "Note 4—Debt" to the accompanying condensed financial statements included in this Quarterly Report on Form 10-Q for further details regarding the terms of the Unsecured Convertible Note.

Research and Development

We started the Phase 3 clinical trials for INN-202, after completing key study start-up activities for the study of adult patients with celiac disease who have persistent abdominal symptoms while on a gluten-free diet. The trial starts with the screening and monitoring of patients with subsequent randomization. We will provide updates from time to time as the trial gets further along. We anticipate that our first Phase 3 trial will have approximately 600 subjects, with three treatment groups (0.25 mg of larazotide, 0.5 mg of larazotide and a placebo arm).

Recent research and development milestones include:

- continued research collaboration with Institut Gustave Roussy to study regulation of intestinal permeability and the gut microbiota using larazotide in immuno-oncology checkpoint inhibitor failure preclinical models;
- continuation of data analysis from pre-clinical models in NASH after successful initial data from studying larazotide in both *ex vivo* and animal models;
- continued research collaboration with Dr. Anthony Blikslager of North Carolina State University to explore life-cycle extension of our lead molecule larazotide acetate;
- continued research collaboration with Dr. James Nataro of the University of Virginia, Charlottesville to study larazotide's effect on Environmental Enteric Dysfunction; and
- continued research collaboration with Dr. Jay Luther and Dr. Raymond Chung at the Gastroenterology Division at Massachusetts General Hospital in order to research the effects of larazotide on certain forms of alcoholic liver disease, such as ASH.

Critical Accounting Policies and Use of Estimates

Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions.

Critical Accounting Policies

Areas of the financial statements where estimates may have the most significant effect include fair value measurements, accrued expenses, share-based compensation, income taxes 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. Except as noted below, there have been no material changes to our critical accounting policies described in "Critical Accounting Policies and Use of Estimates" of the Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on March 18, 2019.

The Short-Term Warrants, March Long-Term Warrants, New Warrants, April Warrants and Placement Agent Warrants that we issued during the six months ended June 30, 2019 are freestanding financial instruments that contain net settlement options and may require the Company to settle these warrants in cash under certain circumstances. We have classified these warrants as liabilities on the accompanying condensed balance sheets. The warrant liabilities are initially recorded at fair value on the date of grant and will be subsequently re-measured to fair value at each balance sheet date until the warrant liabilities are settled. Changes in the fair value of the warrants are recognized as a non-cash component of other income and expense in the accompanying condensed statements of operations and comprehensive loss.

We adopted ASU No. 2016-02, *Leases (Topic 842)*, as amended, as of January 1, 2019 using the modified retrospective approach at the beginning of the period of adoption. Under this approach, the reporting for comparative periods presented in the financial statements are presented in accordance with the legacy lease standard. In addition, we elected the available practical expedients permitted under the transition guidance within the new lease standard.

Under the new leases standard, we recognize a right-of-use ("ROU") asset and lease liability upon commencement of a lease. The ROU asset represents our right to use an underlying asset for the lease term and is included in right-of-use asset on the accompanying condensed balance sheets. Lease liabilities represent our obligation to make lease payments arising from the lease and are included in current and non-current lease liability on the accompanying condensed balance sheets. Operating lease ROU assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. In the absence of an implicit rate, we use their incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. All leases with a term of less than 12 months are not

recognized on the balance sheet. Adoption of the new leases standard resulted in us recognizing a ROU asset and lease liability of less than $0.1 million as of January 1, 2019. The adoption of ASU 2016-02 did not result in a cumulative adjustment to accumulated deficit.

We adopted ASU 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Non-employee Share-Based Payment Accounting* effective January 1, 2019. ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. Beginning on the adoption date, we changed our expense recognition for share-based payments to non-employees to an amount determined at the grant or modification date instead of a variable amount to be re-measured each reporting period. We calculated the fair value of our non-employee grants as of the adoption date and determined that there was no impact to our accumulated deficit or other components of equity upon adoption of ASU 2018-07. The unamortized expense for non-employee grants will be recognized on a straight-line basis over the remaining contractual term of the respective non-employee option agreements.

Recently Issued Accounting Pronouncements

For details of recent Accounting Standards Updates and our evaluation of their adoption on our condensed financial statements, see “Note 1—Summary of Significant Accounting Policies—Recent Accounting Pronouncements” to our condensed financial statements in "Part I. Financial Information - Item I. Financial Statements" included elsewhere in this Quarterly Report on Form 10-Q.

Results of Operations

Comparison of the Three Months Ended June 30, 2019 and 2018

The following table sets forth the key components of our results of operations for the three months ended June 30, 2019 and 2018:

	Three Months Ended June 30,			
	2019	2018	$ Change	% Change
Operating expenses:				
Research and development	$ 3,073,344	$ 1,243,221	$ 1,830,123	147 %
General and administrative	3,049,711	2,132,850	916,861	43 %
Total operating expenses	6,123,055	3,376,071	2,746,984	81 %
Income (loss) from operations	(6,123,055)	(3,376,071)	(2,746,984)	(81)%
Other income (expense), net	1,634,815	(839,481)	2,474,296	295 %
Net loss	$ (4,488,240)	$ (4,215,552)	$ (272,688)	(6)%

Research and Development Expense

Research and development expense for the three months ended June 30, 2019, increased approximately $1.8 million, or 147%, as compared to the three months ended June 30, 2018. The increase was driven primarily by the start of the Phase 3 trial in celiac disease during the three months ended June 30, 2019, which represented an increase of approximately $0.9 million. In addition, non-cash share-based compensation expense increased by approximately $0.7 million primarily due to re-measurement of non-employee stock options during the three months ended June 30, 2018, which resulted in a decrease in expense as a result of the decline in the fair value of options vested during the prior period. Compensation costs and related benefits for our research and development personnel increased by approximately $0.2 million due to an increase in research and development personnel.

General and Administrative Expense

General and administrative expense for the three months ended June 30, 2019, increased approximately $0.9 million, or 43%, as compared to the three months ended June 30, 2018. The increase was driven primarily by an increase in non-cash share-based compensation expense of $0.4 million. The increase in non-cash share-based compensation expense was primarily due to RSUs that vested during the three months ended June 30, 2019. In addition, business development, patent protection of

our intellectual property and other general corporate costs increased approximately $0.3 million and professional fees increased $0.2 million, which includes the write-off of deferred offering costs associated with the ATM facility of $0.1 million.

Other income (expense), net

Other income (expense), net for the three months ended June 30, 2019, decreased by approximately $2.5 million, or 295%, as compared to the three months ended June 30, 2018. The decrease is primarily due to the decrease in non-cash interest expense of $0.5 million, (ii) an unrealized gain from the change in fair value of the warrant liabilities of $1.8 million and (iii) an unrealized gain from the change in fair value of the Unsecured Convertible Note derivative liability of $0.2 million.

Comparison of the Six Months Ended June 30, 2019 and 2018

The following table sets forth the key components of our results of operations for the six months ended June 30, 2019 and 2018:

	Six Months Ended June 30,			
	2019	**2018**	**$ Change**	**% Change**
Operating expenses:				
Research and development	$ 4,271,659	$ 7,601,225	$ (3,329,566)	(44)%
General and administrative	6,164,206	7,103,463	(939,257)	(13)%
Total operating expenses	10,435,865	14,704,688	(4,268,823)	(29)%
Income (loss) from operations	(10,435,865)	(14,704,688)	4,268,823	29 %
Other income (expense), net	1,512,860	(4,470,608)	5,983,468	134 %
Net loss	$ (8,923,005)	$ (19,175,296)	$ 10,252,291	53 %

Research and Development Expense

Research and development expense for the six months ended June 30, 2019, decreased approximately $3.3 million, or 44%, as compared to the six months ended June 30, 2018. The decrease was primarily driven by a decrease of approximately $5.0 million in non-cash share-based compensation expense which is primarily due to a decrease in the options granted and vested during the six months ended June 30, 2019. Non-cash share-based compensation expense also decreased during the six months ended June 30, 2019, due to the decrease in fair value of options as a result of the decline in our stock price. This decrease was partially offset by an increase of approximately $1.4 million associated with the start of our Phase 3 clinical trials in celiac disease and an increase of approximately $0.3 million in compensation costs related to an increase in research and development personnel.

General and Administrative Expense

General and administrative expense for the six months ended June 30, 2019, decreased approximately $0.9 million, or 13%, as compared to the six months ended June 30, 2018. The decrease was driven primarily by a decrease in accounting and legal fees associated with the Merger of $0.6 million, a decrease of $1.0 million in transaction advisory fees associated with the Merger and a decrease of $0.6 million in non-cash stock compensation expense primarily due to the decrease in fair value of options vesting during the period as a result of the decline in our stock price. These decreases were offset by an increase in (i) general and administrative personnel costs of $0.4 million, which includes severance costs for our former chief executive officer of $0.3 million, (ii) costs associated with operating as a public company of $0.2 million, including directors' and officers' liability insurance premiums, investor relations and regulatory fees and (iii) business development, patent protection of our intellectual property and other general corporate costs of $0.7 million.

Other income (expense), net

Other income (expense), net for the six months ended June 30, 2019, decreased by approximately $6.0 million, or 134%, as compared to the six months ended June 30, 2018. The decrease primarily consists of (i) a non-cash charge of $3.1 million for the beneficial conversion feature that was triggered when our convertible debt and accrued interest converted to our common

stock at a 25% discount on January 29, 2018, (ii) an unrealized gain from the change in fair value of the warrant liabilities of $2.7 million, (iii) an unrealized gain from the change in fair value of the Unsecured Convertible Note derivative liability of $0.7 million and (iv) non-cash interest expense of $0.8. These changes were offset by $1.0 million for the loss on extinguishment of debt in March 2019 and $0.3 million in consideration for the Option Agreement associated with the Senior Convertible Note (see Note 4—Debt).

Liquidity and Capital Resources

Sources of Liquidity

As of June 30, 2019, we had cash and cash equivalents of approximately $13.3 million, compared to approximately $5.7 million as of December 31, 2018. The increase in cash was primarily due to the net proceeds from the March 2019 Offering and April 2019 Offering, in addition to the issuance of convertible debt, net of expenditures for business operations, research and development and clinical trial preparations, further described below. We expect to incur substantial expenditures in the foreseeable future for the continued 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 plan to seek funds through debt or equity financings, strategic alliances and licensing arrangements, and other collaborations or sources of financing. However, there can be no assurance that we will be able to raise the additional capital needed to continue our pipeline of research and development programs on terms acceptable to us, on a timely basis or at all. If we are unable to raise additional funds when needed, our ability to develop our product candidates will be impaired. We may also be required to delay, reduce or terminate some or all of our development programs and clinical trials.

March 2019 Offering

On March 17, 2019, we entered into the Purchase Agreement with SDS Capital Partners II, LLC and certain other accredited investors, pursuant to which we sold, on March 18, 2019, 4,181,068 shares of our common stock and issued Short-Term Warrants to purchase up to 4,181,068 shares of our common stock and Long-Term Warrants to purchase up to 2,508,634 shares of common stock. Pursuant to the Purchase Agreement, we issued the shares of common stock and warrants at a purchase price per share of $2.33 for aggregate gross proceeds of approximately $9.7 million. For additional terms of the agreement, see "Recent Development—Corporate Updates—March 2019 Offering" above.

April 2019 Offering

On April 29, 2019, we entered into the April Purchase Agreement pursuant to which we sold, on May 1, 2019, 4,318,272 shares of our common stock at a purchase price of $2.025 per share for aggregate gross proceeds of approximately $7.9 million, after deducting commissions and estimated offering costs. Pursuant to the April Purchase Agreement, we issued warrants to purchase up to 4,318,272 share of common stock at an initial exercise price of $2.13. Additionally, we granted the placement agent warrants to purchase up to 215,914 shares of common stock (the "Placement Agent Warrants"). The Placement Agent Warrants have substantially the same terms as the April warrants, except that the Placement Agent Warrants have an exercise price of $2.53 and have a term of 5 years from the effective date of the offering. For additional terms of the agreement, see "Recent Developments—Corporate Updates—April 2019 Offering" above.

January 2018 Equity Issuance

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 (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 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 $0.6 million 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.

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 $0.3 million, a cash fee of $0.3 million (equal to 10% of the gross proceeds of the Equity Issuance up to a certain cap) and non-accountable expense allowance of approximately $30,000. GPN was paid a cash fee of $0.9 million (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 our outstanding common stock on a fully-diluted basis and IB Pharmaceuticals' securityholders owned approximately 94.2% of our outstanding common stock.

Senior Convertible Note and Exchange Agreement

On January 29, 2018, we entered into a Note Purchase Agreement and Senior Note Payable (the "Note") with a lender. The principal amount of the Note was $4.8 million. The Note was issued at a discount of $1.8 million and net of financing costs, for total proceeds of $3.0 million. Interest on the Note accrued from January 29, 2018, at a rate of 12.5% per annum and quarterly payments of interest only were due beginning on March 30, 2018 and compounded quarterly. On October 4, 2018, we entered into an Amendment and Exchange Agreement ("Exchange Agreement") with the noteholder exchanging the Note for a new Senior Convertible Note (the "Senior Convertible Note").

The principal amount of the Senior Convertible Note was $5.2 million and bore interest at a rate of eight percent (8%) per annum payable quarterly in cash, with a scheduled maturity date of October 4, 2020. The interest rate would automatically increase if there was an event of default to 18% per annum during the default period.

During January 2019, the noteholder issued a redemption notice requiring us to repay the noteholder $1.1 million of principal and accrued interest. On January 7, 2019, we entered into an Option to Purchase Senior Convertible Note ("Option Agreement") with the noteholder. We paid the noteholder $0.3 million in consideration for the noteholder entering into the Option Agreement with us, which was recorded as interest expense in our accompanying condensed statements of operations and comprehensive loss. The Option Agreement provided us with the ability to repay (purchase) the outstanding principal and accrued interest of the Senior Convertible Note any time from January 7, 2019 until March 31, 2019 ("Option Period"). On March 11, 2019, we exercised our repurchase rights from the Option Agreement and paid the noteholder of the Senior Convertible Note approximately $5.3 million, which was the full purchase amount, including accrued interest, of the Senior Convertible Note pursuant to the terms of the Option Agreement. There are no further amounts outstanding under the Senior Convertible Note and the Senior Convertible Note has been canceled.

Amortization of debt discount for the Note and Senior Convertible Note recorded as interest expense for the Note and the Senior Convertible Note totaled approximately $0.7 million and 1.2 million for the three and six months ended June 30, 2018. There was no such expense related to the Note and the Senior Convertible Note during the three and six months ended June 30, 2019.

Unsecured Convertible Promissory Note

On March 8, 2019, we entered into the Note Purchase Agreement with the Convertible Noteholder. Pursuant to the Note Purchase Agreement, we issued the Convertible Noteholder the Unsecured Convertible Note in the principal amount of $5,500,000. The Convertible Noteholder may elect to convert all or a portion of the Unsecured Convertible Note at any time and from time to time into our common stock at a conversion price of $3.25 per share, subject to adjustment for stock splits, dividends, combinations and similar events. We may prepay all or a portion of the Unsecured Convertible Note at any time for an amount equal to 115% of any then outstanding obligations or the portion of the obligations we are prepaying. The purchase price of the Unsecured Convertible Note was $5,000,000, and the Unsecured Convertible Note carries an OID of $500,000, which is included in the principal amount of the Unsecured Convertible Note. In addition, we agreed to pay $20,000 of transaction expenses, which were netted out of the purchase price of the Unsecured Convertible Note. We also incurred additional transactions costs of approximately $37,000, which were recorded as debt issuance costs. As a result of the redemption features of the Unsecured Convertible Note, further described in "Note 4—Debt," we are amortizing the debt

issuance costs and accreting the OID to interest expense over the estimated redemption period of 15 months, using the effective interest method.

The various conversion and redemption features contained in the Unsecured Convertible Note are embedded derivative instruments, which were recorded as a debt discount and derivative liability at the issuance date at their estimated fair value of $1.3 million. Amortization of debt discount and accretion of the OID for the Unsecured Convertible Note recorded as interest expense was approximately $0.3 million and $0.4 million for the three and six months ended June 30, 2019.

The Unsecured Convertible Note bears interest at the rate of 10% (which will increase to 18% upon and during the continuance of an event of default) per annum, compounding on a daily basis. All principal and accrued interest on the Unsecured Convertible Note is due on the second-year anniversary of the Unsecured Convertible Note's issuance.

At any time after the six-month anniversary of the issuance of the Unsecured Convertible Note, (i) if the average volume weighted average price over twenty trading dates exceeds $10.00 per share, we may generally require that the Unsecured Convertible Note convert into shares of its common stock at the $3.25 (as adjusted) conversion price, and (ii) the Convertible Noteholder may elect to require all or a portion of the Unsecured Convertible Note be redeemed by us. If the Convertible Noteholder requires a redemption, we, at our discretion, may pay the redeemed portion of the Unsecured Convertible Note in cash or in our common stock at a conversion rate equal to the lesser of (i) the $3.25 (as adjusted) conversion rate or (ii) 80% of the average of the five lowest volume weighted average price of our Common Stock over the preceding twenty trading days. The Convertible Noteholder may not redeem more than $500,000 per calendar month during the period between the six-month anniversary of the date of issuance until the first-year anniversary of the date of issuance and $750,000 per calendar month thereafter. The obligation or right of us to deliver our shares upon the conversion or redemption of the Unsecured Convertible Note is subject to a 19.99% cap and subject to a floor price trading price of $3.25 (unless waived by us). Any amounts redeemed or converted once the cap is reached or if the market price is less than the $3.25 floor price must be paid in cash.

If there is an Event of Default under the Unsecured Convertible Note, the Convertible Noteholder may accelerate our obligations or elect to increase the outstanding obligations under the Unsecured Convertible Note. The amount of the increase ranges from 5% to 15% depending on the type of default (as defined in the Unsecured Convertible Note). In addition, the Unsecured Convertible Note obligations will be increased if there are delays in our delivery requirements for the shares or cash issuable upon the conversion or redemption of the Unsecured Convertible Note in certain circumstances.

If we issue convertible debt in the future with any terms, including conversion terms, that are more favorable to the terms of the Unsecured Convertible Note, the Convertible Noteholder may elect to incorporate the more favorable terms into the Unsecured Convertible Note. For further details describing our debt obligations, see "Note 4—Debt" to the accompanying condensed financial statements included in this Quarterly Report on Form 10-Q.

At-the-market Offering

On October 26, 2018, we entered into a common stock sales agreement with H.C. Wainwright & Co., LLC and Ladenburg Thalmann & Co. Inc. and filed a prospectus with the SEC related to such offering. We previously filed a Form S-3 that became effective on July 13, 2018 that included the registration of $40 million of our shares of common stock in connection with a potential "at-the-market" offering. Pursuant to the sales agreement, we may issue and sell shares having an aggregate gross sales price of up to $40 million. During the three and six months ended June 30, 2019, we sold 705,714 shares under the "at the market" offering for net proceeds of approximately $1.7 million. This facility was suspended as of June 24, 2019 and has remained suspended since that time.

Cash Flows

The following table sets forth the primary sources and uses of cash for the six months ended June 30, 2019 and 2018:

	Six Months Ended June 30,	
	2019	**2018**
Net cash (used in) provided by:		
Operating activities	$ (10,755,719)	$ (9,280,768)
Investing activities	(9,475)	61,057
Financing activities	18,374,192	19,527,582
Net increase in cash and cash equivalents	$ 7,608,998	$ 10,307,871

Operating Activities

For the six months ended June 30, 2019, our net cash used in operating activities of approximately $10.8 million primarily consisted of a net loss of $8.9 million, a non-cash gain of $3.3 million for the extinguishment of the Senior Convertible Note derivative liability and changes in the fair value of the warrant liabilities and the Unsecured Convertible Note derivative liability and the net change in assets and liabilities of $1.6 million. These decreases were offset by adjustments for non-cash share-based compensation of approximately $1.4 million, a non-cash loss of $1.0 million on the extinguishment of debt and non-cash interest expense of approximately $0.6 million.

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 $19.2 million, offset by adjustments for share-based compensation of approximately $7.0 million, non-cash interest expense of approximately $4.2 million and decreases in accounts payable and accrued expenses of approximately $1.3 million.

Investing Activities

Net cash used in investing activities for the six months ended June 30, 2019 represents purchases of property and equipment. 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 of $14,000.

Financing Activities

For the six months ended June 30, 2019, net cash provided by financing activities of approximately $18.4 million primarily consisted of the proceeds of $20.7 million received from the sale of our common stock and warrants, including proceeds of $0.5 million from the purchase of additional warrants, and $5.0 million from the issuance of the Unsecured Convertible Note. These increases were offset by approximately $6.2 million in debt repayments, $1.0 million in stock issuance costs and $0.1 million in debt issuance costs.

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 in the Equity Issuance and $3.0 million from the issuance of a note payable. These increases were offset by approximately $1.6 million in stock issuance costs.

Capital 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.

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 limited operating history and recurring operating losses, there is substantial doubt that we will continue as a going concern for at least one year following the date of this Quarterly Report on Form 10-Q, without additional financing. 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.

Contractual Obligations and Commitments

In October 2017, we entered into a three-year lease agreement for office space that expires on September 30, 2020 and includes a two-year renewal option. Base annual rent is $60,000. Monthly rent payments of $5,000 are due in advance of the first day of each month for the 24-month term. A security deposit of approximately $5,000 was paid in October 2017 and is included in other assets on the accompanying condensed balance sheets included in the condensed financial statements to this Quarterly Report on Form 10-Q.

Effective January 1, 2019, we adopted ASC 842 using the modified retrospective approach. On the adoption date, we estimated the present value of the lease payments over the remaining term of the lease using a discount rate of 12%, which represented our estimated incremental borrowing rate. The two-year renewal option was excluded from the lease payments as we concluded the exercise of this option was not considered reasonably certain. See Note 8—Commitments and Contingencies for further details regarding the impact of adopting ASC 842.

In November 2018 and February 2019, the Company entered into separation and general release agreements with two former executives that included separation benefits consistent with each former executives' employment agreement. We recognized severance expense totaling $0.3 million during the three and six months ended June 30, 2019, that is being paid in equal installments over 12 months beginning February 2019. In addition, we recognized severance expense totaling $0.3 million during the year ended December 31, 2018, that is being paid in equal installments over 12 months beginning November 2018. The remaining accrued severance obligation in respect of the two former executives is $0.3 million as of June 30, 2019, which is included in accrued expenses on the accompanying condensed balance sheet.

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 sub-license fees and the achievement and timing of these milestones are not probable and estimable, such commitments have not been included on the accompanying condensed balance sheets.

We also enter into agreements in the normal course of business with contract research organizations and other third parties with respect to services for clinical trials, clinical supply manufacturing and other operating purposes that are generally terminable by us with thirty to ninety days advance notice.

For further details, see "Note 8—Commitments and Contingencies" in the accompanying financial statements included in this Quarterly Report on Form 10-Q.

Off-Balance Sheet Arrangements

As of June 30, 2019, 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, 2019. 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, 2019, 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 our audited financial statements for the year ended December 31, 2018, our 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, 2019. Effective July 1, 2019 Edward J. Sitar, CPA, joined the Company as Chief Financial Officer and is one of the steps to remediate this material weakness in future periods.

Changes in Internal Control Over Financial Reporting

As of June 30, 2019, 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

An action is pending in the Superior Court of the State of Delaware captioned *M. Scott Harris, M.D. and Middleburg Consultants Inc. v. Innovate Biopharmaceuticals, Inc.* (the "Delaware Action") filed by M. Scott Harris and Middleburg Consultants, Inc. (collectively, "Harris") on January 8, 2019. As previously disclosed, we strongly deny any wrongdoing alleged in the threatened litigation and firmly believe the allegations in the complaint are entirely without merit and intend to defend against them vigorously. On February 25, 2019, we filed a motion to dismiss the Delaware Action. The motion to dismiss was heard by the Delaware court on June 26, 2019 and we are awaiting the Court's decision. We are unable to estimate the amount of a potential loss or range of potential loss, if any.

Other than as described above, we are not currently a party to any legal or governmental regulatory proceedings, nor is our management aware of any pending or threatened legal or government regulatory proceedings proposed to be initiated against us that would have a material adverse effect on our business, financial condition or operating results.

Item 1A. Risk Factors.

There have been no material changes to the risk factors disclosed in "Item 1A. Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on March 18, 2019, as supplemented by our subsequent Quarterly Reports on Form 10-Q, except as noted below.

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 17, 2018, we filed a shelf registration statement, or the Shelf Registration Statement, which was declared effective on July 13, 2018. Under the Shelf Registration Statement, we may, from time to time, sell our common stock in one or more offerings, including this offering, up to an aggregate dollar amount of $175.0 million (of which up to an aggregate of $40 million may be sold in an "at-the-market" offering as defined in Rule 415 of the Securities Act. The ATM facility was voluntarily suspended effective June 24, 2019). 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 June 30, 2019, we had approximately 35.9 million shares of common stock outstanding and exercisable options and warrants to purchase approximately 2.0 million shares of common stock, excluding out-of-the-money stock options and warrants. In addition, the Unsecured Convertible Note may be converted into shares of our common stock at any time at various conversion prices. The March Long-Term Warrants and Short-Term Warrants have initial exercise prices equal to $2.56 and $4.00 per share, respectively, each subject to certain adjustments. We have also issued to certain existing stockholders additional warrants to purchase up to an aggregate of 3,897,010 shares of our common stock, and have issued warrants to purchase up to 4,318,272 shares of our common stock in a private placement in connection with the offering we completed in April 2019, each of which would have an initial exercise price of $2.13 per share, subject to certain adjustments. We have agreed to file a registration statement registering the issuance of the shares of common stock underlying the March Long-Term Warrants, Short-Term Warrants, the additional warrants issued to certain accredited investors, the warrants issued in connection with the April 2019 offering and warrants issued to the placement agent in connection with that offering. The Short-Term Warrants issued in the March 2019 Offering and the warrants issued in the April 2019 offering were exercisable immediately upon issuance. Therefore, sales of common stock by us or our stockholders under the Shelf Registration Statement or otherwise (including sales pursuant to Rule 144) may represent a significant percentage of our common stock currently outstanding. If we or our stockholders sell, or the market perceives that we or our stockholders intend to sell, substantial amounts of our common stock under the Shelf Registration Statement or otherwise, the market price of our common stock could decline significantly. For example, our closing stock price on July 13, 2018, prior to the Shelf Registration Statement being declared effective, was $23.70 per share, and our closing stock price on July 16, 2018, after the Shelf Registration Statement was declared effective, was $8.08 per share.

The issuance of additional shares of common stock may cause substantial dilution to our existing stockholders and reduce the trading price of our common stock.

We have outstanding and exercisable options and warrants that if exercised would result in the issuance of 2.0 million shares of our common stock as of June 30, 2019, excluding out-of-the-money stock options and warrants. In addition, the Unsecured Convertible Note may be converted into shares of our common stock at any time at various conversion prices. We also sold 4,181,068 shares of common stock in the March 2019 offering and issued the Short-Term Warrants and March Long-Term Warrants

to purchase up to 4,181,068 and 2,508,634 shares of our common stock, respectively, in the concurrent private placement. We also issued to certain existing stockholders additional warrants to purchase up to an aggregate of 3,897,010 shares of our common stock, and in connection with the April 2019 offering, issued warrants to purchase up to an aggregate of 4,318,272 shares of our common stock to the purchasers and placement agent warrants to purchase up to 215,914 shares of our common stock. The issuance of shares upon exercise of warrants and options or conversion of the Unsecured Convertible Note may result in dilution to the interests of other stockholders and may reduce the trading price of our common stock.

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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

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
4.1	Form of Common Stock Purchase Warrant		8-K	001-37797	4.1	May 1, 2019
4.2	Form of Placement Agent Warrant		8-K	001-37797	4.2	May 1, 2019
4.3	Form of New Warrant (included in Exhibit 10.5)		8-K	001-37797	4.1	May 17, 2019
10.1	Amendment to Securities Purchase Agreement, dated April 25, 2019, by and among Innovate Biopharmaceuticals, Inc. and the purchasers party thereto		8-K	001-37797	10.1	April 26, 2019
10.2	Securities Purchase Agreement, dated April 29, 2019, by and among Innovate Biopharmaceuticals, Inc. and the purchasers party thereto		8-K	001-37797	10.1	May 1, 2019
10.3	Engagement Letter, dated April 26, 2019, by and between Innovate Biopharmaceuticals, Inc. and H.C. Wainwright & Co., LLC		8-K	001-37797	10.2	May 1, 2019
10.4	Executive Employment Agreement, dated June 22, 2019, between Innovate Biopharmaceuticals, Inc. and Edward J. Sitar		8-K	001-37797	10.1	June 27, 2019
10.5	Securities Purchase Agreement, dated May 17, 2019, by and among Innovate Biopharmaceuticals, Inc. and the purchasers party thereto (included in Amendment, dated April 25, 2019, to Securities Purchase Agreement, dated as of March 17, 2019, by and among the Company and the Purchasers party thereto, filed as Exhibit 10.1 to Form 8-K filed on April 26, 2019 and incorporated by reference herein)		8-K	001-37797	10.1	May 17, 2019

EXHIBIT NO.	DESCRIPTION	FILED HEREWITH	INCORPORATED BY REFERENCE			
			FORM	FILE NO.	EXHIBIT	FILING DATE
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				

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 8, 2019 By: /s/ Edward J. Sitar
Edward J. Sitar
Chief Financial Officer and Principal Financial Officer

Exhibit 31.1

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

I, Sandeep Laumas, 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/ Sandeep Laumas

Date: August 8, 2019

Sandeep Laumas
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Edward J. Sitar, 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/ Edward J. Sitar
Edward J. Sitar
Chief Financial Officer and Principal Financial Officer
(Principal Financial Officer)

Date: August 8, 2019

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, Sandeep Laumas, 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, 2019 (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/ Sandeep Laumas

Date: August 8, 2019

Sandeep Laumas
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, Edward J. Sitar, Chief Financial Officer and 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, 2019 (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/ Edward J. Sitar

Date: August 8, 2019

Edward J. Sitar
Chief Financial Officer and 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.