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

FORM 10-Q

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

For the quarterly period ended **September 30, 2018**

or

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

Commission file number 001-36602

Immune Pharmaceuticals Inc.

(Exact name of registrant as specified in its charter)

Delaware	**52-1841431**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Id. No.)

1 Bridge Plaza North, Suite 270
Fort Lee, NJ 07024
(Address of principal executive offices)

Registrant's telephone number, including area code: **(201) 464-2677**

(Former name, former address and former fiscal year, if changed since last report) N/A

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 (section 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," "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 November 5, 2018, 49,313,329 shares of the registrant's common stock, par value $0.0001 per share, were issued and outstanding.

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Part I. Financial Information

Item 1. Financial Statements.

Immune Pharmaceuticals Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
($ in thousands, except share amounts)

	September 30, 2018 (Unaudited)	December 31, 2017
ASSETS		
Current assets		
Cash and cash equivalents	$ 76	$ 6,776
Other current assets	288	255
Total current assets	**364**	**7,031**
Property and equipment, net	97	-
In-process research and development acquired	15,000	15,000
Intangible assets, net	5,155	6,477
Other assets	100	100
Total assets	**$ 20,716**	**$ 28,608**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 5,535	$ 3,569
Accrued expenses	1,679	2,120
Advances from related parties	186	266
Notes and loans payable, current portion, net of debt discount	7,462	3,296
Total current liabilities	**14,862**	**9,251**
Notes and loans payable, net of current portion	870	1,457
Deferred tax liability	4,142	4,142
Total liabilities	**19,874**	**14,850**
Commitments and contingencies (Note 12)		
Stockholders' Equity		
Series E Preferred Stock, net of discount, par value $0.0001, 18,000 shares authorized, 3,713 and 12,191 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	-	-
Common stock, $0.0001 par value; authorized 225,000,000 shares; 44,964,491 and 21,002,212 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	4	2
Additional paid-in capital	127,607	127,292
Accumulated deficit	(126,769)	(113,536)
Total stockholders' equity	**842**	**13,758**
Total liabilities and stockholders' equity	**$ 20,716**	**$ 28,608**

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Immune Pharmaceuticals Inc. and Subsidiaries
Condensed Consolidated Statements of Operations
($ in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Revenue	$ -	$ -	$ -	$ -
Costs and expenses:				
Research and development	2,054	1,229	6,163	3,674
General and administrative	1,644	1,610	4,704	4,644
Total costs and expenses	3,698	2,839	10,867	8,318
Loss from operations	**(3,698)**	**(2,839)**	**(10,867)**	**(8,318)**
Non-operating expense:				
Interest expense	(498)	(1,440)	(844)	(4,637)
Loss on impairment of intangible assets	-	-	(653)	-
Gain (loss) on extinguishment of debt	-	(2,145)	181	(2,145)
Liquidated damages	-	-	(1,112)	-
Change in fair value of derivative instrument	9	95	47	95
Other income, net	55	278	15	265
Total non-operating expense	**(434)**	**(3,212)**	**(2,366)**	**(6,422)**
Net loss before income taxes	**(4,132)**	**(6,051)**	**(13,233)**	**(14,740)**
Income tax expense	-	-	-	-
Net loss	**$ (4,132)**	**$ (6,051)**	**$ (13,233)**	**$ (14,740)**
Deemed dividend	(5,541)	-	(11,140)	-
Net loss attributable to common stockholders	**$ (9,673)**	**$ (6,051)**	**$ (24,373)**	**$ (14,740)**
Basic and diluted net loss per common share	**$ (0.24)**	**$ (0.53)**	**$ (0.71)**	**$ (1.47)**
Weighted average common shares outstanding – basic and diluted:	39,508,791	11,322,894	34,319,963	10,010,496

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Immune Pharmaceuticals Inc. and Subsidiaries
Condensed Consolidated Statement of Changes in Stockholders' Equity
($ in thousands, except share amounts)
(Unaudited)

	Series E Preferred Stock		Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance at December 31, 2017	**12,191**	**$ -**	**21,002,212**	**$ 2**	**$ 127,292**	**$ (113,536)**	**$ 13,758**
Conversion of Series E Preferred Stock and dividends	(8,478)	-	23,825,614	2	(2)	-	**-**
Common stock issued to consultant	-	-	100,000	-	38	-	**38**
Down round trigger in connection with Series E Preferred Stock	-	-	-	-	10,127	-	**10,127**
Accretion of down round trigger in connection with Series E Preferred Stock	-	-	-	-	(10,127)	-	**(10,127)**
Down round trigger in connection with warrants	-	-	-	-	1,013	-	**1,013**
Accretion of down round trigger in connection with warrants	-	-	-	-	(1,013)	-	**(1,013)**
Conversion of May 2018 Convertible Notes	-	-	1,845	-	-	-	**-**
Share-based compensation	-	-	-	-	131	-	**131**
Series E Preferred Stock dividends	-	-	-	-	(342)	-	**(342)**
Series E Preferred Stock accreted value from dividends	-	-	-	-	396	-	**396**
Placement agent warrants	-	-	-	-	91	-	**91**
Exercise of warrants	-	-	34,820	-	3	-	**3**
Net loss	-	-	-	-	-	(13,233)	**(13,233)**
Balance at September 30, 2018	**3,713**	**$ -**	**44,964,491**	**$ 4**	**$ 127,607**	**$ (126,769)**	**$ 842**

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Immune Pharmaceuticals Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
($ in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (13,233)	$ (14,740)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	670	427
Amortization of debt discount	845	2,064
Accretion of the April 2017 convertible note conversion premium	-	280
Liquidated damages	1,112	938
Share-based compensation	131	345
Loss on impairment of intangible assets	653	-
(Gain) loss on extinguishment of debt	(181)	2,145
Issuance of common stock to consultant	38	-
Change in fair value of derivative instrument	(47)	(95)
Disposal of equipment	-	267
Accretion of redemption premium on November 2016 convertible note	-	300
Changes in operating assets and liabilities:		
Other assets	(32)	184
Accounts payable	1,966	3,015
Accrued expenses and advances from related parties	(266)	(347)
Net cash used in operating activities	**(8,344)**	**(5,217)**
Cash flows from investing activities:		
Change in restricted cash	-	59
Purchase of property and equipment	(99)	(22)
Net cash (used in) provided by in investing activities	**(99)**	**37**
Cash flows from financing activities:		
Proceeds from May 2018 Convertible Notes	2,007	-
Payment of dividends on Series E Preferred Stock	(162)	-
Repayment of Mablife Notes Payable	(205)	-
Proceeds from September 2018 Convertible Notes	100	-
Exercise of warrants	3	-
Proceeds received from November 2016 and March 2017 Equity Line financings	-	5,383
Financing fees paid on November 2016 and March 2017 Equity Line financing	-	(118)
Payment of commitment fees related to March 2017 Equity Line financing	-	(1,010)
Proceeds from amending certain securities purchase agreements	-	238
Repayment of capital lease	-	(24)
Repayment of November 2016 Convertible Notes	-	(1,350)
Proceeds from April 2017 Convertible Notes	-	440
Repayment of April 2017 Convertible Notes	-	(97)
Proceeds from May 2017 Convertible Notes	-	1,579
Proceeds from July 2017 Convertible Notes	-	245
Proceeds from August 2017 Convertible Notes	-	515
Proceeds from September 2017 Convertible Notes	-	115
Payment of debt issuance costs related to July 2017 Senior Secured Convertible Promissory Note	-	(57)
Repayment of senior secured term loan payable	-	(874)
Net cash provided by financing activities	**1,743**	**4,985**
Decrease in cash	**(6,700)**	**(195)**
Cash at beginning of period	**6,776**	**271**
Cash at end of period	**$ 76**	**$ 76**
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ -	$ 155
Supplemental disclosure of non-cash financing activities:		
Warrants issued in connection with May 2018 Convertible Notes	91	-
Common stock issued to settle liabilities	-	14
Acquisition of Ceplene Rights	-	4,218
Conversion of April 2017 Convertible Notes prepayment into May 2017 Convertible Notes	-	154
Conversion of April 2017 Convertible Notes	-	275
Conversion of May 2017 Convertible Notes	-	1,864
Conversion of July 2017 Senior Secured Convertible Notes	-	2,228

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Immune Pharmaceuticals Inc. and Subsidiaries
Notes to Unaudited Condensed Consolidated Financial Statements

Note 1. Description of Business

Immune Pharmaceuticals Inc., together with its subsidiaries (collectively, "Immune" or the "Company", or "us", "we", "our") is a clinical stage biopharmaceutical company specializing in the development of novel targeted therapeutic agents in the fields of inflammation, dermatology and oncology.

Our lead product candidate is bertilimumab, a first-in-class, human, anti-eotaxin-1 antibody that targets eotaxin-1, a key regulator of inflammation. Phase 2 trials of bertilimumab in bullous pemphigoid ("BP"), our lead indication, as well as in allergic rhinitis and allergic conjunctivitis, have been completed, and a phase 2 clinical trial in ulcerative colitis ("UC") has completed recruiting subjects, although this trial remains blinded. We are also developing a nano-encapsulated topical formulation of cyclosporine-A, which we refer to as "NanoCyclo," for the treatment of atopic dermatitis ("AD") and psoriasis.

Our oncology portfolio includes Ceplene, which is approved in the European Union for the maintenance of remission in patients with Acute Myeloid Leukemia ("AML") in combination with interleukin-2 (IL-2), a nanotechnology antibody platform, which we refer to as "NanomAbs," and two vascular disrupting agents, Azixa and Crolibulin. These programs are currently inactive, and we intend to divest Ceplene and divest or discontinue the other oncology programs. In June 2018, we terminated the license agreement and returned all rights relating to the bispecific antibody platform, which was included previously in our oncology portfolio.

In April 2017, we announced a corporate restructuring with the objective of prioritizing and segregating our research and development efforts and strengthening our financial position. In April 2018, our board of directors determined that it was in the best interest of the Company and its shareholders to terminate the spin-off process and pursue other strategic alternatives for our wholly-owned subsidiary Cytovia Inc. ("Cytovia") in order to monetize its assets through a sale, disposition or similar transaction. In addition, on May 1, 2018, Dr. Daniel Teper, Chief Executive Officer of Cytovia and member of the board of directors of both Immune and Cytovia, resigned from each of these positions, effective immediately. The Board accepted his resignation, which was not due to any disagreement with the Company. See Risk Factors for risks and other matters related to our oncology assets.

Our pain portfolio includes AmiKet and AmiKet Nano, a topical analgesic cream containing amitriptyline and ketamine for the treatment of postherpetic neuralgia ("PHN") and diabetic peripheral neuropathy ("DPN"). We are determining the optimal path forward for this program.

As of September 30, 2018, we did not have any self-developed or licensed products approved for sale by the United States Food and Drug Administration ("FDA"). There can be no assurance that our research and development efforts will be successful, that any of our products will obtain necessary United States or foreign government regulatory approval or that any approved products will be commercially viable.

On April 12, 2017, following receipt of shareholder approval, we announced a reverse stock split of our shares of common stock at a ratio of 1-for-20. Beginning with the opening of trading on April 13, 2017, our common stock began trading on a post-split basis on the Nasdaq Capital Market ("NASDAQ"). Our shareholders ratified the effectiveness of the April 2017 reverse stock split pursuant to Delaware General Corporation Law Sec. 204 at our Annual Meeting of Stockholders, held in relevant part on February 23, 2018, and the ratification proposal received the affirmative vote of the majority of the outstanding shares of our common stock as of the Record Date (as such term is defined in our Definitive Proxy Statement filed with the Securities and Exchange Commission ("SEC") on January 26, 2018). All share and per share amounts in this prospectus have been reflected on a post-split basis.

On February 8, 2018, we announced that we failed to comply with certain listing requirements of Nasdaq First North and, therefore, our shares of common stock would no longer trade on Nasdaq First North as of March 29, 2018.

On December 1, 2017, the Company received a letter from the Listing Qualifications Department of The Nasdaq Stock Market LLC ("Nasdaq LLC") notifying the Company that the Company's common stock did not maintain a minimum closing bid price of $1.00 per share for the preceding 30 consecutive business days as required by Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). On June 4, 2018, the Company received a notice from the Staff of the Listing Qualifications Department (the "Staff") of Nasdaq LLC indicating that, based upon the Company's continued non-compliance with the Minimum Bid Price Requirement and notwithstanding the Company's compliance with the quantitative criteria necessary to obtain a second 180-day period within which to evidence compliance with the Minimum Bid Price Requirement, as set forth in Nasdaq Listing Rule 5810(c)(3)(A), the Staff had determined to delist the Company's securities from Nasdaq unless the Company timely requested a hearing before the Nasdaq Hearings Panel (the "Panel"). The Company timely appealed the delisting notice and appeared in front of the Panel on July 19, 2018. The Panel issued a decision on July 24, 2018, and determined to delist the Company's common stock from NASDAQ and the suspension of trading became effective at the open of business on July 26, 2018. The Panel also informed the Company that Nasdaq LLC would complete the delisting by filing a Form 25 Notification of Delisting with the SEC, after the applicable appeals periods have lapsed. In accordance with NASDAQ's Listing Rules, the Company appealed the delisting determination. However, on October 18, 2018, the Nasdaq Listing and Hearing Review Council (the "Listing Council") affirmed the decision of the Panel.

On July 26, 2018, our shares began trading on the OTCQB, which is operated by OTC Market Groups Inc., under the symbol "IMNP".

Note 2. Going Concern

These condensed consolidated financial statements are presented on the basis that we will continue as a going concern. The going concern concept contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Our ability to continue as a going concern despite insufficient available cash as of the date of this filing to fund the anticipated level of operations for at least the next 12 months from the issuance of this report is dependent on our ability to raise capital and monetize assets through the sale or licensing of drug candidates under development or our oncology asset portfolio.

We have limited capital resources and our operations have been funded by the proceeds of equity and debt offerings. We have devoted substantially all of our cash resources to research and development ("R&D") programs and have incurred significant general and administrative expenses to enable us to finance and grow our business and operations. We have not generated any significant revenue to date and may not generate any revenue for a number of years, if at all. If we are unable to raise additional funds in the future on acceptable terms, or at all, we may be forced to curtail our drug development activities or cease operations.

We have generated losses from operations since inception and we anticipate that we will continue to generate significant losses from operations for the foreseeable future. We had negative working capital of approximately $14.5 million and an accumulated deficit of $126.8 million as of September 30, 2018. Our net loss was $4.1 million and $6.1 million for the three months ended September 30, 2018 and 2017, respectively. Our net loss was $13.2 million and $14.7 million for the nine months ended September 30, 2018 and 2017, respectively. Cash used in operations was $8.3 million and $5.2 million for the nine months ended September 30, 2018 and 2017, respectively. We had approximately $0.1 million in cash as of September 30, 2018.

We will require additional financing over the next twelve months to continue at our expected level of operations. We may be forced to delay, scale back, sell or out-license or eliminate some or all of our R&D programs if we fail to obtain the needed capital on a timely basis. There is no assurance that we will be successful in any capital-raising efforts that we may undertake to fund operations during the next twelve months. We anticipate continuing to issue equity and/or debt securities as a source of liquidity, until we begin to generate positive cash flow to support our operations. Any future sales of securities to finance operations will dilute existing stockholders' ownership. We cannot guarantee when or if we will generate positive cash flow.

The forgoing factors, among others, raise substantial doubt about our ability to continue as a going concern.

Note 3. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of Immune and its subsidiaries: Immune Pharmaceuticals Ltd. ("Immune Ltd."), Immune Pharmaceuticals USA Corp., Maxim Pharmaceuticals, Inc., Cytovia, Inc. and Immune Oncology Pharmaceuticals Inc. All material inter-company transactions and balances have been eliminated in consolidation.

The accompanying unaudited condensed consolidated financial statements were prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and instructions to Form 10-Q and do not include all disclosures necessary for a complete presentation of financial position, results of operations, and cash flows in conformity with U.S. GAAP. These financial statements should be read in conjunction with the consolidated financial statements and related notes for the year ended December 31, 2017 filed on April 2, 2018. The results of operations for the three and nine months ended September 30, 2018 and 2017 are not necessarily indicative of the results that may be expected for the entire fiscal year or for any other interim period. In the opinion of management, the accompanying unaudited interim consolidated financial statements contain all material adjustments, including normal and recurring accruals, necessary to present fairly the Company's consolidated financial position as of September 30, 2018, the results of operations for the three and nine months ended September 30, 2018 and 2017 and cash flows for the nine months ended September 30, 2018 and 2017.

Use of Estimates

In preparing consolidated financial statements in conformity with U.S. GAAP, management is required 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 and expenses during the reported periods. Significant estimates include impairment of long lived assets (including intangible assets and In-Process R&D ("IPR&D")), amortization period of intangible assets, fair value of stock-based compensation, fair value of warrants and derivative liabilities, and valuation of deferred tax assets and liabilities. Actual results could differ from those estimates.

Cash and Cash Equivalents

We consider investments with original maturities of three months or less to be cash equivalents. Restricted cash primarily represents cash not available to us for immediate and general use. We maintain cash accounts with certain major financial institutions in the United States and Israel. Our cash on deposit may exceed United States federally insured limits at certain times during the year.

Intangible Assets

We account for the purchases of intangible assets in accordance with the provisions of **Accounting Standards Classification ("ASC") 350, Intangibles.** We recognize intangible assets based on their acquisition cost. Intangible assets determined to have indefinite lives are not amortized, but rather tested for impairment at least annually or more frequently if events or changes in circumstances indicate that the carrying amount may no longer be recoverable. If any of our intangible assets are considered to be impaired, the amount of impairment to be recognized is the excess of the carrying amount of the assets over its fair value. Intangible assets with definitive lives are reviewed for impairment only if indicators exist in accordance with **ASC 360, Property, Plant and Equipment**, and are amortized or depreciated over the shorter of their estimated useful lives or the statutory or contractual term, and in the case of patents, on a straight-line basis.

We perform an analysis annually to determine whether an impairment of intangible assets has occurred. As of June 30, 2018, we evaluated our intangible assets for human antibodies and anti-ferritin antibodies, because of events that occurred during the second quarter, which indicate that the carrying amount may no longer be recoverable. Based on this evaluation, we determined that these intangible assets had no value and were fully impaired, as discussed in Note 6. Additionally, we evaluated the AmiKet IPR&D as of December 31, 2017 for impairment. There was no impairment as of December 31, 2017. See In-Process Research and Development below for a further discussion regarding the valuation of the AmiKet IPR&D.

In-Process Research and Development

IPR&D represents the estimated fair value assigned to R&D projects acquired in a purchased business combination that have not been completed at the date of acquisition and which have no alternative future use. IPR&D assets acquired in a business combination are capitalized as indefinite-lived intangible assets. These assets remain indefinite-lived until the completion or abandonment of the associated R&D efforts. During the period prior to completion or abandonment, these acquired indefinite-lived assets are not amortized but are tested for impairment annually, or more frequently, if events or changes in circumstances indicate that the asset might be impaired.

We recorded an asset, IPR&D, with an initial book value of $27.5 million, related to the acquisition of AmiKet in August 2013 as part of the merger with Epicept. We completed an impairment analysis of the IPR&D as of December 31, 2016 and concluded that the following factors indicate that the IPR&D asset was impaired: a decision by management to delay indefinitely any further development of AmiKet; the failure to sell or license AmiKet to a third party; and the significant reduction in our market capitalization. For the year ended December 31, 2016, we recorded an impairment charge of $12.5 million in our consolidated statement of operations, which represents the excess of the IPR&D asset's carrying value over its estimated fair value. The estimated fair value of the IPR&D asset of $15 million is based upon the value ascribed to AmiKet in an arm's length agreement, which we negotiated with an unrelated third party and a valuation was performed by an independent specialist as of December 31, 2017.

The nano-encapsulation technology that we utilize in our NanoCyclo product candidate is applicable to AmiKet and we are considering developing Amiket Nano as a next generation, improved formulation of AmiKet with significant new patent protection. We are determining the optimal path forward for this program.

Research and Development

R&D expenses consist primarily of payroll and related costs for our drug development and scientific personnel, clinical trials costs, manufacturing costs, and costs of outsourced R&D services. R&D costs are expensed as incurred.

Translation into United States dollars

The United States dollar is our functional currency. We conduct certain transactions in foreign currencies, particularly, the Israeli Shekel and the Euro, which are recorded at the exchange rate as of the transaction date. All exchange gains and losses from re-measurement of monetary balance sheet items denominated in non-dollar currencies are nominal and reflected as non-operating income or expense in the statements of operations, as they arise.

Stock-based Compensation

We recognize compensation expense for all equity-based payments. Stock based compensation issued to employees is accounted for under **ASC 718, Compensation - Share Compensation** ("ASC 718"). We utilize the Black-Scholes valuation method to recognize compensation expense over the vesting period. The Black-Scholes valuation model requires the use of certain assumptions as inputs, including the expected life, volatility, risk-free interest rate and anticipated forfeiture of the stock options. We utilize the short cut method per the provisions of ASC 718 to calculate the expected life of the options. We base the risk-free interest rate on the rates paid on securities issued by the United States Treasury with a term approximating the expected life of the options. We estimate expected stock price volatility for our common stock by taking the average historical price volatility for industry peers combined with our historical data based on daily price observations. Estimates of pre-vesting option forfeitures are based on our experience. We adjust our estimate of forfeitures over the requisite service period based on the extent to which actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures are recognized through a cumulative catch-up adjustment in the period of change and impacts the amount of compensation expense to be recognized in future periods.

We account for stock-based transactions with non-employees based upon the fair value of the equity instruments issued, in accordance with **ASC 505-50, Equity-Based Payments to Non-Employees**. Significant factors that affect the expense related to equity-based payments to non-employees include the estimated fair market value of the common stock underlying the stock options and the estimated volatility of such fair market value. The value of non-employee options is re-measured every quarter until performance is complete. Income or expense is recognized during the vesting terms. Accounting for equity-based payments to non-employees requires fair value estimates of the equity instrument grant, which we estimate based upon the value of our common stock at the date of grant.

Patents

We charge external patent costs, such as filing fees and associated attorney fees and costs associated with maintaining and defending our patents subsequent to their issuance, to expense as and when incurred.

Clinical Trial Accruals

We outsource the conduct of our pre-clinical and clinical trials to third party contract research organizations (CROs) and clinical investigators. Our clinical supplies are manufactured by third party contract manufacturing organizations (CMOs). Invoicing from these third parties may be monthly based upon services performed or periodically based upon milestones achieved. We accrue these expenses based upon our assessment of the status of each clinical trial and the work completed, and upon information obtained from the CROs and CMOs. Our estimates are dependent upon the timeliness and accuracy of data provided by the CROs and CMOs regarding the status and cost of the studies and may not match the actual services performed by the organizations. Discrepancies could result in adjustments to our research and development expenses recorded in future periods. We have not had any significant adjustments to date.

Recently Issued Accounting Standards

From time to time, new accounting standards are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its consolidated financial position or results of operations upon adoption.

New accounting standards which have been adopted

In January 2016, the FASB issued **Accounting Standards Update No. 2016-01, "Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities"** ("ASU 2016-01"). ASU 2016-01 changes accounting for equity investments, financial liabilities under the fair value option, and presentation and disclosure requirements for financial instruments. ASU 2016-01 does not apply to equity investments in consolidated subsidiaries or those accounted for under the equity method of accounting. In addition, the FASB clarified guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. Equity investments with readily determinable fair values will be measured at fair value with changes in fair value recognized in net income. Companies have the option to either measure equity investments without readily determinable fair values at fair value or at cost adjusted for changes in observable prices minus impairment. The ASU enhances the reporting model for financial instruments, which includes amendments to address aspects of recognition, measurement, presentation and disclosure. ASU 2016-01 was effective for us beginning in the first quarter of 2018. Adoption of ASU 2016-01 did not have a material effect on our consolidated financial statements as we do not hold any publicly traded equity investments.

In August 2016, the FASB issued **Accounting Standards Update No. 2016-15, "Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments"** ("ASU 2016-15"). ASU 2016-15 clarifies how companies present and classify certain cash receipts and cash payments in the statement of cash flows where diversity in practice exists. ASU 2016-15 was effective for us in our first quarter of fiscal 2018. We did not have any changes to the presentation of our Consolidated Statement of Cash Flows upon adoption of the standard.

In October 2016, the FASB issued **Accounting Standards Update No. 2016-16, "Intra-Entity Transfers of Assets Other Than Inventory"** ("ASU 2016-16"). ASU 2016-16 requires the income tax consequences of intra-entity transfers of assets other than inventory to be recognized as current period income tax expense or benefit and removes the requirement to defer and amortize the consolidated tax consequences of intra-entity transfers. ASU 2016-16 was effective for us in our first quarter of fiscal 2018. Adoption of ASU 2016-16 did not have a material effect on our consolidated financial statements as we did not have any intra-entity transfers of assets.

In November 2016, the FASB issued **Accounting Standards Update No. 2016-18, "Statement of Cash Flows (Topic 230) Restricted Cash"** ("ASU 2016-18"). The amendments of ASU No. 2016-18 were issued to address the diversity in classification and presentation of changes in restricted cash and restricted cash equivalents on the statement of cash flows which is currently not addressed under Topic 230. The ASU requires an entity to include amounts generally described as restricted cash and restricted cash equivalents with cash and cash equivalents when reconciling the beginning of period and end of period total amounts on the statement of cash flows. ASU 2016-18 was effective for us in our first quarter of fiscal 2018. Adoption of ASU 2016-18 resulted in reclassification of restricted cash in the consolidated statements of cash flows for the nine months ended September 30, 2017.

New accounting standards which have not yet been adopted

In February 2016, the FASB issued **Accounting Standards Update No. 2016-02, "Leases (Topic 842)"** ("ASU 2016-02"). ASU 2016-02 provides accounting guidance for both lessee and lessor accounting models. Among other things, lessees will recognize a right-of-use asset and a lease liability for leases with a duration of greater than one year. For income statement purposes, ASU 2016-02 will require leases to be classified as either an operating or finance lease. Operating leases will result in straight-line expense while finance leases will result in a front-loaded expense pattern. The new standard will be effective for us on January 1, 2019. We expect the adoption of ASU 2016-02 to result in an increase in right-of-use assets and related liabilities of approximately $500,000 on our consolidated balance sheet related to our assets that are currently classified as operating leases, primarily for office space.

In July 2018, the FASB issued **Accounting Standards Update 2018-11 "Leases (Topic 842) Targeted Improvements"** which provides entities with an alternative transition method for adopting the new lease standard. Entities can elect to initially apply the new leases standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings. Consequently, comparative periods will continue to be accounted for in accordance with the current lease standard (Topic 840) and the disclosures will be in accordance with ASC 840. We are assessing this option in conjunction with its analysis of ASU 2016-02.

In August 2017, the FASB issued **Accounting Standards Update No. 2017-12, "Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities**" ("ASU 2017-12"). ASU 2017-12 provides guidance for improving and more closely aligning a company's financial reporting of its hedging relationships with the objective of a company's risk management activities. Among other provisions, the new standard (1) eliminates the separate measurement and reporting of hedge ineffectiveness and (2) permits an entity to recognize in earnings the initial value of an excluded component under a systematic and rational method over the life of the derivative instrument. The new standard will be effective for us on January 1, 2019. We do not expect the adoption of ASU 2017-12 to have a material effect on our consolidated financial statements as we do not anticipate engaging in any hedging activities.

In March 2018, the FASB Issued **Accounting Standards Update No. 2018-05, Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118** ("ASU 2018-05"). ASU 2018-05 was issued to incorporate into Topic 740 recent SEC guidance related to the income tax accounting implications of the Tax Cut and Jobs Act (the "Tax Act"). The SEC issued Staff Accounting Bulletin No. 118 ("SAB 118") to address concerns about reporting entities' ability to timely comply with the accounting requirements to recognize all of the effects of the Tax Act in the period of enactment. SAB 118 permits companies to disclose that some or all of the income tax effects from the Tax Act are incomplete by the due date of the financial statements, and if possible, disclose a reasonable estimate of such tax effects. ASU 2018-05 is effective immediately. ASU 2018-05 permits companies to use provisional amounts for certain income tax effects of the Tax Act during a one-year measurement period. The provisional accounting impacts for us may change in future reporting periods until the accounting analysis is finalized, which will occur no later than the first quarter of fiscal 2019.

In June 2018, the FASB issued **Accounting Standards Update No. 2018-07, "Improvements to Nonemployee Share-Based Payment Accounting"** ("ASU 2018-07"), to simplify the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. This ASU is effective for public entities for fiscal years beginning after December 15, 2018, with early adoption permitted. Prior to the adoption of ASU 2018-07, stock-based compensation awarded to non-employees was subject to revaluation over its vesting terms. Subsequent to the adoption of ASU 2018-07, non-employee share-based payment awards are measured on the date of grant, similar to share-based payment awards granted to employees. We currently have not adopted this ASU as we are assessing its effect.

Note 4. Derivative Financial Instruments

We account for derivative financial instruments in accordance with **ASC 815-40, "Derivative and Hedging - Contracts in Entity's Own Equity"** ("ASC 815-40"). Instruments that do not have fixed settlement provisions are deemed to be derivative instruments.

On July 17, 2017, we entered into an agreement in principle with Carmelit 9 Nehassim Ltd ("Carmelit") for the sale of original issue discount convertible notes (the "Carmelit Notes"). Also, the holder is entitled to receive 75,000 shares of our common stock subject to approval by our shareholders. We accounted for the obligation to issue Carmelit 75,000 shares as a derivative under ASC 815 because shareholder approval is not within our control and failure to obtain the approval would trigger net-cash settlement. Therefore and because shareholder approval has not been obtained to date, we classified the obligation as a derivative liability with an offset to debt discount on the debt in our consolidated financial statements, recorded at fair value and subject to mark to market until the shares are issued upon shareholder approval. We recorded the derivative liability of $207,750 at inception based on the closing price of our shares on that date. As of September 30, 2018, the fair value of these shares was $5,250 based on the closing price of our shares and we recorded the change in fair value of $37,500 for the nine months ended September 30, 2018.

On October 27, 2017, we entered into an agreement with a consultant providing for the issuance of 50,000 shares to the consultant as partial consideration for the performance of investor relations services. We accounted for the obligation to issue the shares as a derivative because the issuance was subject to Immune Board approval, which was not obtained as of December 31, 2017. We recorded a derivative liability of $40,500 at inception based on the closing price of our shares on that date. Following receipt of board approval, in March 2018, we issued 50,000 shares to the consultant and extinguished the derivative liability. The fair value of these shares was $19,000 based on the closing price of our shares and we recorded the change in fair value of $9,500 for the nine months ended September 30, 2018.

Note 5. Fair Value Measurements

Financial Instruments and Fair Value

We account for financial instruments in accordance with **ASC 820, "Fair Value Measurements and Disclosures"**. ASC 820 establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure 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). The three levels of the fair value hierarchy under ASC 820 are described below:

Level 1 - Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2 - Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly; and

Level 3 - Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

The financial instruments recorded in our consolidated balance sheets consist primarily of cash, notes payable and accounts payable. The carrying amounts of our cash and accounts payable approximate fair value due to their short-term nature. The fair value of our debt approximates its carrying value of approximately $8.3 million. We had no other financial liabilities or assets that were measured at fair value as of September 30, 2018.

Note 6. Intangible Assets

Our intangible assets consist of licenses and patents relating to our bertilimumab and oncology programs and were determined by management to have useful lives ranging between seven and fifteen years. We amortize these intangible assets on a straight-line basis.

On June 15, 2017, we entered into an Asset Purchase Agreement (the "Asset Purchase Agreement") with Meda Pharma SARL, a Mylan N.V. company ("Meda"), to repurchase assets relating to Ceplene (histamine dihydrochloride) including the right to commercialize Ceplene in Europe and to register and commercialize Ceplene in certain other countries, for a fixed consideration of $5.0 million payable in installments over a three-year period and additional contingent payments of $3.0 million which consists of $1.5 million due in year 4 upon the initial achievement of $12.0 million in revenue and $1.5 million due in year 5 upon the initial achievement of $15.0 million in revenue. The assets acquired from Meda include rights to marketing authorizations, trademarks, patents, and other intellectual property related to Ceplene and its use.

In addition, on June 15, 2017, substantially contemporaneous with the entry into the Asset Purchase Agreement, we entered into a Standby Financing Agreement (the "Standby Financing Agreement") with Daniel Kazado (the "Standby Financer") a member of our board of directors and a beneficial owner of our capital stock. See Note 13 for a further description of the Standby Financing Agreement. Currently, we are contemplating the sale or other disposition of our Ceplene assets, pursuant to which we intend to include the $5.0 million financial obligations contemplated by the Asset Purchase Agreement as part of such sale or other disposition on a basis and on terms that are acceptable to our board of directors and, if attainable, without recourse to us. We intend to maintain the regulatory status of Ceplene and our oncology assets while we pursue a strategic transaction, however, management and our board of directors will make decisions in the best interest of its shareholders as this process progresses.

We treated the acquisition as an asset acquisition in accordance with **ASC 805, "Business Combinations"**. We recorded the purchase price for the underlying patents as intangible assets and recorded the present value of the future payments due under the Asset Purchase Agreement of $4.2 million as a corresponding liability. The present value of future payments due under the Asset Purchase Agreement was determined by using our then current borrowing rate of 15% as the relevant discount rate for present value calculations. As of September 30, 2018, the amount due to Meda on a present value basis, classified as current and long-term notes payable is $3.7 million and $0.9 million, respectively. The estimated useful life of these intangible assets is seven years.

As of June 30, 2018, we evaluated our intangible assets for human antibodies and anti-ferritin antibodies because of events that occurred during the quarter, which indicate that the carrying amount may no longer be recoverable. Based on this evaluation (level 3 in the fair value hierarchy), these intangible assets have no value and were fully impaired. For the nine months ended September 30, 2018, we recorded impairment losses of $653,000 on certain intangible assets, as noted above.

The value of our amortizable intangible assets including gross asset value and carrying value is summarized below ($ in thousands):

	Bertilimumab iCo	NanomAbs Yissum	Human Antibodies Kadouche	Anti-ferritin Antibody MabLife	Ceplene Acquisition Intangibles	Total
Balance as of December 31, 2017	**$ 1,419**	**$ 383**	**$ 381**	**$ 318**	**$ 3,976**	**$ 6,477**
Amortization	(126)	(36)	(23)	(23)	(461)	(669)
Impairment	-	-	(358)	(295)	-	(653)
Balance, September 30, 2018	**$ 1,293**	**$ 347**	**$ -**	**$ -**	**$ 3,515**	**$ 5,155**
Gross asset value	**$ 2,509**	**$ 694**	**$ -**	**$ -**	**$ 4,310**	**$ 7,513**
Accumulated Amortization	(1,216)	(347)	-	-	(795)	(2,358)
Balance, September 30, 2018	**$ 1,293**	**$ 347**	**$ -**	**$ -**	**$ 3,515**	**$ 5,155**

Amortization expense amounted to $208,000 and $669,000 for the three and nine months ended September 30, 2018, respectively. Amortization expense amounted to $256,000 and $409,000 for the three and nine months ended September 2017, respectively.

Estimated amortization expense for each of the five succeeding years, based upon intangible assets at September 30, 2018 is as follows ($ in thousands):

Period Ending September 30,	Amount
2019	$ 829
2020	829
2021	829
2022	829
2023	829
Thereafter	1,010
Total	**$ 5,155**

Note 7. Accrued Expenses

Accrued expenses consist of the following ($ in thousands):

	September 30, 2018	December 31, 2017
Professional fees	$ 83	$ 284
Consulting fees	967	832
License fees	-	421
Dividends	-	216
Salaries and employee benefits	156	105
Severance	307	-
Other	166	262
Total	**$ 1,679**	**$ 2,120**

Note 8. Notes and Loan Payable

We are party to loan agreements as follows ($ in thousands):

	September 30, 2018	December 31, 2017
Mablife Notes Payable [(2)]	$ -	$ 394
Asset Acquisition Payable, net of discount of $445 [(3)]	4,555	4,359
May 2018 Convertible Notes, net of discount of $216 [(4)]	3,677	-
September 2018 Notes, net of discount of $3 [(1)]	100	-
Total notes and loans payable	**$ 8,332**	**$ 4,753**
Notes and loans payable, net of debt discount, current portion	$ 7,462	$ 3,296
Notes and loans payable, noncurrent portion	870	1,457
Total notes and loans payable, net of discount	**$ 8,332**	**$ 4,753**

Repayments under the Company's existing debt agreements consist of the following ($ in thousands):

Period Ending September 30,	Amount
2019	$ 7,997
2020	1,000
Total	**$ 8,997**

September 2018 Notes (1)

On September 12, 2018, we entered into a securities purchase agreement (the "Purchase Agreement") with Power Up Lending Group Ltd. (the "Purchaser") for the sale of $103,000 in aggregate principal amount of convertible notes (the "September 2018 Notes") which was consummated on September 14, 2018.

The September 2018 Notes bear interest at a rate of 12% per annum, payable in arrears on the maturity date of September 11, 2019, or upon acceleration or by prepayment. Any amount of principal or interest on the September 2018 Notes which is not paid when due shall bear interest at a rate of 22% per annum from the due date thereof until the same is paid. At any time during the one-hundred seventy (170) days ended March 1, 2019, we may prepay the Notes by paying a prepayment premium between 15% and 35%, based on the date paid, of the outstanding principal plus accrued and unpaid interest.

The September 2018 Notes are convertible into shares of our common stock, par value $0.0001 per share, beginning on March 1, 2019 at a conversion price equal to sixty-one percent (61%) of the average of the lowest two closing bid prices of our common stock during the twenty (20) trading days immediately preceding conversion. The number of shares issuable upon any conversion is limited to 4.99% of our then issued and outstanding common stock. There are no registration rights or warrants being granted to the Purchaser in this transaction.

In October 2018, we repaid the September 2018 Notes in full, which included a prepayment premium of 20% and accrued interest.

MabLife Notes Payable (2)

In March 2012, we acquired from MabLife SAS ("MabLife") through an assignment agreement, all rights, titles and interests in and to the patent rights, technology and deliverables related to the anti-Ferritin mAb, AMB8LK, including its nucleotide and protein sequences and its ability to recognize human acid and basic ferritins. The consideration was as follows: (i) $0.6 million payable in six annual installments (one of such installments being an upfront payment made upon execution of the agreement), and (ii) royalties of 0.6% of net sales of any product containing AMB8LK or the manufacture, use, sale, offering or importation of which would infringe on the patent rights with respect to AMB8LK. In February 2014, the parties revised the payment arrangement for the purchase of the original assignment rights to provide that the remaining payments of $0.1 million per year would be due each year in 2016 and 2017. We did not make those payments on a timely basis.

In February 2014, we acquired from MabLife, through an assignment agreement, all rights, titles and interests in and to the patent rights, technology and deliverables related to the use of anti-ferritin monoclonal antibodies in the treatment of some cancers, nucleotide and protein sequences of an antibody directed against an epitope common to human acidic and basic ferritins, monoclonal antibodies or antibody-like molecules comprising these sequences. As full consideration for the secondary patent rights, we agreed to pay a total of $150,000 of which $15,000 and $25,000 was paid in 2014 and 2013, respectively, and $25,000 would be paid on the second through fourth anniversary of the agreement and an additional $35,000 on the fifth anniversary of the agreement. We did not make those payments on a timely basis.

During the first quarter of 2015, MabLife informed us that it had filed for bankruptcy. On May 30, 2017, we received a summons from the bankruptcy court-liquidator to appear before the commercial court of Evry, France on September 19, 2017. In December 2017, we reached an agreement with the bankruptcy court-liquidator to settle all amounts due to Mablife for a payment of approximately $205,000. We paid the settlement amount in January 2018 and received confirmation by the commercial court on May 28, 2018. Based on this approved settlement, we wrote off the remaining $181,000 of debt to gain on extinguishment of debt in the three months ended June 30, 2018.

For the nine months ended September 30, 2018 and 2017, interest expense was $0.

Asset Acquisition Payable (3)

In conjunction with the Asset Purchase Agreement with Meda described in Note 6, we agreed to pay a fixed consideration of $5.0 million, payable in installments over a three-year period as follows: (i) $1.5 million on the earlier of: (1) the successful transfer to us of all of the marketing authorizations for the product or (2) the date which is six months after the Completion Date (as defined in the Asset Purchase Agreement); (ii) $1.5 million on the first anniversary of the Completion Date; (iii) $1.0 million on the second anniversary of the Completion Date; and (iv) $1.0 million on the third anniversary of the Completion Date. We recorded current and long-term debt of $3.7 million and $0.9 million, respectively, representing the amount due to Meda calculated on a present value basis. For the nine months ended September 30, 2018, interest expense was $195,000.

We are currently in default under the Asset Purchase Agreement. If not cured, we bear significant risk to our business plan regarding Ceplene, including the loss of such rights. Under the Asset Purchase Agreement, we were obligated to make payments to Meda of $1,500,000 (the "First Initial Consideration") no later than December 15, 2017 and $1,500,000 on June 15, 2018. Under that agreement, we had a 30-day grace period to make the payment of the First Initial Consideration or agree to a payment plan with Meda. On January 31, 2018, Meda delivered to us a default notice, demanding payment of the First Initial Consideration no later than February 15, 2018. We have yet to make any payments to Meda. Accordingly, Meda could terminate the Asset Purchase Agreement and cause us to forfeit the European rights to Ceplene without consideration to us and cancel our further obligations under the agreement except the First Initial Consideration would remain due and payable. If such action were to occur, we would need to either agree to a new license with Meda or renegotiate terms of a purchase from Meda of the European rights to Ceplene. There can be no guarantee that we would be able to come to terms with Meda. Loss of the European rights to Ceplene would impair our ability to execute our business plan with respect to our oncology related assets.

May 2018 Convertible Notes (4)

On May 14, 2018, we entered into a securities purchase agreement (the "May 2018 Purchase Agreement") with certain institutional investors for the sale of $2,781,000 in aggregate principal amount of original issue discount convertible notes with net proceeds of $2,007,000 (the "May 2018 Convertible Notes") which was consummated on May 18, 2018. The May 2018 Convertible Notes included a 20% original issue discount of $556,000, an 8% placement agent fee of $178,000 and other placement agent expenses of $40,000. In addition, the placement agent received 474,667 warrants with an exercise price of $0.47 per share and are exercisable as of November 18, 2018. We calculated the fair value of these warrants as $91,000 using the Black-Scholes model and recorded the fair value as debt discount with an offset to additional paid-in capital. Original issue discount and debt issuance costs was $865,000 and is being amortized over six months.

The May 2018 Convertible Notes are convertible at any time at a conversion price of $0.375 per share, subject to adjustment upon an event of default or significant corporate transaction, provided that unless shareholder approval is obtained, the maximum amount of shares of our common stock that may be issued upon conversion is 6,397,456 shares of common stock (or 19.99% of the issued and outstanding shares of common stock on the closing date). The conversion price is not subject to adjustment for future equity issuances at prices below the then prevailing conversion price and we are under no obligation to obtain shareholder approval in connection with the offering.

The May 2018 Convertible Notes are due and payable upon the earlier of (a) November 18, 2018 and (b) the closing of one or more subsequent financings with gross proceeds equal to at least $3,000,000 in the aggregate. The holders of the May 2018 Convertible Notes have the option to extend the maturity date of the notes through February 18, 2019. The May 2018 Convertible Notes represent senior indebtedness of the Company.

The May 2018 Convertible Notes become immediately due at the Mandatory Default Amount, which is 140% of the outstanding principal amount of the note, plus all accrued interest and unpaid interest, and all other amounts, costs, expenses and liquidated damages, due if our common stock shall not be eligible for listing or quotation for trading on NASDAQ and shall not be eligible to resume listing or quotation for trading thereon within five trading days. Additionally, interest on the May 2018 Convertible Notes would accrue daily at an interest rate of 1.5% per month on the then outstanding principal amount. Also, the holder may to elect to convert all or any portion of the remaining principal amount into shares of common stock at a price per share equal to the lowest daily VWAP for the 15 days prior to conversion but in no event, at a conversion price below par value.

On June 4, 2018, we received a notice from the Staff of Nasdaq LLC indicating that, based upon our continued non-compliance with the minimum $1.00 bid price requirement for continued listing on NASDAQ, as set forth in the Rule as of May 30, 2018, the Staff had determined to delist our securities from NASDAQ unless we timely requested a hearing before the Panel. We timely appealed the delisting notice and appeared in front of the Panel on July 19, 2018. The Panel issued a decision on July 24, 2018 and affirmed the Staff's decision to delist our common stock from NASDAQ, with suspension of trading effective at the open of business on July 26, 2018. The suspension of trading on NASDAQ triggered a default on the May 2018 Convertible Notes. Accordingly, as of June 30, 2018, we recorded the Mandatory Default Amount of $1.1 million as liquidated damages, which represents an additional 40% of principal but did not record an embedded derivative related to the lowest VWAP for the 15 days prior to conversion as this amount was immaterial to the consolidated financial statements. As of September 30, 2018, there were no additional adjustments.

In connection with the financing on October 9, 2018 described in Note 15, Subsequent Events (the "Financing"), the holders of our May 2018 Convertible Notes agreed to waive the outstanding event of default thereunder resulting from the suspension of the trading of the common stock on NASDAQ (other than the required increase in the principal amount of the May 2018 Convertible Notes) and to certain amendments, including adding the OTCQX and OTCQB trading markets to the default provisions for listing or quotation for trading, to the May 2018 Convertible Notes to enable us to consummate the Financing in exchange for an aggregate amendment fee of $49,220.

Upon the issuance of the May 2018 Convertible Notes on May 18, 2018, the conversion price for the Series E Convertible Preferred Stock and the exercise price of warrants issued with the Series E Convertible Preferred Stock ("Series E Warrants") were adjusted to $0.30. On July 26, 2018, upon the suspension of trading on NASDAQ, the conversion price for the Series E Convertible Preferred Stock and the exercise price of warrants issued with the Series E Convertible Preferred Stock were adjusted to $0.20. On August 14, 2018, upon a conversion of $175 of May 2018 Convertible Notes, the conversion price for the Series E Convertible Preferred Stock and the exercise price of warrants issued with the Series E Convertible Preferred Stock were adjusted to $0.0759. Based on the above down round triggers, we recorded a deemed dividend for the three and nine months ended September 30, 2018 of $5,100,000 and $10,699,000, respectively, based on the change in fair value, in our consolidated statement of operations, of which $10,127,000 was related to the Series E Convertible Preferred Stock and $572,000 was related to the Series E Warrants.

For the three and nine months ended September 30, 2018, interest expense was $433,000 and $649,000, respectively, related to the amortization of original issue discount and debt issuance costs for the May 2018 Convertible Notes. For the nine months ended September 30, 2018 liquidated damages was $1,112,000 related to the Mandatory Default for the May 2018 Convertible Notes.

Note 9. Income Taxes

The Company has recognized a deferred tax liability of $4.1 million as of September 30, 2018 and December 31, 2017 related to the purchase of the AmiKet IPR&D. This deferred tax liability was recorded to account for the book vs. tax basis difference related to the IPR&D intangible asset, which was recorded in connection with the merger with Epicept Ltd. This deferred tax liability was excluded from sources of future taxable income, as the timing of its reversal cannot be predicted due to the indefinite life of this IPR&D. Accordingly, this deferred tax liability cannot be used to offset the valuation allowance.

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company's deferred tax assets relate primarily to its net operating loss carryforwards and other balance sheet basis differences. In accordance with **ASC 740, "Income Taxes,**" the Company recorded a valuation allowance to fully offset the gross deferred tax asset, because it is not more likely than not that the Company will realize future benefits associated with these deferred tax assets at September 30, 2018 and December 31, 2017.

Note 10. Stockholders' Equity

(a) Stock options and stock award activity

The following table illustrates the common stock options granted during the nine months ended September 30, 2018:

Title	Grant date	No. of options	Weighted average exercise price	Weighted average grant date fair value	Vesting terms	Assumptions used in Black-Scholes option pricing model	
Consultants	January - September 2018	15,000	$ 0.34	$ 0.29	Immediately	Volatility	114 -118%
						Risk free interest rate	2.22 -2.82%
						Expected term, in years	6
						Dividend yield	0.00%
Management, Directors and Employees	January - September 2018	57,000	$ 0.25	$ 0.22	2 years	Volatility	118%
						Risk free interest rate	2.96%
						Expected term, in years	6
						Dividend yield	0.00%

The following table illustrates the common stock options granted during the nine months ended September 30, 2017:

Title	Grant date	No. of options	Weighted average exercise price	Weighted average grant date fair value	Vesting terms	Assumptions used in Black-Scholes option pricing model	
Management, Directors and Employees	January - September 2017	366,500	$ 4.00	$ 2.60	1-3 years	Volatility	109-115%
						Risk free interest rate	2.22-2.53%
						Expected term, in years	6-10
						Dividend yield	0.00%

The following table illustrates the stock awards during the nine months ended September 30, 2018.

Title	Grant date	No. of stock awards	Weighted average grant date fair value	Vesting terms
Consultants	January - September 2018	100,000	$ 0.38	Immediately

The fair value of stock awards was determined using the share price on the date of grant.

There were no stock awards during the nine months ended September 30, 2017.

The following table summarizes information about stock option activity for the nine months ended September 30, 2018:

	Options				
	No. of options	Weighted average exercise price	Exercise price range	Weighted average grant date fair value	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2017	**519,014**	**$ 9.80**	**$0.80 - $80.00**	**$ 9.40**	**$ -**
Granted	72,000	$ 0.27	$0.25-$0.34	$ 0.23	$ -
Forfeited/cancelled	(111,351)	$ 22.23	$2.68-$80.00	$ 19.12	-
Outstanding at September 30, 2018	**479,663**	**$ 5.40**	**$0.25 - $61.00**	**$ 5.80**	**$ -**
Exercisable at September 30, 2018	**356,787**	**$ 7.00**	**$0.25 - $61.00**	**$ 7.60**	**$ -**

As of September 30, 2018, unamortized stock-based compensation for stock options was $0.1 million, with a weighted-average recognition period of approximately 2.1 years.

(b) Warrants

The following table illustrates warrants granted during the nine months ended September 30, 2018:

Title	Grant date	No. of warrants	Weighted average exercise price	Weighted average grant date fair value	Vesting terms	Assumptions used in Black-Scholes option pricing model	
Investors	January - September 2018	474,667	$ 0.47	$ 0.19	Six months	Volatility	118%
						Risk free interest rate	2.90%
						Expected term, in years	5
						Dividend yield	0.00%

The following table illustrates warrants granted during the nine months ended September 30, 2017:

Title	Grant date	No. of warrants	Weighted average exercise price	Weighted average grant date fair value	Vesting terms	Assumptions used in Black-Scholes option pricing model	
Investors	January - September 2017	52,910	$ 10.00	$ 3.80	Immediately	Volatility	109%
						Risk free interest rate	1.89%
						Expected term, in years	5
						Dividend yield	0.00%
Noteholders	January - September 2017	387,597	$ 0.86	$ 1.96	Immediately	Volatility	105%
						Risk free interest rate	1.91%
						Expected term, in years	5
						Dividend yield	0.00%

The following table summarizes information about warrants outstanding at September 30, 2018:

	Number of Warrants	Weighted Average Exercise Price	Exercise price range
Warrants outstanding at December 31, 2017	**18,695,677**	**$ 3.00**	**$0.86-$200.00**
Warrants issued	474,667	0.47	$ 0.47
Warrants increased	4,004,147	0.08	$ 0.08
Warrants exercised	(34,820)	.08	.08
Outstanding and exercisable at September 30, 2018	**23,139,671**	**$ 1.61**	**$0.08-$200.00**

The 83,333 warrants issued with the April 2017 Convertible Notes were valued using the Monte Carlo model, which is a pricing model that incorporates all of the required inputs of a Black-Scholes model and Monte Carlo simulation process that capture additional features of the warrant related to its fair value estimate, but are outside of the Black-Scholes model. The warrants contain a provision whereby if the Company completes a transaction with an effective price per share lower than the exercise price of the warrants then the exercise price shall be reduced and the number of warrant shares issuable shall be increased such that the aggregate exercise price payable after taking into account the decrease in the exercise price, shall be equal to the aggregate exercise price prior to such adjustment. The allocated fair value of the warrant of $180,000 is the mean of the present value of the future cash flows resulting from the Monte Carlo simulation process. The fair value of $180,000 was calculated using the Monte Carlo model and the allocated value of $180,000 was recorded as additional paid-in capital. In 2017, the number of warrants increased to 387,597 and exercise price lowered to $0.86 due to the above provision. During the nine months ended September 30, 2018, the number of warrants increased by 4,004,147 to 4,391,744 and the exercise price lowered to $0.0759 due to the above provision. Based on the above provision, we recorded a deemed dividend for the three and nine months ended September 30, 2018 of $441,000 and $441,000, respectively, based on the change in fair value, in our consolidated statement of operations.

Stock-based compensation expense for stock options and awards and warrants for the three months ended September 30, 2018 and 2017 was $9,000 and $180,000, respectively, which has not been tax-effected due to the recording of a full valuation allowance against net deferred tax assets. Stock-based compensation expense for stock options and awards and warrants for the nine months ended September 30, 2018 and 2017 was $131,000 and $345,000, respectively, which has not been tax-effected due to the recording of a full valuation allowance against net deferred tax assets.

(c) Series E Convertible Preferred Stock

For the nine months ended September 30, 2018, 8,478 shares of Series E Convertible Preferred Stock were converted into 23,825,614 shares of our common stock.

As of September 24, 2018, we notified the holders of Series E Convertible Preferred Stock that funds are not legally available for the payment of dividends and that such dividends shall accrete to and increase the outstanding stated value of the Series E Convertible Preferred Stock and shall thereafter no longer be accrued and unpaid dividends. As of September 30, 2018, dividends in accrued expenses of $396,000 were adjusted and recorded in additional paid in capital. For the nine months ended September 30, 2018, we recorded dividends of approximately $342,000.

Note 11. Loss Per Share

Basic and diluted loss per share is computed by dividing loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Diluted weighted average shares outstanding for the nine months ended September 30, 2018 and 2017 excludes shares underlying stock options, warrants, convertible notes and convertible preferred because the effects would be anti-dilutive. Accordingly, basic and diluted loss per share is the same. Such excluded shares are summarized as follows:

	Three month period ended September 30,		Nine month period ended September 30,	
	2018	**2017**	**2018**	**2017**
Common stock options	479,663	688,041	479,663	688,041
Shares issuable upon conversion of Series E Preferred Stock (including dividends and assuming $0.0759 price)	58,051,054	-	58,051,054	-
Shares potentially issuable upon conversion of May 2018 convertible notes (assuming $0.375 price)	10,382,865	-	10,382,865	-
Shares potentially issuable upon conversion of April 2017 convertible notes (assuming $1.00 floor price)	-	152,355	-	152,355
Shares potentially issuable upon conversion of May 2017 convertible notes (assuming $1.00 floor price)	-	480,000	-	480,000
Shares potentially issuable upon conversion of July 2017 Senior Secured convertible note (assuming (0.75 floor price)	-	1,589,879	-	1,589,879
Share potentially issuable upon conversion of July 2017 convertible note (assuming $1.00 floor price)	-	300,000	-	300,000
Shares potentially issuable upon conversion of August 2017 convertible note (assuming $1.00 floor price)	-	858,000	-	858,000
Shares potentially issuable upon conversion of September 2017 convertible notes (assuming $1.00 conversion price)	-	149,500	-	149,500
Warrants	23,139,671	1,019,627	23,139,671	1,019,627
Total shares excluded from calculation	92,053,253	5,237,402	92,053,253	5,237,402

Note 12. Commitments and Contingencies

(a) Leases

In August 2018, we relocated our headquarters to Fort Lee, New Jersey under a lease agreement. The lease is for a term of seventy-five months with the first three months' rent abated. Annual fixed base rent for the first year is $74,000, the second year is $102,000, the third year is $105,000, the fourth year is $108,000, the fifth year is $111,000, the sixth year is $115,000 and the final three months is $29,000.

Immune Ltd. occupies shared office space on a month-to-month basis in Jerusalem, Israel. Rent expense is approximately $1,000 per month. Immune Ltd. occupied shared office space on a month-to-month basis in Tel-Aviv, Israel through May 31, 2018. Rent expense was approximately $2,000 per month.

As of August 31, 2018, we terminated our lease for office space in Englewood Cliffs, New Jersey. Lease expense was approximately $3,000 per month. Cytovia occupied shared office space on a month-to-month basis in New York, New York , which ceased on August 31, 2018. Rent expense was approximately $4,000 per month.

We recorded rent expense of $59,000 and $405,000 for the nine months ended September 30, 2018 and 2017, respectively.

Future minimum lease payments under non-cancelable leases as of September 30, 2018 are as follows ($ in thousands):

Period Ending September 30,	**Amount**
2019	$ 91
2020	102
2021	105
2022	109
2023	112
Thereafter	124
Total	**$ 643**

(b) Licensing Agreements

We are a party to several research and licensing agreements, including iCo, BNS, Yissum, Dalhousie and Shire Biochem, which may require us to make payments to the other party upon the attaining certain milestones or as royalties as defined in the agreements.

(c) Litigation

On May 9, 2018, we received a complaint against us, Immune Pharmaceuticals, Ltd., our former CEO and Board Member, Daniel Teper and our former CFO, Serge Goldner, for approximately $2.8 million that was filed in the Tel Aviv District Court based on an agreement with our subsidiary, from 2011, relating to a loan of $260,000 which was repaid in full in 2011. The plaintiff claimed that the damages were based on certain warrants to purchase shares of our common stock, to participate in a future public offering or merger of the Company, with certain discounted terms and cash damages that it did not receive. In October 2014, we received a written demand from the plaintiff for damages and the parties discussed a settlement of this matter; however, until receipt of the complaint, we had not heard from the plaintiff since 2015. At this very early stage, we are unable to assess the validity or merits of the claim. We will review the claims and intend to vigorously defend against this action.

From time to time, we are involved in legal proceedings arising in the ordinary course of business. We believe there is no other litigation pending that could have, individually or in the aggregate, a material adverse effect on its results of operations or financial condition.

Note 13. Related Party Transactions

Dr. Teper, our former CEO and former member of our Board, advanced cash to us of approximately $0.2 million, which remains owed as of September 30, 2018. This amount has been reflected in advances from related parties in our consolidated balance sheets.

As of September 30, 2018, there is approximately $0.1 million owed to our directors and management for directors' fees and expense reimbursements. This amount is included in accounts payable in our consolidated balance sheets.

On August 28, 2018, Elliot M. Maza resigned all positions held by him with us, including his positions as our Chief Executive Officer and President and as a member of our board of directors. In connection with his resignation, Mr. Maza entered into a Termination Agreement (the "Termination Agreement") and a General Release of Claims with us (the "Release"). Pursuant to the Termination Agreement, we agreed to pay Mr. Maza a severance payment in the amount of $300,000 (the "Severance Amount"). The Severance Amount will be paid to Mr. Maza in equal installments in accordance with our customary payroll practices; provided, however, that any outstanding monthly installments will be accelerated in the event of a "Company Sale" (as defined in the Termination Agreement). In addition, the Company will reimburse Mr. Maza for the cost of continued medical insurance for a period of up to nine months. As of September 30, 2018, a balance of $307,000 is included in accrued expenses in our consolidated balance sheets.

On June 15, 2017, substantially contemporaneous with the entry into the Asset Purchase Agreement (see Note 8), we entered into a Standby Financing Agreement (the "Standby Financing Agreement") with Daniel Kazado (the "Standby Financer"), a member of our board of directors and a beneficial owner of our capital stock. Currently, we are contemplating the sale or other disposition of our Ceplene assets, pursuant to which we intend to include the $5.0 million financial obligations contemplated by the Asset Purchase Agreement as part of such sale or other disposition on a basis and on terms that are acceptable to our board of directors and, if attainable, without recourse to us. The Standby Financing Agreement remains in effect in order to support the financial obligations of the Company to pay the fixed consideration installments, in the aggregate amount of $5,000,000, due under and in accordance with the terms of the Asset Purchase Agreement. In the event that we cannot effectuate the sale or disposition of our Ceplene assets on terms reasonably acceptable to us and in a timeline necessary to satisfy the financial obligations of the Asset Purchase Agreement (including, without limitation, that such funding be on a basis that is without recourse to us), then, pursuant to the terms of the Standby Financing Agreement, the Standby Financer shall lend us or Cytovia (as determined in the discretion of our board of directors) an amount in immediately available funds equal to the fixed consideration installment payment then due and payable under the Asset Purchase Agreement (the "Standby Commitment"). The loan made by the Standby Financer in respect of such fixed payment shall be evidenced by a promissory note in an aggregate principal amount equal to the amount of funds lent by the Standby Financer. The Standby Commitment shall expire on the earliest of (a) satisfaction in full by the Standby Financer of his obligations under the Standby Financing Agreement, (b) Cytovia having obtained funding on terms reasonably acceptable to us and (c) the Company having been fully discharged of and released from all liability of all of its obligations under the Asset Purchase Agreement.

Note 14. Pint Licensing Agreement

On July 10, 2017, Cytovia entered into an exclusive licensing agreement (the "Licensing Agreement") with Pint Pharma International S.A. ("Pint"), a specialty pharmaceutical company focused on Latin America and other markets, for the marketing, commercialization and distribution of Ceplene throughout Latin America (the "Territory", defined as Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, French Guiana, British Guiana, Suriname, Guatemala, Haiti, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Uruguay and Venezuela) through Pint and one or more of its affiliates. Pursuant to the Licensing Agreement, Pint will also pay Cytovia (i) 35% of net sales in the territory (ii) a milestone payment of $0.5 million when net sales of Ceplene in the Territory first reach $10.0 million in any calendar year and (iii) a milestone payment of $1.25 million when net sales of Ceplene in the Territory first reach $25.0 million in any calendar year. Cytovia further granted Pint and its affiliates certain sub-licensing rights to Ceplene, and a right of first refusal on any new products of Cytovia within the Territory during the term of the Licensing Agreement.

With regard to any regulatory approvals and filings related to the commercialization of Ceplene within the Territory, Pint shall be the applicant, holder of such regulatory approvals and will be responsible for the content of such regulatory submissions, as well as all costs and expenses related to, among other items delineated in the Licensing Agreement, the fees, filings, compliance, registration and maintenance of such required regulatory approval matters. Cytovia shall be responsible for providing (or if in the control of a third party, to ensure such third party provides) all appropriate documentation, samples and other information in support of Pint in connection with its regulatory submissions, compliance and maintenance matters in the Territory concerning the Ceplene products.

Additionally, in connection with the Licensing Agreement, the parties thereto agreed that Pint Gmbh, an affiliate of Pint, will separately enter into an investment agreement upon satisfaction of the condition that the commercialization of the Ceplene and the Combination Therapy has been met (defined to mean when Ceplene is commercialized by Pint together with a new product in the Territory, pursuant to which, Pint Gmbh will make to an investment of $4.0 million into Cytovia in exchange for an equity interest in Cytovia. In July 2018, a global pharmaceutical and services company announced that it acquired the ex-United States rights to the drug other than Ceplene comprising the Combination Therapy. Accordingly, the condition for the investment from Pint can no longer be satisfied.

We are currently contemplating the sale, disposition or other strategic transaction involving our Ceplene assets. This process is in its early stages and, therefore, it is too soon to definitively state how the Licensing Agreement will be impacted or addressed, or if a sale or other disposition will be consummated.

Note 15. Subsequent Events

We have evaluated events and transactions subsequent to September 30, 2018 and through the date these consolidated financial statements were included in this Form 10-Q and filed with the SEC.

On October 9, 2018, we entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with an institutional investor pursuant to which we sold to the investor $5.5 million in principal amount of our Senior Secured Redeemable Convertible Notes (the "October 2018 Notes") for $2 million in cash and a $3 million promissory note (the "Investor Note") payable upon the earlier of the effectiveness of a registration statement covering the resale of the shares issuable upon conversion of the October 2018 Notes or one year.

The October 2018 Notes bear compounded interest at a rate of 10% per annum, subject to adjustment as specified in the October 2018 Notes and mature five years from the issuance date. The October 2018 Notes are secured by first priority security interests on all of our assets, other than all tangible and intangible assets associated with Ceplene (histamine dihydrochloride) unless such assets are not disposed of by March 31, 2019. The October 2018 Notes are convertible into shares of our common stock at a conversion price of $0.075 per share, subject to certain adjustments, at the option of the holder thereof or, in certain circumstances, at our option. In the event of a conversion, any accrued interest and any interest make-whole amount will be paid in cash or, in certain circumstances, shares of common stock valued on a formula basis specified in the October 2018 Notes. At maturity, the October 2018 Notes will automatically convert into shares of common stock unless redeemed for cash at our option in whole but not in part at 100% of the face amount thereof plus accrued interest. Prior to maturity and subject to certain limitations, the October 2018 Notes are redeemable in whole or in part in cash at our option at 100% of the face amount to be redeemed plus an interest make-whole payment or in whole at 125% of the face amount thereof.

We also issued to the investor warrants ("October 2018 Warrants") exercisable for three years from the issuance date to purchase up to 50 million shares of common stock at an exercise price of $0.10 per share, subject to full-ratchet price protection in the event that we issue or is deemed to issue shares of common stock at a price per share less than the then-current exercise price of the October 2018 Warrants (subject to certain exceptions). In the event of certain fundamental transactions (generally involving the sale or acquisition of the company or all or substantially all of our assets), the holder of the October 2018 Warrants has the right to require us (or any successor entity) to repurchase the October 2018 Warrants at the Black-Scholes value thereof calculated pursuant to a formula specified in the October 2018 Warrants.

In the Securities Purchase Agreement, we agreed to file a registration statement covering the resale of the shares of common stock issuable upon the conversion of the October 2018 Notes and the exercise of the October 2018 Warrants.

We do not currently have sufficient shares of common stock authorized for issuance in the event that the October 2018 Notes are converted in full and the October 2018 Warrants are fully exercised. In the Securities Purchase Agreement, we agreed to call a special meeting of stockholders within 90 days to obtain stockholder approval for an increase in our authorized common stock to enable us to fulfill our obligations under the October 2018 Notes and the October 2018 Warrants.

In connection with the financing described above (the "Financing"), the holders of our May 2018 Convertible Notes agreed to waive the outstanding event of default thereunder resulting from the suspension of the trading of the common stock on NASDAQ (other than the required increase in the principal amount of the May 2018 Convertible Notes) and to certain amendments, including adding the OTCQX and OTCQB trading markets to the default provisions for listing or quotation for trading, to the May 2018 Convertible Notes to enable us to consummate the Financing in exchange for an aggregate amendment fee of $49,220.

Upon the issuance of the October 2018 Notes and October 2018 Warrants on October 9, 2018, the conversion price for the Series E Convertible Preferred Stock and the exercise price of warrants issued with the Series E Warrants were adjusted to $0.0682 and further adjusted to $0.0541 as of October 17, 2018, which was four trading days immediately following the public announcement on October 10, 2018 of the October 2018 Notes and October 2018 Warrants.

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

The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2017, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2017 filed on April 2, 2018. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. We have based these forward-looking statements on our current expectations and projections of future events. Such statements reflect our current views with respect to future events and are subject to unknown risks, uncertainties and other factors that may cause results to differ materially from those contemplated in such forward-looking statements. Statements made in this document related to, among other statements, the development, commercialization and market expectations of our drug candidates, to the establishment of corporate collaborations, and to our operational projections are forward-looking and are made pursuant to the safe harbor provisions of the Securities Litigation Reform Act of 1995. Among the factors that could result in a materially different outcome are the inherent uncertainties accompanying new product development, action of regulatory authorities and the results of further clinical trials. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including but not limited to those set forth under the caption "Risk Factors" in the Annual Report on Form 10-K for the year ended December 31, 2017, and those updated Risk Factors set forth in this Quarterly Report on Form 10-Q, for the period ended September 30, 2018.

Overview

We are a clinical stage biopharmaceutical company specializing in the development of novel targeted therapeutic agents in the fields of immunology, inflammation, dermatology and oncology.

Our lead product candidate is bertilimumab, a first-in-class, human, anti-eotaxin-1 antibody that targets eotaxin-1, a key regulator of inflammation, Bertilimumab has completed phase 2 trials in bullous pemphigoid ("BP"), our lead indication, as well as in allergic rhinitis and allergic conjunctivitis, and is currently in a phase 2 clinical trial in ulcerative colitis ("UC"). Also, we are developing a topical nano-encapsulated formulation of cyclosporine-A, which we refer to as "NanoCyclo," for the treatment of atopic dermatitis ("AD") and psoriasis.

Our oncology portfolio includes Ceplene, which is approved in the European Union for the maintenance of remission in patients with Acute Myeloid Leukemia ("AML") in combination with interleukin-2 (IL-2), and a nanotechnology combination platform, which we refer to as "NanomAbs", Azixa, and Crolibulin. In June 2018, we terminated the license agreement and returned all rights relating to the bispecific antibody platform, which was included previously in our oncology portfolio. We intend to divest all of our oncology assets.

Our pain portfolio includes AmiKet and AmiKet Nano, a topical analgesic cream containing amitriptyline and ketamine for the treatment of postherpetic neuralgia ("PHN") and diabetic peripheral neuropathy ("DPN"). We are determining the optimal path forward for this program.

Ceplene®, LidoPain®, Epicept®, Amiket™, and Azixa™ are trademarks that we own. Each trademark, trade name or service mark of any other company appearing in this annual report on Form 10-Q belongs to its respective holder.

Business Strategy

Our business strategy is to develop novel therapeutics with the potential to treat or prevent immunologic and inflammatory diseases. We intend to obtain revenues from licensing fees, milestone payments, development fees, royalties and/or sales related to the use of our drug candidates or intellectual property for specific therapeutic indications or applications.

In April 2017, we announced a corporate restructuring with the objective of prioritizing and segregating our research and development efforts and strengthening our financial position. Accordingly, we had announced plans to separate our oncology business as a separate, stand-alone company, through a proposed spinoff of our wholly-owned subsidiary Cytovia Inc. ("Cytovia"). The contemplated spin-off was subject to the satisfaction of certain conditions, including separate capitalization from third-party sources to fund Cytovia's start-up and operational costs, expenses of the spin-off and other relevant items. In April 2018, following careful consideration and lack of sufficient capital to support the spin-off, our board of directors determined that it was in the best interest of the Company and its shareholders to terminate the spin-off process and pursue other strategic alternatives for Cytovia in order to monetize its assets through a sale, disposition or similar transaction. In addition, on May 1, 2018, Dr. Daniel Teper, Chief Executive Officer of Cytovia and member of the board of directors of both Immune and Cytovia, resigned from each of these positions, effective immediately. The Board accepted his resignation, which was not due to any disagreement with the Company. See Risk Factors for risks and other matters related to our oncology assets.

Recent Developments

Departure of Chief Executive Officer and Directors

On August 28, 2018, Elliot M. Maza resigned all positions held by him with us, including his positions as our Chief Executive Officer and President and as a member of our board of directors. In connection with his resignation, Mr. Maza entered into a Termination Agreement (the "Termination Agreement") and a General Release of Claims with us (the "Release"). Pursuant to the Termination Agreement, we agreed to pay Mr. Maza a severance payment in the amount of $300,000 (the "Severance Amount"). The Severance Amount will be paid to Mr. Maza in equal installments in accordance with our customary payroll practices; provided, however, that any outstanding monthly installments will be accelerated in the event of a "Company Sale" (as defined in the Termination Agreement). In addition, the Company will reimburse Mr. Maza for the cost of continued medical insurance for a period of up to nine months.

On September 10, 2018, Dr. Cameron Durrant, a member of our Board of Directors resigned as a director of the Company, effective immediately.

Appointment of Interim Chief Executive Officer and Director

On August 28, 2018, Tony Fiorino, M.D., Ph.D., our Chief Medical Officer and Chief Operating Officer will assume the role of Interim Chief Executive Officer. Dr. Fiorino will also retain his duties as Chief Medical Officer and Chief Operating Officer. In connection with his appointment as Interim Chief Executive Officer, Dr. Fiorino was also elected to our Board of Directors to fill the vacancy resulting from Mr. Maza's resignation. In addition, Dr. Fiorino has assumed the role of President.

Our Business

Results of Operations

Three months ended September 30, 2018 compared to the three months ended September 30, 2017

Revenues

We recorded no revenue for the three months ended September 30, 2018 and 2017. We are in the early stages of development of our product candidates and we have not completed the development of bertilimumab or other drug candidates. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year.

Research and development expense ($ in thousands)

	Three months ended September 30,		
	2018	2017	Change
Research and development	$ 2,054	$ 1,229	$ 825

Research and development ("R&D") expenses increased by $825,000 or 67% to $2.1 million for the three months ended September 30, 2018, as compared to $1.2 million for the three months ended September 30, 2017. The increase was primarily driven by increases in (i) clinical trial expenses of $0.5 million, (ii) patent expenses of $0.1 million and (iii) employee compensation expense of $0.2 million.

General and administrative expense ($ in thousands)

	Three months ended September 30,		
	2018	2017	Change
General and administrative	$ 1,644	$ 1,610	$ 34

General and administrative ("G&A") expenses remained consistent at $1.6 million for the three months ended September 30, 2018, as compared to $1.6 million for the three months ended September 30, 2017. The change was primarily the same due to increases in (i) investor relations fees of $0.1 million, (ii) employee compensation expense of $0.3 million and (iii) legal fees of $0.1 million offset by decreases in (vi) consulting expenses of $0.2 million, (v) stock-based compensation expense of $0.2 million and (vi) audit and accounting services of $0.1 million.

Non-operating expense ($ in thousands)

	Three months ended September 30,		
	2018	2017	Change
Non-operating expense	$ 434	$ 3,212	$ (2,778)

Non-operating expense was $0.4 million for the three months ended September 30, 2018, as compared with $3.2 million for the three months ended September 30, 2017, a decrease of $2.8 million or 86%.

Non-operating expense for the three months ended September 30, 2018 primarily consisted of amortization of the original issue discount for the Asset Acquisition Note Payable of $0.1 million and amortization of original issue discount and debt issuance costs for the May 2018 Convertible Notes of $0.4 million.

Non-operating expense for the three months ended September 30, 2017 primarily consisted of amortization of original issue discount of $0.8 million for the May 2017 Convertible Notes and $0.4 million in liquidated damages on the November 2016 convertible notes. In addition, non-operating expense consisted of loss on extinguishment of debt of $2.1 million relating to the MEF I, LP Senior Secured Convertible Note and the Amendment of the May 2017 Convertible Notes.

Nine months ended September 30, 2018 compared to the nine months ended September 30, 2017

Revenues

We recorded no revenue for the nine months ended September 30, 2018 and 2017. We are in the early stages of development of our product candidates and we have not completed the development of bertilimumab or other drug candidates. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year.

Research and development expense ($ in thousands)

	Nine months ended September 30,		
	2018	2017	Change
Research and development	$ 6,163	$ 3,674	$ 2,489

Research and development (“R&D”) expenses increased by $2.5 million or 68% to $6.2 million for the nine months ended September 30, 2018, as compared to $3.7 million for the nine months ended September 30, 2017. The increase was primarily driven by increases in (i) clinical trial expenses of $1.7 million, (ii) R&D consulting expense of $0.7 million, (iii) amortization of Ceplene acquisition intangibles of $0.3 million, (iv) employee compensation expense of $0.3 million , and (v) patent expenses of $0.1 million. This cumulative increase was offset partially by decreases in (vi) licenses of $0.3 million, (vii) the write-off of lab equipment in the second quarter of 2017 of $0.2 million and (viii) stock-based compensation expense of $0.1 million.

General and administrative expense ($ in thousands)

	Nine months ended September 30,		
	2018	2017	Change
General and administrative	$ 4,704	$ 4,644	$ 60

General and administrative ("G&A") expenses remained consistent at $4.7 million for the nine months ended September 30, 2018, as compared to $4.7 million for the nine months ended September 30, 2017. The change was primarily the same due to increases in (i) investor relations fees of $0.2 million and (ii) employee compensation expense of $0.4 million offset by decreases in (iii) rent of $0.3 million, (iv) legal fees of $0.1 million, (v) stock-based compensation expense of $0.1 million and (vi) audit and accounting services of $0.1 million.

Non-operating expense ($ in thousands)

	Nine months ended September 30,		
	2018	2017	Change
Non-operating expense	$ 2,366	$ 6,422	$ (4,056)

Non-operating expense was $2.4 million for the nine months ended September 30, 2018, as compared with $6.4 million for the nine months ended September 30, 2017, a decrease of $4.1 million or 63%.

Non-operating expense for the nine months ended September 30, 2018 primarily consisted of the impairment of intangible assets of $0.7 million, amortization of the original issue discount for the Asset Acquisition Note Payable of $0.2 million, amortization of original issue discount and debt issuance costs for the May 2018 Convertible Notes of $0.6 million and liquidated damages of $1.1 million related to the May 2018 Convertible Notes, offset by a gain on extinguishment of Mablife Notes Payable of $0.2 million.

Non-operating expense for the nine months ended September 30, 2017 primarily consisted of loss on extinguishment of $2.1 million relating to the repayment of the Hercules Loan Agreement and the MEF I, LP Senior Secured Convertible Note and the Amendment of the May 2017 Convertible Notes. In addition, non-operating expense primarily consisted of amortization of original issue discount of $2.0 million for the May 2017 Convertible Notes, interest expense of $0.6 million relating to the April 2017 Convertible Notes, interest expense of $0.1 million and $0.3 million of amortization of original issue discount and early termination fee on the Loan Agreement with Hercules, $0.1 million of amortization of discount on amount due to Meda and $0.1 million of amortization of original issue discount on various other notes. In addition, interest expense included $0.8 million in liquidated damages and $0.3 million in redemption premium recorded on the November 2016 convertible notes.

Liquidity and Capital Resources

We have generated losses from operations since inception and we anticipate that we will continue to generate significant losses from operations for the foreseeable future. At September 30, 2018, we had a working capital deficit of approximately $14.5 million. Accumulated deficit amounted to $126.8 million and $113.5 million at September 30, 2018 and December 31, 2017, respectively. Net loss for the nine months ended September 30, 2018 and 2017 was $13.2 million and $14.7 million, respectively. Net cash used in operating activities was $8.3 million and $5.2 million for nine months ended September 30, 2018 and 2017, respectively.

We have limited capital resources and operations since inception have been funded with the proceeds from equity and debt financings and license fee arrangements. As of September 30, 2018, we had approximately $0.1 million in cash. If we fail to raise additional capital or obtain substantial cash inflows from potential partners within the next six months, we may be forced to curtail or cease operations. We cannot assure you that financing will be available in a timely manner, on favorable terms or at all.

Management has evaluated whether there is substantial doubt about our ability to continue as a going concern and has determined that substantial doubt existed as of the date of this filing. This determination was based on the following factors: (i) our available cash as of the date of this filing will not be sufficient to fund its anticipated level of operations for the next 12 months from the filing of this quarterly report; (ii) we may not identify commercial partners to support development of our drug candidates; and (iii) if we fail to obtain the needed capital, we will be forced to delay, scale back, or eliminate some or all of its R&D programs or perhaps cease operations. In the opinion of management, these factors, among others, raise substantial doubt about the ability of us to continue as a going concern.

The following table summarizes select balance sheet and working capital amounts as at September 30, 2018 and December 31, 2017 ($ in thousands):

	As of September 30, 2018	As of December 31, 2017	Change
Cash	$ 76	$ 6,776	$ (6,700)
Working capital deficit	$ (14,498)	$ (2,220)	$ (12,278)
Notes and loans payable, current portion	$ (7,462)	$ (3,296)	$ (4,166)

Cash Flow Activities

The following table summarizes our cash flows for the periods set forth below ($ in thousands):

	Nine months ended September 30,		
	2018	2017	Change
Net cash used in operating activities	$ (8,344)	$ (5,217)	$ (3,127)
Net cash (used in) provided by investing activities	$ (99)	$ 37	$ (136)
Net cash provided by financing activities	$ 1,743	$ 4,985	$ (3,242)

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2018 was $8.3 million compared with net cash used in operating activities for the nine months ended September 30, 2017 of $5.2 million.

Net cash used in operating activities during the nine months ended September 30, 2018, exclusive of changes in operating assets and liabilities was $10.0 million, which consists primarily of the net loss of $13.2 million, as adjusted for (i) amortization of debt discount of $0.8 million, (ii) depreciation and amortization expense of $0.7 million, (iii) loss on impairment of intangible assets of $0.7 million, (iv) liquidated damages of $1.1 million and (v) stock-based compensation of $0.1 million, offset by (vi) a gain on extinguishment of debt of $0.2 million. Changes in operating assets and liabilities in the nine months ended September 30, 2018 was $1.7 million primarily due to a $2.0 million increase in accounts payable, which was offset by a corresponding decrease in accrued expenses and related parties of $0.3 million.

The net cash used in operating activities during the nine months ended September 30, 2017, exclusive of changes in operating assets and liabilities, was $8.1 million including the net loss of $14.7 million, stock-based compensation expense of $0.3 million, depreciation and amortization, including debt discount and debt issuance costs of $2.5 million and loss on extinguishment of debt of $2.1 million. Changes in operating assets and liabilities in the nine months ended September 30, 2017 was $2.9 million primarily due to a $3.0 million increase in accounts payable and an increase in other assets of $0.2 million, which was offset by a corresponding decrease in accrued expenses of $0.3 million.

Investing Activities

During the nine months ended September 30, 2018, net cash used in investing activities amounted to $99,000 for purchases of property and equipment for the new office space.

During the nine months ended September 30, 2017, net cash provided by investing activities amounted to $37,000 related to a decrease in restricted cash of $59,000, which was offset by $22,000 in purchases of computer software.

Financing Activities

During the nine months ended September 30, 2018, net cash provided by financing activities was $1.7 million. This was comprised of proceeds from the May 2018 Convertible Notes of $2.0 million and proceeds from the September 2018 Notes of $0.1 million offset by repayments of Mablife Notes Payable of $0.2 million and dividends paid on Series E Convertible Preferred Stock of $0.2 million.

During the nine months ended September 30, 2017, net cash provided by financing activities was $5.0 million. This was comprised of proceeds from the Equity Line financings of $5.4 million, proceeds from the May 2017 Convertible Notes of $1.6 million, proceeds from the April 2017 Convertible Notes of $0.4 million and proceeds, proceeds from July 2017 Convertible Notes of $0.2 million, proceeds from August 2017 Convertible Notes of $0.5 million, proceeds from September 2017 Convertible Notes of $0.1 million, of $0.2 million related to the amendment of certain securities purchase agreements. This was partially offset by the repayment of $1.4 million related to the November 2016 convertible notes, $0.9 million repayment of the Loan Agreement with Hercules, repayment of April 2017 Convertible Notes of $0.1 million, $1.0 million payment of commitment fees, and $0.1 million in financing fees paid related to the Equity Line financings.

Recently Issued Accounting Standards

See Note 3 to the Consolidated Financial Statements, *Summary of Significant Accounting Policies,* for a discussion of recent accounting developments.

Off-Balance Sheet Arrangements

As of September 30, 2018, we had no off-balance sheet arrangements. We have no guarantees or obligations other than those that arise out of the Company's ordinary business operations.

Critical Accounting Policies and Significant Judgments and Estimates

A summary of our significant accounting policies is contained in the notes to our consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2017. There have been no material changes to those policies during the nine months ended September 30, 2018.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are not required to provide information required by this item because we are a smaller reporting company, as that term is defined in Item 10(f)(1) of Regulation S-K.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Principal Accounting Officer and supervision of our Principal Executive Officer, who also is our Principal Financial Officer, is responsible for our disclosure controls and procedures pursuant to Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified under the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to its principal executive officer and its principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management conducted an evaluation of the effectiveness of our disclosure controls and procedures as of September 30, 2018. Based on this evaluation, our management concluded that as of September 30, 2018, our disclosure controls and procedures were not effective at a reasonable assurance level due to the material weaknesses identified in our internal control over financial reporting as of September 30, 2018, which our management views as an integral part of our disclosure controls and procedures. Management's assessment identified the following material weaknesses in our internal control over financial reporting: lack of segregation of duties due to lack of sufficient accounting and finance personnel, lack of sufficient entity level controls, and lack of a sufficient technology infrastructure to support the financial reporting function.

Our management plans to remediate these weaknesses by using third parties to perform accounting tasks, enhancing procedures for recording and reviewing complex transactions, performing more independent reconciliations or reviews and hiring more people. Our planned remediation efforts to address lack of sufficient technology infrastructure include upgrading and engaging technology consultants with specific financial reporting expertise using our accounting and financial reporting system. We believe that these remediation efforts, if successfully implemented, will improve our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

During the quarter ended September 30, 2018, we initiated remediation efforts and are working on implementing the controls described above in response to previously identified material weaknesses. Other than described above, there have been no other changes in our internal control over financial reporting that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

Part II. Other Information

Item 1. Legal Proceedings.

See Note 12(c) - "Commitments and Contingencies", of the Notes to Unaudited Consolidated Financial Statements for detailed information regarding the status of our lawsuits and other disputes.

On May 9, 2018, we received a complaint against us, our subsidiary, our former CEO and Board Member, Daniel Teper and our former CFO, Serge Goldner, for approximately $2.8 million that was filed in the Tel Aviv District Court based on an agreement with our subsidiary, from 2011, relating to a loan of $260,000 which was repaid in full in 2011. The plaintiff claimed that the damages were based on certain warrants to purchase shares of our common stock, to participate in a future public offering or merger of the Company, with certain discounted terms and cash damages that it did not receive. In October 2014, we received a written demand from the plaintiff for damages and the parties discussed a settlement of this matter in 2015; however, until receipt of the complaint, we had not heard from the plaintiff since 2015. At this stage, we are unable to assess the validity or merits of the claim. We will review the claims and intend to vigorously defend against this action.

We are not involved in any legal proceedings which management believes may have a material adverse effect on our business, financial condition, operations, cash flows, or prospects. From time to time in the ordinary course of our business, we receive threats of litigation and/or we may be involved in legal proceedings which can include, but are not limited to employment claims, product claims, patent infringement, securities matters, shareholder demands and other matters in which companies such as us may be involved. We do not believe that any of these claims and proceedings against us as they arise are likely to have, individually or in the aggregate, a material adverse effect on our financial condition or results of operations.

Item 1A. Risk Factors.

Our operations and financial results are subject to various risks and uncertainties, including those described below, which could adversely affect our business, financial condition, result of operations, cash flows, and the trading price of our common stock. There are numerous and varied risks as set forth below that may prevent us from achieving our goals, and the risks we describe are not the only ones facing us. If any of these risks actually occur, or if any risks or uncertainties not presently known to us or that we currently deem immaterial impair our business or operations, then our business, financial condition or results of operations may be materially adversely affected. In such cases, the trading price of our common stock could decline and investors could lose all or part of their investment.

Risks related to our financial position and need for additional capital

We have limited liquidity.

As of September 30, 2018, our cash and cash equivalents balance was $0.1 million, which we believe will not be sufficient to fund our anticipated level of operations for at least the next 12 months, and our working capital deficit was $14.5 million. Our cash used in operations was $11.6 million and $12.3 million for the fiscal years ended December 31, 2017 and 2016, respectively and $8.3 million for the nine months ended September 30, 2018.

We have financed our operations to date through private placements and public offerings of common and preferred stock and convertible debt securities and borrowings under secured loans. Our revenue to date has been immaterial and consisted of royalties on licensed patents and sales of Ceplene used in clinical trials.

Our ability to continue operations depends on our ability to access the capital markets, license our technology to third parties and obtain regulatory approval to market our drugs. We expect to finance our cash needs from additional equity or debt financing, or strategic alliances on products until we can achieve profitability and positive cash flows from operating activities, if ever.

We have incurred operating losses since our inception. We expect to incur operating losses for the foreseeable future and may never achieve or maintain profitability.

Since our inception in July 2010, we have incurred significant losses and expect to continue to operate at a net loss in the foreseeable future. Our net loss was $13.2 million and $14.7 million for nine months ended September 30, 2018 and 2017, and our accumulated deficit as of September 30, 2018 was $126.8 million. Our cash used in operations was $8.3 million and $5.2 million for the nine months ended September 30, 2018 and 2017, respectively. We have devoted substantially all of our financial resources and efforts on the development of bertilimumab, our phase 2 drug candidate for the treatment of inflammatory diseases, and our other drug candidates. We are still in the early stages of development of our product candidates. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we continue the research and development of our product candidates.

We have limited capital resources and operations since inception have been funded with the proceeds from equity and debt financings and license fee arrangements. As of September 30, 2018, we had $0.1 million in cash and cash equivalents. We intend to finance our need for working capital from additional equity or debt financing, the sale of its Ceplene assets and a collaboration or other agreement with respect to bertilimumab. We cannot assure you that we will be able to obtain sufficient funding to continue our operations. Any financing, sale of assets or collaboration agreement may be on terms that are not favorable to us and may not be available on any terms. If we fail to raise additional capital or obtain substantial cash inflows from potential partners within the next six months, we may be forced to curtail or cease operations.

To become and remain profitable, we must, either alone or with partners, succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval, and establishing and managing our collaborations at various stages of each candidate's development. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Other than Ceplene, none of the Company's drug candidates has received FDA or foreign regulatory marketing approval. In order to grant marketing approval, the FDA or foreign regulatory agencies must conclude that clinical data establish the safety and efficacy of the Company's drug candidates. Furthermore, the Company's strategy includes entering into collaborations with third parties to participate in the development and commercialization of its products. In the event that third parties have control over the preclinical development or clinical trial process for a product candidate, the estimated completion date would largely be under control of that third party rather than under the Company's control. The Company cannot forecast with any degree of certainty which of its drug candidates will be subject to future collaborations or how such arrangements would affect its development plan or capital requirements.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the FDA or EMA to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase and revenue could be further delayed.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our Company could also cause you to lose part or all of your investment.

The estimates and judgments we make, or the assumptions on which we rely, in preparing our consolidated financial statements could prove inaccurate.

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges accrued by us and related disclosure of contingent assets and liabilities. Such estimates and judgments include revenue recognition, inventory, valuation of stock-based awards, research and development expenses and income tax. We base our estimates on historical experience, facts and circumstances known to us and on various other assumptions that we believe to be reasonable under the circumstances. We cannot provide assurances, however, that our estimates, or the assumptions underlying them, will not change over time or otherwise prove inaccurate. If this is the case, we may be required to restate our consolidated financial statements, which could, in turn, subject us to securities class action litigation. Defending against such potential litigation relating to a restatement of our consolidated financial statements would be expensive and would require significant attention and resources of our management. Moreover, our insurance to cover our obligations with respect to the ultimate resolution of any such litigation may be inadequate. As a result of these factors, any such potential litigation could have a material adverse effect on our financial results and cause our stock price to decline, which could in turn subject us to securities class action litigation.

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all. If we fail to raise the necessary additional capital, we will be unable to complete the development and commercialization of our product candidates or continue our development programs.

Our operations have consumed substantial amounts of cash since our inception in 2010. We will require additional capital for the further development and commercialization of our product candidates and to fund our other operating expenses and capital expenditures.

We cannot be certain that additional funding will be available on acceptable terms or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may need to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. We may need to seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available. Any of these events could significantly harm our business, financial condition and results of operations.

We expect that a large percentage of our future research and development expenses will be incurred in support of current and future preclinical and clinical development programs. These expenditures are subject to numerous uncertainties in timing and cost to completion. We test our product candidates in numerous preclinical studies for toxicology, safety and efficacy. We then conduct early stage clinical trials for each drug candidate. As we obtain results from clinical trials, we may elect to discontinue or delay clinical trials for certain product candidates or programs in order to focus resources on more promising product candidates or programs. Completion of clinical trials may take several years but the length of time generally varies according to the type, complexity, novelty and intended use of a drug candidate. The cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development.

In order to carry out our business plan and implement our strategy, we will need to obtain additional financing and may choose to raise additional funds through public or private equity or debt financing, licensing arrangements, strategic collaborations, asset sales, government grants, or other arrangements. We cannot be sure that any additional funding will be available on terms favorable to us, or at all. Furthermore, any additional equity or equity-related financing may be dilutive to our stockholders, and debt or equity financing, if available, may subject us to restrictive covenants and significant interest costs. We may be required to relinquish our rights to certain of our product candidates or marketing territories if we obtain funding through licensing arrangements or strategic collaborations.

In addition, certain investors may be unwilling to invest in our securities if we are unable to maintain the listing of our common stock on a United States national securities exchange. Our inability to raise capital when needed would harm our business, financial condition and results of operations, and could cause our stock price to decline or require that we wind down our operations altogether.

The report of the Independent Registered Public Accounting Firm on our financial statements for the year ended December 31, 2017 includes an explanatory paragraph that expresses substantial doubt about our ability to continue as a going concern.

The Independent Registered Public Accounting Firm's Report issued in connection with our audited financial statements for the year ended December 31, 2017 states that there is "substantial doubt about our ability to continue as a going concern". Our ability to continue as a going concern is dependent on a combination of several factors, including, our ability to raise capital by issuing debt or equity securities to investors, license or sell our product candidates to other pharmaceutical companies, and generate revenues from successfully developed products. If we are not able to continue our business as a going concern, we may be forced to liquidate our assets for an amount less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose part or all of their investment.

We may be exposed to market risk and interest rate risk that may adversely impact our financial position, results of operations or cash flows.

We may be exposed to market risk, i.e. the risk of loss related to changes in market prices, including foreign exchange rates, of financial instruments that may adversely impact our financial position, results of operations or cash flows. In addition, our investments may be exposed to market risk due to fluctuation in interest rates, which may affect its interest income and the fair market value of investments, if any. At present, our investments consist primarily of cash and cash equivalents. We may invest in investment-grade marketable securities with maturities of up to three years, including commercial paper, money market funds, and government/non-government debt securities. The primary objective of our investment activities is to preserve principal while maximizing the income that we receive from our investments without significantly increasing risk of loss.

We are exposed to fluctuations in currency exchange rates, which could have an adverse effect on us.

Our foreign currency exposures give rise to market risk associated with exchange rate movements of the United States dollar, our functional and reporting currency, mainly against the New Israeli Shekel, ("NIS"), the Euro and the British pound sterling. A significant portion of our expenses are denominated in United States dollars (with certain expenses payable to Israeli personnel, including sub-contractors and consultants, in the NIS). Our United States dollar expenses consist principally of payments made to personnel in the United States, including sub-contractors and consultants for preclinical studies, clinical trials and other research and development activities. We anticipate that the bulk of our expenses will continue to be denominated in United States dollars and the NIS. If the United States dollar fluctuates significantly against the NIS, the Euro or the British pound sterling it may have a negative impact on our results of operations.

To date, we have not engaged in hedging transactions. In the future, we may enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of our principal operating currencies. These measures, however, may not adequately protect us from the material adverse effects of such fluctuations. Exchange rate fluctuations resulting in a devaluation of the NIS, the Euro or the British pound sterling compared with the United States dollar could have a material adverse impact on our results of operations and share price.

We are in default under our agreement for the acquisition of the European rights to Ceplene. If not cured, we bear significant risk to our business plan regarding Ceplene, including the loss of such rights.

Under an asset purchase agreement between Immune and Meda Pharma SARL ("Meda"), we were obligated to make a payment to Meda of $1,500,000 (the "First Initial Consideration") no later than December 15, 2017. Under that agreement, we had a 30-day grace period to make the payment or work out a payment plan with Meda. On January 31, 2018, Meda delivered to us a default notice under the asset purchase agreement, demanding payment of the First Initial Consideration no later than February 15, 2018. We have yet to make this payment. Accordingly, Meda could terminate the asset purchase agreement, and cause the loss by us of certain Ceplene-related assets without consideration to us and cancel our further obligations under the agreement. If such action were to occur, we would need to either work out a license with Meda or renegotiate terms of a purchase of the European Ceplene rights from Meda. There can be no guarantee that we would be able to work out such a deal. Loss of the Ceplene related assets would materially impair our ability to execute our business plan with respect to our oncology related assets and have a negative effect on our financial condition.

Our level of indebtedness could adversely affect our business, financial condition and results of operations and our ability to meet our payment obligations under such indebtedness.

As of September 30, 2018, we had approximately $8.3 million of indebtedness, net of debt discount and issuance costs, outstanding. This level of debt could have significant consequences on our future operations, including:

- increasing our vulnerability to adverse economic and industry conditions;
- making it more difficult for us to meet our payment and other obligations under our existing indebtedness;
- making it more difficult to obtain any necessary future financing for working capital, capital expenditures, debt service requirements or other purposes;
- requiring the dedication of a substantial portion of any cash flow from operations to service our indebtedness, thereby reducing the amount of cash flow available for other purposes, including capital expenditures;
- placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital than we have; and
- limiting our flexibility in planning for, or reacting to, changes in our business and the markets in which we compete.

Any of the above-listed factors could have an adverse effect on our business, financial condition and results of operations and our ability to meet our payment obligations under our convertible notes.

Our ability to meet our payment and other obligations under our indebtedness depends on our ability to generate significant cash flow in the future. This, to some extent, is subject to general economic, financial, competitive, legislative and regulatory factors as well as other factors that are beyond our control. We cannot assure you that our business will generate cash flow from operations, or that future borrowings will be available to us, in an amount sufficient to enable us to meet our payment obligations under the convertible notes and to fund other liquidity needs. If we are not able to generate sufficient cash flow to service our debt obligations, we may need to refinance or restructure our debt, sell assets, reduce or delay capital investments, or seek to raise additional capital. If we are unable to implement one or more of these alternatives, we may not be able to meet our payment obligations under our existing indebtedness.

Servicing our indebtedness requires a significant amount of cash or common stock, and we may not have sufficient cash flow from our business to service our debt.

We will be required to pay accrued interest on our indebtedness in cash or, in certain circumstances, shares of our common stock. Our ability to make scheduled payments of interest depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt in cash and make necessary capital expenditures.

If we are unable to generate sufficient cash flow to satisfy payment obligations under our existing indebtedness, we may be required to adopt one or more alternatives, such as selling assets or obtaining additional equity capital on terms that may be onerous or highly dilutive. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

We are subject to a number of restrictive covenants, which may restrict our business and financing activities. Such restrictions may affect, and in many respects limit or prohibit, among other things, our ability to:

- incur additional indebtedness for borrowed money (except permitted indebtedness);
- grant liens (except permitted liens);
- repurchase shares of common stock or common stock equivalents (subject to certain limited exceptions);
- repay or repurchase outstanding indebtedness (subject to certain limited exceptions);
- pay cash dividends or distributions on our equity securities; or
- enter into certain related party transactions.

These restrictions may prevent us from taking actions that we believe would be in the best interests of our business, and may make it difficult for us to successfully execute our business strategy or effectively compete with companies that are not similarly restricted. We also may incur future debt obligations that might subject us to additional restrictive covenants that could affect our financial and operational flexibility. If we are unable to service our indebtedness, we may be required to restructure or refinance all or part of our existing debt, sell assets, reduce capital expenditures, borrow more money or raise equity, some or all of which may not be available to us on terms acceptable to us, if at all, or such alternative strategies may yield insufficient funds to make required payments on our indebtedness. In addition, our ability to comply with the restrictive covenants in our indebtedness could be affected by our future performance and events or circumstances beyond our control. Failure to comply with these covenants would result in an event of default under such indebtedness, the potential acceleration of our obligation to repay outstanding debt and the potential foreclosure on the collateral securing such debt, and could cause a cross-default under our other outstanding indebtedness. We cannot assure you that we will be granted waivers or amendments to these agreements if for any reason we are unable to comply with these agreements. Any of the above risks could materially adversely affect our business, financial condition, cash flows and results of operations.

Risks Related to Our Business and Industry

We are heavily dependent on the success of our technologies and product candidates, and we cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized.

To date, we have invested a significant portion of our efforts and financial resources in the acquisition and development of our product candidates. We have not demonstrated our ability to perform the functions necessary for the successful acquisition, development or commercialization of the technologies we are seeking to develop. As an early stage company, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. Our future success is substantially dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize such product candidates. Our product candidates are currently in preclinical development or in clinical trials. Our business depends entirely on the successful development and commercialization of our product candidates, which may never occur. We currently generate no revenues from the sale of any drugs, and we may never be able to develop or commercialize a marketable drug.

The successful development, and any commercialization, of our technologies and any product candidates would require us to successfully perform a variety of functions, including:

- developing our technology platform;
- identifying, developing, manufacturing and commercializing product candidates;
- entering into successful licensing and other arrangements with product development partners;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

Our operations have been limited to organizing our company, acquiring, developing and securing our proprietary technology and identifying and obtaining early preclinical data or clinical data for various product candidates. These operations provide a limited basis for you to assess our ability to continue to develop our technology, identify product candidates, develop and commercialize any product candidates we are able to identify and enter into successful collaborative arrangements with other companies, as well as for you to assess the advisability of investing in our securities. Each of these requirements will require substantial time, effort and financial resources.

Each of our product candidates will require additional preclinical or clinical development, management of preclinical, clinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, building of a commercial organization, and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA, or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. In addition, our product development programs contemplate the development of companion diagnostics by our third-party collaborators. Companion diagnostics are subject to regulation as medical devices and must themselves be cleared or approved for marketing by the FDA or certain other foreign regulatory agencies before we may commercialize our product candidates.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. It is not uncommon for companies in the biopharmaceutical industry to suffer significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be successful.

Product candidate development risk is heightened by any changes in the planned clinical trials compared to the completed clinical trials. As product candidates are developed through preclinical to early and late stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and methods of administration, are altered along the way in an effort to optimize processes and results. While these types of changes are common and are intended to optimize the product candidates for late stage clinical trials, approval and commercialization, such changes do carry the risk that they will not achieve these intended objectives.

We have not previously initiated or completed a corporate-sponsored clinical trial. Consequently, we may not have the necessary capabilities, including adequate staffing, to successfully manage the execution and completion of any clinical trials we initiate, in a way that leads to our obtaining marketing approval for our product candidates in a timely manner, or at all.

In the event we are able to conduct a pivotal clinical trial of a product candidate, the results of such trial may not be adequate to support marketing approval. Because our product candidates are intended for use in life- threatening diseases, in some cases we ultimately intend to seek marketing approval for each product candidate based on the results of a single pivotal clinical trial. As a result, these trials may receive enhanced scrutiny from the FDA. For any such pivotal trial, if the FDA disagrees with our choice of primary endpoint or the results for the primary endpoint are not robust or significant relative to control, are subject to confounding factors, or are not adequately supported by other study endpoints, including possibly overall survival or complete response rate, the FDA may refuse to approve a BLA or an NDA based on such pivotal trial. The FDA may require additional clinical trials as a condition for approving our product candidates.

Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

Although we are planning for certain clinical trials relating to bertilimumab, we may experience delays in our clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- reaching agreement on acceptable terms with prospective CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining IRB, approval at each site;
- recruiting suitable patients to participate in a trial;
- clinical sites deviating from trial protocol or dropping out of a trial;
- having patients complete a trial or return for post-treatment follow-up;
- developing and validating companion diagnostics on a timely basis, if required;
- adding new clinical trial sites;
- manufacturing sufficient quantities of product candidate for use in clinical trials; or
- Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

Furthermore, we intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we intend to have agreements governing their committed activities, for which we will have limited influence over their actual performance. We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board ("DSMB"), for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Competition for patients in conducting clinical trials may prevent or delay product development and strain our limited financial resources.

Many pharmaceutical companies are conducting clinical trials in patients with the disease indications that our potential drug products target. As a result, we must compete with them for clinical sites, physicians and the limited number of patients who fulfill the stringent requirements for participation in clinical trials. Also, due to the confidential nature of clinical trials, we do not know how many of the eligible patients may be enrolled in competing studies and who are consequently not available to us for our clinical trials. Our clinical trials may be delayed or terminated due to the inability to enroll enough patients. Patient enrollment depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites and the eligibility criteria for the study. The delay or inability to meet planned patient enrollment may result in increased costs and delays or termination of the trial, which could have a harmful effect on our ability to develop products.

The regulatory review and approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval from the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, review and approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing with partners; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Other than with respect to Ceplene, we have not previously submitted a BLA or an NDA to the FDA or similar drug approval filings to comparable foreign authorities for any product candidate, and we cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenues will be dependent, in part, upon our collaborators' ability to obtain regulatory approval of the companion diagnostics to be used with our product candidates, as well as the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patients that we are targeting for our product candidates are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval to commercialize our product candidates both in the United States, the European Union and in additional foreign countries. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions.

Healthcare reform measures could hinder or prevent our product candidates' commercial success.

In both the United States and certain foreign jurisdictions, there have been and we expect there will continue to be a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. The U.S. government and other governments have shown significant interest in pursuing healthcare reform. In particular, the Medicare Modernization Act of 2003 revised the payment methodology for many products under the Medicare program in the United States. This has resulted in lower rates of reimbursement. In 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, collectively the Affordable Care Act ("PPACA"), was enacted. The PPACA substantially changes the way healthcare is financed by both governmental and private insurers. Further, The Tax Cuts and Jobs Act of 2017 repealed the requirement that individuals maintain health insurance coverage or face a penalty (known as the "individual mandate"). The removal of this provision, coupled with the threat of the repeal of other PPACA provisions, may increase instability of the insurance marketplace and may have consequences for the coverage and accessibility of prescription drugs. President Trump and HHS Secretary Azar have announced support for regulatory provisions that would limit the PPACA and number of healthcare reform programs initiated under the Obama administration. Such government-adopted reform measures may adversely impact the pricing of healthcare products and services in the U.S. or internationally and the amount of reimbursement available from governmental agencies or other third-party payors.

Legislative changes to or regulatory changes under the ACA remain possible under the current administration. The American Health Care Act of 2017 (“AHCA”), which would repeal and replace key portions of the ACA, was passed by the U.S. House of Representatives but ultimately was not passed by the U.S. Senate. In addition, in January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. More recently, the Senate Republicans introduced and then updated a bill to replace the ACA known as the Better Care Reconciliation Act of 2017. The Senate Republicans also introduced legislation to repeal the ACA without companion legislation to replace it, and a "skinny" version of the Better Care Reconciliation Act of 2017. Each of these measures was rejected by the full Senate. In December 2017, tax reform legislation was signed into law that eliminates the individual insurance mandate provisions of the ACA. Congress will likely consider other legislation to replace elements of the ACA. We expect that the ACA, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to successfully commercialize our products.

We expect that the ACA, as well as other healthcare reform measures that have and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for products and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect the demand for any drug products for which we may obtain regulatory approval, as well as our ability to set satisfactory prices for our products, to generate revenues, and to achieve and maintain profitability.

In addition, President Trump has indicated that reducing the price of prescription drugs will be a priority of his administration. The implementation of any price controls or caps on prescription drugs, whether at the federal level or state level, could adversely affect our business, operating results and financial condition.

The effect of comprehensive U.S. tax reform legislation on us, whether adverse or favorable, is uncertain at this time.

On December 22, 2017, President Trump signed into law H.R. 1, "An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018" (informally titled the "Tax Cuts and Jobs Act"). Among a number of significant changes to the U.S. federal income tax rules, the Tax Cuts and Jobs Act (the "Act") reduces the marginal U.S. corporate income tax rate from 35% to 21%, limits the deduction for net interest expense, limits the deduction for net operating losses and eliminates net operating loss carrybacks, modifies or repeals many business deductions and credits, shifts the United States toward a more territorial tax system, and imposes new taxes to combat erosion of the U.S. federal income tax base. Our net deferred tax assets and liabilities will be revalued at the newly enacted U.S. corporate rate, and the impact will be recognized in our tax expense in the year of enactment. We continue to examine the impact this tax reform legislation may have on our business. However, the effect of the Tax Cuts and Jobs Act on us and our affiliates, whether adverse or favorable, is uncertain, and may not become evident for some period of time.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the principal members of our management, scientific and clinical team. Although we have entered into employment letter agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. We do not carry any “key man” insurance that would provide us with proceeds in the event of the death or disability of any key members of senior management, our investment team, or senior marketing personnel. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

A variety of risks associated with operating internationally could materially adversely affect our business.

In addition to our United States operations, we have operations in Israel through our wholly-owned subsidiary, Immune Pharmaceuticals Ltd. We face risks associated with our operations in Israel, including possible unfavorable regulatory, pricing and reimbursement, legal, political, tax and labor conditions, which could harm our business. We are also conducting and in the future plan to continue to conduct clinical trials of product candidates in Israel. We are subject to numerous risks associated with international business activities in Israel and elsewhere, including:

- compliance with differing or unexpected regulatory requirements for our products;
- compliance with Israeli laws with respect to our wholly owned subsidiary, Immune Ltd.;
- difficulties in staffing and managing foreign operations;
- foreign government taxes, regulations and permit requirements;
- United States and foreign government tariffs, trade restrictions, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, natural disasters, war, events of terrorism or political instability in particular foreign countries;
- fluctuations in currency exchange rates, which could result in increased operating expenses and reduced revenues;
- compliance with tax, employment, immigration and labor laws, regulations and restrictions for employees living or traveling abroad;
- changes in diplomatic and trade relationships; and
- challenges in enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States.

These and other risks associated with our international operations in Israel and elsewhere may materially adversely affect our business, financial condition and results of operations.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our current and future contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we are not aware of any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture our product candidates and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

Risks Related to Regulatory Development, Approval and other Legal Compliance

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to develop and then commercialize our product candidates or will not be able to do so as soon as anticipated, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development, applications for regulatory approval, and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States, by the EMA in the European Union and similar regulatory authorities outside the United States and the European Union. Failure to obtain approval of clinical trial applications may delay or prevent us from developing our drugs in one or more jurisdictions. Similarly, failure to obtain marketing approval for a product candidate (NDA, BLA, or MAA) will prevent us from commercializing that product candidate. While our executives have experience with the IND, NDA, BLA, CTA and MAA processes, we expect to rely on third parties to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing development and later marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. For example, new drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed. If any of our product candidates with such an indication receives marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the product.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive and uncertain and may ultimately fail or take many years to achieve . If additional clinical trials are required for certain jurisdictions, these trials can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved, and may ultimately be unsuccessful. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review process for each submitted product application, may cause delays in the review and approval of an application. Any new laws or regulations that have the effect of imposing additional costs or regulatory burden on pharmaceutical manufacturers, or otherwise negatively affect the industry, could adversely affect our ability to successfully commercialize our products and product candidates. In addition, President Trump has indicated that reducing the price of prescription drugs sold in the United States will be a priority of his administration and has recently proposed plans to implement this priority. The implementation of any price controls or caps on prescription drugs, whether at the federal, state level or via other relevant agencies, could adversely affect our business, operating results and financial condition.

Regulatory authorities have substantial discretion in the approval process and may reject a marketing application as deficient or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical studies and clinical trials could delay, limit or prevent marketing approval of a product candidate. Any marketing approval(s) we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Although we have met with the FDA regarding the development of bertilimumab, it is possible that the FDA may change its requirements or require us to conduct additional preclinical studies and/or clinical trials that may delay the development and approval of this drug. Unfavorable data from our clinical trials may restrict the potential development and commercialization of bertilimumab or lead to the termination of its development.

Ceplene is approved by the EMA and registered in over 30 countries in Europe and Israel. It also has Orphan Drug Designation in both the European Union and United States for AML. The FDA however, refused to file the Ceplene NDA submission due to the lack of an Overall Survival primary endpoint in the study and the lack of an IL-2 treatment alone control arm. Based on new biologic and clinical findings that have been studied and analyzed since the last communication with the FDA, we are planning further formal discussions with the FDA regarding a path forward for registration in the United States.

If we experience delays in obtaining approval or if we fail to obtain approval of any of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

The results from completed preclinical studies and early stage clinical trials may not be predictive of results in later stage trials and may not be predictive of the likelihood of regulatory approval.

We and our partners (as the case may be) discuss with, and obtain guidance from, regulatory authorities on clinical trial protocols. Over the course of conducting clinical trials, circumstances may change, such as standards of safety, efficacy or medical practice, which could affect regulatory authorities' perception of the adequacy of any of our clinical trial designs or the data we develop from our clinical trials. Clinical trial designs that were discussed with regulatory authorities prior to their commencement may subsequently be considered insufficient for approval at the time of application for regulatory approval. Changes in circumstances could affect our ability to conduct clinical trials as planned, including our ability to obtain current, timely and/or sufficient supplies of the products being tested. Even with successful clinical safety and efficacy data, we may be required to conduct additional, expensive trials to obtain regulatory approval. Any failure or significant delay in beginning new clinical trials or completing ongoing clinical trials for our product candidates, or in receiving regulatory approval for the commercialization of our product candidates, may severely harm our business and delay or prevent us from being able to generate revenue and our stock price will likely decline.

The results of our clinical trials are uncertain, which could substantially delay or prevent us from bringing our product candidates to market.

Before we can obtain regulatory approval for a product candidate, we must undertake extensive clinical testing in humans to demonstrate safety and efficacy to the satisfaction of the FDA or other regulatory agencies. Clinical trials are very expensive and difficult to design and implement. The clinical trial process is also time consuming. The commencement and completion of our clinical trials could be delayed or prevented by several factors, including:

- delays in obtaining regulatory approvals to commence or continue a study;
- delays in reaching agreement on acceptable clinical trial parameters;
- slower than expected rates of patient recruitment and enrollment;
- inability to demonstrate effectiveness or statistically significant results in our clinical trials;
- unforeseen safety issues;
- uncertain dosing issues;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

We cannot assure you that our planned clinical trials will begin or be completed on time or at all, or that they will not need to be restructured prior to completion. Significant delays in clinical testing will impede our ability to commercialize our product candidates and generate revenue from product sales and could materially increase our development costs. Completion of clinical trials may take several years or more, but the length of time generally varies according to the type, complexity, novelty and intended use of a product candidate.

There is no guarantee that we will maintain Fast Track designation for bertilimumab.

In September 2018, bertilimumab received Fast Track Designation from the FDA for the treatment of BP. The FDA may rescind Fast Track designation at any time if a product no longer meets the qualifying criteria. There is no guarantee that bertilimumab will continue to meet the Fast Track qualifying criteria.

We rely on third parties over which we have little or no control to conduct clinical trials for our product candidates and their failure to perform their obligations in a timely or competent manner may delay development and commercialization of our product candidates.

The nature of clinical trials and our business strategy requires us to rely on clinical research centers and other third parties to assist us with clinical testing and certain research and development activities. As a result, our success is dependent upon the success of these third parties in performing their responsibilities. We cannot directly control the adequacy and timeliness of the resources and expertise applied to these activities by such third parties. If such contractors do not perform their activities in an adequate or timely manner, the development and commercialization of our product candidates could be delayed. We may enter into agreements from time to time with additional third parties for our other product candidates whereby these third parties undertake significant responsibility for research, clinical trials or other aspects of obtaining FDA approval. As a result, we may face delays if these additional third parties do not conduct clinical studies and trials, or prepare or file regulatory related documents, in a timely or competent fashion. The conduct of the clinical studies by, and the regulatory strategies of, these additional third parties, over which we have limited or no control, may delay or prevent regulatory approval of our product candidates, which would delay or limit our ability to generate revenue from product sales.

We may not be able to successfully conduct clinical trials due to various process-related factors which could negatively impact our business plans. The successful start and completion of any of our clinical trials within time frames consistent with our business plans is dependent on regulatory authorities and various factors, which include, but are not limited to, our ability to:

- recruit and retain employees, consultants or contractors with the required level of expertise;
- recruit and retain sufficient patients needed to conduct a clinical trial;
- enroll and retain participants, which is a function of many factors, including the size of the relevant population, the proximity of participants to clinical sites, activities of patient advocacy groups, the eligibility criteria for the trial, the existence of competing clinical trials, the availability of alternative or new treatments, side effects from the therapy, lack of efficacy, personal issues and ease of participation;
- timely and effectively contract with (under reasonable terms), manage and work with investigators, institutions, hospitals and the contract research organizations ("CROs") involved in the clinical trial;
- negotiate contracts and other related documents with clinical trial parties and institutional review boards, such as informed consents, CRO agreements and site agreements, which can be subject to extensive negotiations that could cause significant delays in the clinical trial process, with terms possibly varying significantly among different trial sites and CROs and possibly subjecting us to various risks;
- ensure adherence to trial designs and protocols agreed upon and approved by regulatory authorities and applicable legal and regulatory guidelines;
- manage or resolve unforeseen adverse side effects during a clinical trial;
- conduct the clinical trials in a cost-effective manner, including managing foreign currency risk in clinical trials conducted in foreign jurisdictions and cost increases due to unforeseen or unexpected complications such as enrollment delays, or needing to outsource certain Company functions during the clinical trial; and
- execute clinical trial designs and protocols approved by regulatory authorities without deficiencies.

If we are not able to manage the clinical trial process successfully, our business plans could be delayed or be rendered unfeasible for us to execute within our planned or required time frames, or at all.

If we receive regulatory approval, our marketed products will also be subject to ongoing FDA and/or foreign regulatory agency obligations and continued regulatory review, and if we fail to comply with these regulations, we could lose approvals to market any products, and our business would be seriously harmed.

Following initial regulatory approval of any of our product candidates, we will be subject to continuing regulatory review, including review of adverse experiences and clinical results that are reported after our products become commercially available. This would include results from any post-marketing tests or vigilance required as a condition of approval. The manufacturer and manufacturing facilities we use to make any of our product candidates will also be subject to periodic review and inspection by the FDA or foreign regulatory agencies. If a previously unknown problem or problems with a product, manufacturing or laboratory facility used by us is discovered, the FDA or foreign regulatory agency may impose restrictions on that product or on the manufacturing facility, including requiring us to withdraw the product from the market. Any changes to an approved product, including the way it is manufactured or promoted, often require FDA approval before the product, as modified, can be marketed. Our manufacturers and we will be subject to ongoing FDA requirements for submission of safety and other post-market information. If we or our manufacturers fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications;
- impose restrictions on operations;
- close the facilities of manufacturers; or
- seize or detain products or require a product recall.

In addition, the policies of the FDA or other applicable regulatory agencies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature, or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad.

Any regulatory approval we receive for our product candidates will be limited to those indications and conditions for which we are able to show clinical safety and efficacy.

Any regulatory approval that we may receive for our current or future product candidates will be limited to those diseases and indications for which such product candidates are clinically demonstrated to be safe and effective. For example, in addition to the FDA approval required for new formulations, any new indication to an approved product also requires FDA approval. If we are not able to obtain regulatory approval for a broad range of indications for our product candidates, our ability to effectively market and sell our product candidates may be greatly reduced and may harm our ability to generate revenue.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by regulatory authorities, our regulatory approvals will be limited to those indications that are specifically submitted to the regulatory agency for review. These "off-label" uses are common across medical specialties and may constitute the best treatment for many patients in varied circumstances. Regulatory authorities in the United States generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow regulatory rules and guidelines relating to promotion and advertising may cause the regulatory agency to delay its approval or refuse to approve a product, the suspension or withdrawal of an approved product from the market, recalls, fines, disgorgement of money, operating restrictions, injunctions or criminal prosecutions and penalties, any of which could harm our business.

If we market any approved products in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.

The FDA enforces laws and regulations that require that the promotion of pharmaceutical products be consistent with the approved prescribing information. While physicians may prescribe an approved product for a so-called "off label" use, it is unlawful for a pharmaceutical company to promote its products in a manner that is inconsistent with its approved label and any company which engages in such conduct can subject that company to significant liability. Similarly, industry codes in the EU and other foreign jurisdictions prohibit companies from engaging in off-label promotion and regulatory agencies in various countries enforce violations of the code with civil penalties. While we intend to ensure that our promotional materials are consistent with our label, regulatory agencies may disagree with our assessment and may issue untitled letters, warning letters or may institute other civil or criminal enforcement proceedings. In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include the U.S. Anti-Kickback Statute, the U.S. False Claims Act and similar state laws. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

The U.S. Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not, in all cases, meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, recent health care reform legislation has strengthened these laws. For example, the Health Care Reform Law, among other things, amends the intent requirement of the U.S. Anti-Kickback Statute and criminal health care fraud statutes; a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Health Care Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the U.S. Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the U.S. False Claims Act. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid.

Over the past few years, several pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicare or Medicaid for non-covered, off-label uses; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Most states also have statutes or regulations similar to the U.S. Anti-Kickback Statute and the U.S. False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include substantial civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, substantial criminal fines and imprisonment.

Our lead product candidate, bertilimumab, is a biologic and may face biosimilar competition.

With the enactment of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") as part of the Health Care Reform Law, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created in the United States The new abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable." The FDA defines an interchangeable biosimilar as a product that, in terms of safety or diminished efficacy, presents no greater risk when switching between the biosimilar and its reference product than the risk of using the reference product alone. Under the BPCIA, an application for a biosimilar product cannot be submitted to the FDA until four years, or approved by the FDA until 12 years, after the original brand product identified as the reference product was approved under a BLA.

We believe that if bertilimumab or any of our other product candidates were to be approved as biological products under a BLA, such approved products should qualify for the 12-year period of exclusivity. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Risks Related to Our Dependence on Third Parties

Any collaborations that we enter into could be important to our business. If we are unable to maintain any of these collaborations, or if these collaborations are not successful, our business could be adversely affected.

We intend to enter into collaborations with other biopharmaceutical companies to develop our product candidates and generate funding for our research programs. Currently, we have no agreement with any commercial partner and we may never secure a commercial partner. These collaborations may pose a number of risks, including:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we would potentially lose the right to pursue further development or commercialization of the applicable product candidates;
- collaborators may learn about our technology and use this knowledge to compete with us in the future;
- results of collaborators' preclinical or clinical trials could produce results that harm or impair other products using our technology;
- there may be conflicts between different collaborators that could negatively affect those collaborations and potentially others; and
- the number and type of our collaborations could adversely affect our attractiveness to future collaborators or acquirers.

If any collaborations we enter into do not result in the successful development and commercialization of our products or if one of our collaborators terminates its agreement with us, we may not receive any future research and development funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our continued development of our product candidates could be delayed and we may need additional resources to develop additional product candidates. All of the risks relating to our product development, regulatory approval and commercialization also apply to the activities of our collaborators and there can be no assurance that our collaborations will produce positive results or successful products on a timely basis or at all.

Additionally, subject to its contractual obligations to us, if a collaborator of ours is involved in a business combination or otherwise changes its business priorities, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities and our stock price could be adversely affected.

We may in the future determine to collaborate with additional pharmaceutical and biotechnology companies for development and potential commercialization of therapeutic products. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may not be able to access therapeutic payloads that would be suitable to development with our platform, have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our product platform and our business may be materially and adversely affected.

We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

Currently, we rely on third-party CROs to conduct our ongoing clinical trials and do not plan to independently conduct clinical trials of our other product candidates. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct and manage our clinical trials. These agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that would delay our product development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with regulatory standards, commonly referred to as good clinical practices ("GCPs"), for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Other countries' regulatory agencies also have requirements for clinical trials with which we must comply. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

We contract with third parties for the manufacture of our product candidates for preclinical and clinical testing and expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities that meet the FDA's current cGMP requirements for the production of any product candidates used in humans. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for the commercial manufacture if any of our product candidates once they receive marketing approval. This reliance on third parties increases the risk that we may not have sufficient quantities of our product candidates on a timely basis or at all or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture our product according to our specifications;
- failure to manufacture our product according to our schedule or at all;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for required raw materials used in the manufacture of our product candidates, including our lead product candidate bertilimumab. If our contract manufacturer cannot perform as agreed, we may be required to replace such manufacturer and we may be unable to replace them on a timely basis or at all.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

Risks Related to the Commercialization of Our Product Candidates

Even if any of our product candidates (other than Ceplene) receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Other than Ceplene, which has been approved for sale in the European Union, if any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well established in the medical community, and physicians may continue to rely on these treatments. In addition, many new drugs have been recently approved and many more are in the pipeline for the same diseases for which we are developing our product candidates. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- efficacy, safety and other potential advantages compared to alternative treatments;
- ability to offer products for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- strength of marketing and distribution support;
- availability of third-party coverage and adequate reimbursement for our product candidates;
- prevalence and severity of their side effects;
- any restrictions on the use of our products together with other medications;
- interactions of our products with other medicines patients are taking; and
- inability of certain types of patients to take the product.

If we are unable to establish effective sales, marketing and distribution capabilities or enter into agreements with third parties with such capabilities, we may not be successful in commercializing our product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product for which we obtain marketing approval, we will need to establish a sales and marketing organization or make arrangements with third parties to perform sales and marketing functions.

In the future, we expect to build a focused specialty sales and marketing infrastructure to market or co-promote some of our product candidates in the United States and potentially elsewhere, if and when they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or educate physicians on the benefits of our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- inability to obtain sufficient coverage and reimbursement from third-party payors and governmental agencies.

Outside the United States, we expect to rely on third parties to sell, market and distribute our product candidates. We may not be successful in entering into arrangements with such third parties or may be unable to do so on terms that are favorable to us. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our product candidates. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources, established presence in the market and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors.

Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, sales and marketing and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. Major competing products to our lead drug, bertilimumab, such as Remicade and Humira are expected to become available on a generic basis over the coming years. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive generic products. Multiple other new drugs will be launched prior to bertilimumab in its various target indications but may limit its potential market acceptance. NanomAbs are competing with other ligand nanoparticle conjugates developed by well-funded companies such as BIND Therapeutics and Merrimack. They are also competing with other types of Bio-Conjugates including antibody drug conjugates developed by Seattle Genetics and Immunogen. Insufficient funding or inability to secure timely corporate partnerships will prevent us from successfully developing the commercial opportunity with NanomAbs.

Even if we are able to commercialize any product candidates (other than Ceplene), the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product-licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control, including possible price reductions, even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy period of time, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the United States healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be sufficient to generate a profit. Reimbursement may affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved for by the FDA or similar regulatory authorities outside the United States Moreover, eligibility for reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

We currently hold $5.0 million in clinical trial liability insurance coverage in the aggregate and per incident, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Our Intellectual Property

Our ability to protect our intellectual property rights will be critically important to the success of our business, and we may not be able to protect or enforce these rights in the United States or abroad.

We own or hold licenses to a number of issued United States patents and United States pending patent applications, as well as foreign patents and patent applications. Our success depends in part on our ability to obtain patent protection both in the United States and in other countries for our product candidates, as well as the methods for treating patients in the product indications using these product candidates. Our ability to protect our product candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Even if our product candidates, as well as methods for treating patients for prescribed indications using these product candidates are covered by valid and enforceable patents and have claims with sufficient scope, disclosure and support in the specification, the patents will provide protection only for a limited amount of time. Accordingly, rights under any issued patents may not provide us with sufficient protection for our product candidates or provide sufficient protection to afford us a commercial advantage against competitive products or processes.

In addition, we cannot guarantee that any patents issued from any pending or future patent applications owned by or licensed to us. Even if patents have issued or will issue, we cannot guarantee that the claims of these patents are or will be valid or enforceable or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. Furthermore, different countries have different procedures for obtaining patents, and patents issued in different countries offer different degrees of protection against use of the patented invention by others. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

The patent positions of biotechnology companies, including our patent position, involve complex legal and factual questions, and, therefore, validity and enforceability cannot be predicted with certainty. Patents may be challenged, deemed unenforceable, invalidated, or circumvented. Our patents can be challenged by our competitors who can argue that our patents are invalid, unenforceable, lack utility, or sufficient written description or enablement, or that the claims of the issued patents should be limited or narrowly construed. Patents also will not protect our product candidates if competitors devise ways of making or using these product candidates without legally infringing our patents. The Federal Food, Drug, and Cosmetic Act and FDA regulations and policies create a regulatory environment that encourages companies to challenge branded drug patents or to create non-infringing versions of a patented product in order to facilitate the approval of abbreviated new drug applications for generic substitutes. These same types of incentives encourage competitors to submit new drug applications that rely on literature and clinical data not prepared for or by the drug sponsor, providing a less burdensome pathway to approval.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.
- We or our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing on our intellectual property rights.
- It is possible that our pending patent applications will not lead to issued patents.
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.
- Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.
- We may not develop additional proprietary technologies that are patentable.
- The patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our technologies, product candidates, and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets and we have the funds to enforce our rights, if necessary.

The expiration of our owned or licensed patents before completing the research and development of our product candidates and receiving all required approvals in order to sell and distribute the products on a commercial scale can adversely affect our business and results of operations.

In addition, the laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the United States If we fail to apply for intellectual property protection or if we cannot adequately protect our intellectual property rights in these foreign countries, our competitors may be able to compete more effectively against us, which could adversely affect our competitive position, as well as our business, financial condition and results of operations.

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Litigation regarding patents, patent applications and other proprietary rights may be expensive and time consuming. If we are involved in such litigation, it could cause delays in bringing product candidates to market and harm our ability to operate.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. The pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents in the future and allege that the use of our technologies infringes these patent claims or that we are employing their proprietary technology without authorization.

Litigation relating to the ownership and use of intellectual property is expensive, and our position as a relatively small company in an industry dominated by very large companies may cause us to be at a significant disadvantage in defending our intellectual property rights and in defending against claims that our technology infringes or misappropriates third party intellectual property rights. However, we may seek to use various post- grant administrative proceedings, including new procedures created under the America Invents Act, to invalidate potentially overly-broad third-party rights. Even if we are able to defend our position, the cost of doing so may adversely affect our ability to grow, generate revenue or become profitable. Although we have not yet experienced any patent litigation, we may in the future be subject to such litigation and may not be able to protect our intellectual property at a reasonable cost, or at all, if such litigation is initiated. The outcome of litigation is always uncertain, and in some cases could include judgments against us that require us to pay damages, enjoin us from certain activities or otherwise affect our legal or contractual rights, which could have a significant adverse effect on our business.

In addition, third parties may challenge or infringe upon our existing or future patents. Proceedings involving our patents or patent applications or those of others could result in adverse decisions regarding the patentability of our inventions relating to our product candidates and/or the enforceability, validity or scope of protection offered by our patents relating to our product candidates.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may:

- incur substantial monetary damages;
- encounter significant delays in bringing our product candidates to market; and/or
- be precluded from participating in the manufacture, use or sale of our product candidates or methods of treatment requiring licenses.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including Patent Office administrative proceedings, such as inter-party reviews, and reexamination proceedings before the USPTO or oppositions and revocations and other comparable proceedings in foreign jurisdictions. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

Despite safe harbor provisions, third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents, of which we are currently unaware, with claims to materials, formulations, methods of doing research or library screening, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be published patent applications, which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtain a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtain a license, limit our use, or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available to us on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, limit our use, pay royalties or redesign our infringing product candidates, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Third-party claims of intellectual property infringement may prevent or delay our drug discovery and development efforts.

Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete. Because we operate in a highly technical field of research and development of small molecule drugs, we rely in part on trade secret protection in order to protect our proprietary trade secrets and unpatented know-how. However, trade secrets are difficult to protect, and we cannot be certain that others will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, to protect our trade secrets and unpatented know-how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. We also typically obtain agreements from these parties which provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

We license patent rights from third-party owners. Such licenses may be subject to early termination if we fail to comply with our obligations in our licenses with third parties, which could result in the loss of rights or technology that are material to our business.

We are a party to licenses that give us rights to third-party intellectual property that is necessary or useful for our business, and we may enter into additional licenses in the future. Under these license agreements we are obligated to pay the licensor fees, which may include annual license fees, milestone payments, royalties, a percentage of revenues associated with the licensed technology and a percentage of sublicensing revenue. In addition, under certain of such agreements, we are required to diligently pursue the development of products using the licensed technology. If we fail to comply with these obligations and fail to cure our breach within a specified period of time, the licensor may have the right to terminate the applicable license, in which event we could lose valuable rights and technology that are material to our business. If the licensor retains control of prosecution of the patents and patent applications licensed to us, we may have limited or no control over the manner in which the licensor chooses to prosecute or maintain its patents and patent applications and have limited or no right to continue to prosecute any patents or patent applications that the licensor elects to abandon. The loss of any such rights provided under our license agreements could materially harm our financial condition and operating results.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

If we are unable to obtain licenses needed for the development of our product candidates, or if we breach any of the agreements under which we license rights to patents or other intellectual property from third parties, we could lose licensing rights that are important to our business.

If we are unable to maintain and/or obtain licenses needed for the development of our product candidates in the future, we may have to develop alternatives to avoid infringing on the patents of others, potentially causing increased costs and delays in drug development and introduction or precluding the development, manufacture, or sale of planned products. Some of our licenses provide for limited periods of exclusivity that require minimum license fees and payments and/or may be extended only with the consent of the licensor. We can provide no assurance that we will be able to meet these minimum license fees in the future or that these third parties will grant extensions on any or all such licenses. This same restriction may be contained in licenses obtained in the future.

Additionally, we can provide no assurance that the patents underlying any licenses will be valid and enforceable. To the extent any products developed by us are based on licensed technology, royalty payments on the licenses will reduce our gross profit from such product sales and may render the sales of such products uneconomical. In addition, the loss of any current or future licenses or the exclusivity rights provided therein could materially harm our business financial condition and our operations.

If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

Our success also depends upon the skills, knowledge and experience of our scientific and technical personnel and our consultants and advisors, as well as our licensors. To help protect our proprietary know-how and our inventions for which patents may be unobtainable or difficult to obtain, we rely on trade secret protection and confidentiality agreements. Unlike some of our competitors, we maintain our proprietary libraries for ourselves as we believe they have proven to be superior in obtaining strong binder product candidates. To this end, we require all of our employees, consultants, advisors and contractors to enter into agreements, which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

From time to time we may need to license patents, intellectual property and proprietary technologies from third parties, which may be difficult or expensive to obtain.

We may need to obtain licenses to patents and other proprietary rights held by third parties to successfully develop, manufacture and market our drug products. As an example, it may be necessary to use a third party's proprietary technology to reformulate one of our drug products in order to improve upon the capabilities of the drug product. If we are unable to timely obtain these licenses on reasonable terms, our ability to commercially exploit such drug products may be inhibited or prevented.

Risks related to our common stock

The price of our common stock is volatile and fluctuates substantially, which could result in substantial losses for purchasers of our shareholders.

Our stock price is often volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that often is unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

- success of competitive products or technologies;
- results of clinical trials of our product candidates or those of our competitors;
- developments related to our existing or any future collaboration;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- recruitment or departure of key personnel;
- level of expenses related to any of our product candidates or clinical development programs; product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- other factors described in this "Risk Factors" section.

A significant number of shares of our common stock are issuable pursuant to outstanding shares of convertible preferred stock and warrants, and we expect to issue additional shares of common stock in the future. Conversion, exercise or sales of these securities will dilute the interests of other security holders and may depress the price of our common stock.

As of September 30, 2018, there were 44,964,491 shares of common stock outstanding, with up to 58,051,054 shares of common stock issuable upon conversion of outstanding convertible preferred stock and accreted dividends; 17,641,180 shares of common stock issuable upon exercise of outstanding warrants issued in connection with the convertible preferred stock; 10,382,865 shares potentially issuable upon conversion of May 2018 convertible notes (assuming $0.375 price); 5,498,491 shares of common stock issuable upon exercise of other outstanding warrants; and 479,663 shares of common stock issuable upon exercise of outstanding options. In addition, we may issue additional common stock and warrants from time to time to finance our operations, to fund potential acquisitions or in connection with additional stock options or other equity awards granted to our employees, officers, directors and consultants under our 2015 Plan. The issuance of additional shares of common stock, convertible securities or warrants to purchase common stock, the perception that such issuances may occur, or exercise of outstanding warrants, convertible securities or options will have a dilutive impact on other shareholders and could have a material negative effect on the market price of our common stock.

We do not have sufficient shares of common stock authorized to satisfy our obligations under certain of our outstanding securities and the failure to have sufficient shares of common stock authorized for issuance could have a material adverse effect on our company.

We are currently authorized to issue 225,000,000 shares of common stock under our Third Amended and Restated Certificate of Incorporation, as amended. As of November 5, 2018, 49,313,329 shares of common stock were issued and outstanding, 657,146 were reserved for issuance under our existing stock option and equity incentive compensation plans, and the remaining shares were reserved for issuance upon the conversion or exercise of our outstanding convertible securities and warrants. However, as of November 5, 2018, we were required to have a total of 521,644,702 shares of common stock reserved for issuance upon the conversion of the Series E Stock, the exercise of the Series E Warrants, the conversion of outstanding Debentures and the exercise of October Debenture Warrants (all hereafter defined). Accordingly, we do not currently have sufficient authorized shares of common stock available to meet our contractual obligations under these instruments.

On October 23, 2017, the Company consummated a public offering of 18,000 shares of Series E Convertible Preferred Stock (the "Series E Stock") and warrants to purchase 17,676,000 shares of Common Stock (the "Series E Warrants"). As of November 5, 2018, 3,489 shares of Series E Stock were outstanding and convertible into 69,651,017 shares of Common Stock.

On May 14, 2018, we consummated a private placement of Convertible Debentures (the "May Debentures"). The May Debentures are convertible into shares of common stock at a conversion price of $0.375 per share, subject to certain adjustments. As of the record date we had outstanding $3.9 million under the May Debentures convertible into an aggregate of 10,382,865 shares.

On October 9, 2018, we consummated a private placement of $5.5 million in principal amount of the Company's Senior Secured Redeemable Convertible Debentures (the "October Debentures" and, together with the May Debentures, the "Debentures"). The October Debentures are convertible into shares of common stock at a conversion price of $0.075 per share, subject to certain adjustments, at the option of the holder thereof or, in certain circumstances, at our option. As of November 5, 2018, 73,333,333 shares of common stock are issuable upon the conversion of the outstanding October Debentures. We also issued warrants (the "October Debenture Warrants") to purchase up to 50 million shares of common stock. As of November 5, 2018, all of the October Debenture Warrants are currently outstanding. Upon the increase of the our authorized common stock, under the terms of the October Debentures, we are required to reserve for issuance 366,666,667 additional shares of common stock.

Our obligations under the October Debentures are secured by a first priority security interests in all of our assets, other than Ceplene. If we are not able to increase our authorized common stock, we will be in default of our obligations under the October Debentures. Upon an event of default, among other things, the holders of the October Debentures could accelerate our obligation to repay the October Debentures, the holders of the October Debentures could exercise their remedies under the October Debentures, including taking ownership of the collateral. In addition, under the terms of the Series E Stock, the Series E Warrants and the October Debenture Warrants, if a holder is unable to receive shares of common stock upon the conversion or exercise of such securities, as applicable, we would be liable for certain damages under the terms of such securities. Accordingly, the failure to have sufficient shares of common stock authorized for issuance would have a material adverse effect on our company.

In addition, if we do not have sufficient available shares of common stock for issuance, we will not be able to fund our capital needs through the issuance of common stock or securities convertible, exchangeable or otherwise giving the holder the right to acquire shares of common stock. As a result, we may not be able to obtain funding necessary for our continued operations on acceptable terms, or at all. In the event that we are not able to fund our ongoing need for capital, we would not be able to continue our development work and would be required to liquidate our assets or seek bankruptcy protection.

If there is no active, liquid and orderly trading market for our common stock, which may make it difficult to for you to sell shares of our common stock purchased in this offering.

Our common stock is quoted on the OTC Markets Group Inc. OTCQB Venture Market. There is no assurance that an active, liquid and orderly trading market will be sustained. As a result, your ability to sell shares of our common stock purchased in this offering may be limited. Investors may be unable to resell shares of our common stock at or above the price for which they purchased them, at or near quoted bid prices, or at all. Further, an inactive market may also impair our ability to raise capital by selling additional equity in the future, and may impair our ability to raise capital necessary to fund our operations.

Our common stock may be subject to the "penny stock" rules of the SEC, and the trading market in our common stock is limited, which makes transactions cumbersome and may reduce the value of an investment in the stock.

Rule 15g-9 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, establishes the definition of a "penny stock," for the purposes relevant to us, as any equity security that has a market price of less than $5.00 per share or with an exercise price of less than $5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require: (i) that a broker or dealer approve a person's account for transactions in penny stocks in accordance with the provisions of Rule 15g-9; and (ii) the broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased, provided that any such purchase shall not be effected less than two business days after the broker or dealer sends such written agreement to the investor.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must: (i) obtain financial information, investment experience and investment objectives of the person; and (ii) make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be reasonably expected to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which: (i) sets forth the basis on which the broker or dealer made the suitability determination; and (ii) in highlight form, confirms that the broker or dealer received a signed, written agreement from the investor prior to the transaction. Generally, brokers may be less willing to execute transactions in securities subject to the "penny stock" rules. This may make it more difficult for investors to dispose of our common stock and cause a decline in the market value of our common stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading, the commissions payable to both the broker or dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements must be sent disclosing recent price information for the penny stock held in the account and information regarding the limited market in penny stocks. As a result, it may be more difficult to execute trades of our common stock which may have an adverse effect on the liquidity of our common stock.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about our business or us. Currently, one analyst in the U.S covers our stock. Our stock price likely would decline if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our target pre-clinical or clinical studies and operating results fail to meet the expectations.

Provisions in our Certificate of Incorporation, as amended (our "Certificate of Incorporation") and amended and restated bylaws (our "Bylaws") and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our Certificate of Incorporation and our Bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. Among other things, these provisions include those establishing:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our Board of Directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our Board of Directors to elect a director to fill a vacancy created by the expansion of the Board of Directors or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our Board of Directors;
- the ability of our Board of Directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our Board of Directors to alter our Bylaws without obtaining stockholder approval;

- the required approval of the holders of at least three-quarters (75%) of the shares entitled to vote at an election of directors to adopt, amend or repeal our Bylaws or repeal the provisions of our Certificate of Incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the Chairman of the Board of Directors, the chief executive officer, the president or the Board of Directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our Board of Directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

Moreover, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Capital appreciation, if any, will be your sole source of gain because we do not anticipate paying any cash dividends on our common stock in the foreseeable future.

We have never declared or paid cash dividends on our common stock. Currently, we intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of certain of our outstanding securities prohibit us from paying dividends on our common stock. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We may incur substantial costs in connection with litigation and other disputes.

In the ordinary course of business, we may, and in some cases have, become involved in lawsuits and other disputes such as securities claims, intellectual property challenges, including interferences declared by the USPTO, and employee matters – among other potential claims. Securities class action litigation often has been brought in the past against a company following a decline in the market price of its securities, among other reasons. This and other risks are especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. It is possible that we may not prevail in claims made against us in such disputes even after expending significant amounts of money and company resources in defending our positions in such lawsuits and disputes. The outcome of such lawsuits and disputes is inherently uncertain and may have a negative impact on our business, financial condition and results of operations.

Our management has identified internal control deficiencies, which our management believes constitute material weaknesses. Any future material weaknesses or deficiencies in our internal control over financial reporting could harm stockholder and business confidence in our financial reporting, our ability to obtain financing and other aspects of our business.

In connection with the preparation of our audited financial statements as of and for the years ended December 31, 2017 and 2016, we concluded that a material weakness existed in internal control over financial reporting. As of December 31, 2017, we carried out an assessment of the effectiveness of our internal control over financial reporting based on the framework in Internal Control — Integrated Framework (2013), updated and reissued by the Committee of Sponsoring Organizations (2013) ("COSO Framework").

Based on our evaluation under the COSO Framework, our management concluded that our internal control over financial reporting was not effective as of December 31, 2017. In connection with the above assessment, management identified material weaknesses in the control environment relating to lack of sufficient entity level controls, segregation of duties issues due to lack of sufficient accounting and finance personnel, accounting for complex financial transactions and lack of a sufficient technology infrastructure to support the financial reporting function.

A material weakness is a significant deficiency, or combination of significant deficiencies, that results in there being more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis by management or employees in the normal course of performing their assigned functions. Although we have attempted to address the identified material weaknesses, management has concluded that our internal controls over financial reporting were not effective at December 31, 2017. Therefore, we cannot be certain that, in the future, additional material weaknesses or significant deficiencies will not exist or otherwise be discovered. If our efforts to address the weakness identified are not successful, or if other deficiencies occur, these weaknesses or deficiencies could result in misstatements of our results of operations, restatements of our financial statements, a decline in our stock price and investor confidence or other material effects on our business, reputation, financial condition or liquidity.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit No.	Description of Exhibit
31.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Exchange Act Rules 13a- 14(a) and 15d-14(a), adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101.INS	XBRL Instance Document*
101.SCH	XBRL Taxonomy Extension Schema Document*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document *
101.LAB	XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document*

* Filed herewith.

SIGNATURE PAGE

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 thereunto duly authorized.

IMMUNE PHARMACEUTICALS INC.

By: /s/ Tony Fiorino
Anthony Fiorino, M.D. Ph.D.
President and Interim Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)
November 14, 2018

By: /s/ John P. Clark
John P. Clark
Controller
(Principal Accounting Officer)
November 14, 2018

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302(a) OF THE SARBANES-OXLEY ACT OF 2002

I, Dr. Anthony "Tony" Fiorino, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Immune Pharmaceuticals Inc.;

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. I am 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. 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.

Date: November 14, 2018

/s/ Tony Fiorino

Anthony Fiorino, M.D. Ph.D.
President and Interim Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Immune Pharmaceuticals Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Tony Fiorino, Principal Executive Officer and Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C § 1350, as adopted pursuant to § 906 of the Sarbanes -Oxley Act of 2002, that:

1) 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.

/s/ Tony Fiorino
Tony Fiorino, M.D. Ph.D.
Interim Chairman, President and Interim Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

November 14, 2018