

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

FORM 10-K

(Mark One)

Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
For the Fiscal Year Ended December 31, 2017

Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
For the transition period from \_\_\_\_ to \_\_\_\_

Commission File No. 001-36602

**Immune Pharmaceuticals Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**52-1841431**

(IRS Employer Identification No.)

**550 Sylvan Avenue, Englewood Cliffs, NJ 07632**

(Address of principal executive offices) (Zip code)

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

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

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.0001 per share	The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark whether the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark whether the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes   
No

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendments to this Form 10-K.

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 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

Non-accelerated filer

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 June 30, 2017, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of shares of common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate), computed by reference to the closing bid price of such shares on the NASDAQ Capital Markets was \$29,813,510.

As of March 20, 2018, the registrant had 31,903,280 shares of common stock on a post-split basis, par value \$0.0001 per share, outstanding.



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### **CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, or Form 10-K, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions. These forward-looking statements are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. All forward-looking statements speak only as of the date of this Form 10-K, are expressly qualified in their entirety by the cautionary statements included in this Form 10-K and are subject to a number of risks, uncertainties and assumptions, including those described under the sections in this Form 10-K entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Form 10-K.

These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These factors include, but are not limited to, the following:

- our limited liquidity;
- our ability to continue to meet our obligations under existing debt agreements;
- our ability to raise additional funds sufficient to meet our working capital requirements;
- our limited operating history;
- our history of operating losses since our inception;
- our ability to continue to operate as a going concern;
- our ability to maintain the listing of our common stock on NASDAQ;
- our ability to protect our intellectual property;
- risks associated with litigation;
- our reliance on collaborative partners and others for further clinical trials, development, manufacturing and commercialization of our product candidates;
- our ability to complete our planned clinical trials (or initiate other trials) in accordance with our estimated timelines due to delays;
- the cost, delays and uncertainties associated with our scientific research, product development, clinical trials and regulatory approval process;
- risks relating to the uncertainty surrounding healthcare reform, effects on the healthcare market, insurance reimbursement rates or product revenues;
- our dependence upon key personnel;
- our ability to find partners for our products on attractive terms, on a timely basis, or at all;
- our ability to obtain approval to market and commercialize any of our product candidates;
- our expectations regarding government and third-party payor coverage and reimbursement;
- the proposed spin-off of our oncology business, including the completion and timing of the spin-off and its anticipated benefits, costs and tax treatment, and
- the highly competitive nature of our business.

Further, any forward-looking statement speaks only as of the date on which it is made. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties, or how they may affect us. Except as required by law, we do not intend to update or revise the forward-looking statements in this Form 10-K after the date of this Form 10-K, whether as a result of any new information, future events, changed circumstances or otherwise. This Form 10-K also contains market data related to our business and industry. This market data includes projections that are based on a number of assumptions. If these assumptions turn out to be incorrect, actual results may differ from the projections based on these assumptions. As a result, our markets may not grow at the rates projected by these data, or at all. The failure of these markets to grow at these projected rates may have a material adverse effect on our business, financial condition, results of operations and the market price of our common stock.

## PART I

### ITEM 1. BUSINESS.

#### Overview

Immune Pharmaceuticals Inc., together with its subsidiaries (collectively, “Immune” or the “Company” or “us,” “we,” or “our”) is 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, fully human, anti-eotaxin-1 antibody, currently in phase 2 clinical trials for bullous pemphigoid (“BP”) and ulcerative colitis (“UC”). Also, we are developing “NanoCyclo,” a topical nano-encapsulated formulation of cyclosporine, for the treatment of atopic dermatitis (“AD”) and psoriasis.

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.

Our oncology portfolio includes Ceplene, which is approved in the European Union for the maintenance of remission in patients with Acute Myeloid Leukemia (“AML”) and Azixa and crolibulin, two clinical-stage, vascular disrupting agents (“VDA”) which have demonstrated encouraging preliminary proof of concept study results. In addition, we have two oncology platform assets, consisting of a bispecific antibody platform and a nanotechnology combination platform, which we refer to as “NanomAbs.” We intend to divest these oncology assets, which are held in our oncology-focused subsidiary, Cytovia Inc (“Cytovia”).

Our current product portfolio is summarized below:

#### *Summary of Immune’s Asset Portfolio*

<b>Program</b>	<b>Primary Indication(s)</b>	<b>Status</b>
<b>Bertilimumab</b>	Bullous Pemphigoid	Phase 2
	Ulcerative colitis	Phase 2
<b>NanoCyclo</b>	Atopic Dermatitis, Psoriasis	Preclinical
<b>Ceplene/IL-2</b>	Acute Myeloid Leukemia	Phase 3 (US)
		Approved (European Union)
<b>Crolibulin</b>	Solid Tumors	Phase 2
<b>Azixa</b>	Glioblastoma multiforme	Phase 2
<b>NanomAbs</b>	Solid Tumors	Preclinical
<b>Bispecific Antibodies</b>	Oncology	Preclinical
<b>AmiKet/AmiKet Nano</b>	Neuropathic Pain	Phase 2
<b>Lido PAIN</b>	Pain	Phase 2

Ceplene<sup>®</sup>, LidoPain<sup>®</sup>, Epicept<sup>®</sup>, Amiket<sup>™</sup>, and Azixa<sup>™</sup> are trademarks that we own. This Annual Report on Form 10-K contains references to our trademarks. Solely for convenience, trademarks and trade names referred to in this report, including logos, artwork and other visual displays, may appear without the <sup>®</sup> or <sup>™</sup> symbols, but such references, or the lack thereof, are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

#### History- Reverse Merger

On August 25, 2013, Immune Pharmaceuticals Ltd., a privately held Israeli company (“Immune Ltd.”) consummated a merger transaction (the “Merger”) with EpiCept Corporation (“EpiCept”), a Delaware corporation, pursuant to a definitive Merger Agreement and Plan of Reorganization, dated as of November 7, 2012, as amended (the “Merger Agreement”) by and among EpicEpt, EpiCept Israel Ltd., an Israeli company and a wholly-owned subsidiary of EpiCept (“Merger Sub”) and Immune Ltd. Pursuant to the Merger Agreement, Merger Sub merged with and into Immune Ltd., following which Immune Ltd. became a wholly-owned subsidiary of EpiCept and the former stockholders of Immune Ltd. received shares of EpiCept, which constituted a majority of the outstanding shares of Immune. EpiCept changed its name to Immune Pharmaceuticals Inc. upon consummation of the Merger.

## **Reverse Stock-Split**

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 Form 10-K have been reflected on a post-split basis.

## **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 on our core assets, bertilimumab and NanoCyclo product candidates, while streamlining our operations by divesting or spinning off our non-core assets, including our oncology asset portfolio consisting of Ceplene, Azixa, crolibulin, NanomAbs and our bispecific antibody platform. We announced our plan to pursue a spin-off of Cytovia Inc. (“Cytovia”) our oncology focused subsidiary into a separate, stand-alone company, under the management and leadership of our founder and former Chief Executive Officer, Dr. Daniel Teper. We intend to develop bertilimumab for a variety of indications and NanoCyclo for the treatment of AD and moderate psoriasis. We are evaluating AmiKet and AmiKet Nano for the treatment of PHN and DNP and will determine an optimal path forward for this program.

Cytovia will focus on the development and commercialization of novel oncology and hematology therapeutics. Consistent with our objective to preserve our capital to support development of bertilimumab and NanoCyclo, Cytovia, led by Dr. Teper, is seeking separate capitalization from third-party sources for Cytovia’s start-up costs, expenses of the spin-off, payment of costs related to Ceplene and other relevant items. This capitalization from third party sources is a prerequisite to further continuation of the spin-off process. If the necessary capitalization is not obtained in the near future, we do not expect to pursue completion of the spin-off process and instead will determine the optimal path forward to monetize these assets. This strategy will allow us to focus our resources and build upon our promising clinical stage pipeline in immunotherapy and dermatology related indications and thereby unlock our intrinsic value.

## **Products and Programs**

### ***Bertilimumab***

Our lead product candidate, bertilimumab, is a first-in-class, human monoclonal antibody that targets eotaxin-1, a chemokine that plays a role in both innate and adaptive immune responses and modulates the cross-talk between key cells involved in inflammation. Chemokines are small proteins that can act as chemical attractants of inflammatory cells to sites of inflammation and infection. We licensed all non-ocular uses of bertilimumab from iCo Therapeutics Inc. in 2011.

Eotaxin-1 has been shown to be a chemoattractant for eosinophils, which are inflammatory cells that play an important role in the pathogenesis of allergic airway diseases, inflammatory bowel disease, skin conditions and potentially in many other conditions. By neutralizing eotaxin-1, bertilimumab may prevent the migration and activation of eosinophils, thus helping to relieve inflammatory conditions associated with eotaxin-1. Bertilimumab has potential applications as a treatment for a variety of allergic and inflammatory diseases, including BP, inflammatory bowel disease, AD, and asthma, among others. Bertilimumab was shown to have biological activity in a variety of preclinical studies, with high affinity and specificity for human eotaxin-1 and was safe and well-tolerated in primates. In a phase 1 clinical study consisting of a single intravenous (“IV”) administration to healthy volunteers, bertilimumab demonstrated excellent safety and tolerability (no significant adverse events and no anti-bertilimumab antibodies) and demonstrated an elimination half-life consistent with biweekly dosing. In phase 2 studies, bertilimumab has been safely administered via intravenous, intranasal and ocular routes of administration and has shown activity in patients with allergic rhinitis. Currently, bertilimumab is being studied in two active clinical programs, BP and UC.

We believe that if successfully developed and approved by the United States Food and Drug Administration (“FDA”), European Medicines Agency (“EMA”) or other regulatory authorities, bertilimumab could address both large and orphan underserved markets that have limited treatment alternatives.

### ***Bertilimumab and Bullous Pemphigoid***

Published studies have suggested that eotaxin-1 plays a role in the pathogenesis of BP. Therefore, bertilimumab, which blocks eotaxin-1 has the potential to be an effective therapeutic agent for BP patients.

In October 2015, we submitted an Investigational New Drug Application (“IND”) to the FDA for the study of bertilimumab in patients with BP. In February 2016, we launched a phase 2a clinical trial, IMNP BP-01, “*Evaluation of Safety, Efficacy and Pharmacodynamic Effect of Bertilimumab in Patients with Bullous Pemphigoid*” (ClinicalTrials.gov Identifier: NCT02226146). This trial is an open-label, single arm study in adults with moderate to extensive BP being conducted at sites in the United States and Israel. The primary end point is safety and secondary endpoints include a variety of efficacy measures related to clinical signs and symptoms and tapering of systemic corticosteroids. Subjects in this study receive bertilimumab IV at a dose of 10 mg/kg on days 0, 12 and 28 and are followed for a total of 84 days. In addition, they receive oral prednisone at a maximum initial dose of 30 mg/day, which is to be tapered rapidly according to the subject’s clinical status.

In February 2017, we reported results from the first three subjects enrolled in the study and in September 2017, we announced results from the first six subjects enrolled. These results were presented at the Late-Breaking Research Forums during the 2018 American Academy of Dermatology Annual Meeting in San Diego, CA in February 2018.

The interim analysis showed that the six subjects in the study experienced a decline in the Bullous Pemphigoid Disease Area Index (BPDAI) Total Activity Score of 85% (p=0.0096). All six subjects in the study achieved a greater than 50% reduction in their BPDAI Total Activity Score by the final assessment, and four of the six patients had a greater than 90% reduction. Bertilimumab was well tolerated in all six subjects and no serious adverse events were reported. Moreover, these six subjects received approximately 30 mg per day less prednisone over the course of the study than they would have been expected to receive in a standard BP treatment regimen.

In October 2014, we requested Orphan Drug Designation from the FDA for the use of bertilimumab in treating BP. The FDA did not grant the request because the application lacked data from a disease-specific animal model or clinical trials. In February 2017, we filed a new request, including preliminary results from three subjects in the BP-01 clinical trial. In August 2017, the FDA indicated that the additional clinical data that we provided was not sufficient to support an Orphan Drug Designation. We will determine the timing of a new request based on our assessment of the robustness of the supporting data. We do not intend to disclose the timing or content of any subsequent Orphan Drug Designation requests submitted to FDA or any other regulatory agency.

### ***Bertilimumab and Ulcerative Colitis***

Published studies have suggested that eotaxin-1 plays a role in the pathogenesis of UC. In June 2015, we initiated a phase 2 study, IMNP UC-01, “*Evaluation of Safety, Efficacy, Pharmacokinetics and Pharmacodynamics of Bertilimumab in Patients with Active Moderate to Severe Ulcerative Colitis*” (ClinicalTrials.gov Identifier: NCT01671956) at sites in Israel. In 2016, we expanded the study to include sites in Russia.

IMNP UC-01 is a randomized, double blind, placebo-controlled trial in adult patients with active moderate-to-severe UC. Subjects are randomized in a 2:1 ratio to receive bertilimumab or placebo and receive bertilimumab 10 mg/kg IV or placebo on days 0 and 14 and 28, and are followed for safety and efficacy measures for 12 weeks. The primary end point is clinical response assessed by the Mayo Clinic Ulcerative Colitis Disease Index at 8 weeks. Secondary end points include assessment of mucosal injury and clinical remission.

### ***NanoCyclo***

In January 2016, we entered into a worldwide exclusive licensing agreement with BioNanoSim Ltd. (“BNS”) an Israeli company led by Professor Simon Benita, former Head of the Drug Research Institute at the Hebrew University of Jerusalem, for the development of a topical nano-encapsulated formulation of cyclosporine.

Cyclosporine, an oral immunosuppressive drug used for organ transplantation and the treatment of a variety of immunologic diseases, does not penetrate the skin and thus has never been developed to treat dermatological inflammatory conditions such as atopic dermatitis and psoriasis. The NanoCyclo technology is designed to deliver cyclosporine into the epidermis and dermis. NanoCyclo has shown efficacy in several preclinical models of skin inflammation.

We are conducting additional preclinical efficacy and toxicity studies on NanoCyclo to select a formulation to move forward into clinical development. Because cyclosporine is no longer patent-protected and is approved for systemic administration, NanoCyclo potentially could be developed under the FDA’s 505(b)(2) pathway, which is typically a faster process than the traditional 505(b)(1) regulatory submission required for new chemical entities. We intend to develop NanoCyclo as a topical treatment for atopic dermatitis and psoriasis.

### ***AmiKet and AmiKet Nano***

AmiKet is a topical analgesic cream containing two FDA-approved drugs: amitriptyline, an antidepressant often used to treat chronic pain disorders; and ketamine, an N-methyl-D-aspartic acid (“NMDA”) antagonist that is used as an intravenous anesthetic. AmiKet has completed phase 1 and 2 clinical trials involving 1,700 patients for the treatment of neuropathic pain. In 2010, the FDA granted AmiKet Orphan Drug Designation for the treatment of PHN. A PHN phase 3 clinical trial has been designed based on prior clinical studies, including a phase 2 trial that showed comparable efficacy of AmiKet and oral gabapentin (ClinicalTrials.gov Identifier: NCT00475904). In addition to PHN, AmiKet may be developed for the treatment of DPN and chemotherapy-induced neuropathic pain.

We are conducting research on a new and improved formulation of AmiKet, which we refer to as “AmiKet Nano,”utilizing a proprietary and patent-protected nano-encapsulation technology developed by Professor Benita and licensed from Yissum Research Development Company, the technology transfer company of the Hebrew University of Jerusalem, Ltd. AmiKet Nano may offer similar efficacy or improved efficacy with lower doses of amitriptyline and ketamine, thus improving the therapeutic index and safety profile of the program. We are determining the optimal path forward for this program.

### ***LidoPAIN***

LidoPAIN is an adhesive-backed, lidocaine-based patch for the treatment of acute lower back pain. In 2003, our predecessor, EpiCept Corporation, entered into a license agreement with Endo Pharmaceuticals Inc. (“Endo”) pursuant to which it granted to Endo the exclusive worldwide right to commercialize LidoPAIN and to use certain of our patents for the development of certain other non-sterile, topical lidocaine patches, including Lidoderm, Endo’s non-sterile topical lidocaine-containing patch for the treatment of chronic lower back pain. In July 2015, the license agreement was amended. We transferred to Endo its previously licensed patents related to the use of topical lidocaine in acute and chronic back pain and Endo granted to us a royalty-free, non-exclusive, fully transferable license to those patents. Endo will make undisclosed milestone payments to us if Endo receives approval for a back-pain indication for a lidocaine-based product. We regained full exclusive rights to develop, commercialize and license LidoPAIN. We intend to divest this non-core asset.

### ***Oncology***

In April 2017, we announced our plan to pursue a spin-off of Cytovia, our oncology subsidiary, into a separate, stand-alone company. Our oncology programs include the following:

#### ***Ceplene***

Ceplene (histamine dihydrochloride), our lead oncology product candidate, is a first-in-class, small molecule, targeting the Histamine-2 Receptor. Ceplene was approved for marketing in Europe in 2008 and Israel in 2010 and has been granted Orphan Drug Designation in the United States and E.U. for the treatment of AML.

We acquired the rights to Ceplene in the United States and Israel in the Merger. On June 15, 2017, we entered into an Asset Purchase Agreement with Meda Pharma Sarl, a Mylan NV company, to repurchase assets relating to Ceplene, including the right to commercialize Ceplene in Europe and to register and commercialize Ceplene in certain other countries (the “Asset Purchase Agreement”). Cytovia intends to undertake commercialization efforts in Europe, Asia and Latin America.

Cytovia intends to develop Ceplene for use in combination with low dose Interleukin-2 (“IL-2”) (Proleukin<sup>®</sup>) to overcome immunosuppression in AML and potentially other malignancies. Ceplene is thought to suppress tumor growth by inhibiting NOX-2, in turn inhibiting macrophage and leukemic cell reactive oxygen species production, allowing IL-2 activation of natural killer (“NK”) and cytotoxic T cells, with consequent leukemic cell death. Data from a European study presented at the American Association of Cancer Research Annual Meeting in April 2016 demonstrated that Ceplene in conjunction with IL-2 is active in monocytic forms of AML.

Cytovia plans to finalize a phase 3 protocol for a single pivotal study assessing overall survival in AML to support an NDA filing in the United States for Ceplene in remission maintenance in AML. The study will compare Ceplene plus low dose IL-2 to placebo plus low dose IL-2. The primary end point will be overall survival at 2 years with a secondary end point of Leukemia Free Survival. An independent interim analysis will be conducted at one year for both futility, and to assess the one-year efficacy based on Event Free Survival.

### ***Crolibulin***

Crolibulin is a novel small molecule VDA and apoptosis inducer for the treatment of patients with solid tumors and is a novel microtubule destabilizer that is selective for pathologic vasculature. Crolibulin has shown promising vascular targeting activity with potent anti-tumor activity in preclinical in vitro and in vivo studies and in a Phase I clinical trial conducted in part by the National Cancer Research Institute. The molecule has been shown to induce tumor cell apoptosis and selectively inhibit growth of proliferating cell lines, including multi-drug resistant cell lines. Murine models of human tumor xenografts demonstrated crolibulin inhibits growth of established tumors of a number of different cancer types. In preclinical animal tumor models, combination therapy has demonstrated synergistic activity with cytotoxic drugs as well as anti-angiogenic drugs. This may support further development of crolibulin in cancers other than anaplastic thyroid cancer, including but not limited to refractory ovarian cancer and neuro-endocrine tumors.

### ***Azixa***

Azixa (verubulin) is a novel microtubular destabilizer that functions as a VDA. It evades multidrug resistance pumps, thus crossing the blood-brain-barrier and achieving high central nervous system concentrations. In phase 1 and 2 clinical trials in glioblastoma multiforme (“GBM”), evidence of objective response was seen, including in patients who had failed previous bevacizumab (Avastin) therapy. Azixa has Orphan Drug Designation for GBM in the United States.

### ***NanomAbs***

NanomAbs is an antibody-drug conjugate platform that allows the targeted delivery of combinations of chemotherapeutics into cancer cells. NanomAbs is potentially capable of generating novel drugs with enhanced profiles as compared to stand-alone antibodies. The technology conjugates monoclonal antibodies to drug loaded nanoparticles to target drugs to specific cells. NanomAbs selectively accumulates in diseased tissues and cells, resulting in higher drug accumulation at the site of action with minimal off-target exposure.

### ***Bispecific Antibodies***

In December 2015, we published data regarding a novel bispecific antibody platform for the production of tetravalent IgG1-like bispecific antibodies. The prototype bispecific antibody retained effector functions and mediated redirect killing of target cells by cytokine induced killer T cells demonstrating direct anti-cancer effects in vitro as well as anti-tumor activity and improved survival in a mouse xenograft model of disseminated leukemia. We believe that this platform may be used to generate novel bispecific antibodies against immuno-oncology targets. This work was developed by a collaborative European consortium and funded in part by a European grant.

## Material Agreements

### *Bertilimumab*

#### *iCo Therapeutics Inc.*

In December 2010, iCo Therapeutics Inc. (“iCo”) granted Immune an option to sub-license the use and development of bertilimumab for all human indications, other than ocular indications, pursuant to a Product Sublicense Agreement. iCo obtained exclusive license rights to intellectual property relating to bertilimumab pursuant to a license agreement with Cambridge Antibody Technology Group Plc dated December 20, 2006, and to which we became a party. On June 24, 2011, we exercised our option and obtained a worldwide license from iCo pursuant to the Product Sublicense Agreement. We paid iCo \$0.5 million and issued to iCo common stock and warrants to purchase our common stock. iCo is entitled to \$32.0 million in milestone payments plus royalties on future development and sales of bertilimumab. Milestones include the first dosing in a phase 3 clinical trial, filing a Biologics License Application/Marketing Authorization Application (“BLA/MMA”) and approval of a BLA/MAA in any indication and the achievement of \$100 million in aggregate sales of licensed products for use in IBD. The term of the license lasts until the expiration of all payment obligations on a country-by-country basis, being on the later to occur of (a) the tenth (10th) anniversary of the first commercial sale of a licensed product in an applicable country or (b) the expiration date in such country of the last to expire of any issued iCo patent that includes at least one valid claim that claims the particular licensed product or its manufacture or use, at which point the license will be deemed fully paid, perpetual and irrevocable with respect to that country. iCo retains the worldwide exclusive right to the use of bertilimumab (iCo-008) for all ocular applications.

#### *Lonza Sales AG*

In May 2012, Lonza Sales AG (“Lonza”) granted us a non-exclusive worldwide license (the “Lonza License”) under certain know-how and patent rights to use, develop, manufacture, market, sell, offer, distribute, import and export bertilimumab produced through the use of Lonza’s system of cell lines, vectors and know-how. We are not obligated to manufacture bertilimumab through the use of Lonza’s system.

We agreed to pay Lonza (i) a royalty of 1% of the net selling price of bertilimumab manufactured by Lonza; or (ii) an annual payment of approximately \$0.1 million (first payable upon commencement of phase 2 clinical trials) plus a royalty of 1.5% of the net selling price of bertilimumab if it is manufactured by us or one of our strategic partners; or (iii) an annual payment of approximately \$0.5 million (first payable upon commencement of the relevant sublicense) plus a royalty of 2% of the net selling price of bertilimumab if it is manufactured by any party other than Lonza, us or one of our strategic partners. The royalties are subject to a 50% reduction based on the lack of certain patent protections, including the expiration of patents, on a country-by-country basis. Unless earlier terminated, the license agreement continues until the expiration of the last enforceable valid claim to the licensed patent rights, which began to expire in 2014 and continued to expire between 2015 and 2016, or for so long as the System Know How (as defined in the License) is identified and remains secret and substantial, whichever is later. We considered the System Know How as secret and substantial as of December 31, 2017 and accordingly, the license remains in effect as of that date.

For the year ended December 31, 2017, there were no payments due related to this license.

On June 27, 2011, we entered into a manufacturing agreement with Lonza for the manufacture of bertilimumab for use in our phase 2 bertilimumab clinical trials. See “Manufacturing” below.

We completed the manufacturing of bertilimumab with Lonza in 2016 and intend to manufacture further supplies of bertilimumab with another manufacturer. Therefore, we do not intend to utilize the Lonza License in the future and will not be subject to the royalty obligations contained therein.

### **NanoCyclo**

#### *BioNanoSim Ltd*

In January 2016, our wholly owned subsidiary, Immune Ltd., entered into a definitive research and license agreement with BNS, a Yissum spin-off company. We obtained from BNS an exclusive worldwide sublicense, with a right to further sublicense, for the development, manufacturing and commercialization of certain inventions and research results regarding Yissum’s patents in connection with nanoparticles for topical delivery of cyclosporine-A (NanoCyclo) for all topical skin indications. As consideration for the grant of the license, we are required to pay the following consideration:

- an annual maintenance fee of \$30,000, commencing on January 1, 2021, which will increase by 30% each year up to a maximum annual maintenance fee of \$0.1 million and may be credited against royalties or milestone payments payable in the same calendar year;
- a license fee in the amount of \$0.5 million, paid in 2016;
- royalties on net sales of products (as such term is defined in the License) by us of up to 5%, subject to certain possible reductions in certain jurisdictions;

- sublicense fees in the amount of 18% of any non-sales related consideration received by us from a sublicense or an option to receive a sublicense for the products and/or the licensed technology (as such terms are defined in the license); and
- milestone payments of up to approximately \$4.5 million and 250,000 shares of our common stock (12,500 shares after giving effect to the April 2017 Reverse Stock Split) upon the achievement of certain regulatory, clinical development and commercialization milestones. In the event that we receive consideration from a sublicensee for any such milestones, we will pay to BNS the higher of either (a) the amount of the particular milestone payment or (b) the amount of the sublicense fees that are due for such sublicensee consideration paid to us.

In addition, we are obligated to reimburse BNS within 60 days for expenses relating to patent fees and will sponsor a 12-month research program to prepare the program for IND submission.

In November 2017, we issued 250,000 shares valued at \$225,000 to BNS without giving effect to the impact of the April 2017 Reverse Stock Split because we decided that the importance of the NanoCyclo program and the need to maintain a positive working relationship with BNS warranted ignoring the impact of the Reverse Split and instead issuing 250,000 Shares to BNS as if the Reverse Split had not occurred.

For the year ended December 31, 2016, we paid a license fee of \$0.5 million and approximately \$0.2 million in research fees. For the year ended December 31, 2017, we paid approximately \$0.3 million in research fees.

## **AmiKet and AmiKet Nano**

### ***Dalhousie University***

In July 2007, we entered into a license agreement with Dalhousie University (“Dalhousie”) under which we obtained an exclusive license to certain patents for the topical use of tricyclic anti-depressants and N-methyl-D-aspartate (“NMDA”) receptor antagonists as topical analgesics for neuralgia. These and other patents cover the combination treatment consisting of amitriptyline and ketamine in AmiKet. We obtained worldwide rights to make, use, develop, sell and market products utilizing the licensed technology in connection with passive dermal applications. We are obligated to make payments to Dalhousie upon achievement of specified milestones and royalties based on annual net sales derived from the products incorporating the licensed technology. In April 2014, we entered into a Waiver and Amendment to the license agreement pursuant to which Dalhousie agreed to irrevocably waive our obligation to pay maintenance fees. In exchange, we agreed to pay Dalhousie royalties of 5% of net sales of licensed technology in countries in which patent coverage is available and 3% of net sales in countries in which data protection is available. Also, we agreed to amend the timing and increase the amounts of the milestone payments payable under the license agreement.

### ***Yissum***

In June 2015, we entered into a definitive research and license agreement with Yissum. We obtained an exclusive, worldwide license from Yissum, with certain sublicensing rights, to make commercial use of certain of Yissum’s patents and know-how in connection with a topical nano-formulated delivery of AmiKet for the development, manufacturing, marketing, distribution and commercialization of products based on the technology. As consideration for the grant of the license, we are required to pay the following consideration:

- an annual maintenance fee of \$30,000 commencing on June 25, 2020, which maintenance fee shall increase by 30% each year, up to a maximum annual maintenance fee of \$0.1 million and may be credited against royalties or milestone payments payable in the same calendar year;
- royalties on net sales of products (as such term is defined in the license) by us in the amount of up to 3%, subject to certain possible reductions in certain jurisdictions;
- milestone payments of up to approximately \$4.5 million upon the achievement of certain regulatory, clinical development and commercialization milestone; and
- reimbursement of related patent fees

In addition, we agreed to fund an annual research program in the amount of approximately \$0.5 million, plus VAT and any applicable taxes, commencing on October 1, 2015 (or such other time as mutually agreed between the parties). The results of the research, including any patents or patent applications will automatically be licensed to us.

For the year ended December 31, 2016, we paid research fees of approximately \$0.1 million. As of December 31, 2017, \$250,000 is due to Yissum for research fees.

## **Oncology**

### **Ceplene**

#### ***Meda Pharma SARL***

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 million payable in installments over a three-year period. The assets acquired from Meda include rights to marketing authorizations, trademarks, patents, and other intellectual property related to Ceplene and its use. Under the terms of the Asset Purchase Agreement, we have agreed to pay Meda a fixed price, which is payable in installments, as well as additional amounts contingent on the achievement of certain milestones.

#### ***Daniel Kazado***

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. Currently, we intend to finance the \$5.0 million financial obligations contemplated by the Asset Purchase Agreement through Cytovia on a basis that is on terms that are acceptable to our board of directors and without recourse to us. The Standby Financer will 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 Cytovia has not obtained funding on terms reasonably acceptable to us (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, at or prior to each installment date, 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.

***Pint Pharma International S.A.*** 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”, as more fully defined in the Licensing Agreement) through Pint and one or more of its affiliates. Pursuant to the Licensing Agreement, Cytovia is entitled to (i) 35% of Ceplene net sales in the Territory (ii) a milestone payment of \$0.5 million when net sales of Ceplene in the Territory 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 reach \$25.0 million in any calendar year (collectively, the “Ceplene Payments”). Cytovia further granted Pint and its affiliates certain sublicensing 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 product(s).

Additionally, in connection with the Licensing Agreement, the parties agreed that Pint GmbH, an affiliate of Pint, will separately enter into an investment agreement, pursuant to which Pint GmbH will make an investment of \$4.0 million at series A valuation into Cytovia in exchange for an equity interest in Cytovia. Dr. Massimo Radaelli, Executive Chairman of Pint, will also join the board of Cytovia upon completion of the investment and effective spin off of Cytovia from us, if and as consummated.

## **NanomAbs**

### *Yissum*

In April 2011, we entered into a license agreement with Yissum, which includes patents, research results and know-how developed by Professor Simon Benita related to the NanomAbs technology. Yissum granted us an exclusive license, with a right to sub-license, to make commercial use of the licensed technology in order to develop, manufacture, market, distribute or sell products derived from the license. As consideration for the grant of the license, we are required to pay the following consideration:

- royalties in the amount of up to 4.5% of net sales;
- beginning on the sixth anniversary, an annual license maintenance fee between \$30,000 for the first year and up to a maximum of \$0.1 million thereafter;
- research fees of at least \$0.3 million for the first year and at least \$0.1 million from the second year through the sixth year (but, not to exceed \$1.8 million in the aggregate);
- milestone payments of up to \$8.6 million, based on the attainment of certain milestones, including IND application submission, patient enrollment in clinical trials, regulatory approval and commercial sales;
- sub-license fees in amounts up to 18% of any sub-license consideration; and
- equity consideration in the amount of 8% of our shares of common stock on a fully diluted basis.

The license expires, on a country-by-country basis, upon the later of the expiration of (i) the last valid licensed patent, (ii) any exclusivity granted by a governmental or regulatory body on any product developed through the use of the licensed technology or (iii) the 15-year period commencing on the date of the first commercial sale of any product developed through the use of the licensed technology. Upon the expiration of the license, we will have a fully paid, non-exclusive license to the licensed technology.

For the year ended December 31, 2017, we paid research fees of approximately \$0.1 million.

## **Bispecific Antibodies**

### *SATT Sud-Est*

In January 2017, we entered into an exclusive patent sub-license agreement with SATT Sud-Est, (“SATT”) a French technology transfer office of the five universities of the Provence-Alpes-Cote-d’Azur and Corsica regions in France, relating to certain patents covering the development, use, manufacture and commercialization of monoclonal and bispecific antibodies targeting components of the tumor microenvironment and angiogenic factors. In addition, SATT agreed to grant us an exclusive option relating to the pro-angio vascular endothelial growth factor (“VEGF”) invention to be filed as a patent application during the term of the agreement. We will have a month after the filing of the patent to exercise the option. In consideration of the sub-license and option agreement, we agreed to pay an approximately \$0.2 million upfront payment, with \$0.1 million payable in January 2017 and the remainder payable in three equal quarterly payments thereafter beginning in March 2017. As of December 31, 2017, we have not made any payments. In addition, we agreed to certain milestone and royalty payments for each monoclonal and bispecific product developed.

### *Atlante Biotech SAS*

In December 2015, we entered into an exclusive license with Atlante Biotech SAS (“Atlante”) relating to the patents and know-how for a new format of bispecific antibody platform. The technology, the result of a collaborative European consortium led by Dr. Jean Kadouche and funded by a European grant, developed the novel platform for the production of tetravalent IgG1-like bispecific antibodies. A prototype bispecific antibody utilizing the platform was shown to retain effector functions and mediate redirect killing of target cells by cytokine induced killer T cells. Moreover, the bispecific antibody demonstrated direct in-vitro and in-vivo anti-cancer effects in tumor models and improved survival in a mouse xenograft model of disseminated leukemia.

## **Other Material Agreements**

### ***MabLife SAS***

In March 2012, we acquired from MabLife SAS (“MabLife”), a biotechnology company specializing in research and development of antibody-based therapeutics for the treatment of cancers, autoimmune and inflammatory disorders, all right, title and interest in and to the patent rights, technology and deliverables related to the anti-Ferritin monoclonal antibody (“AMB8LK”), including its nucleotide and protein sequences, its ability to recognize human acid and basic ferritins, or a part of its ability to recognize human acid and basic ferritins. The consideration was: \$0.6 million payable in six equal installments (total payments to date totaled \$0.2 million) and 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. We are required to assign the foregoing rights back to MabLife if it fails to make any of the required payments, is declared insolvent or bankrupt or terminates the agreement.

In February 2014, we acquired from MabLife all rights, titles and interests in and to the secondary patent rights 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.

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 \$0.2 million. We paid the settlement amount in January 2018 and are awaiting confirmation by the commercial court.

### ***Endo Pharmaceuticals Inc.***

In December 2003, EpiCept entered into a license agreement (“License Agreement”) with Endo Pharmaceuticals Inc. (“Endo”) under, which EpiCept granted Endo (and its affiliates) the exclusive (including as to EpiCept and its affiliates) worldwide right to commercialize LidoPAIN, adhesive-backed, lidocaine-based patch for the treatment of acute lower back pain. EpiCept also granted Endo worldwide rights to use certain of EpiCept’s patents for the development of certain other non-sterile, topical lidocaine patches, including Lidoderm, Endo’s non-sterile topical lidocaine-containing patch for the treatment of chronic lower back pain. We assumed the License Agreement upon the Merger.

Under the License Agreement, we are entitled to receive milestone payments of up to \$52.5 million upon the achievement of various milestones relating to product development, regulatory approval and sales-based royalties on sales of LidoPAIN and Endo’s own back pain product, if covered by our patents. Royalties are payable until generic equivalents to the LidoPAIN product are available or until expiration of the patents covering LidoPAIN, whichever is sooner. Also, we are eligible to receive milestone payments from Endo of up to \$30 million upon the achievement of specified regulatory and net sales milestones of Lidoderm, Endo’s chronic lower back pain product candidate, if covered by our patents. The License Agreement terminates upon the later of the conclusion of the royalty term, on a country-by-country basis, and the expiration of the last applicable EpiCept patent covering licensed Endo product candidates on a country-by-country basis. Either party may terminate the agreement upon an uncured material breach by the other or, subject to the relevant bankruptcy laws, upon a bankruptcy event of the other.

In July 2015, we amended the License Agreement. We transferred to Endo its previously licensed patents related to the use of topical lidocaine in acute and chronic back pain and Endo granted to us a royalty-free, non-exclusive, fully transferable license to those patents. Endo will make undisclosed milestone payments to us if Endo receives approval for a back pain indication for a lidocaine-based product. We regained full exclusive rights to develop, commercialize and license LidoPAIN.

### ***Dr. Jean Kadouche and Alan Razafindrastita***

In December 2011, Dr Jean Kadouche sold, assigned and transferred to us the entire right, title and interest for all countries, in and to any and all patents and inventions related to mice producing human antibodies and a method of preparation of human antibodies (the “Human Antibody Production Technology Platform”) for 40,000 shares of our common stock and \$20,000 (paid to Dr. Kadouche and Alan Razafindrastita). Through the Human Antibody Production Technology Platform and additional laboratory work, human immune systems and specific cell lines were introduced in mice, enabling the mice to produce human monoclonal antibodies.

## ***Shire BioChem Inc.***

In connection with the Merger, we acquired a license agreement for the rights to the MX2105 series of apoptosis inducer anti-cancer compounds from Shire BioChem Inc. (“Shire BioChem”), (formerly known as BioChem Pharma, Inc.). Under the license agreement, we are required to pay Shire BioChem a portion of any sublicensing payments we receive if we relicense the series of compounds or make milestone payments to Shire BioChem totaling up to \$26.0 million and pay a royalty on product sales if we develop the compounds internally for the treatment of a cancer indication.

### **Intellectual Property**

We seek to protect our product candidates and our technology through a combination of patents, trade secrets, proprietary know-how, regulatory exclusivity and contractual restrictions on disclosure.

We own or license rights with respect to patents and patent applications relating to bertilimumab, NanoCyclo, AmiKet and AmiKet Nano, Ceplene, antibodies and other product candidates. The patent positions for our product candidates and platforms include 24 granted United States patents, 113 granted foreign patents, 12 pending United States applications, and 26 pending foreign patent applications. We intend to seek patent term extensions in the United States for approved products. The length of the patent term extension will vary and is related to the length of time the drug is under regulatory review while the patent is in force.

Our patent positions are as follows:

- A license to a patent family that covers a composition of matter of bertilimumab and a method of using bertilimumab to screen for an antibody or antibody fragment that binds eotaxin-1, including: four registered patents in the United States and registered patents in Europe (Switzerland, Germany, France, United Kingdom (UK), and Ireland), Brazil, Canada, Israel, Australia, Japan, New Zealand and Singapore, and one pending patent application in the United States. The U.S. patents will expire, without extension between March 2021 and August 2022. The foreign patents and patents granted with respect to pending patent applications in this family will expire, without extension, in March 2021.
- All rights, title and interest in and to a patent application family that covers a method for treating an inflammatory bowel disease with an anti-human eotaxin antibody, including bertilimumab in the United States, Europe, Australia, Canada, China, Israel, and New Zealand. Any patents granted with respect to the pending patent application will expire, without extension, in March 2034.
- A license to a PCT patent application that covers a method for treating altered hepatic function and/or insulin resistance with an anti-human eotaxin antibody, including bertilimumab. Any patents granted with respect to the pending PCT patent application will expire, without extension, in June 2037.
- All rights, title and interest in and to a provisional patent application that covers a method for treating bullous pemphigoid with reduced or no corticosteroids via administration of an anti-human eotaxin antibody, including bertilimumab.
- A license to a patent family that covers polymer-based nanoparticles for the dermal or systemic delivery of therapeutic compounds, including: registered patents in Australia, China, Israel, and Japan and pending patent applications in Canada, China, Europe, India, South Korea, and the U.S. Any patents granted with respect to this pending patent application will expire, without extension, in January 2032.
- A license to a provisional patent application that covers a powder comprising polymer-based nanoparticles and topical and ophthalmic formulations of nanoparticles. Any patents granted with respect to this pending patent application will expire, without extension, in February 2039.
- All rights, title and interest in and to several families of patents related to the AmiKet product, including four granted U.S. patents, as well as granted patents in Canada, Chile, Hong Kong, Israel, Mexico, New Zealand, and Singapore. Patent applications for this family are pending in Mexico. These granted patents and any patents granted with respect to any pending patent applications will expire, without extension, between 2018 and 2023. These patents and patent application have claims directed to topical uses of tricyclic antidepressants, such as amitriptyline, and NMDA receptor antagonists, such as ketamine, as treatments for relieving pain, including neuropathic pain.

- A license to a patent family that covers Lidopain anesthetic patch, including 2 granted U.S. patents, a granted Mexico patent, and a pending Mexico patent application. These granted patents and any patents granted with respect to any pending patent applications will expire, without extension, between March 2020 and March 2021.
- All rights, title and interest in and to patents covering the synthesis of histamine dihydrochloride (Ceplene) and its use for treating cancer, including five granted U.S. patents, as well as a registered Australian, European (Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Monaco, Netherlands, Portugal, Spain, Sweden, Switzerland, and UK), Canadian, China, Hong Kong, Indian, Israel, and Japanese patents. The U.S. patents will expire in January 2019 and October 2021, and the other patents will expire in December 2019. There are pending PCT and US Provisional patent applications as well. Any patents granted with respect to any pending patent applications will expire, without extension in 2037 and 2038, respectively.
- All rights, title and interest in and to U.S., China, India, Japanese, and South Korean patents related to Azixa and uses thereof. The U.S. composition and methods patents will expire, without extension, in November 2026 and January 2030, respectively. The other patents will expire in July 2024.
- All rights, title and interest in and to U.S. and Canadian patents and European and Canadian patent applications related to crolibulin, structurally related analogs, and uses thereof. The U.S. patents will expire, without extension, between July 2022 and November 2029. The granted Canadian patent and any pending patent applications will expire in July 2027.
- A license to a patent family that covers bispecific antibodies, including granted US and China patents, as well as pending Canadian, European, Indian, Japanese, Mexican, and Korean patent applications. The U.S. patent will expire, without extension, in March 2033, while the other patent and any patents granted with respect to any pending patent applications will expire, without extension, in July 2032.
- All rights, title and interest in and to the U.S. and European (Germany, Switzerland, Spain, UK, Italy, and France) registered patents that cover an anti-ferritin antibody composition of matter and/or methods of use for targeting of a molecule to certain tumors and for localizing a tumor in a subject. The European patents directed to the use will expire, without extension, in January 2020. The U.S. patent, which benefits from patent term adjustment from the United States Patent and Trademark Office (“USPTO”), will expire in January 2022. The European patents directed to the composition of matter will expire, without extension, in September 2027. The U.S. composition of matter patent, which benefits from patent term adjustment from the USPTO, will expire in July 2030.

We seek to protect our proprietary information by requiring our employees, consultants, contractors, outside partners and other advisers to execute, as appropriate, nondisclosure and assignment of invention agreements upon commencement of their employment or engagement. Also, we require confidentiality or material transfer agreements from third parties that receive our confidential data or materials.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our technologies and product candidates as well as successfully defending these patents against third-party challenges. We have various compositions of matter and use patents, which have claims directed to our product candidates or their methods of use. Our patent policy is to pursue, maintain, defend, retain and secure patents and patent rights, whether developed internally or licensed from third parties, for the technology, inventions and improvements related to our core portfolio of product candidates and that are or may be commercially important to the development of our business. Also, we rely on trade secrets, technical know-how and continuing innovation to develop and maintain our competitive position.

The pharmaceutical, biotechnology and other life sciences industries are characterized by the existence of a large number of patents and frequent litigation based upon allegations of patent infringement. We believe that our current activities fall within the scope of the exemptions provided by 35 United StatesC. Section 271(e) in the United States and Section 55.2(1) of the Canadian Patent Act, each of which covers activities related to developing information for submission to the FDA and its counterpart agency in Canada. The possibility of an infringement claim against us increases as potential products progress toward commercialization. We attempt to ensure that our product candidates and the methods we employ to manufacture them do not infringe other parties’ patents and other proprietary rights, yet competitors or other parties may assert that we have infringed on their patents or other proprietary rights.

We rely on trade secrets and technical know-how to develop and maintain our competitive position. We seek to protect our proprietary processes, in part, through confidentiality and invention assignment agreements with our employees, consultants, scientific advisors, contractors and commercial partners. Also, we seek to preserve the integrity and confidentiality of our data, trade secrets and technical know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems. Such agreements or security measures are not immune from breach, and we may not have adequate remedies for any breach. Furthermore, our trade secrets may become known or be independently discovered by competitors or others.

## **Manufacturing**

We do not own or operate manufacturing facilities for any of our product candidates, nor do we plan to develop our own manufacturing operations in the foreseeable future. We depend on third party contract manufacture organizations for all of our bulk drug substance and drug candidates for our preclinical and clinical trials.

Where applicable, manufacturers of our products are required to comply with applicable Good Manufacturing Practices (“GMP”) regulations, which require, among other things, quality control and quality assurance, as well as the corresponding maintenance of records and documentation. In addition, changes to the manufacturing process generally require prior Regulatory Health Authority approval before being implemented. We take responsibility to ensure that all of the processes, methods and equipment are compliant with GMP for drugs on an ongoing basis, as mandated by the FDA and other regulatory authorities, and conduct audits of our vendors, contract laboratories and suppliers.

The raw materials that we use to manufacture our product candidates are readily available commodities commonly used in the pharmaceutical industry.

### ***Bertilimumab***

Lonza has manufactured all of our bertilimumab phase 2 clinical trial material pursuant to a manufacturing agreement that we signed with Lonza in 2011. In addition, we rely on certain third parties to perform filling, finishing, labeling, packaging, distribution, laboratory testing and other services related to the manufacture of our bertilimumab clinical supply.

In 2014, we entered into an agreement with Probiogen AG to develop a new Chinese Hamster Ovary (“CHO”) derived cell line for the manufacture of bertilimumab with improved characteristics, including higher yield, as compared to the bertilimumab derived from the manufacturing process utilized by Lonza. In 2015, we transferred the CHO cell line to STC Biologics for the development of the new manufacturing process for bertilimumab.

### ***Ceplene***

Currently, Lonza manufactures our clinical and commercial supply of Ceplene. Cytovia plans to qualify a backup manufacturer in the near future.

## **Contract Research Organizations**

We outsource our clinical trial activities to Clinical Research Organizations (“CROs”). We utilize CROs that comply with guidelines from the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, which attempt to harmonize the FDA and the EMA regulations and guidelines. We create our drug development plans and manage our CROs according to the specific requirements of the drug candidate under development. We ensure that our CROs comply with relevant federal regulations, including 21 C.F.R. parts 50, 54, 56, 58 and 318, which pertain to, among other things, institutional review boards, informed consent, financial conflicts of interest by investigators, good laboratory practices and submission of IND applications.

## **Marketing, Sales and Commercialization**

We do not have any internal sales, marketing or distribution infrastructure or capabilities. We intend to pursue commercialization relationships, including strategic alliances and licensing, with pharmaceutical companies and other strategic partners, which are equipped to market and/or sell our products if we receive regulatory approval for any of our product candidates. We may out-license some or all of our worldwide patent rights to more than one party to achieve the fullest development, marketing and distribution of any of our product candidates.

## **Environmental Matters**

We and our agents and service providers, including manufacturers, may be subject to various environmental, health and safety laws and regulations, including those governing air emissions, water and wastewater discharges, noise emissions, the use, management and disposal of hazardous, radioactive and biological materials and wastes and the cleanup of contaminated sites. We believe that our business, operations and facilities, including, to our knowledge, those of our agents and service providers, are being operated in compliance in all material respects with applicable environmental and health and safety laws and regulations.

## **Government Regulation**

The FDA and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements upon companies involved in the clinical development, manufacture, marketing and distribution of drugs, such as the drugs that we are developing. These agencies and other federal, state and local entities regulate the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion, distribution, post-approval monitoring and reporting, sampling and export and import of our drug candidates.

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (the “FDCA”) and the implementing of regulations in the FDCA. The processes, rules, regulations and requirements of other regulatory agencies, such as that of the EMA which regulates drug approvals in the European Union, are similar though not identical to those of the FDA (see “International Regulations” below).

The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA’s refusal to approve pending New Drug Applications (“NDAs”) or Biologics License Applications (“BLAs”) withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA’s good laboratory practice (“GLP”) regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;
- approval by an independent institutional review board (“IRB”) at each clinical site before each trial may be initiated;
- performance of adequate and well controlled human clinical trials in accordance with good clinical practice (“GCP”) requirements to establish the safety and efficacy of the proposed drug product for each indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current GMP requirements and to assure that the facilities, methods and controls are adequate to preserve the drug’s identity, strength, quality and purity; and
- FDA review and approval of the NDA.

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical trials involve the administration of the investigational new drug to human patients under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research patients provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health (the “NIH”) for public dissemination on their [www.clinicaltrials.gov](http://www.clinicaltrials.gov) website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase 1 clinical trial: The drug is initially introduced into healthy human volunteers or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.
- Phase 2 clinical trial: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3 clinical trial: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Each of phase 1, phase 2 and phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB’s requirements or if the drug has been associated with unexpected serious harm to patients.

A drug being studied in clinical trials may be made available to individual patients in certain circumstances. Pursuant to the 21st Century Cures Act (the “Cures Act”) which was signed into law in December 2016, the manufacturer of an investigational drug for a serious disease or condition is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational drug. This requirement applies on the latest of 60 calendar days after the date of enactment of the Cures Act or the first initiation of a phase 2 or phase 3 trial of the investigational drug.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product’s chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act (“PDUFA”) guidelines that are currently in effect, the FDA has a goal of ten months from the date of “filing” of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a “filing” decision.

In addition, under the Pediatric Research Equity Act of 2003 (“PREA”) as amended and reauthorized, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

The FDA also may require submission of a risk evaluation and mitigation strategy (“REMS”) plan to ensure that the benefits of the drug outweigh its risks. The REMS plan could include medication guides, physician communication plans, assessment plans, or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product’s continued safety, quality and purity.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with Current Good Manufacturing Practice (“cGMP”) requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA’s satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug’s safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Under the Orphan Drug Act of 1983, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the name of the sponsor, identity of the drug or biologic and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not shorten the duration of the regulatory review or approval process, but does provide certain advantages, such as a waiver of PDUFA fees, enhanced access to FDA staff and potential waiver of pediatric research requirements.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full NDA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the application user fee. A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

## **Coverage and Reimbursement**

Sales of our drug candidates, if approved, will depend, in part, on the extent to which such products will be covered by third-party payors, such as government health care programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly limiting coverage or reducing reimbursements for medical products and services. In addition, the United States government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any drug candidates that we develop will be made on a payor-by-payor basis. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its formulary it will be placed. The position on a payor's list of covered drugs, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our drug candidates or a decision by a third-party payor to not cover our drug candidates could reduce physician usage of our drug candidates, once approved, and have a material adverse effect on our sales, results of operations and financial condition.

## **Other Healthcare Laws**

We are subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we conduct our business, including our clinical research, proposed sales, marketing and educational programs. Failure to comply with these laws, where applicable, can result in the imposition of significant civil penalties, criminal penalties, or both.

The United States laws that may affect our ability to operate, among others, include: the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; certain state laws governing the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; the federal healthcare programs' Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs; federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent; federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; the Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the United States Department of Health and Human Services information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; and state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

In addition, many states have similar laws and regulations, such as anti-kickback and false claims laws that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws.

## **Healthcare Reform**

Current and future legislative proposals to further reform healthcare or reduce healthcare costs may result in lower reimbursement for our products. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could significantly reduce our revenues from the sale of our products.

For example, implementation of the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, collectively the Affordable Care Act (“PPACA”) has substantially changed healthcare financing and delivery by both governmental and private insurers, and significantly impacted the pharmaceutical industry. The PPACA, among other things, established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, and provided incentives to programs that increase the federal government’s comparative effectiveness research. Since its enactment there have been judicial and Congressional challenges to certain aspects of the PPACA. Some of the provisions of the PPACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the PPACA. In addition, the current administration and Congress will likely continue to seek legislative and regulatory changes, including repeal and replacement of certain provisions of the PPACA. Prior to the 2016 United States elections, regulations under the PPACA were expected to continue to be drafted, released, and finalized through the next several years. However, throughout 2017 President Trump and members of Congress sought to repeal and replace the PPACA and implement regulatory changes to limit the PPACA and other healthcare reform programs enacted under President Obama’s administration. For example, in January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Another example is the recent United States tax reform legislation enacted by Congress and signed into law by President Trump, The Tax Cuts and Jobs Act of 2017, which repealed the requirement that individuals maintain health insurance coverage or face a penalty (known as the “individual mandate”). President Trump’s administration, Alex Azar, head of Health and Human Services, and Congress will likely continue to seek legislative and regulatory changes to reform healthcare, including repeal and replacement of certain provisions of the PPACA.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. In August 2011, then President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation’s automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect through 2025 unless additional Congressional action is taken. Additionally, in January 2013, then President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. More recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. For example, there have been several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

We expect additional federal and state, as well as foreign, healthcare reform measures will be adopted in the future, any of which could result in reduced demand for our products or additional pricing pressure.

### **International Regulations**

Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement also vary greatly from country to country. Although governed by the applicable country, clinical trials conducted outside of the United States typically are administered with the three-phase sequential process described above under “Government Regulation—United States” However, the foreign equivalent of an IND is not a prerequisite to performing pilot studies or phase 1 clinical trials.

Under European Union regulatory systems, we may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is required for oncology products and is available for medicines produced by biotechnology or which are highly innovative, provides for the grant of a single marketing authorization that is valid for all member states. This authorization is a marketing authorization application. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval. This procedure is referred to as the mutual recognition procedure.

In addition, regulatory approval of prices is required in most countries other than the United States. We face the risk that the resulting prices would be insufficient to generate an acceptable return to us, our shareholders or our collaborators.

## **Research and Development**

We have devoted substantial efforts and resources to advancing our intellectual property estate and scientific research and drug development. Generally, research and development expenditures are allocated to specific research projects. Due to various uncertainties and risks, it is not possible to accurately predict future spending or time to completion by project or project category. Research and Development costs were \$5.5 million and \$8.3 million during the fiscal years ended December 31, 2017 and 2016, respectively. We will require additional investments in research and development to bring our product candidates to market.

## **Competition**

We operate in highly competitive segments of the biopharmaceutical markets. We face competition from many different sources, including commercial pharmaceutical and biotechnology companies, academic institutions, government agencies, and private and public research institutions. Many of our competitors have significantly greater financial, product development, manufacturing and marketing resources than we possess. Large pharmaceutical companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. As a result, these companies may obtain marketing approval more rapidly and may be more effective in selling and marketing their products than us. Smaller or early stage companies may prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Also, many universities and private and public research institutes are active in cancer research, some in direct competition with us. Adequate protection of intellectual property, successful product development, adequate funding and retention of skilled, experienced and professional personnel are among the many factors critical to our success.

## **Employees**

As of March 15, 2018, our workforce consisted of five full time United States and two full time Israeli employees.

## **Corporate and Available Information**

Immune (formerly EpiCept) was incorporated in Delaware in March 1993. Immune Ltd., incorporated in Israel in July 2010, entered into a definitive merger agreement with EpiCept in November 2012, which was completed on August 25, 2013. Our principal executive offices are located at 550 Sylvan Avenue, Suite 101, Englewood Cliffs, NJ 07632. Our telephone number is (201) 464-2677, and our website address is [www.immunepharma.com](http://www.immunepharma.com).

The information contained in, or accessible through our website does not constitute a part of and is not deemed or otherwise incorporated by reference in this Annual Report on Form 10-K. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports, are available to you free of charge through the "Investors — SEC Filings" section of our website as soon as reasonably practicable after such materials have been electronically filed with, or furnished to, the Securities and Exchange Commission. Our shares of common stock are listed on The Nasdaq Capital Market under the symbol "IMNP."

## **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, results of operations, cash flows, and the trading price of our common stock. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may materially affect our business operations.*

## **Risks relating to our financial position and need for additional capital**

### ***We have limited liquidity.***

As of December 31, 2017, our cash and cash equivalents balance was \$6.8 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 as \$2.2 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.

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 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.***

We have incurred significant losses since inception and expect to continue to incur losses for the foreseeable future. We incurred net losses of \$17.9 million and \$32.7 million, resulting in a total accumulated deficit of \$113.5 million and \$95.6 million, for the fiscal years ended December 31, 2017 and 2016, respectively.

We have devoted substantially all of our financial resources and efforts to developing bertilimumab, NanoCyclo, Nano AmiKet and the products in our oncology portfolio. We are in the early stages of development of our product candidates and 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 must succeed in developing and commercializing products that generate significant revenue to become and remain profitable, which will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our 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 in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, we may never generate revenues that are significant enough to achieve profitability.

None of our drug candidates has received FDA or foreign regulatory marketing approval (except Ceplene). In order to grant marketing approval, the FDA or foreign regulatory agencies must conclude that our clinical data and that of our collaborators establish the safety and efficacy of our drug candidates. Furthermore, our strategy includes entering into collaborations with third parties to participate in the development and commercialization of our 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 our control. We cannot forecast with any degree of certainty which of our drug candidates will be subject to future collaborations or how such arrangements would affect its development plan or capital requirements.

We are unable to predict accurately the timing or amount of increased expenses or when, or if, we will be able to achieve profitability due to the numerous risks and uncertainties associated with pharmaceutical product development. In addition, our expenses could increase and revenue could be further delayed 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.

We may not be able to sustain or increase profitability on a quarterly or annual basis even if we achieve profitability. 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.

***We have a limited operating history, expect to continue to incur substantial operating losses and may be unable to obtain additional financing, causing substantial doubt about our ability to continue as a going concern over the next twelve months from the filing of this annual report. The report of the Independent Registered Public Accounting Firm includes an explanatory paragraph that expresses substantial doubt about our ability to continue as a going concern.***

We commenced operations in 2010. Our limited operating history hinders an evaluation of our prospects, which should be considered in light of the risks, expenses and difficulties frequently encountered in the establishment of a business in a new industry, characterized by a number of market entrants and intense competition, and in the shift from development to commercialization of new products based on innovative technologies.

Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel to satisfy needs from expected growth. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability on the part of our management to manage growth could delay the execution of our business plans or disrupt our operations. As a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors.

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.

In connection with the preparation of our audited financial statements as of and for the year ended December 31, 2017, our management has evaluated whether there is substantial doubt about our ability to continue as a going concern and has determined that substantial doubt existed 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 within 12 months after the financial statements were issued; (ii) we may not identify commercial partners to support development of its drug candidates; and (iii) if we fail to obtain 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.

***If we fail to comply with the continued minimum closing bid requirements of the NASDAQ Capital Market LLC ("NASDAQ") or other requirements for continued listing, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.***

Our common stock is listed for trading on the NASDAQ. We must satisfy NASDAQ's continued listing requirements, including, among other things, a minimum closing bid price requirement of \$1.00 per share for 30 consecutive business days. If a company's common stock trades for 30 consecutive business days below the \$1.00 minimum closing bid price requirement, NASDAQ will send a deficiency notice to us, advising that it has been afforded a "compliance period" of 180 calendar days to regain compliance with the applicable requirements. Thereafter, if such a company does not regain compliance with the bid price requirement, a second 180-day compliance period may be available.

On December 1, 2017, we received a notification letter from NASDAQ informing us that for the last 30 consecutive business days, the bid price of our securities had closed below \$1.00 per share. This notice had no immediate effect on our NASDAQ listing and we have 180 calendar days, or until May 30, 2018, to regain compliance. The closing bid price of our securities must be at least \$1.00 per share for a minimum of ten consecutive business days to regain compliance.

If we are unable to regain compliance with the minimum stockholders' equity requirement by May 30, 2018, or such further extended period as may be provided by NASDAQ, our securities may be delisted from NASDAQ, which could reduce the liquidity of our common stock materially and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and business development opportunities. Such a delisting likely would impair your ability to sell or purchase our common stock when you wish to do so. Further, if we were to be delisted from NASDAQ, our common stock may no longer be recognized as a "covered security" and we would be subject to regulation in each state in which we offer our securities. Thus, delisting from NASDAQ could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly impact the ability of investors to trade our securities and would negatively impact the value and liquidity of our common stock.

***We may be unable to license our product candidate AmiKet on terms that reflect the current carrying value of the asset, or at all, which would negatively affect our financial condition and results of operations.***

We perform analyses periodically to determine whether an impairment exists related to any of our intangible non-depreciable assets. Our annual impairment analysis for 2016 determined that a change in the carrying value of in-process research and development (“IPR&D”) related to the AmiKet program (which includes AmiKet and AmKet Nano, a new and improved formulation of AmiKet using the nano-encapsulation technology that we licensed from Yissum) was required. As a result, we decreased the carrying value of the IPR&D asset from \$27.5 million as of December 31, 2015 to \$15.0 million as of December 31, 2016. An independent valuation of the IPR&D related to the AmiKet program as of December 31, 2017 confirmed that no change in the carrying value was required as of that date. There is no assurance that future analysis would not result in further impairment of the fair value attributable to the AmiKet IPR&D. If we are unable to successfully develop AmiKet or AmiKet Nano or if we sell or license AmiKet or AmiKet Nano on terms materially less favorable than the assumptions used in the current valuation of the AmiKet IPR&D, the carrying value of the asset would be further impaired, which could materially adversely affect our financial condition and results of operations.

***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 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.

## 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 December 31, 2017, there were 21,002,212 shares of common stock outstanding, with up to 19,948,582 shares of common stock issuable upon conversion of outstanding convertible preferred stock; 17,676,000 shares of common stock issuable upon exercise of outstanding warrants issued in connection with the convertible preferred stock; 1,019,677 shares of common stock issuable upon exercise of other outstanding warrants; and 519,014 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.

*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 capital stock. Currently, we intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, our certificate of designation of Series E Convertible Preferred Stock prohibits us from paying dividends on our outstanding equity securities. 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.

***The proposed spin-off of our oncology business is subject to various risks and uncertainties and may not be completed on the terms or timeline currently contemplated, if at all, and will involve significant time and expense, which could harm our business, results of operations and financial condition.***

In April 2017, we announced plans to separate our oncology business as a separate, stand-alone company. The transaction is subject to satisfaction of certain conditions, including separate capitalization from third-party sources to fund Cytovia’s start-up costs, expenses of the spin-off, payment of costs related to Ceplene and other relevant items. Unanticipated developments could delay, prevent or otherwise adversely affect this proposed spin-off, including but not limited to failure to obtain the necessary capitalization, disruptions in general market conditions or potential problems, delays or difficulties in satisfying conditions and obtaining approvals and clearances or litigation or other legal proceedings that may arise as a result of the proposed spin-off. In addition, consummation of the spin-off will require clearance of a Form 10 registration statement with the SEC and final approval from our Board of Directors. Therefore, we cannot assure that we will be able to complete the spin-off on the terms or on the timeline that we announced, if at all.

Significant expenses in connection with the spin-off will be incurred, and such costs and expenses may be greater than we anticipate and capitalization of such initial costs may not be attainable in a timely manner, if at all. In addition, completion of the spin-off will require a significant amount of management time and effort which may disrupt our business or otherwise divert management’s attention from other aspects of our business operations. Any such difficulties could adversely affect our business, results of operations and financial condition.

***The proposed spin-off may not achieve some or all of the anticipated benefits.***

If the spin-off is completed, there is uncertainty as to whether the anticipated operational, financial and strategic benefits of the spin-off will be achieved. There can be no assurance that the combined value of the common stock of the two publicly-traded companies will be equal to or greater than what the value of our common stock would have been had the proposed separation not occurred. The combined value of the common stock of the two companies could be lower than anticipated for a variety of reasons, including, but not limited to, the inability of the new spin-off company to operate and compete effectively as an independent company, and the stock price of the common stock of each of the two companies could experience periods of volatility. If we fail to achieve the anticipated benefits of the spin-off, our stock price could decline.

***If the spin-off does not qualify as a transaction that is generally tax-free for U.S. federal income tax purposes, we and our stockholders could be subject to significant tax liabilities.***

We intend to obtain an opinion of outside counsel regarding the qualification of the distribution in the spin-off, together with certain related transactions, as a transaction that is generally tax-free for U.S. federal income tax purposes. The opinion will be based and rely on, among other things, certain facts and assumptions, as well as certain representations, statements and undertakings of Immune and the new spin-off company, including those relating to the past and future conduct of Immune and the new spin-off company. If any of these facts, assumptions, representations, statements or undertakings are, or become, inaccurate or incomplete, or if we or the new spin-off company breach any of their respective covenants in the separation documents, the opinion of counsel may be invalid and the conclusions reached therein could be jeopardized. It is also possible that the U.S. Internal Revenue Service, or the IRS, could determine that the distribution in the spin-off, together with certain related transactions, is taxable for U.S. federal income tax purposes if it determines that any of these facts, assumptions, representations, statements or undertakings are incorrect or have been violated or if it disagrees with the conclusions in the opinion of counsel. An opinion of counsel is not binding on the IRS or any court and there can be no assurance that the IRS will not challenge the conclusions reached in the opinion. If the distribution in the spin-off, together with certain related transactions, is ultimately determined to be taxable, we and our stockholders that are subject to U.S. federal income tax could incur significant tax liabilities.

#### **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 and by the EMA and similar regulatory authorities outside the United States and Europe. Failure to obtain approval of clinical trial applications, CTAs, in European Union countries 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 our 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 may take many years. 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. In addition, there is still uncertainty with respect to the impact President Trump's administration and the Congress may have, if any, and any changes will likely take time to unfold. 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. 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.

***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, any of which could harm our business.

***Our lead product candidate, bertilimumab, is a biologic and may face an uncertain duration of market exclusivity.***

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. The new law is complex and is only beginning to be interpreted by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. While it is uncertain when any such processes may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

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. However, there is a risk that the United States Congress could amend the BPCIA to significantly shorten this exclusivity period as proposed by President Obama, potentially creating the opportunity for generic competition sooner than anticipated. 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 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 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.

***We may expand our business through the acquisition of companies or businesses or by entering into collaborations or in-licensing product candidates that could disrupt our business and harm our financial condition.***

We may in the future seek to expand our pipeline and capabilities by acquiring one or more companies or businesses, entering into collaborations or in-licensing one or more product candidates. Acquisitions, collaborations and in-licenses involve numerous risks, including:

- potentially dilutive issuance of equity securities;
- substantial cash expenditures;
- incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition;
- difficulties in assimilating the operations and technology of the acquired companies;
- potential disputes regarding contingent consideration;
- the assumption of unknown liabilities of the acquired businesses;
- diverting our management's attention away from other business concerns;
- entering markets in which we have limited or no direct experience; and
- potential loss of our key employees or key employees of the acquired companies or businesses.

Our experience in making acquisitions, entering collaborations and in-licensing product candidates is limited. We cannot assure you that any acquisition, collaboration or in-license will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired company or business or in-licensed product candidate. In addition, our future success would depend in part on our ability to manage the rapid growth associated with some of these acquisitions, collaborations and in-licenses. We cannot assure you that we would be able to successfully combine our business with that of acquired businesses, manage a collaboration or integrate in-licensed product candidates or that such efforts would be successful. Furthermore, the development or expansion of our business or any acquired business or company or any collaboration or in-licensed product candidate may require a substantial capital investment by us. We may use our securities as payment for all or a portion of the purchase price or acquisitions. If we issue significant amounts of our equity securities for such acquisitions, this would result in substantial dilution of the equity interests of our stockholders.

#### **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 Employee Matters and Managing Growth and Other Risks Related to Our Business**

***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.

## **ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

## **ITEM 2. PROPERTIES**

In February 2015, we signed a lease agreement with ARE-EAST RMR Science Park, LLC, New York, NY, for corporate headquarters space at the Alexandria Center in New York City. In August 2015, we signed an amendment to the Alexandria Center lease agreement for an additional 1,674 square feet to be used for lab space and additional offices. Effective May 1, 2017, we terminated the lease agreement with ARE-EAST RMR Science Park, LLC, and forfeited a security deposit in the amount of \$177,000 and relocated our headquarters to 550 Sylvan Avenue, Englewood Cliffs, NJ 07632 under a lease agreement with 550 Sylvan Avenue, LLC. Lease expense is approximately \$2,950 per month. The lease may be terminated upon two months' written notice to the landlord.

On February 26, 2018, we entered into a six-year lease agreement with Bridge Plaza Realty Associates L.L.C. for approximately 3,000 square feet of office space at One Bridge Plaza, Fort Lee, New Jersey, to commence on April 1, 2018 at a fixed basic rent of approximately \$9,000 per month. Also, on that date, we provided written notice to the landlord of 550 Sylvan Avenue, LLC of our intention to vacate those premises.

Our oncology subsidiary, Cytovia, Inc., occupies shared office space on a month to month basis at 12 E 49th Street, New York, NY 10017. Immune Ltd. occupies shared office space on a month to month basis in offices in Tel-Aviv and Jerusalem, Israel

We recorded rent expense of \$0.1 million and \$0.6 million for the years ended December 31, 2017 and 2016, respectively.

## **ITEM 3. LEGAL PROCEEDINGS**

Immune Pharmaceuticals Inc. was the defendant in litigation involving a dispute with the plaintiffs Kenton L. Cowley and John A. Flores. The complaint alleges breach of contract, breach of covenant of good faith and fair dealing, fraud and rescission of contract with respect to the development of a topical cream containing ketamine and butamben, known as EpiCept NP-2. A summary judgment in Immune's favor was granted in January 2012 and the plaintiffs filed an appeal in the United States Court of Appeals for the Ninth Circuit in September 2012. A hearing on the motion occurred in November 2013. In May 2014, the court scheduled the trial in November 2014 and a mandatory settlement conference in July 2014. In July 2014, the parties failed to reach a settlement at the mandatory settlement conference. The case was tried by a jury, which rendered a decision on March 23, 2015, in favor of us on all causes of action.

In April 2015, the plaintiffs filed a motion for a new trial, which was heard by the Court on June 8, 2015. In October 2015, the court denied the plaintiff's motion for a new trial. On October 9, 2015, the plaintiffs filed a notice of appeal to the United States Court of Appeals for the Ninth Circuit. On February 13, 2018, the Appellate Court affirmed the district court's judgment in our favor.

During the years ended December 31, 2017 and 2016, in connection with this litigation matter, we incurred legal costs of approximately \$0.1 million and \$0.1 million, respectively.

## **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

## **PART II**

## **ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

### **Market Information**

Our common stock is listed on The NASDAQ Capital Market under the symbol "IMNP." The last reported sale price for our common stock on March 20, 2018 was \$0.38 per share.

On February 7, 2018, the Disciplinary Committee of Nasdaq Stockholm AB decided that our common shares listed on Nasdaq First North Stockholm shall be delisted. The Nasdaq First North Disciplinary Board noted that we were not in compliance with certain of the regulations of First North Premier over a prolonged period. The Disciplinary Board acknowledged that we had recently taken measures to insure compliance. However, these measures were deemed insufficient to rectify the numerous prior breaches of the Nasdaq First North Rule Book. Consequently, the Disciplinary Committee decided to remove our shares from trading on Nasdaq Stockholm. The Committee's decision stated that the delisting would be effected by March 29, 2018 at the latest; however, Nasdaq First North determined that the last day of trading would be March 9, 2018.

The delisting does not affect the trading status of our shares listed on the Nasdaq Capital Market in the United States. All shares of our common stock, including those that were listed on Nasdaq First North up to March 9, 2018, remain eligible for trading on The Nasdaq Capital Market in the United States, and will be subject to the rules and requirements for continued listing on The Nasdaq Capital Market.

The table below sets forth closing information on the range of high and low sales prices for our common stock as reported by The NASDAQ Capital Market during the periods indicated on a post-split basis.

	<u>High</u>	<u>Low</u>
<b>2017</b>		
First Quarter	\$ 4.76	\$ 2.62
Second Quarter	5.02	2.11
Third Quarter	3.28	1.01
Fourth Quarter	1.90	0.50
<b>2016</b>		
First Quarter	\$ 16.60	\$ 8.00
Second Quarter	12.80	4.00
Third Quarter	11.00	5.00
Fourth Quarter	7.20	3.20

### Stockholders

As of March 20, 2018, there were 82 stockholders of record of our 31,903,280 outstanding shares of common stock. This number does not reflect persons or entities that hold their stock in nominee or “street” name through various brokerage firms.

### Dividends

We have never declared or paid dividends on our common stock and do not anticipate paying any cash dividends for the foreseeable future. Our ability to pay cash dividends was prohibited by the terms of our credit facility with Hercules Capital.

### Unregistered Sales of Equity Securities

None.

### Issuer Purchases of Equity Securities

None.

### ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

### ITEM 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis should be read in conjunction with the Consolidated Financial Statements included elsewhere in this report and the “Cautionary Note Regarding Forward-Looking Statements” above.*

### 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, fully human, anti-eotaxin-1 antibody, currently in phase 2 clinical trials for bullous pemphigoid (“BP”) and ulcerative colitis (“UC”). Also, we are developing “NanoCyclo,” a topical nano-encapsulated formulation of cyclosporine, for the treatment of atopic dermatitis (“AD”) and psoriasis.

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.

Our oncology portfolio includes Ceplene, which is approved in the European Union for the maintenance of remission in patients with Acute Myeloid Leukemia (“AML”) and Azixa and crolibulin, two clinical-stage, vascular disrupting agents (“VDA”) which have demonstrated encouraging preliminary proof of concept study results. In addition, we have two oncology platform assets, consisting of a bispecific antibody platform and a nanotechnology combination platform, which we refer to as “NanomAbs.” We intend to divest these oncology assets, which are held in our oncology-focused subsidiary, Cytovia Inc (“Cytovia”).

#### European Union *Summary of Immune’s Asset Portfolio*

<b>Program</b>	<b>Primary Indication(s)</b>	<b>Status</b>
<b>Bertilimumab</b>	Bullous Pemphigoid Ulcerative colitis	Phase 2 Phase 2
<b>NanoCyclo</b>	Atopic Dermatitis, Psoriasis	Preclinical
<b>Ceplene/IL-2</b>	Acute Myeloid Leukemia	Phase 3 (US) Approved (European Union)
<b>Crolibulin</b>	Solid Tumors	Phase 2
<b>Azixa</b>	Glioblastoma multiforme	Phase 2
<b>NanomAbs</b>	Solid Tumors	Preclinical
<b>Bispecific Antibodies</b>	Oncology	Preclinical
<b>AmiKet/AmiKet Nano</b>	Neuropathic Pain	Phase 2
<b>Lido PAIN</b>	Pain	Phase 2

Ceplene<sup>®</sup>, LidoPain<sup>®</sup>, Epicept<sup>®</sup>, Amiket<sup>™</sup>, and Azixa<sup>™</sup> are trademarks that we own. Each trademark, trade name or service mark of any other company appearing in this annual report on Form 10-K 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 on our core assets, bertilimumab and NanoCyclo product candidates, while streamlining our operations by divesting or spinning off our non-core assets, including our oncology asset portfolio consisting of Ceplene, Azixa, crolibulin, Nanomabs and our bispecific antibody platform. We announced our plan to pursue a spin-off of Cytovia Inc. (“Cytovia”) our oncology focused subsidiary into a separate, stand-alone company, under the management and leadership of our founder and former Chief Executive Officer, Dr. Daniel Teper. We intend to develop bertilimumab for a variety of indications and NanoCyclo for the treatment of AD and moderate psoriasis. We are evaluating AmiKet and AmiKet Nano for the treatment of PHN and DNP and will determine an optimal path forward for this program.

Cytovia will focus on the development and commercialization of novel oncology and hematology therapeutics. Consistent with our objective to preserve our capital to support development of bertilimumab and NanoCyclo, Cytovia, led by Dr. Teper, is seeking separate capitalization from third-party sources for Cytovia's start-up costs, expenses of the spin-off, payment of costs related to Ceplene and other relevant items. This capitalization from third party sources is a prerequisite to further continuation of the spin-off process. If the necessary capitalization is not obtained in the near future, we do not expect to pursue completion of the spin-off process and instead will determine the optimal path forward to monetize these assets. This strategy will allow us to focus our resources and build upon our promising clinical stage pipeline in immunotherapy and dermatology related indications and thereby unlock our intrinsic value.

#### *Reverse stock split*

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 Form 10-K have been reflected on a post-split basis.

## **Results of Operations**

### *Year ended December 31, 2017 compared to the year ended December 31, 2016*

#### *Revenues*

We recorded no revenue during the years ended December 31, 2017 and 2016. We are in the early stages of development of our product candidates, and we have not completed the development of bertilimumab, NanoCyclo 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)*

	<b>Years ended December 31,</b>		
	<b>2017</b>	<b>2016</b>	<b>Change</b>
Research and development	\$ 5,517	\$ 8,333	\$ (2,816)

Research and development ("R&D") expenses decreased by \$2.9 million or 34% to \$5.5 million for the year ended December 31, 2017 as compared to \$8.3 million for the year ended December 31, 2016. The decrease was driven by (i) a decrease of \$0.2 million in licensing fee expenses, (ii) a decrease of \$2.8 million in clinical trial expenses, (iii) a decrease of \$0.5 million in employee compensation expense resulting from a corporate restructuring in April 2017, and (iv) a decrease in stock based compensation expense of \$0.5 million. This cumulative decrease was offset partially by (i) an increase in R&D consulting expense of \$0.9 million and (ii) amortization of Ceplene acquisition intangibles of \$0.3 million.

#### *General and administrative expense (\$ in thousands)*

	<b>Years ended December 31,</b>		
	<b>2017</b>	<b>2016</b>	<b>Change</b>
General and administrative	\$ 6,606	\$ 6,427	\$ 179

General and administrative ("G&A") expenses increased by \$0.2 million or 3% to \$6.6 million for the year ended December 31, 2017 from \$6.4 million for the year ended December 31, 2016. The increase primarily was due to an increase in (i) audit and accounting services of \$0.2 million related to the filing of registration statements and other SEC documents, (ii) legal fees of \$1.1 million, (iii) consulting fees of \$0.4 million, (iv) rent expense of \$0.5 million primarily related to the reversal of a rent liability in 2016, offset by a decrease in (v) stock based compensation expense of \$1 million, (vi) investor relations fees of \$0.4 million and (vii) salaries and benefits of \$0.6 million primarily due to the writeoff of unpaid bonuses.

*In-process research and development impairment expense (\$ in thousands)*

	Years ended December 31,		
	2017	2016	Change
In-process research and development impairment expense	\$ -0-	\$ 12,500	\$ (12,500)

In-process research and development (“IPR&D”) impairment expenses of \$12.5 million in 2016 was related to the write down of our IPR&D related to AmiKet, based on the following factors: a significant reduction in our market capitalization; failure to execute a sale or partnership of AmiKet; and our decision at that time to indefinitely postpone any further development of AmiKet. In 2017, we decided to develop AmiKet Nano based on a review of a market analysis conducted by prior management. An independent valuation consultant confirmed the valuation of the AmiKet and AmiKet Nano asset is in excess of the carrying value of the IPR&D.

*Non-operating expense (\$ in thousands)*

	Years ended December 31,		
	2017	2016	Change
Non-operating expense	\$ 7,739	\$ 10,257	\$ (2,518)

Non-operating expense was \$7.5 million during the year ended December 31, 2017, compared with \$10.3 million during the year ended December 31, 2016, a decrease of \$2.8 million.

Non-operating expense for the year ended December 31, 2017 consisted of (i) interest expense of \$3.6 million of which \$1.2 million relates to the May 2017 Convertible Notes, \$0.6 million relates to the April 2017 Convertible Notes, \$0.4 million relates to the Loan Agreement with Hercules and includes amortization of original issue discount and early termination fee, amortization of original issue discount of \$0.2 million relates to the July 2017 Senior Secured Convertible Promissory Note, \$0.3 million relates to the July 2017 Convertible Notes, \$0.3 million relates to the August 2017 Convertible Notes, \$0.1 million relates to the acquisition note payable to Meda, \$0.1 million relates to various other notes and \$0.4 million relates to redemption premium, amortization of debt discount, debt issuance costs and original issue discount for the November 2016 convertible notes; (ii) a gain on change in fair value of derivative instruments of \$0.2 million; (iii) a loss on disposal of equipment of \$0.3 million; (iv) loss on extinguishment of debt 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; (v) liquidated damages of \$1.8 million of which \$1 million relates to the May 2017 Convertible Notes and \$0.8 million relates to the November 2016 convertible notes; and (vi) \$0.1 million of other expense.

Non-operating expense for the year ended December 31, 2016 included interest expense of \$1.3 million, primarily relating to cash interest paid and amortization of the debt discount relating to the Loan Agreement with Hercules and a loss on the change in fair value of derivative liability instruments of \$8.7 million, representing the change in fair value of the derivative liability associated with the Series D Preferred Stock. Interest expense included \$0.3 million in liquidated damages related to the convertible note that we issued to HLHW IV, LLC.

*Income tax benefit (\$ in thousands)*

	Years ended December 31,		
	2017	2016	Change
Income tax benefit	\$ 1,973	\$ 4,856	\$ (2,883)

The income tax benefit in 2017 was \$2.0 million. The U.S. federal corporate tax rate was reduced from 34% to 21% due to the Tax Cuts and Jobs Act, enacted in December 2017. As a result of the tax rate reduction, the deferred tax liability was reduced by \$1.8 million. The New York City Biotechnology Tax Credit gave rise to an additional \$0.2 million tax benefit.

Income tax benefit was \$4.9 million during the year ended December 31, 2016. During the year ended December 31, 2016, the AmiKet IPR&D was written down to \$15.0 million resulting in a reduction of the deferred tax liability by \$4.9 million from \$10.9 million to \$5.9 million.

### **Deemed Dividend**

We recorded approximately \$7.0 million in deemed dividends for the year ended December 31, 2017 resulting from issuance of our Series E Preferred Stock, which contains a beneficial conversion feature.

We recorded approximately \$8.0 million in deemed dividends for the year ended December 31, 2016 resulting from conversions of our Series D Preferred Stock.

### **Impact of Inflation**

The impact of inflation upon our revenue and income / (loss) from operations during each of the past two fiscal years has not been material to our financial position or results of operations for those years.

### **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 December 31, 2017, we had a working capital deficit of approximately \$2.2 million. Accumulated deficit amounted to \$113.5 million and \$95.6 million at December 31, 2017 and 2016, respectively. Net loss for the years ended December 31, 2017 and 2016 was \$19.9 million and \$32.7 million, respectively. Net cash used in operating activities was \$11.6 million and \$12.3 million for years ended December 31, 2017 and 2016, 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 December 31, 2017, we had \$6.8 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 annual report; (ii) we may not identify commercial partners to support development of its 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 audit report prepared by our independent registered public accounting firm relating to our consolidated financial statements for the year ended December 31, 2017 includes an explanatory paragraph expressing substantial doubt about our ability to continue as a going concern.

The following table summarizes select balance sheet and working capital amounts as of December 31, 2017 and December 31, 2016 (\$ in thousands):

	<b>As of December 31, 2017</b>	<b>As of December 31, 2016</b>	<b>Change</b>
Cash and cash equivalents	\$ 6,776	\$ 271	\$ 6,505
Working capital deficit	\$ (2,220)	\$ (8,521)	\$ (6,301)
Notes and loans payable, current portion	\$ (3,296)	\$ (2,739)	\$ 557

### **Cash Flow Activities**

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

	<b>For the year ended December 31,</b>		
	<b>2017</b>	<b>2016</b>	<b>Change</b>
Net cash used in operating activities	\$ (11,559)	\$ (12,307)	\$ (748)
Net cash provided by (used in) investing activities	\$ 31	\$ (50)	\$ 81
Net cash provided by financing activities	\$ 18,033	\$ 8,085	\$ 9,980

### ***Operating Activities***

Net cash used in operating activities for the year ended December 31, 2017 was \$11.6 million, as compared to \$12.3 million for the year ended December 31, 2016.

Net cash used in operating activities during the year ended December 31, 2017 was \$9.2 million exclusive of changes in operating assets and liabilities, which consists of the net loss of \$17.9 million, as adjusted for (i) stock based compensation expense of \$0.5 million, (ii) depreciation and amortization expense of \$0.7 million, (iii) amortization of debt discount and debt issuance costs of \$2.6 million, (iv) liquidated damages of \$1.8 million, (v) accretion of premiums of \$0.6 million, (vi) loss on disposal of equipment of \$0.3 million and (vii) loss on extinguishment of debt of \$2.1 million. Changes in operating assets and liabilities in the year ended December 31, 2017 of \$2.4 million negatively impacted net cash used in operating activities primarily due to a decrease in deferred tax liability of \$1.8 million and a decrease in accrued expenses of \$0.8 million offset by a decrease in other assets of \$0.2 million.

Net cash used in operating activities for the year ended December 31, 2016 was \$8.5 million exclusive of changes in operating assets and liabilities, which consists of the net loss of \$32.7 million, as adjusted for (i) stock based compensation of \$2 million, (ii) depreciation and amortization expense of \$0.4 million, (iii) amortization of debt issuance costs of \$0.6 million, (iv) in-process research and development impairment of \$12.5 million and (v) changes in the fair value of derivative liability instruments of \$8.7 million. Changes in operating assets and liabilities in the year ended December 31, 2016 of \$3.8 million negatively impacted net cash used in operating activities primarily due to a decrease in deferred tax liability of \$4.9 million offset by an increase in accounts payable of \$1.2 million.

### ***Investing Activities***

During the year ended December 31, 2017, net cash provided by investing activities was \$31,000, primarily related to a decrease in restricted cash of \$59,000, which was offset by \$28,000 in purchases of computer software.

During the year ended December 31, 2016, net cash used in investing activities amounted to \$50,000, primarily related to an increase in restricted cash of \$29,000 plus \$21,000 in purchases of office and laboratory equipment.

### ***Financing Activities***

During the year ended December 31, 2017, net cash provided by financing activities was \$18 million. This amount primarily was comprised of proceeds from the issuance of (i) Series E Convertible Preferred Stock of \$16 million, (ii) Equity Line financings of \$5.4 million, (iii) May 2017 Convertible Notes of \$1.6 million, (iv) April 2017 Convertible Notes of \$0.4 million, and (v) August 2017 Convertible Notes of \$0.5 million. These amounts were partially offset by the repayment of (i) \$1.4 million related to the November 2016 convertible notes, (ii) \$0.9 million related to the Loan Agreement with Hercules, (iii) \$0.5 million related to the May 2017 Convertible Notes, (iv) \$0.9 million related to the August 2017 Convertible Notes, (v) \$1.2 million related to the July 2017 Senior Secured Convertible Notes and (vi) \$1.2 million of commitment and transaction fees.

For the year ended December 31, 2016, net cash provided by financing activities was \$8.1 million. This amount was comprised primarily of proceeds from the sale of our common stock of approximately \$7.7 million and proceeds from the issuance of the convertible note to HLHW IV, LLC ("HLHW") of \$1.0 million. In addition, we received \$1.5 million of advances from related parties of which \$0.3 million was repaid during 2016. These amounts were offset by the repayment of notes and loans payable of \$1.2 million and the payment of fees related to sales of our common stock of \$0.5 million.

Historically, we have funded our operations through the sale of debt and equity securities. We anticipate issuing equity and/or debt as a source of liquidity, when needed, until we begin to generate positive cash flow to support our operations. We cannot give any assurance that the necessary capital will be raised or that, if funds are raised, it will be on favorable terms.

### ***Off-Balance Sheet Arrangements***

As of December 31, 2017, we did not have any off-balance sheet arrangements. We have no guarantees or obligations other than those that arise out of our ordinary business operations.

## Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon the consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America (“United States GAAP”). The preparation of these financial statements and related disclosures in compliance with United States GAAP requires the application of appropriate technical accounting rules and guidance as well as the use of estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities. The application of these policies involves judgments regarding future events, including the likelihood of success of particular product candidates, regulatory challenges, and the fair value of certain assets and liabilities. These judgments, in and of themselves, could materially affect the financial statements and disclosures based on varying assumptions, which may be appropriate to use. In addition, the financial and operating environment may also have a significant effect, not only on the operation of the business, but on the results reported through the application of accounting measures used in preparing the financial statements and related disclosures, even if the nature of the accounting policies have not changed.

On an ongoing basis, we evaluate these estimates, utilizing historic experience, consultation with experts and other methods we consider reasonable. In any event, actual results may differ substantially from our estimates. Any effects on our business, financial position or results of operations resulting from revisions to these estimates are recorded in the period in which the information that gives rise to the revision becomes known.

Our significant accounting policies are summarized in Item 15 — Note 3, *Summary of Significant Accounting Policies*, Note 4, *Derivative Financial Instruments* and Note 5, *Fair Value Measurements* to the Consolidated Financial Statements. We identify our most critical accounting policies as those that are the most pervasive and important to the portrayal of our financial position and results of operations, and that require the most difficult, subjective and/or complex judgments by management regarding estimates about matters that are inherently uncertain.

<u>Accounting Policy</u>	<u>Judgments/Uncertainties Affecting Application</u>
Derivative Instruments	Assumptions used in valuation techniques Assumptions used in forecasting borrowings Market maturity and economic conditions
Income Taxes and Valuation Allowance for Deferred Tax Assets	Ability to be sustained upon audit examination of taxing authorities Interpret existing tax statute and regulations upon application to transactions Ability to utilize tax benefits through carry backs to prior periods and carry forwards to future periods
Impairment of Long Lived Assets	Recoverability of investment through future operations Regulatory and political environments and requirements Estimated useful lives of assets Estimates of future cash flows Estimates of fair value Judgment about triggering events indicating impairment
Intangible Assets	Estimated useful lives for intangible assets Judgment about impairment triggering events Estimates of fair value Fair value estimate of intangible assets acquired in business combinations
Contingencies	Estimated financial impact of event(s) Judgment about likelihood of event(s) occurring Regulatory and political environments and requirements

### ***Recent Accounting Standards***

See Item 15 — Note 3 to the Consolidated Financial Statements, *Summary of Significant Accounting Policies*, for a discussion of recent accounting standards.

## **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are a smaller reporting company. Accordingly, we are not required to provide the information required by this Item.

## **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

See our consolidated financial statements filed with this Annual Report on Form 10-K under Item 15 below.

## **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

On December 7, 2017, our Audit Committee notified BDO USA, LLP ("BDO") our former independent registered public accounting firm that the Company and its Audit Committee had determined to dismiss BDO effective as of such date. On and effective as of December 7, 2017, we entered into an engagement letter with Marcum, LLP ("Marcum") as approved by the Audit Committee and engaged Marcum to act as our independent registered public accounting firm.

BDO's audit report on our financial statements for the years ended December 31, 2016 and 2015 did not contain an adverse opinion or a disclaimer of opinion, and was not qualified or modified as to uncertainty, audit scope or accounting principles except as follows:

BDO's audit reports stated that our financial statements have been prepared assuming that we will continue as a going concern. As discussed in the Notes to the financial statements, we had negative working capital, an accumulated deficit and recurring losses from operations as of the date of each financial statement and we expect continuing future losses, which raise substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

During our most recent fiscal year and any subsequent interim period through September 30, 2017, there were no disagreements with BDO on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of BDO, would have caused it to refer to the subject matter thereof regarding its report. During the fiscal year ended December 31, 2016 and any subsequent interim period through September 30, 2017, there have been no reportable events, as defined in Item 304(a)(1)(v) of Regulation S-K of the Securities and Exchange Commission, except that our internal controls over financial reporting were not effective due to the existence of material weaknesses in our internal controls over financial reporting, identified in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and Quarterly Reports on Form 10-Q for the quarters ended March 31, 2017, June 30, 2017 and September 30, 2017, relating to the lack of sufficient entity level controls, lack of segregation of duties 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. The Audit Committee has discussed these matters with BDO for the fiscal year ended December 31, 2016 and management has begun to implement remediation measures as disclosed in our periodic reports.

During our two most recent fiscal years and any subsequent period through September 30, 2017, neither we nor anyone acting on our behalf consulted Marcum regarding the application of accounting principles to any completed or proposed transactions nor regarding any matter that was the subject of a disagreement with our independent accountant or any reportable event, as defined in Item 304(a)(1)(v) of Regulation S-K of the Securities and Exchange Commission.

In deciding to appoint Marcum, the Audit Committee reviewed auditor independence issues and existing commercial relationships with Marcum and concluded that Marcum has no commercial relationship with us that would impair its independence for the fiscal year ending December 31, 2017.

## **ITEM 9A. CONTROLS AND PROCEDURES**

### *(a) Evaluation of Disclosure Controls and Procedures*

Our management, with the participation and supervision of our Principal Executive Officer, who also is our Principal Financial Officer, are 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, including our Principal Executive Officer who is also our Principal Financial Officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2017. Based on this evaluation, our Principal Executive Officer concluded that as of December 31, 2017, 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 December 31, 2017 (discussed in paragraph (b) to this Item 9A), which our management views as an integral part of our disclosure controls and procedures.

*(b) Management's Annual Report on Internal Control over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended, as a process designed by, or under the supervision of our Chief Executive Officer who is also our Principal Financial Officer and effected by our Board of Directors, management and other personnel 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. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of ours are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2017. 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.

In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013) as the framework to evaluate effectiveness. Because of the material weaknesses described above, management believes that, as of December 31, 2017, our internal controls over financial reporting was not effective based on those criteria.

During 2017, we began to address the material weakness relating to lack of entity level controls identified in our Annual Report on Form 10-K for the year ended December 31, 2016 and quarters ended March 31, June 30 and September 30, 2017 by leveraging the financial reporting and internal control expertise of our Chief Executive Officer, who has served as Chief Financial Officer in similarly sized biotechnology companies.

Management intends to continue its remediation plan in fiscal year 2018 in response to the other identified material weakness in financial reporting. Our planned remediation efforts to address lack of segregation of duties and accounting for complex financial transactions include 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.

(c) *Changes in Internal Controls*

During the quarter ended December 31, 2017, we continued remediation efforts and are still working on implementing certain controls identified above in response to previously identified material weaknesses. Once fully implemented, we believe that they will materially affect our internal control over financial reporting and serve to remediate our material weaknesses.

**ITEM 9B. OTHER INFORMATION**

None.

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

**Directors and Executive Officers**

The table below sets forth the name, age and position of each of our current directors and executive officers as of March 15, 2018.

<b>Name</b>	<b>Age</b>	<b>Position</b>
<b><i>Directors and Executive Officers</i></b>		
Elliot Maza <sup>(4)</sup>	62	President, Chief Executive Officer and Director (Principal Executive Officer and Principal Financial Officer)
Tony Fiorino, MD, PhD	50	Chief Operating Officer and Chief Medical Officer
Cameron Durrant, M.D. <sup>(1) (2) (3)</sup>	57	Lead Director
Daniel Teper, PharmD <sup>(4)</sup>	58	Director
Daniel Kazado	53	Director
Jeffrey Paley, M.D. <sup>(1) (2) (3)</sup>	50	Director
John Neczesny <sup>(1) (3) (4)</sup>	54	Director

(1) Member of our Audit Committee.

(2) Member of our Compensation Committee.

(3) Member of our Nominating and Corporate Governance Committee.

(4) Member of Transactions Committee.

**Business Experience**

The following is a brief account of the education and business experience of our current directors and executive officers:

*Elliot M. Maza, JD, CPA (inactive)* 62, has been the Interim Chief Executive Officer of the Company since April 21, 2017 and permanent CEO since September 2017. He became a director of the Company on January 14, 2015. Prior to joining the Board, Mr. Maza served as a consultant to the Company from November 2014 to January 2015. Mr. Maza has been the Chairman of the Board of Directors, Chief Executive Officer and Chief Financial Officer of Intellect Neurosciences, Inc., a biotechnology company focused on the development of therapeutics for neurodegenerative diseases since July 2014. From May 2006 to June 2014, Mr. Maza has served in several management positions at Intellect Neurosciences, Inc. Mr. Maza served as the Executive Vice President of Intellect Neurosciences, Inc. from May 2006 to March 2007 and as President from March 2007 to October 2011. He has served as Chief Financial Officer of Intellect Neurosciences, Inc. from May 2006 to the present. Mr. Maza was appointed to the board of directors of Intellect Neurosciences, Inc. on June 26, 2007. From July 2011 until January 2014, Mr. Maza served as Chief Executive Officer and CFO of Biozone Pharmaceuticals, Inc., Pittsburg, CA (OTCBB: BZNE) (now known as CoCrystal Inc.), a manufacturer of prescription and over-the-counter (OTC) drug products and anti-aging and skin care products. From December 2003 to May 2006, Mr. Maza served as Chief Financial Officer of Emisphere Technologies, Inc., a biopharmaceutical company specializing in oral drug delivery. From March 1999 to December 2003, he was a partner at Ernst and Young, LLP. During the period from May 1989 to March 1999, Mr. Maza served as an Associate and subsequently Vice President in the Fixed Income divisions of Goldman Sachs, Inc. and JP Morgan Securities, Inc. Mr. Maza practiced tax and corporate law at Sullivan and Cromwell in New York from September 1985 to April 1989. We believe that Mr. Maza is qualified to serve as the Interim Chief Executive Officer and director of the Company based on his experience as a senior executive in several biotech and biopharma companies.

*Tony Fiorino, MD, PhD, 50*, was appointed Chief Medical Officer and Chief Operating Officer of the Company in August 2017. Dr. Fiorino served as President and Chief Executive Officer of Triumvira Immunologics, an immuno-oncology company developing a novel engineered T cell platform, 2015-2017. Dr. Fiorino was the Chief Executive Officer of BrainStorm Cell Therapeutics (NASDAQ: BCLI) a leading developer of adult stem cell technologies for neurodegenerative diseases, 2014-2015. During his tenure, BrainStorm conducted a phase 2 trial of neurotrophic factor-secreting mesenchymal stem cells in amyotrophic lateral sclerosis, raised \$25 million in equity capital, and uplisted to the NASDAQ. Dr. Fiorino was the Founder, President and CEO of EnzymeRx from 2008-2010, where he led the acquisition of a late-stage pre-clinical biologic and the development of the compound through phase 2 clinical trials and its subsequent sale to 3SBio and worked as an independent consultant to biotechnology and pharmaceutical companies and investment funds from 2008-2014. Before founding EnzymeRx, Dr. Fiorino worked as a biotechnology and pharmaceuticals analyst and portfolio manager at firms including JP Morgan, Citigroup, and Pequot Capital. Dr. Fiorino earned an MD and a PhD from the Albert Einstein College of Medicine, where he studied the differentiation of liver progenitor cells, and a BS from the Massachusetts Institute of Technology. We believe that Dr. Fiorino is qualified to serve as Chief Medical Officer and Chief Operating Officer of the Company based on his educational background and experience as a senior executive in several biotech and biopharma companies.

*Cameron Durrant, MD, MBA, 57*, joined our board of directors in July 2014. Dr. Durrant is CEO and Chairman of the Board of Humanigen, Inc. since January 2016. Dr. Durrant served as President and Chief Executive Officer of ECR Pharmaceuticals Co., Inc. (“ECR”) a subsidiary of Hi-tech Pharmacal Co., Inc. (NASDAQ: HITK), from September 2012 to April 2014. From January 2010 to September 2012, Dr. Durrant served as a consultant to several biopharma companies, as the Founder, CEO and CFO of PeditRx, Inc. (subsequently acquired) and on several biotech and medical device company boards. As well as holding CEO and CFO roles, he has acted as Chairman, Treasurer and Chief Accounting Officer and convened, sat on or chaired the audit, nominating, governance, compensation committees of various biotech companies. He has been an executive at blue-chip big pharma, including Johnson and Johnson, Pharmacia Corporation (until its acquisition by Pfizer), GSK and Merck. He is a founding director of Bexion Pharmaceuticals, a private biotech/nanotech oncology company in Phase I and a board member of two private medical device companies. He has served as Executive Chairman and CEO of Anavex (a public company), former CEO of PediaMed Pharmaceuticals (acquired by Connetics Corporation) and former board member of Topaz Pharmaceuticals (acquired by sanofi-aventis). He was the 2005 winner of the Ernst and Young Ohio and Kentucky ‘Entrepreneur of the Year’ winner and a national finalist, named as a PharmaVoice Red Jacket honoree in 2017. Dr. Durrant earned his MD from the Welsh National School of Medicine, Cardiff, UK, his DRCOG from the Royal College of Obstetricians and Gynecologists, London, UK, his MRCGP from the Royal College of General Practitioners, London, UK, his DipCH from the Melbourne Academy, Australia and his MBA from Henley Management College, Oxfordshire, UK. We believe that Dr. Durrant is qualified to serve on our board of directors based on his operating experience as a sitting CEO of a public biotech and his experience as an executive and director of several biotech companies.

*Daniel Gedeon Teper, Pharm. D., MBA, 58*, was the Chief Executive Officer of the Company from August 25, 2013 until April 21, 2017. He was appointed as a director in connection with the merger transaction between the Company and Immune Ltd, in August 2013. From August 25, 2013 to December 15, 2014, Dr. Teper also served as Chairman of our Board of Directors. Dr. Teper founded Immune Ltd., a wholly-owned subsidiary of the Company, and served as its chairman and chief executive officer from January 2010 to August 2013. From 2005 to 2009, Dr. Teper served as New York-based Managing Partner and Head of North America at Bionest Partners, a global management consulting firm, where he advised pharmaceutical and public biotechnology companies with respect to corporate strategy, business development, mergers and acquisitions, new product development and commercialization. From 2000 to 2004, Dr. Teper held various senior management roles in the United States, including senior vice president of sales and business development at Softwatch, an Internet healthcare company, where he assisted in raising \$30 million in venture capital and expanding the company to over 150 employees. From 1996 to 1999, Dr. Teper served as global president of HAVAS-Euro Rscg Healthcare Worldwide, where he expanded operations internationally and advised pharmaceutical companies on global launches of major new drugs in multiple disease areas. Dr. Teper worked for Novartis from 1984 to 1990, serving at the headquarters in Basel, Switzerland from 1984 to 1985 and serving out of the United States from 1985 to 1990, during which time he held management responsibilities in sales and marketing and was appointed head of new product development for Cardiovascular Products. From 1990 to 1992, Dr. Teper held general management positions in France, including Senior Vice President and head of marketing and sales of Laboratories at GlaxoSmithKline and President and Chief Operating Officer of Laboratories at Delagrang (which was acquired by Synthelabo, a predecessor to Sanofi). Dr. Teper holds a Doctor of Pharmacy degree from Paris XI University and an MBA from INSEAD, where he was a J. Salmon scholar. We believe that Dr. Teper is qualified to serve as on our board of directors due to his many years of service as our former Chief Executive Officer, his extensive knowledge of our Company and his extensive experience within our industry.

*Daniel Kazado, 52, Daniel Kazado, 53*, became a Director of the Company on October 10, 2013 and served as Chairman of the Board of Directors from December 15, 2014 to October 19, 2016. Mr. Kazado has served as a senior advisor to Melini Capital Corp., a family owned private and public equity firm investing internationally in several industries, since its incorporation in 2010. Melini Capital Corp. has been an early and significant investor in Immune Pharmaceuticals from March 2011. In 1992, Mr. Kazado founded DMA Altiam, a management consulting firm that advised boards of directors and senior management in multiple industries. DMA Altiam grew to include 25 professionals over the course of fifteen years, and in 2002 Mr. Kazado sold the company to Altran Technologies, a global engineering and management consulting group with revenues of over \$1.0 billion. Mr. Kazado holds a bachelor's degree in Business Administration and a master's degree in Management from Lyon University in France. We believe that Mr. Kazado is qualified to serve on our board of directors based on his experience with advising boards of directors and senior management of in multiple industries, including our industry, with respect to management and other business aspects.

*Jeffrey Paley, MD, 50*, became a Director of the Company on February 23, 2016. Dr. Paley brings over 19 years of experience in the healthcare industry. Dr. Paley has been an active clinician and consultant for over 30 analysts and portfolio managers in the biotechnology, pharmaceutical, specialty pharmaceutical and medical technology arenas, reviewing the clinical, preclinical and regulatory pedigrees of numerous therapeutics and devices. Dr. Paley has also consulted for several biotechnology and specialty pharmaceutical companies, most notably in the areas of clinical development and business development and he has engineered transactions worth over \$600 million. Dr. Paley founded Access Medical Associates in 2003, after spending five years on the full-time academic faculty of Weill Cornell Medical College, where he served as a Director of Clinical Research at the Cornell Internal Medicine Associates. At Weill Cornell, Dr. Paley was a Principal or Co-Principal Investigator on several studies of diabetes, hypertension, and cholesterol disorders. He has served as a Director of Kellbenx and Retrophin and currently serves as a Director of Kalytera, Caelum Biosciences, Avenue Therapeutics and Remote Radiology Inc. Dr. Paley trained at Harvard Medical School and completed a residency in Internal Medicine at Massachusetts General Hospital. We believe that Dr. Paley is qualified to serve as a Director of the Company based on his extensive experience in the healthcare industry.

*John Neczesny, MBA, 54*, became a Director of the Company on February 2, 2016. Mr. Neczesny is a Managing Partner at Blue Ox Healthcare Partners, LLC, a private investment firm providing capital to growth-stage healthcare companies. He was previously a Managing Director at Oberon Securities, LLC as an investment banker to healthcare companies and Vice President, Corporate Development at Par Pharmaceutical Companies. From 1998 to 2008, Mr. Neczesny was an investment banker at Bear Stearns & Co. Inc. in the Healthcare group, where he rose to Managing Director and was involved in numerous M&A and capital markets transactions for pharmaceutical, biotechnology and medical technology companies. He earlier spent 9 years in business development and project management in contract laboratory and data management businesses. Mr. Neczesny earned an MBA in Finance from New York University Stern School of Business and a Bachelor of Science degree in Chemistry from the University of Delaware. We believe that Mr. Neczesny is qualified to serve as a director of the Company based on his experience with numerous transactions involving pharmaceutical and biotechnology companies.

#### **Family Relationships**

There are no family relationships among any of our current or former directors or executive officers.

## **Arrangements between Officers and Directors**

To our knowledge, there is no arrangement or understanding between any of our officers or directors and any other person, including Directors, pursuant to which the officer or director was selected to serve as an officer or director.

## **Involvement in Certain Legal Proceedings**

We are not aware of any of our directors or officers being involved in any legal proceedings in the past ten years relating to any matters in bankruptcy, insolvency, criminal proceedings (other than traffic and other minor offenses), or being subject to any of the items set forth under Item 401(f) of Regulation S-K.

## **Corporate Governance**

### **General**

We believe that good corporate governance is important to ensure that the Company is managed for the long-term benefit of our stockholders. This section describes key corporate governance practices that we have adopted.

### **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than ten percent of a registered class of our equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. Officers, directors and greater than ten percent stockholders are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file.

To our knowledge, based solely upon a review of Forms 3, 4, and 5 furnished to us during the fiscal year ended December 31, 2017, we believe that the directors, executive officers, and greater than ten percent beneficial owners have complied with all applicable filing requirements during the fiscal year ended December 31, 2017.

### **Code of Conduct and Ethics**

We have adopted a Code of Business Conduct and Ethics that applies to all its employees, including our Principal Executive Officer and Principal Financial Officer, and a Supplemental Code of Ethics that specifically applies to our Chief Executive Officer and Principal Financial Officer. The text of the Code of Business Conduct and Ethics and the Supplemental Code of Ethics are publicly available on our website at [www.immunopharma.com](http://www.immunopharma.com).

Disclosure regarding any amendments to, or waivers from, provisions of the code of conduct and ethics that apply to our directors, principal executive and financial officers will be posted on the “Investors-Corporate Governance” section of our website at [www.immunopharma.com](http://www.immunopharma.com) or will be included in a Current Report on Form 8-K, which we will file within four business days following the date of the amendment or waiver.

### **Audit Committee and Financial Experts**

The Audit Committee of the Board is composed entirely of directors who are not our current or former employees, each of whom meets the applicable definition of “independent” as promulgated by the Securities and Exchange Commission and as defined by the rules of The NASDAQ Capital Market as such standards apply specifically to members of audit committees. The current members of the Compensation Committee are Cameron Durrant, M.D. (Chairman) and Messrs. Paley and Neczesny. The Board of Directors has determined that Dr. Durrant is an “audit committee financial expert” as the Securities and Exchange Commission has defined that term in Item 407 of Regulation S-K based on his experiences as a Chief Executive Officer and Chief Financial Officer of several publicly traded biopharmaceutical companies.

Mr. Maza served on the Audit Committee during the fiscal year ended December 31, 2016 until his resignation from the Audit Committee on April 21, 2017. Dr. Durrant was elected Chairman on May 10, 2017 following the resignation of Mr. Maza. Mr. Neczesny was appointed to the Board of Directors and to our Audit Committee on February 2, 2016. Mr. Paley was elected to the Audit Committee on May 10, 2017. Our Audit Committee met four times during the fiscal year ended December 31, 2017.

The Audit Committee is responsible for retaining and overseeing our independent registered public accounting firm, approving the services performed by our independent registered public accounting firm and reviewing our annual financial statements, accounting policies and our system of internal controls. A copy of the Audit Committee’s written charter is publicly available on the “Investors-Corporate Governance-Committees” section of our website at [www.immunopharma.com](http://www.immunopharma.com).

## **Compensation Committee**

The Compensation Committee of the Board is composed entirely of directors who are not our current or former employees, each of whom meets the applicable definition of “independent” as defined by the rules of The NASDAQ Capital Market. The current members of the Compensation Committee are Dr. Durrant, M.D. (Chairman), and Dr. Paley. Mr. Maza served on the Compensation Committee prior to his appointment as our Interim Chief Executive Officer.

None of the members of the Compensation Committee during fiscal 2017 and 2016 (i) had any relationships requiring disclosure by us under the SEC’s rules requiring disclosure of related party transactions or (ii) was an executive officer of a company of which an executive officer of the Company is a director.

The Compensation Committee is responsible for establishing and administering our executive compensation policies. The role of the Compensation Committee is to (i) formulate, evaluate and approve compensation of our directors, executive officers and key employees, (ii) oversee all compensation programs involving the use of our stock, and (iii) produce, if required under the securities laws, a report on executive compensation for inclusion in our proxy statement for its annual meeting of stockholders. The duties and responsibilities of the Compensation Committee under its charter include:

- Annually reviewing and setting compensation of executive officers;
- Periodically reviewing and making recommendations to the Board with respect to compensation of non-employee directors;
- Reviewing and approving corporate goals and objectives relevant to Chief Executive Officer compensation, evaluating the Chief Executive Officer’s performance in light of those goals and objectives, and setting the Chief Executive Officer’s compensation levels based on this evaluation;
- Reviewing competitive practices and trends to determine the adequacy of the executive compensation program;
- Approving and overseeing incentive compensation and equity-based plans for executive officers that are subject to Board approval;
- Making recommendations to the Board as to our compensation philosophy and overseeing the development and implementation of compensation programs;
- Periodically reviewing and making recommendations to the Board with respect to compensation of non-employee directors; and
- Reviewing and approving corporate goals and objectives relevant to Chief Executive Officer compensation, evaluating the Chief Executive Officer’s performance in light of those goals and objectives, and setting the Chief Executive Officer’s compensation levels based on this evaluation;

When appropriate, the Compensation Committee may, in carrying out its responsibilities, form and delegate authority to subcommittees. This process leads to a recommendation for any changes in salary, bonus terms and equity awards, if any, based on performance, which recommendations are then reviewed and approved by the Compensation Committee.

The Compensation Committee has the authority, at our expense, to select, retain, terminate and set the fees and other terms of our relationship with any outside advisors who assist it in carrying out its responsibilities, including compensation consultants or independent legal counsel.

## **Nominating and Governance Committee**

The Board has a standing Nominating and Governance Committee, which consists of Jeffrey Paley, M.D. (Chairman), Cameron Durrant, M.D. and John Neczesny. The Nominating and Governance Committee may employ a variety of methods for identifying and evaluating nominees for director. The current members of the Nominating and Governance Committee qualify as independent as defined by the rules of the NASDAQ Stock Market.

The Nominating and Governance Committee regularly assesses the size of the Board, the need for particular expertise on the Board, and whether any vacancies on the Board are expected due to retirement or otherwise. Candidates may be evaluated at regular or special meetings of the Nominating and Governance Committee and may be considered at any point during the year.

## ITEM 11. EXECUTIVE COMPENSATION

### Summary Compensation Table

The following table sets forth the total compensation earned, paid or accrued during the last two fiscal years ended December 31, 2017 and 2016 by our (i) Chief Executive Officer; (ii) Chief Medical and Operating Officer; (iii) former Chief Executive Officer and (iv) our two next most highly compensated former executive officers during the fiscal year ended December 31, 2017, collectively referred to as the “named executive officers.”

<u>Name/Principal Position</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Stock Awards (\$)</u>	<u>Option Awards(\$)</u> <sup>(2)</sup>	<u>All Other Compensation (\$)</u>	<u>Total (\$)</u>
<i>Elliot Maza,</i> Chief Executive Officer	2017	320,833 <sup>(1)</sup>		294,515 <sup>(3)</sup>		615,348
<i>Tony Fiorino,</i> Chief Medical and Operating Officer	2017	136,986		83,246 <sup>(4)</sup>		220,232
<i>Daniel G. Teper,</i> Former Chief Executive Officer	2017	320,769	-	-	-	320,769
	2016	360,000	-	139,364 <sup>(5)</sup>	-	499,364
<i>Monica Luchi,</i> Former Chief Medical Officer	2017	198,923	-	-	-	198,923
	2016	360,000	-	54,056 <sup>(6)</sup>	-	414,056
<i>John Militello,</i> Former VP Finance and Controller	2017	283,317	-	-	-	283,317
	2016	220,000	-	36,037 <sup>(7)</sup>	-	256,037

(1) Amount includes bonus payment of \$70,000.

(2) Amounts represent the aggregate grant date fair value in accordance with FASB ASC Topic 718. See Note 10 to our consolidated financial statements included in this Annual Report on Form 10-K for the year ended December 31, 2017.

(3) On May 10, 2017, the Company’s Board, pursuant to the recommendation of the Compensation Committee granted to Mr. Maza an option to purchase up to 30,000 shares of our common at an exercise price of \$2.68 per share and vesting immediately. On July 18, 2017, the Company’s Board, pursuant to the recommendation of the Compensation Committee, granted an option to Mr. Maza to purchase up to 100,000 shares of our common stock at an exercise price of \$2.69 per share and vesting over a two-year period, with one-half vesting immediately and the remaining vesting quarterly.

(4) On September 14, 2017, the Company’s Board, pursuant to the recommendation of the Compensation Committee granted to Dr. Fiorino an option to purchase up to 90,000 shares of our common at an exercise price of \$1.10 per share, vesting over a three-year period, with 15% vesting after 90 days, 15% on the first-year anniversary and the remaining options vesting quarterly over the remaining two-year period.

(5) On June 1, 2016, the Company’s Board, pursuant to the recommendation of the Compensation Committee granted to Dr. Teper an option to purchase up to 9,000 shares of our common at an exercise price of \$8.00 per share, vesting over a three-year period, with one-third vesting after the first year and the remaining options vesting quarterly thereafter. On June 24, 2016, the Company’s Board, pursuant to the recommendation of the Compensation Committee, granted an option to Dr. Teper to purchase up to 15,000 shares of our common stock at an exercise price of \$7.60 per share and vesting immediately.

(6) On June 1, 2016, the Company’s Board, pursuant to the recommendation of the Compensation Committee granted an option to Dr. Luchi to purchase up to 9,000 shares of our common at an exercise price of \$8.00 per share and vesting over a three-year period, with one-third vesting after the first year and the remaining options vesting quarterly.

- (7) On June 1, 2016, the Company's Board, pursuant to the recommendation of the Compensation Committee granted to Mr. Militello an option to purchase up to 6,000 shares of our common stock at an exercise price of \$8.00 per share and vesting over a three-year period, with one-third vesting after the first year and the remaining options vesting quarterly.

## **Narrative Disclosure to Summary Compensation Table**

### **Mr. Elliot Maza**

Effective December 1, 2017, we entered into an employment agreement with Elliot Maza, our CEO, and our Board of Directors also appointed him to the additional positions of President, Principal Financial Officer and Secretary, until such time as a new Principal Financial Officer may be retained. Mr. Maza was appointed permanent CEO in September 2017, after serving in this capacity on an interim basis since April 2017 and as a Director since January 2015.

The Company and Mr. Maza entered into an employment agreement dated November 29, 2017 (the "Maza Employment Agreement") which provides that Mr. Maza will be entitled to receive an annual base salary of \$400,000. Mr. Maza will be eligible to receive a potential annual target cash bonus up to 75% of his annual base salary, which is based on achievement of financial goals and other objectives, as defined and approved by our Board of Directors. In addition, Mr. Maza is eligible to participate in all employee benefit plans, programs and arrangements, and all fringe benefits and perquisites that are made available to our senior executives, including health insurance coverage in accordance with the terms of our health insurance plan.

Pursuant to the terms of the Maza Employment Agreement, Mr. Maza is entitled to a grant of options to purchase a number of shares of our common stock representing up to seven percent (7%) of our total outstanding shares on the date of grant, subject to achievement of certain goals and in accordance with Schedule I of the Maza Employment Agreement. The award is subject to and in accordance with the terms and provisions of our 2015 Equity Incentive Plan. No options have yet been granted to Mr. Maza pursuant to the Maza Employment Agreement.

The Maza Employment Agreement will terminate upon the death or disability of Mr. Maza. In addition, we may terminate the Maza Employment Agreement with or without cause, and Mr. Maza may terminate the Maza Employment Agreement for or without good reason, in each case, subject to satisfaction of certain notice requirements set out in the Maza Employment Agreement. In the event we terminate the Maza Employment Agreement without cause or Mr. Maza terminates the Maza Employment Agreement for good reason, Mr. Maza is entitled to the following benefits: (i) an amount equal to twelve (12) months of Mr. Maza's base salary for the year in which the termination for good reason occurs plus (ii) the amount of the actual bonus earned by Mr. Maza for the year prior to the year of termination, pro-rated based on the number of days Mr. Maza was employed by us during the year of termination as compared to the total number of days in such year. Payment is contingent upon Mr. Maza's signature of a release that is satisfactory to us in form and in substance. The Maza Employment Agreement does not provide for any payments in the event that it is terminated by us for cause or by Mr. Maza without good reason.

### **Dr. Tony Fiorino**

Effective August 14, 2017, we entered into an employment agreement with Dr. Tony Fiorino, our Chief Medical Officer and Chief Operation Officer (the "Fiorino Employment Agreement"). Under the terms of the Fiorino Employment Agreement, Dr. Fiorino is entitled to receive an annual base salary of \$360,000. In addition, Dr. Fiorino is eligible to receive, subject to the board of directors' approval, an annual minimum bonus of 10% of his base salary. Dr. Fiorino is also eligible to participate in all employee benefit plans, programs and arrangements, and all fringe benefits and perquisites that are made available to our senior executives, including but not limited to, health insurance coverage in accordance with the terms of our health insurance plan.

In addition, as of the effective date of the Fiorino Employment Agreement, we granted to Dr. Fiorino options to purchase 90,000 shares of our common stock, at a price per share equal to the market share price on the date of grant. Of this amount, 15% vested ninety (90) days following the date of grant; 15% vests on the first-year anniversary of the date of grant (the "Anniversary") and 70% vests in equal portions at the end of each three (3) month period over the course of a two (2) year period commencing on the Anniversary, subject to acceleration under certain events.

The Fiorino Employment Agreement may be terminated upon death, disability, by us with or without cause or by Dr. Fiorino with or without good reason. In the event the Fiorino Employment Agreement is terminated for good reason by Dr. Fiorino, he shall be entitled to receive his base salary for a period of six (6) months. If the Fiorino Employment Agreement is terminated by us without cause, Dr. Fiorino shall be entitled to receive his base salary for a period of six (6) months. In each case, payment is contingent upon Dr. Fiorino's signature of a release that is satisfactory to us in form and in substance. The Fiorino Employment Agreement does not provide for any payments in the event that it is terminated by us for cause or by Dr. Fiorino without good reason.

If we terminate the Fiorino Employment Agreement without cause, or if Dr. Fiorino terminates the Fiorino Employment Agreement for good reason, one half (50%) of unvested stock options granted to him shall vest immediately.

#### **Dr. Daniel G. Teper**

On June 4, 2014, we entered into an employment agreement with Dr. Teper (the "Teper Employment Agreement"). Under the terms of the Teper Employment Agreement, Dr. Teper is entitled to receive an annual base salary of \$260,000. In addition, Dr. Teper is eligible to receive, subject to the board of directors' approval, an annual incentive award, contingent upon his achievement of goals mutually agreed upon by Dr. Teper and us, of up to \$360,000 for each calendar year of his term of employment, which may be granted in cash or in equity equivalent and an annual bonus of up to 100% of his base salary. During fiscal years 2015 and 2016, no bonus was paid to Dr. Teper. Under the term of the Employment Agreement, Dr. Teper is also eligible to participate in all employee benefit plans, programs and arrangements, and all fringe benefits and perquisites that are made available to our senior executives, including but not limited to, health insurance coverage in accordance with the terms of our health insurance plan.

The Teper Employment Agreement may be terminated upon death, disability, by us with or without cause or by Dr. Teper with or without good reason. In the event the Teper Employment Agreement is terminated for Good Reason by Dr. Teper, he shall be entitled to receive his base salary for a period of three (3) months. If the Teper Employment Agreement is terminated by us without cause, Dr. Teper shall be entitled to receive his base salary for a period of six (6) months. In each case, payment is contingent upon Dr. Teper's signature of a release that is satisfactory to us in form and in substance. The Teper Employment Agreement does not provide for any payments in the event that it is terminated by us for cause or by Dr. Teper without good reason.

On June 23, 2014, Immune Ltd. and Dr. Teper entered into an amendment to that certain employment agreement, by and between Immune Ltd. and Dr. Teper, dated September 1, 2011 (the "Amendment"). The Amendment was effective as of June 1, 2014. Pursuant to the Amendment, (i) Dr. Teper's base annual salary will be \$100,000 (or NIS 20,500 per month) increased to \$141,463 (or NIS 29,000 per month) on January 1, 2015, for services rendered by Dr. Teper to Immune Ltd. (ii) the notice period for termination by employee was reduced to three months and by Immune Ltd. was reduced to six months, and (iii) Dr. Teper is entitled to up to 10 paid vacation days, which can be accumulated, subject to certain conditions. The employment agreement of Dr. Teper with Immune Ltd. was in addition to the existing Employment Agreement between us and Mr. Teper entered into on June 4, 2014, as described above. However, on February 28, 2015, Dr. Teper and Immune Ltd. terminated, effective as of January 1, 2015, Mr. Teper's employment agreement with Immune Ltd. In connection with the termination, we and Dr. Teper amended Dr. Teper's Employment Agreement. Pursuant to the amendment, effective as of January 1, 2015, Dr. Teper's annual base salary increased from \$260,000 to \$360,000.

Effective as of April 21, 2017, the Board accepted the resignation of Daniel Teper as Chief Executive Officer. Dr. Teper will remain a member of the Board and will focus his efforts, in conjunction with the Board, on developing and beginning execution of a plan to establish Cytovia, Inc., a subsidiary of the Company, as an independent oncology business.

In connection with Dr. Teper's resignation from the Company, we entered into a Separation Agreement (the "Separation Agreement") with Dr. Teper, which provides, among other things, that the parties recognize that Dr. Teper has an interest in pursuing opportunities in the field of oncology research and development and commercialization as currently being contemplated or pursued through the Company or its subsidiary, Cytovia, Inc. ("Cytovia"). The Separation Agreement provides that the parties anticipate that they will cooperate in good faith to assist Dr. Teper in developing Cytovia or a company to be formed by Dr. Teper ("NewCo"), and we agree that we will, for a period of three months from the termination date, use commercially reasonable efforts – consistent with the best interests of the Company and its stockholders and subject to the fiduciary duties of the Board – to develop and begin execution of a plan to establish an independent oncology business, either through Cytovia or NewCo, which may involve the transfer by Immune of some or all of its oncology assets to Cytovia or NewCo, as applicable. In addition, the Separation Agreement gives Dr. Teper a right of first negotiation, for a period of six months, with respect to any sale or license of our oncology assets at a price reasonably acceptable to us. The Separation Agreement includes a cooperation provision, a non-disparagement covenant as well as a release of claims by Dr. Teper.

On October 21, 2017, the Company and Dr. Teper agreed that he would no longer be entitled to any compensation as an employee of the Company but instead would be entitled to receive compensation as a member of our Board of Directors in the same amount as the independent members of our Board.

#### **Dr. Monica Luchi**

On November 2, 2015, we entered into an employment agreement with Dr. Luchi (the "Luchi Employment Agreement"). Under the terms of the Luchi Employment Agreement, Dr. Luchi is entitled to receive an annual base salary of \$360,000. In addition, Dr. Luchi is eligible to receive, subject to the board of directors' approval, an annual incentive award, contingent upon her achievement of goals mutually agreed upon by Dr. Luchi and the Company, of up to \$180,000 for each calendar year of her term of employment, which may be granted in cash or in equity equivalent. During fiscal years 2015 and 2016, no bonus was paid to Dr. Luchi. Under the terms of the Employment Agreement, Dr. Luchi is eligible to participate in all employee benefit plans, programs and arrangements, and all fringe benefits and perquisites that are made available to our senior executives, including but not limited to, health insurance coverage in accordance with the terms of our health insurance plan.

The Luchi Employment Agreement may be terminated upon death, disability, by us with or without cause or by Dr. Luchi with or without good reason. In the event the Luchi Employment Agreement is terminated for good reason by Dr. Luchi, she is entitled to receive her base salary for a period of three (3) months. If the Luchi Employment Agreement is terminated by us without cause, Dr. Luchi is entitled to receive her base salary for a period of three (3) months. In each case, payment is contingent upon Dr. Luchi's signature of a release that is satisfactory to us in form and in substance. The Luchi Employment Agreement does not provide for any payments in the event that it is terminated by us for cause or by Dr. Luchi without good reason. Upon termination for a change in control, Dr. Luchi is entitled to receive her base salary for a period of six (6) months.

Effective October 28, 2015, Dr. Luchi was granted an option to purchase 20,000 shares of our common stock, at an exercise price of \$19.60, the closing price of the shares of our common stock on the date of the grant by the Board. The options vest over a three-year period, with one third vesting on the first-year anniversary and the remaining vesting quarterly thereafter, subject to acceleration in the event of (i) Change of Control (as defined in the Luchi Employment Agreement); or (ii) termination by us without cause.

On June 1, 2016, our Board, pursuant to the recommendation of the Compensation Committee granted an option to Dr. Luchi to purchase up to 9,000 shares of our common stock at an exercise price of \$8.00 per share and vesting over a three-year period, with one-third vesting after the first year and the remaining options vesting quarterly.

On June 6, 2017, Dr. Luchi provided notice of her resignation from the Company. No severance payments or other remuneration was triggered as a result of Dr. Luchi's resignation. Dr. Luchi's final termination from the Company was effective as of June 30, 2017.

#### **John Militello**

On December 31, 2015, we entered into an employment agreement with Mr. Militello (the "Militello Employment Agreement"). Under the terms of the Militello Employment Agreement, Mr. Militello is entitled to receive an annual base salary of \$220,000. In addition, Mr. Militello is eligible to receive, subject to the Board's approval, an annual incentive award, contingent upon his achievement of goals mutually agreed upon by Mr. Militello and the Company, of up to \$77,000 for each calendar year of his term of employment, which may be granted in cash or in equity equivalent. During fiscal year 2016, no bonus was paid to Mr. Militello. Under the terms of the Militello Employment Agreement, Mr. Militello is eligible to participate in all employee benefit plans, programs and arrangements, and all fringe benefits and perquisites that are made available to our senior executives, including but not limited to, health insurance coverage in accordance with the terms of our health insurance plan.

The Militello Employment Agreement may be terminated upon death, disability, by us with or without cause or by Mr. Militello with or without good reason (as defined in the Militello Employment Agreement). In the event the Militello Employment Agreement is terminated for good reason by Mr. Militello, he is entitled to receive his base salary for a period of three (3) months. If the Militello Employment Agreement is terminated by us without cause, Mr. Militello is entitled to receive his base salary for a period of three (3) months. In each case, payment is contingent upon Mr. Militello's signature of a release that is satisfactory to us in form and in substance. The Militello Employment Agreement does not provide for any payments in the event that it is terminated by us for cause or by Mr. Militello without good reason. Upon termination for a change in control, Mr. Militello is entitled to receive his base salary for a period of six (6) months.

Effective December 31, 2015, Mr. Militello was granted an option to purchase 6,250 shares of our Common Stock, at an exercise price of \$14.60 per share, the closing price of the shares of our Common Stock on the date of the grant by the Board, which options vest over a three-year period, with one third vesting on the first year anniversary and the remaining vesting quarterly thereafter subject to acceleration in the event of (i) Change of Control (as defined in the Militello Employment Agreement); or (ii) termination by us without cause, pursuant to the terms and subject to the conditions of our stock option plan.

On June 1, 2016, our Board, pursuant to the recommendation of the Compensation Committee granted to Mr. Militello an option to purchase up to 6,000 shares of our Common Stock at an exercise price of \$8.00 per share and vesting over a three-year period, with one-third vesting after the first year and the remaining options vesting over the following eight quarters thereafter at the rate of one-twelfth of the original total per quarter.

On November 20, 2017, our management and Mr. Militello mutually agreed that it was in their respective best interests to terminate their employment relationship. Mr. Militello relinquished his position from the Company effective November 21, 2017.

### Outstanding Equity Awards at Fiscal Year End

The following table sets forth information for each named executive officer regarding outstanding stock options on the last day of the fiscal year ended December 31, 2017:

#### Option Awards Number of Securities Underlying Unexercised Options (#)

Name	Number Exercisable <sup>(1)</sup>	Number Unexercisable	Option Exercise Price	Option Expiration Date
Elliot Maza	2,500 <sup>(3)</sup>	-	\$ 37.80	01/21/25
	2,000 <sup>(4)</sup>	-	10.60	01/29/26
	2,500 <sup>(4)</sup>	-	8.00	06/01/26
	18,750 <sup>(4)</sup>	6,250	4.00	01/25/27
	30,000 <sup>(5)</sup>	-	2.68	05/10/27
	56,250 <sup>(6)</sup>	43,750	2.69	07/18/27
Tony Fiorino	13,500 <sup>(7)</sup>	76,500	\$ 1.10	09/14/27
Daniel G. Teper <sup>(2)</sup>	1,546 <sup>(8)</sup>	-	\$ 14.10	07/10/22
	618 <sup>(5)</sup>	-	19.80	04/11/23
	37,500 <sup>(9)</sup>	-	47.60	02/02/24
		12,500 <sup>(10)</sup>		
	4,500	4,500 <sup>(11)</sup>	\$ 8.00	06/01/26
	15,000 <sup>(5)</sup>	-	7.60	06/24/26
Monica Luchi	- <sup>(12)</sup>	-	\$ 19.60	11/19/25
	- <sup>(12)</sup>	-	8.00	06/01/26
John Militello	2,875 <sup>(13)</sup>	-	\$ 39.60	04/17/25
	417 <sup>(13)</sup>	-	36.80	07/19/25
	3,646 <sup>(13)</sup>	-	14.60	12/31/25
	2,500 <sup>(13)</sup>	-	8.00	06/01/26

- 1) The options have not been, and may never be, exercised and actual gains, if any, on exercise will depend on the value of the shares of common stock on the date of exercise.
- 2) Effective as of April 21, 2017, the Board accepted the resignation of Dr. Teper as Chief Executive Officer. Dr. Teper will remain a member of the Board and will focus his efforts, in conjunction with the Board, on developing and beginning execution of a plan to establish Cytovia.
- 3) These options were fully vested in January 2016.
- 4) These options vest quarterly over one year from date of grant.
- 5) These options were fully vested on the date of grant.
- 6) These options vest over a two-year period, with one-half vesting immediately and the remaining options vesting quarterly.
- 7) These options vest over a three-year period, with 15% vesting after 90 days, 15% on the first-year anniversary and the remaining options vesting quarterly over the remaining two-year period
- 8) These options were fully vested on August 24, 2012.
- 9) These options vest quarterly over three years from date of grant.
- 10) On May 6, 2015, our Board granted an option to purchase up to 12,500 shares of our common stock to Dr. Teper, as performance-based compensation with an exercise price of \$37.40 per share and that will vest upon achievement of certain operational, financing, and partnership objectives. As a result of Dr. Teper's resignation as Chief Executive Officer on April 21, 2017, these options have been forfeited.
- 11) These options vest over three years from the date of grant with one-third vesting after the first year and the remaining options vesting quarterly thereafter.
- 12) These options were forfeited three months after termination on September 30, 2017.
- 13) These options were forfeited three months after termination on February 21, 2018.

#### Director Compensation

The following table sets forth the total compensation paid or accrued during the fiscal year ended December 31, 2017 to our non-employee members of our board of directors who serve on our board of directors.

Name	Option Awards Outstanding	Fees Earned or Paid in Cash (\$) <sup>(1)</sup>	Option Awards (\$) <sup>(2)</sup>	Total (\$)
Elliot Maza <sup>(3)</sup>	162,000	18,333	92,646	110,979
Daniel Kazado <sup>(4)</sup>	37,000	40,000	92,646	132,646
John Neczesny <sup>(5)</sup>	32,000	60,000	92,646	152,646
Jeff Paley <sup>(6)</sup>	35,000	60,000	92,646	152,646
Cameron Durrant <sup>(7)</sup>	34,500	92,933	92,646	185,579
Daniel Teper <sup>(8)</sup>	63,664	6,667	-	6,667

- (1) All non-employee directors receive an annual cash fee of \$40,000 for their service on our board of directors. Such cash fee is for a 1-year term from October 2016 through October 2017.
- (2) Amounts represent the aggregate grant date fair value in accordance with FASB ASC Topic 718. For the assumptions made in the valuation of our equity awards see Note 10 to our consolidated financial statements included in this Annual Report on Form 10-K for the year ended December 31, 2017.
- (3) Effective April 21, 2017, Mr. Maza was appointed interim Chief Executive Officer and as such Mr. Maza resigned as Chairman of the Audit Committee and as a member of the Compensation Committee.
- (4) Mr. Kazado was elected as the Chairman of the Board of Directors effective December 15, 2014 until October 16, 2016 and was entitled to receive an additional annual fee of \$80,000 in addition to the \$40,000 fee for service on our board of directors. Mr. Kazado still continues to be a director. Mr. Kazado was paid \$60,000 of his board fees in our common stock in 2016.
- (5) Mr. Neczesny was appointed to the Board of Directors effective February 23, 2016. As Chairman of the Transactions Committee, Mr. Neczesny is entitled to receive an additional annual fee of \$20,000 in addition to the \$40,000 fee for service on our Board of Directors.
- (6) Dr. Paley was appointed to the Board of Directors effective February 23, 2016. As Chairman of the Governance and Nominating Committee, Dr. Paley is entitled to receive an additional annual fee of \$20,000 in addition to the \$40,000 fee for service on our Board of Directors.
- (7) Dr. Durrant was appointed to the Board of Directors effective July 14, 2014. As the Chairman of the Compensation Committee, Dr. Durrant is entitled to receive an additional annual fee of \$20,000 for services on our Board of Directors. Also, on January 10, 2015, Dr. Durrant was appointed the Lead Director of the Company and is entitled to receive an additional annual fee of \$20,000. Effective May 10, 2017, Dr. Durrant was appointed the Chairman of the Audit Committee and is entitled to receive an additional annual fee of \$20,000.
- (8) Effective November 1, 2017, Dr. Teper is entitled to receive an annual fee of \$40,000 for his service on our board of directors.

#### **Narrative to Director Compensation Table**

In October 2013, our Board agreed upon a schedule of director compensation applicable to our non-employee directors, providing for compensation of non-employee directors in cash and stock options. Our non-employee members of the Board are entitled to cash compensation of \$40,000 per year as a base fee plus \$20,000 per year for service as a chairperson of a committee of the Board, other than the nominating and corporate governance committee, and up to 50% of the base fee for service as the Lead Independent Director of the Board. In addition, upon appointment to the Board, each member of the Board will be granted stock options to purchase 2,500 shares of our common stock that vest on the date of grant and stock options to purchase 2,500 shares of our common stock that vest quarterly over a three-year period. The exercise price of all of the foregoing options will be the fair market value on the date of the grant. In addition, we reimburse our non-employee directors for their out-of-pocket expenses incurred in connection with attending board and committee meetings.

## Equity Compensation Plan Information

The following table provides certain aggregate information, as of December 31, 2017, with respect to all of our equity compensation plans then in effect:

Plan Category <sup>(1)</sup>	(a) No. of securities to be issued upon exercise of outstanding options and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights (\$)	(c) No. of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plan approved by security holders <sup>(2)</sup>	421,062	\$ 3.55	328,938
Equity compensation plan approved by security holders <sup>(3)</sup>	65,042	\$ 46.65	-
Equity compensation plan not approved by security holders <sup>(4)</sup>	33,076	\$ 15.72	-

(1) For further information, see Note 10 to the consolidated financial statements.

(2) This plan consists of the 2015 Equity Incentive Plan.

(3) This plan consists of the 2005 Equity Incentive Plan, as amended and restated, which expired in September 2015.

(4) This plan consists of the 2013 Immune Pharmaceuticals Inc. Stock Ownership and Option Plan (the "2013 Plan"). In September 2013, the 2013 Plan assumed the outstanding options that had been originally issued through the Immune Ltd. Plan, which was assumed by the Company in connection with the Merger on August 25, 2013. No additional shares were issued from the 2013 Plan.

## ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

### Equity Compensation Plan Information

Reference is made to the information contained in the Equity Compensation Plan Information table contained in Item 11 of this Annual Report.

### Security Ownership of Certain Beneficial Holders and Management

The following table sets forth certain information regarding the beneficial ownership of our common stock by (i) each person who, to our knowledge, owns more than 5% of our common stock, (ii) each of our current directors and the named executive officer identified under the heading "Executive Compensation" and (iii) all of our current directors and executive officers as a group. We have determined beneficial ownership in accordance with applicable rules of the SEC, and the information reflected in the table below is not necessarily indicative of beneficial ownership for any other purpose. Under applicable SEC rules, beneficial ownership includes any shares of common stock as to which a person has sole or shared voting power or investment power and any shares of common stock which the person has the right to acquire within 60 days after May 16, 2017 through the exercise of any option, warrant or right or through the conversion of any convertible security. Unless otherwise indicated in the footnotes to the table below and subject to community property laws where applicable, we believe, based on the information furnished to us that each of the persons named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned.

The information set forth in the table below is based on 31,903,280, shares of our common stock issued and outstanding on March 20, 2018. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed to be outstanding all shares of common stock subject to options, warrants, rights or other convertible securities held by that person that are currently exercisable or will be exercisable within 60 days after March 20, 2018. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the principal address of each of the stockholders below is in care of Immune Pharmaceutical Inc., 550 Sylvan Avenue, Suite 101, Englewood Cliffs, NJ 07632.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage Beneficially Owned
<b>5% + Stockholders:</b>		
	-	-%
<b>Executive Officers and Directors:</b>		
Elliot Maza <sup>(1)</sup>	130,750	*
Tony Fiorino <sup>(2)</sup>	13,500	*
Daniel G. Teper <sup>(3)</sup>	344,542	1.08%
Daniel Kazado <sup>(4)</sup>	72,247	*
Cameron Durrant <sup>(5)</sup>	34,750	*
John Neczesny <sup>(6)</sup>	32,000	*
Jeff Paley <sup>(7)</sup>	35,400	*
All current executive officers and directors as a group (7 persons) <sup>(8)</sup>	663,189	2.08%

\* Represents beneficial ownership of less than 1% of the shares of common stock.

(1) Consists of 130,750 shares issuable upon the exercise of stock options that are exercisable within the next 60 days.

(2) Consists of 13,500 shares issuable upon the exercise of stock options that are exercisable within the next 60 days.

(3) Includes 59,164 shares issuable upon the exercise of stock options that are exercisable within the next 60 days and warrants to purchase 1,388 shares of our common stock that are exercisable within the next 60 days.

(4) Consists of 37,000 shares issuable upon the exercise of stock options that are exercisable within the next 60 days and warrants to purchase 562 shares of our common stock that are exercisable within the next 60 days.

(5) Includes 34,500 shares issuable upon the exercise of stock options that are exercisable within the next 60 days and warrants to purchase 50 shares of our common stock that are exercisable within the next 60 days.

(6) Consists of 32,000 shares issuable upon the exercise of stock options that are exercisable within the next 60 days.

(7) Consists of 35,400 shares issuable upon the exercise of stock options that are exercisable within the next 60 days.

(8) See footnotes 2 through 7.

### Change in Control

We are not aware of any arrangement that might result in a change in control in the future. We have no knowledge of any arrangements, including any pledge by any person of our securities, the operation of which may at a subsequent date result in a change in the Company's control.

## ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The following is a description of transactions since January 1, 2017 to which we have been a party, in which the amount involved exceeded or will exceed the lesser of \$120,000 or 1% of the average of our total assets at year-end for the last two years, and in which any of our executive officers, directors or holders of more than 5% of our common stock, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest other than compensation arrangements, which are described in the section above titled "Executive Officer and Director Compensation."

### ***(a) Promissory Notes issued to Certain Related Parties***

#### *Daniel Kazado*

On July 15, 2016, our Board approved, and we issued a \$0.3 million promissory note to Daniel Kazado. The note bears interest at a rate of 5% per year and matures one year from the date of issuance. The outstanding balance of the note may be paid in cash or, at the option of either party, converted into shares of our common stock at a conversion rate of \$9.00 per share, the last bid price of our common stock on the date of approval. On August 4, 2016, we exercised our option to pay off the promissory note in full by issuing 33,333 restricted shares of our common stock. Pursuant to applicable securities laws these restricted shares may not be transferred or sold at least for a period of six months or unless they have been registered for sale pursuant to the Securities Act of 1933, as amended.

#### *Daniel Teper*

On June 24, 2016, our Board approved, and we issued a \$0.4 million promissory note to Daniel G. Teper, our then Chief Executive Officer and an Immune director. The note bears interest at a rate of 5.0% per year and matures one year from the date of issuance. The outstanding balance of the note may be paid in cash or, at the option of either party, converted into shares of our common stock at a conversion rate of \$8.20 per share, the last bid price of our common stock on the date of approval. On August 4, 2016, we exercised our option to pay off the promissory note in full by issuing 43,445 restricted shares of our common stock. Pursuant to applicable securities laws these restricted shares may not be transferred or sold at least for a period of six months and unless they have been registered for sale pursuant to the Securities Act of 1933, as amended.

During 2016, Dr. Teper, also made advances of \$0.9 million to us of which we repaid \$0.7 million prior to December 31, 2016, including \$0.4 million which was paid in shares of our common stock. The balance of \$0.2 million owed to Dr. Teper as of December 31, 2016 has been reflected in advances from related parties in the consolidated balance sheets.

#### *Monica Luchi*

On July 15, 2016, our Board approved, and we issued a \$0.4 million promissory note to Monica Luchi, our former Chief Medical Officer. The note bears interest at a rate of 5.0% per year and matures one year from the date of issuance. The outstanding balance of the note may be paid in cash or, at the option of either party, converted into shares of our common stock at a conversion rate of \$0.45 per share, the last bid price of our common stock on the date of approval. On August 4, 2016, we exercised our option to pay off the promissory note in full by issuing 38,889 restricted shares of our common stock. Pursuant to applicable securities laws these restricted shares may not be transferred or sold at least for a period of six months and unless they have been registered for sale pursuant to the Securities Act of 1933, as amended.

### ***(b) Standby Financing Agreement - Daniel Kazado***

Daniel Kazado was our Chairman of the Board from December 15, 2014 until October 19, 2016 and is a member of the Board of Directors. In April 2014, we entered into a \$5.0 million revolving line of credit with Melini Capital Corp., an existing stockholder who is related to Mr. Kazado. Borrowings under the revolving line of credit were to incur interest at a rate of 12% per year, payable quarterly. The revolving line of credit was unsecured and subordinated to the Loan Agreement with Hercules. The revolving line of credit expired on November 30, 2016. No amounts were drawn from the revolving line of credit.

On June 15, 2017, 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 intend to finance the \$5.0 million financial obligations contemplated by the Asset Purchase Agreement through Cytovia on a basis that is on terms that are acceptable to our board of directors and without recourse to us. The Standby Financer will support the financial obligations of us 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 Cytovia has not obtained funding on terms reasonably acceptable to us (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, at or prior to each installment date, 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.

### **Director Independence**

The Board has reviewed the materiality of any relationship that each of our directors has with us, either directly or indirectly. Based upon this review, we believe that Dr. Durrant, Mr. Neczesny, and Dr. Paley qualify as independent directors in accordance with the standards set by the NASDAQ and Rule 10A-3 promulgated under the Securities Exchange Act of 1934, as amended.

### **ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

#### ***Audit Fees.***

The aggregate fees billed and expected to be billed for professional services rendered by Marcum LLP for the 2017 fiscal year, primarily related to the audit of our annual consolidated financial statements for the 2017 fiscal year, were approximately \$145,000 (including direct engagement expenses).

The aggregate fees billed for professional services rendered by BDO USA, LLP for the 2016 fiscal year, primarily related to the audit of our annual consolidated financial statements for the 2016 fiscal year, the reviews of the financial statements included in our Quarterly Reports on Form 10-Q for the 2016 fiscal year, comfort letters and registration statements, were \$449,265 (including direct engagement expenses).

#### ***Audit-Related Fees***

No fees were billed by Marcum LLP for audit-related services for the 2017 fiscal year.

No fees were billed by BDO USA, LLP for audit-related services for the 2016 fiscal year.

#### ***Tax Fees***

No fees were billed by Marcum LLP for tax-related services for the 2017 fiscal year.

The aggregate fees billed for tax-related services for the 2016 fiscal year rendered by BDO USA, LLP were \$32,280.

#### ***All Other Fees***

No fees were billed by Marcum LLP for services other than the audit for the 2017 fiscal year.

No fees were billed by BDO USA, LLP for services other than the audit and tax services for the 2016 fiscal year.

#### ***Pre-Approval Policy.***

The Audit Committee is required to pre-approve all auditing services and permitted non-audit services (including the fees and terms thereof) to be performed for us by our independent auditor or other registered public accounting firm, subject to the de minimis exceptions for permitted non-audit services described in Section 10 A (i)(1)(B) of the Securities Exchange Act of 1934 that are approved by the Audit Committee prior to completion of the audit. The Audit Committee, through the function of the Chairman, has given general pre-approval for 100% of specified audit, audit-related, tax and other services.

## ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) *Financial Statements*. For the financial statements included in this annual report, see “Index to the Financial Statements” on page F-1.

(a)(2) *Financial Statement Schedules*. All schedules are omitted because they are not applicable or because the required information is included in the financial statements or notes thereto.

(a)(3) *Exhibits*. The list of exhibits filed as a part of this annual report is set forth on the Exhibit Index immediately preceding such exhibits and is incorporated by reference in this Item 15(a)(3).

(b) *Exhibits*. See Exhibit Index.

(c) *Separate Financial Statements and Schedules*. None.

### EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
<a href="#"><u>2.1</u></a>	<a href="#"><u>Merger Agreement and Plan of Reorganization, dated as of November 7, 2012, by and among EpiCept Corporation, EpiCept Israel Ltd. and Immune Pharmaceuticals Ltd.; Amendment to Merger Agreement and Plan of Reorganization, dated as of November 27, 2012; Amendment No. 2 to Merger Agreement and Plan of Reorganization, dated as of February 11, 2013; Amendment No. 3 to Merger Agreement and Plan of Reorganization, dated as of March 14, 2013; and Amendment No. 4 to Merger Agreement and Plan of Reorganization, dated as of June 17, 2013; (incorporated by reference to the Company’s Definitive Proxy Statement on Form DEF 14A filed with the SEC on June 18, 2013).</u></a>
<a href="#"><u>2.2</u></a>	<a href="#"><u>Agreement and Plan of Merger, dated as of September 6, 2005, among EpiCept Corporation, Magazine Acquisition Corp. and Maxim Pharmaceuticals, Inc. (incorporated by reference to Exhibit 2.1 to Maxim Pharmaceuticals Inc.’s Current Report on Form 8-K filed with the SEC on September 6, 2005).</u></a>
<a href="#"><u>3.1</u></a>	<a href="#"><u>Third Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company’s Current Report on Form 8-K filed with the SEC on May 21, 2008).</u></a>
<a href="#"><u>3.2</u></a>	<a href="#"><u>Amendment to the Third Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company’s Current Report on Form 8-K filed with the SEC on July 9, 2009).</u></a>
<a href="#"><u>3.3</u></a>	<a href="#"><u>Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company’s Current Report on Form 8-K filed with the SEC on January 14, 2010).</u></a>
<a href="#"><u>3.4</u></a>	<a href="#"><u>Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company’s Current Report on Form 8-K filed with the SEC on August 21, 2013).</u></a>
<a href="#"><u>3.5</u></a>	<a href="#"><u>Certificate of Designation of Preferences, Rights and Limitations of Series C 8% Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Company’s Current Report on Form 8-K filed with the SEC on March 11, 2014).</u></a>
<a href="#"><u>3.6</u></a>	<a href="#"><u>Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitations of Series C 8% Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Company’s Current Report on Form 8-K filed with the SEC on June 23, 2014).</u></a>
<a href="#"><u>3.7</u></a>	<a href="#"><u>Certificate of Designations of Preferences, Rights and Limitations of Series D Redeemable Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Company’s Current Report on Form 8-K filed with the SEC on July 29, 2015).</u></a>
<a href="#"><u>3.8</u></a>	<a href="#"><u>Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Company’s Current Report on Form 8-K filed with the SEC on February 18, 2010).</u></a>
<a href="#"><u>3.9</u></a>	<a href="#"><u>Certificate of Amendment to Articles of Incorporation, dated April 12, 2017 (incorporated by reference to Exhibit 3.1 to the Company’s Current Report on Form 8-K filed with the SEC on April 19, 2017).</u></a>
<a href="#"><u>4.4</u></a>	<a href="#"><u>Common Stock Purchase Warrant, dated August 23, 2013 (incorporated by reference to Exhibit 10.2 to the Company’s Current Report on Form 8-K filed with the SEC on August 29, 2013).</u></a>
<a href="#"><u>4.5</u></a>	<a href="#"><u>Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to the Company’s Current Report on Form 8-K filed March 11, 2014).</u></a>

- [4.6](#) [Form of Common Stock Purchase Warrant \(incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on June 23, 2014\).](#)
- [4.7](#) [Form of Restated Series A Warrant and Restated Series B Warrant \(incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on August 14, 2014\).](#)
- [4.8](#) [Form of Warrant \(incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on November 20, 2014\).](#)
- [4.9](#) [Form of Warrant \(July 16, 2015\) \(incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on July 17, 2015\).](#)
- [4.10](#) [Form of Warrant to be issued to Hercules Capital \(July 2015\) \(incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on July 29, 2015\).](#)
- [10.1](#) [Loan and Security Agreement, dated May 27, 2011, by and among MidCap Funding III, LLC, EpiCept Corporation, Maxim Pharmaceuticals, Inc. and Cytovia, Inc. \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on May 31, 2011\).](#)
- [10.2](#) [Consent Agreement, dated June 18, 2012, by and among MidCap Funding III, LLC, EpiCept Corporation, Maxim Pharmaceuticals, Inc. and Cytovia, Inc. \(incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the SEC on June 21, 2012\).](#)
- [10.3](#) [First Amendment to Loan and Security Agreement dated August 27, 2012, by and among MidCap Funding III, LLC, EpiCept Corporation, Maxim Pharmaceuticals, Inc. and Cytovia, Inc. \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on August 31, 2012\).](#)
- [10.4](#) [Second Amendment to Loan and Security Agreement with Midcap Funding III, LLC, dated July 31, 2013 \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on August 1, 2013\).](#)
- [10.5](#) [Third Amendment to Loan and Security Agreement with Midcap Funding III, LLC, dated August 23, 2013 \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on August 29, 2013\).](#)
- [10.6](#) [Fourth Amendment, Consent and Waiver to Loan and Security Agreement by and among Immune Pharmaceutical Inc., Maxim Pharmaceuticals Inc., Cytovia, Inc. and MidCap Funding III, LLC \(incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on March 11, 2014\).](#)
- [10.7†](#) [Amended and Restated 2005 Equity Incentive Plan \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on May 30, 2007\).](#)
- [10.8†](#) [Immune Pharmaceuticals Inc. 2013 Stock Ownership and Option Plan \(incorporated by reference to Exhibit 99.2 to the Company's Registration Statement on Form S-8 filed with the SEC on September 2, 2014\).](#)
- [10.9†](#) [Form of incentive stock option granted under Amended and Restated 2005 Equity Incentive Plan \(incorporated by reference to Exhibit 99.3 to the Company's Registration Statement on Form S-8 filed with the SEC on September 2, 2014\).](#)
- [10.10†](#) [Form of 102 capital gains stock option award agreement, granted in Israel, under Amended and Restated 2005 Equity Incentive Plan \(incorporated by reference to Exhibit 99.4 to the Company's Registration Statement on Form S-8 filed with the SEC on September 2, 2014\).](#)
- [10.11†](#) [Immune Pharmaceuticals Inc. 2015 Equity Incentive Plan \(incorporated by reference to Exhibit 99.1 to the Company's Registration Statement on Form S-8 filed with the SEC on December 24, 2015\).](#)
- [10.12†](#) [Form of Stock Option Award Agreement under the Registrant's 2015 Equity Incentive Plan \(incorporated by reference to Exhibit 99.2 to the Company's Registration Statement on Form S-8 filed with the SEC on December 24, 2015\).](#)
- [10.13†](#) [Employment Letter Agreement dated June 4, 2014, by and between Immune Pharmaceuticals Inc. and Daniel G. Teper \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on June 6, 2014\).](#)
- [10.14†](#) [Employment Agreement dated as of September 1, 2011, between Immune Pharmaceuticals Ltd. and Daniel G. Teper \(incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K filed with the SEC on April 9, 2014\).](#)
- [10.15†](#) [Amendment to Employment Agreement dated June 23, 2014, by and between Immune Pharmaceuticals Ltd. and Daniel G. Teper \(incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 14, 2014\).](#)

- [10.17](#) [Securities Purchase Agreement dated March 10, 2014, by and among the Company and the Purchasers part thereto \(incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on March 11, 2014\).](#)
- [10.18](#) [Services Agreement, dated as of August 6, 2013, by and between Immune Pharmaceuticals Ltd. and Melini Capital Corp \(incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 19, 2013\).](#)
- [10.19](#) [Option Agreement, dated as of August 10, 2013, by and between Immune Pharmaceuticals Ltd. and Melini Capital Corp \(incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 19, 2013\).](#)
- [10.21](#) [Consulting Services Agreement, dated as of August 10, 2013, by and between Immune Pharmaceuticals Ltd. and Jean Kadouche \(incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 19, 2013\) \(incorporated by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K filed with the SEC on April 9, 2014\).](#)
- [10.22](#) [Research and License Agreement, dated as of April 6, 2011, by and between Immune Pharmaceuticals Ltd. and Yisum Research Development Company of The Hebrew University of Jerusalem, Ltd. \(incorporated by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K filed with the SEC on April 9, 2014\).](#)
- [10.23](#) [First Amendment to the Research and License Agreement dated September 26, 2011, between Immune Pharmaceuticals Ltd. and Yisum Research Development Company of The Hebrew University of Jerusalem, Ltd. \(incorporated by reference to Exhibit 10.29 to the Company's Annual Report on Form 10-K filed with the SEC on April 9, 2014\).](#)
- [10.24±](#) [Product Sublicense Agreement dated as of December 7, 2010, by and between Immune Pharmaceuticals Ltd., Immune Pharmaceuticals Corporation and iCo Therapeutics Incorporated \(incorporated by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K filed with the SEC on April 9, 2014\).](#)
- [10.25](#) [Assignment Agreement, dated as of March 28, 2012, by and between Immune Pharmaceuticals Ltd. and Mablife S.A.S. \(f/k/a Monoclonal Antibodies Therapeutics M.A.P.\) \(incorporated by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-K filed with the SEC on April 9, 2014\).](#)
- [10.26](#) [Assignment Agreement Amendment, dated as of February 8, 2014, by and between Immune Pharmaceuticals Ltd. and Mablife S.A.S. \(f/k/a Monoclonal Antibodies Therapeutics M.A.P.\) \(incorporated by reference to Exhibit 10.32 to the Company's Annual Report on Form 10-K filed with the SEC on April 9, 2014\).](#)
- [10.27](#) [Sublicense Agreement, dated as of August 27, 1999, between Epitome Pharmaceuticals Limited \(Dalhousie University\) and American Pharmed Labs, Inc. \(incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1 filed with the SEC on May 3, 2005\).](#)
- [10.28](#) [License Agreement, dated as of March 1, 2004, by and between Shire Biochem Inc., Maxim Pharmaceuticals, Inc. and Cytovia, Inc., as amended \(incorporated by reference to Exhibit 10.1 to each of Maxim Pharmaceuticals, Inc.'s Quarterly Reports on Form 10-Q filed with the SEC on May 7, 2004 and May 5, 2005, respectively\).](#)
- [10.29](#) [Waiver and Amendment to License Agreement, dated as of April 3, 2014, by and between Immune Pharmaceuticals Inc. and Dalhousie University \(incorporated by reference to Exhibit 10.35 to the Company's Annual Report on Form 10-K filed with the SEC on April 9, 2014\).](#)
- [10.30](#) [Revolving Line of Credit, dated as of April 17, 2014, by and between Immune Pharmaceuticals Inc. and Melini Capital Corp. \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on April 11, 2014\).](#)
- [10.31](#) [Form of Amendment Agreement \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on August 14, 2014\).](#)
- [10.32](#) [Lease Agreement, dated as of December 30, 2014, by and between Immune Pharmaceuticals Inc. and ARE-East River Science Park, LLC \(incorporated by reference to Exhibit 10.38 to the Company's Annual Report on Form 10-K filed with the SEC on April 15, 2015\).](#)
- [10.33](#) [Second Amendment to Lease Agreement, dated as of August 31, 2015, by and between Immune Pharmaceuticals Inc. and ARE-East River Science Park, LLC \(incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 16, 2015\).](#)

- [10.34†](#) [Employment Letter Agreement dated January 21, 2015, by and between Immune Pharmaceuticals Inc. and Gad Berdugo \(incorporated by reference to Exhibit 10.1 to the Company's Current Report Form 8-K filed with the SEC on January 21, 2015\).](#)
- [10.35](#) [License Agreement, dated as of December 18, 2003, by and between Endo Pharmaceuticals Inc. \(incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1 filed with the SEC on May 3, 2005\).](#)
- [10.36](#) [Amendment, by and between Immune Pharmaceuticals Inc. and Endo Pharmaceuticals Inc., dated July 7, 2015 \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on with the SEC on July 8, 2015\).](#)
- [10.37†](#) [First Amendment to Employment Agreement, dated February 28, 2015, by and between Immune Pharmaceuticals Inc. and Daniel G. Teper \(incorporated by reference to Exhibit 10.41 to the Company's Annual Report on Form 10-K filed with the SEC on April 15, 2015\).](#)
- [10.38†](#) [Termination Agreement and General Release, dated February 28, 2015, by and between Immune Pharmaceuticals, Ltd. and Daniel G. Teper \(incorporated by reference to Exhibit 10.42 to the Company's Annual Report on Form 10-K filed with the SEC on April 15, 2015\).](#)
- [10.39](#) [Form of Securities Exchange Agreement \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 17, 2015\).](#)
- [10.40](#) [Loan and Security Agreement, dated July 29, 2015, by and among Immune Pharmaceuticals Inc. and Immune Pharmaceuticals USA Corp., Immune Pharmaceuticals Ltd., as guarantor, and Hercules Capital, as agent for itself and lender \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 29, 2015\).](#)
- [10.41](#) [Stock Purchase Agreement, dated as of July 28, 2015, by and between Immune Pharmaceuticals Inc. and the investor named therein \(registered direct offering\) \(incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on July 29, 2015\).](#)
- [10.42](#) [Stock Purchase Agreement, dated as of July 28, 2015, by and between Immune Pharmaceuticals Inc. and the investor named therein \(private placement\) \(incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the SEC on July 29, 2015\).](#)
- [10.43](#) [Form of Voting Agreement \(incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the SEC on July 29, 2015\).](#)
- [10.44†](#) [Employment Agreement dated November 1, 2015, by and between Immune Pharmaceuticals Ltd. and Miri Ben-Ami \(incorporated by reference to Exhibit 10.44 to the Company's Annual Report on Form 10-K filed with the SEC on March 30, 2016\).](#)
- [10.45†](#) [Employment Agreement dated November 18, 2015, by and between Immune Pharmaceuticals Inc. and Monica E. Luchi \(incorporated by reference to Exhibit 10.45 to the Company's Annual Report on Form 10-K filed with the SEC on March 30, 2016\).](#)
- [10.46†](#) [Employment Agreement, dated as of December 31, 2015, by and between Immune Pharmaceuticals Inc. and John Militello \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on December 31, 2015\).](#)
- [10.47†](#) [Release and Consulting Agreement, dated as of December 28, 2015, by and between Immune Pharmaceuticals Inc. and Gad Berdugo \(incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on December 31, 2015\).](#)
- [10.48](#) [Research and License Agreement, dated as of January 1, 2016, by and between BioNanoSim Ltd. and Immune Pharmaceuticals Ltd. \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on January 7, 2016\).](#)
- [10.49](#) [Capital Access Agreement, dated as of April 19, 2016, by and between the Company and Regatta Select Healthcare, LLC \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K with the SEC on April 20, 2016\).](#)
- [10.50](#) [Amendment to Capital Access Agreement, dated as of June 10, 2016, by and between the Company and Regatta Select Healthcare, LLC \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K with the SEC on June 13, 2016\).](#)
- [10.51](#) [June Capital Access Agreement, dated as of June 10, 2016, by and between the Company and Regatta Select Healthcare, LLC \(incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K with the SEC on June 13, 2016\).](#)
- [10.52](#) [Amendment No. 1 to License Option Agreement \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K with the SEC on July 19, 2016\).](#)
- [10.53](#) [Form of Note \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K with the SEC on July 19, 2016\).](#)

<a href="#"><u>10.54</u></a>	<a href="#"><u>Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K with the SEC on August 3, 2016).</u></a>
<a href="#"><u>10.55</u></a>	<a href="#"><u>Form of Warrant (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K with the SEC on August 3, 2016).</u></a>
<a href="#"><u>10.56</u></a>	<a href="#"><u>Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K with the SEC on September 7, 2016).</u></a>
<a href="#"><u>10.57</u></a>	<a href="#"><u>Agreement dated September 15, 2016 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K with the SEC on September 16, 2016).</u></a>
<a href="#"><u>10.58</u></a>	<a href="#"><u>Securities Purchase Agreement, dated as of November 17, 2016, by and between the Company and HLHW, IV LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K with the SEC on November 22, 2016).</u></a>
<a href="#"><u>10.59</u></a>	<a href="#"><u>Form of Convertible Note, dated as of November 17, 2016 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K with the SEC on November 22, 2016).</u></a>
<a href="#"><u>10.60</u></a>	<a href="#"><u>Registration Rights Agreement, dated as of November 17, 2016, by and between the Company and HLHW, IV LLC (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K with the SEC on November 22, 2016).</u></a>
<a href="#"><u>10.61</u></a>	<a href="#"><u>Common Stock Purchase Agreement, dated as of November 17, 2016, by and between the Company and HLHW IV, LLC (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K with the SEC on November 22, 2016).</u></a>
<a href="#"><u>10.62</u></a>	<a href="#"><u>Common Stock Purchase Agreement, dated as of February 3, 2017, by and between the Company and HLHW IV, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K with the SEC on February 3, 2017).</u></a>
<a href="#"><u>10.63</u></a>	<a href="#"><u>Common Stock Purchase Agreement, dated as of March 22, 2017, by and between the Company and HLHW IV, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K with the SEC on March 23, 2017).</u></a>
<a href="#"><u>10.64</u></a>	<a href="#"><u>Securities Purchase Agreement, dated as of April 10, 2017, by and between the Company and EMA Financial, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K with the SEC on April 19, 2017).</u></a>
<a href="#"><u>10.67</u></a>	<a href="#"><u>Convertible Note, dated as of April 10, 2017 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K with the SEC on April 19, 2017).</u></a>
<a href="#"><u>10.68</u></a>	<a href="#"><u>Registration Rights Agreement, dated as of April 10, 2017, by and between the Company and EMA Financial, LLC (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K with the SEC on April 19, 2017).</u></a>
<a href="#"><u>10.69</u></a>	<a href="#"><u>Common Stock Purchase Warrant dated as of April 10, 2017, by and between the Company and EMA Financial, LLC (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K with the SEC on April 19, 2017).</u></a>
<a href="#"><u>10.70</u></a>	<a href="#"><u>Separation Agreement, dated April 21, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K with the SEC on April 27, 2017).</u></a>
<a href="#"><u>10.71</u></a>	<a href="#"><u>Employment Agreement, dated as of November 29, 2017, by and between the Company and Elliot Maza (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on December 4, 2017).</u></a>
<a href="#"><u>10.72</u></a>	<a href="#"><u>Research and License Agreement, dated as of June 25, 2015, by and between Yissum Research Development Company of The Hebrew University of Jerusalem, Ltd. and Immune Pharmaceuticals Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on June 29, 2015).</u></a>
<a href="#"><u>21.1*</u></a>	<a href="#"><u>List of Subsidiaries of Immune Pharmaceuticals Inc.</u></a>
<a href="#"><u>23.1*</u></a>	<a href="#"><u>Consent of Marcum LLP. Independent registered public accounting firm.</u></a>
<a href="#"><u>23.2*</u></a>	<a href="#"><u>Consent of BDO USA, LLP. Independent registered public accounting firm.</u></a>
<a href="#"><u>31.1*</u></a>	<a href="#"><u>Certification of Principal Executive Officer and Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15(d)-14(a), adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u></a>
<a href="#"><u>32.1**</u></a>	<a href="#"><u>Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 United StatesC. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u></a>
101.INS*	XBLR Instance Document
101.SCH*	XBLR Taxonomy Extension Schema Document
101.CAL*	XBLR Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBLR Taxonomy Extension Definition Linkbase Document
101.LAB*	XBLR Taxonomy Extension Label Linkbase Document
101.PRE*	XBLR Taxonomy Extension Presentation Linkbase Document

\* Filed herewith.

\*\* Furnished herewith.

† Management contract or compensatory plan or arrangement.

± Confidential treatment has been granted with respect to certain portions of this exhibit.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

IMMUNE PHARMACEUTICALS INC.

By: /s/ Elliot M. Maza  
Elliot M. Maza  
*Chief Executive Officer*  
April 2, 2018

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons in the capacities indicated and on the dates indicated:

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<u>/s/Elliot M. Maza</u> Elliot M. Maza	President, Chief Executive Officer and Director (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)	April 2, 2018
<u>/s/ Daniel Kazado</u> Daniel Kazado	Director	April 2, 2018
<u>/s/ Dr. Cameron Durrant</u> Dr. Cameron Durrant	Director	April 2, 2018
<u>/s/ Dr. Daniel G. Teper</u> Dr. Daniel G. Teper	Director	April 2, 2018
<u>/s/ John A. Neczesny</u> John A. Neczesny	Director	April 2, 2018
<u>/s/ Dr. Jeffrey Paley</u> Jeffrey Paley	Director	April 2, 2018

## INDEX TO FINANCIAL STATEMENTS

### IMMUNE PHARMACEUTICALS INC. AND SUBSIDIARIES CONSOLIDATED FINANCIAL STATEMENTS

<a href="#">Report of Independent Registered Public Accounting Firm – Marcum LLP</a>	<a href="#">F-2</a>
<a href="#">Report of Independent Registered Public Accounting Firm – BDO USA, LLP</a>	<a href="#">F-3</a>
<a href="#">Consolidated Balance Sheets as of December 31, 2017 and 2016</a>	<a href="#">F-4</a>
<a href="#">Consolidated Statements of Operations for the Years Ended December 31, 2017 and 2016</a>	<a href="#">F-5</a>
<a href="#">Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2017 and 2016</a>	<a href="#">F-6</a>
<a href="#">Consolidated Statements of Cash Flows for the Years Ended December 31, 2017 and 2016</a>	<a href="#">F-7</a>
<a href="#">Notes to Consolidated Financial Statements</a>	<a href="#">F-8</a>

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of  
Immune Pharmaceuticals Inc.

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Immune Pharmaceuticals Inc. (the "Company") as of December 31, 2017, the related consolidated statements of operations, stockholders' equity and cash flows for the year ended December 31, 2017, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017, and the results of its operations and its cash flows for the year ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

### Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has a working capital deficiency, a significant accumulated deficit, recurring losses from operations, with the expectation of losses from operations for the foreseeable future, and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Marcum Ilp

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Marcum Ilp

We have served as the Company's auditor since 2017.

New Haven, Connecticut  
April 2, 2018

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders  
Immune Pharmaceuticals Inc.  
New York, New York

We have audited the accompanying balance sheet of Immune Pharmaceuticals Inc. as of December 31, 2016 and the related statements of operations, stockholders' equity and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Immune Pharmaceuticals Inc. as of December 31, 2016, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has negative working capital, an accumulated deficit, recurring losses from operations and expects continuing future losses that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As discussed in Note 1 to the consolidated financial statements, on April 12, 2017, the Company approved a reverse stock split with a ratio of 1-for-20. As a result, common stock share amounts included in these consolidated financial statements have been retrospectively adjusted.

/s/ BDO USA, LLP

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New York, New York  
May 17, 2017

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

	December 31, 2017	December 31, 2016
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 6,776	\$ 271
Restricted cash	-	59
Other current assets	255	314
<b>Total current assets</b>	<b>7,031</b>	<b>644</b>
Property and equipment, net	-	316
In-process research and development acquired	15,000	15,000
Intangible assets, net	6,477	2,806
Other assets	100	339
<b>Total assets</b>	<b>\$ 28,608</b>	<b>\$ 19,105</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 3,569	\$ 3,522
Accrued expenses	2,120	2,620
Advances from related parties	266	236
Notes and loans payable, current portion, net of debt discount	3,296	2,739
Obligations under capital lease, current portion	-	48
<b>Total current liabilities</b>	<b>9,251</b>	<b>9,165</b>
Notes and loans payable, net of current portion	1,457	1,442
Obligations under capital lease, net of current portion	-	52
Deferred tax liability	4,142	5,933
<b>Total liabilities</b>	<b>14,850</b>	<b>16,592</b>
<b>Commitments and contingencies (Note 12)</b>		
<b>Stockholders' Equity</b>		
Series E Preferred Stock, net of discount, par value \$0.0001, 18,000 shares authorized, 12,191 and 0 shares issued and outstanding as of December 31, 2017 and December 31, 2016, respectively	-	-
Common stock, \$0.0001 par value; authorized 225,000,000 shares; 21,002,212 and 8,123,766 shares issued and outstanding at December 31, 2017 and December 31, 2016, respectively	2	1
Additional paid-in capital	127,292	98,159
Accumulated deficit	(113,536)	(95,647)
<b>Total stockholders' equity</b>	<b>13,758</b>	<b>2,513</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 28,608</b>	<b>\$ 19,105</b>

The accompanying notes are an integral part of the consolidated financial statements.

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

	<b>For The Years Ended</b>	
	<b>December 31,</b>	
	<b>2017</b>	<b>2016</b>
<b>Revenue</b>	\$ -	\$ -
<b>Operating expenses:</b>		
Research and development	5,517	8,333
General and administrative	6,606	6,427
In-process research and development impairment expense	-	12,500
Total operating expenses	12,123	27,260
<b>Loss from operations</b>	<b>(12,123)</b>	<b>(27,260)</b>
<b>Non-operating expense:</b>		
Interest expense	(3,655)	(1,555)
Change in fair value of derivative instruments	177	(8,656)
Loss on disposal of equipment	(325)	-
Loss on extinguishment of debt	(2,145)	-
Liquidated damages	(1,763)	-
Other expense, net	(28)	(46)
<b>Total non-operating expense:</b>	<b>(7,739)</b>	<b>(10,257)</b>
<b>Net loss before income taxes</b>	<b>(19,862)</b>	<b>(37,517)</b>
Income tax benefit	1,973	4,856
<b>Net loss</b>	<b>(17,889)</b>	<b>(32,661)</b>
Deemed dividend	(6,864)	(7,973)
<b>Loss attributable to common stockholders</b>	<b>\$ (24,753)</b>	<b>\$ (40,634)</b>
<b>Basic and diluted loss per common share</b>	<b>\$ (2.11)</b>	<b>\$ (9.58)</b>
 Weighted average common shares outstanding - basic and diluted	 11,755,713	 4,240,075

The accompanying notes are an integral part of the consolidated financial statements.

**Consolidated Statement of Stockholders' Equity**  
**For the Years Ended December 31, 2017 and 2016**  
(\$ in thousands, except share amounts)

	Series E Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
<b>Balance at January 1, 2016</b>	-	\$ -	1,621,747	\$ -	\$ 70,849	\$ (62,986)	\$ 7,863
Conversion of Series D Preferred Stock to common stock and accretion of deemed dividend	-	-	4,735,589	1	16,882	-	16,883
Shares Sold in HLHW Equity Financing	-	-	625,000	-	2,445	-	2,445
Shares Issued per the Capital Access Agreements	-	-	360,000	-	1,924	-	1,924
Share Purchase Agreements	-	-	407,063	-	3,348	-	3,438
Costs related to equity financing	-	-	201,711	-	(603)	-	(603)
Promissory note converted to common stock	-	-	115,667	-	1,006	-	1,006
Reclassification of Hercules warrants derivative liability to additional paid-in capital	-	-	-	-	46	-	46
Common stock issued to settle liabilities	-	-	28,670	-	240	-	240
Exercise of stock options	-	-	10,819	-	16	-	16
Share-based compensation	-	-	17,500	-	2,006	-	2,006
Net loss	-	-	-	-	-	(32,661)	(32,661)
<b>Balance at December 31, 2016</b>	-	-	8,123,766	1	\$ 98,159	(95,647)	2,513
Issuance of Series E Preferred Stock, net of issuance costs of \$1,059	18,000	-	-	-	8,690	-	8,690
Issuance of warrants in connection with Series E Preferred Stock, net of issuance costs of \$896	-	-	-	-	7,355	-	7,355
Beneficial conversion feature in connection with Series E Preferred Stock	-	-	-	-	6,864	-	6,864
Accretion of beneficial conversion feature in connection with Series E Preferred Stock	-	-	-	-	(6,864)	-	(6,864)
Conversion of Series E Preferred Stock and dividends	(5,809)	-	6,923,778	1	(1)	-	-
Common stock issued in connection with November 2016 Equity Line	-	-	1,100,000	-	4,014	-	4,014
Common stock issued in connection with March 2017 Equity Line	-	-	496,895	-	1,600	-	1,600
Financing fees related to November 2016 and March 2017 Equity Lines	-	-	-	-	(118)	-	(118)
Commitment fees and adjustment to shares issued related to November 2016 Equity Line	-	-	(184,211)	-	(902)	-	(902)
Common stock issued to settle liabilities	-	-	3,825	-	14	-	14
Common stock issued to consultant	-	-	250,000	-	225	-	225
Share Purchase agreements and amendments	-	-	(8,024)	-	238	-	238
Shares issued in conjunction with May 2017 Convertible Notes	-	-	421,455	-	574	-	574
Rounding shares issued in connection with Reverse Split	-	-	10,595	-	-	-	-
April 2017 Convertible Notes warrant fair value and accretion of conversion premium	-	-	-	-	460	-	460
Conversion of April 2017 Convertible Notes	-	-	462,323	-	389	-	389
Conversion of July 2017 Senior Secured Convertible Note	-	-	1,991,864	-	2,228	-	2,228
July 2017 Senior Secured Convertible Note Conversion Discount	-	-	-	-	598	-	598
Conversion of May 2017 Convertible Notes	-	-	1,409,946	-	1,864	-	1,864
May 2017 Convertible Notes Waiver	-	-	-	-	1,611	-	1,611
Share-based compensation	-	-	-	-	526	-	526
Series E Preferred Stock dividends	-	-	-	-	(232)	-	(232)
Net loss	-	-	-	-	-	(17,889)	(17,889)
<b>Balance at December 31, 2017</b>	12,191	\$ -	21,002,212	\$ 2	\$ 127,292	\$ (113,536)	\$ 13,758

The accompanying notes are an integral part of the consolidated financial statements.

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

	For the Year Ended December 31,	
	2017	2016
<b>Cash flows from operating activities:</b>		
Net loss	\$ (17,889)	\$ (32,661)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	657	393
Amortization of debt discount and debt issuance costs	2,648	606
Accretion of the April 2017 convertible note conversion premium	280	-
Accretion of redemption premium on November 2016 convertible note	300	-
Loss on extinguishment	2,145	-
Liquidated damages	1,763	-
Stock-based compensation expense	526	2,006
Issuance of common stock to consultant	225	-
Change in fair value of derivative instruments	(177)	8,656
Loss on disposal of equipment	325	-
In-process research and development impairment	-	12,500
Changes in operating assets and liabilities:		
Other assets	298	(25)
Accounts payable	(30)	1,253
Accrued expenses and advances from related parties	(839)	(98)
Change in deferred taxes	(1,791)	(4,937)
<b>Net cash used in operating activities</b>	<b>(11,559)</b>	<b>(12,307)</b>
<b>Cash flows from investing activities:</b>		
Change in restricted cash	59	(29)
Purchase of property and equipment	(28)	(21)
<b>Net cash provided by (used in) investing activities</b>	<b>31</b>	<b>(50)</b>
<b>Cash flows from financing activities:</b>		
Proceeds from Series E Preferred Stock and warrants	16,044	-
Payment of Series E Preferred Stock dividends	(16)	-
Proceeds from May 2017 Convertible Notes	1,579	-
Repayments of May 2017 Convertible Notes	(480)	-
Proceeds from April 2017 Convertible Notes	440	-
Repayment of April 2017 Convertible Notes	(97)	-
Proceeds from August 2017 Convertible Notes	515	-
Repayments of August 2017 Convertible Notes	(858)	-
Proceeds from September 2017 Convertible Notes	115	-
Repayments of September 2017 Convertible Notes	(150)	-
Proceeds from July 2017 Convertible Notes	245	-
Repayments of July 2017 Convertible Notes	(300)	-
Repayment of July 2017 Senior Secured Convertible Promissory Note	(1,192)	-
Payment of debt issuance costs related to July 2017 Senior Secured Convertible Promissory Note	(57)	-
Proceeds from amending certain securities purchase agreements	238	-
Proceeds received from November 2016 and March 2017 Equity Line financings	5,383	2,445
Financing fees paid on November 2016 and March 2017 Equity Line financings	(118)	(505)
Repayment of November 2016 Convertible Notes	(1,350)	-
Payment of commitment fees related to March 2017 Equity Line financings	(1,010)	-
Proceeds received from sale of common stock	-	5,272
Proceeds received from exercise of options and warrants	-	16
Proceeds received from sale of convertible note	-	1,000
Repayment of Loan Agreement	(874)	(1,229)
Payment of capital lease	(24)	(96)
Repayment of related party loans	-	(280)
Proceeds from related party loans	-	1,462
<b>Net cash provided by financing activities</b>	<b>18,033</b>	<b>8,085</b>
<b>Net increase (decrease) in cash</b>	<b>6,505</b>	<b>(4,272)</b>
Cash and cash equivalents at beginning of year	271	4,543
<b>Cash at end of year</b>	<b>\$ 6,776</b>	<b>\$ 271</b>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	\$ 156	\$ 416
Cash paid for income taxes	-	81
<b>Supplemental disclosure of non-cash financing activities:</b>		
Deemed dividend	6,864	7,973

Conversion of promissory notes to common stock	-	1,006
Common stock issued to settle liabilities	14	240
Reclassification of Hercules warrants derivative liability to additional paid in capital	-	46
Settlement of liability with promissory note	-	60
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	389	-
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 the consolidated financial statements.

**Immune Pharmaceuticals Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements**

**Note 1. Business Description**

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 immuno-inflammation, dermatology and oncology.

Our lead product candidate is bertilimumab, a first-in-class, fully human antibody, currently in phase 2 clinical trials. Bertilimumab targets eotaxin-1, a key regulator of inflammation. 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, and a nano-encapsulated formulation of AmiKet, a topical analgesic cream containing amitriptyline and ketamine, which we refer to as “AmiKet Nano”, for the treatment of postherpetic neuralgia (“PHN”) and diabetic peripheral neuropathy (“DPN”).

Our oncology portfolio includes Ceplene, which is approved in the European Union for the maintenance of remission in patients with Acute Myeloid Leukemia (“AML”) and Azixa and crolibulin, two clinical-stage, vascular disrupting agents (“VDA”) which have demonstrated encouraging preliminary proof of concept study results. In addition, we have two oncology platform assets, consisting of a bispecific antibody platform and a nanotechnology combination platform, which we refer to as “NanomAbs”.

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 addition, we announced our plan to pursue a spin-off of Cytovia Inc., our oncology focused subsidiary (“Cytovia”), into a separate, stand-alone company. Cytovia will focus on the development and commercialization of novel oncology and hematology therapeutics, including Ceplene, Azixa, crolibulin, NanomAbs and our bispecific antibody platform.

As of December 31, 2017, 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.

Our common stock is listed on the Nasdaq Capital Market (“NASDAQ”) under the symbol IMNP. On April 12, 2017, we announced a reverse stock split of our shares of common stock at a ratio of 1-for-20. Our common stock began trading on a post-split basis on NASDAQ beginning with the opening of trading on April 13, 2017. Our shareholders ratified the effectiveness of the April 2017 reverse stock split at our Annual Meeting of Stockholders, held and adjourned on February 15, 2018, and reconvened on February 23, 2018. All share and per share amounts in this Form 10-K have been reflected on a post-split basis.

**Note 2. Going Concern**

These 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.

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 \$2.2 million and an accumulated deficit of \$113.5 million as of December 31, 2017. Our net loss was \$17.9 million and \$32.7 million for the fiscal years ended December 31, 2017 and 2016, respectively. Cash used in operations was \$11.6 and \$12.3 million for the years ended December 31, 2017 and 2016, respectively. We had approximately \$6.8 million in cash as of December 31, 2017.

We will require additional financing in fiscal 2018 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 2018. 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 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 consolidated financial statements were prepared in accordance with accounting principles generally accepted in the United States of America ("United States GAAP") and instructions to Form 10-K.

#### ***Use of Estimates***

In preparing consolidated financial statements in conformity with United States 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. In particular, we evaluated the AmiKet IPR&D as of December 31, 2017 and 2016 for impairment. We determined that it is more likely than not that the AmiKet IPR&D was impaired as of December 31, 2016. 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.

## Property and Equipment

Property and equipment are carried at cost, less accumulated depreciation. Depreciation is recognized using the straight-line method over the useful life of the related asset. Expenditures for maintenance and repairs that do not improve or extend the expected useful life of the assets are expensed to operations while major repairs are capitalized.

	<u>Method</u>	<u>Estimated Useful Life (Years)</u>
Computers and accessories	Straight-line	3 - 5
Equipment	Straight-line	3 - 5
Furniture and fixtures	Straight-line	3 - 7

Property and equipment consisted of the following (\$ in thousands):

	<u>December 31,</u>	
	<u>2017</u>	<u>2016</u>
Computers and software	\$ -	\$ 103
Equipment	-	284
Furniture and fixtures	-	94
	-	481
Less accumulated depreciation	-	(165)
	<u>\$ -</u>	<u>\$ 316</u>

During the year ended December 31, 2017, we disposed of property and equipment of approximately \$325,000. This was comprised of the disposal of lab related property and equipment of approximately \$267,000 upon the termination of the lease agreement in May 2017 and the disposal of financial software not placed in service of approximately \$58,000. Depreciation expense amounted to approximately \$19,000 and \$88,000 for the years ended December 31, 2017 and 2016, respectively.

## 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. 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 for the year ended December 31, 2016. The estimated fair value of the IPR&D asset as of December 31, 2016 was based upon the value ascribed to AmiKet in an arm's length agreement, which we negotiated with an unrelated third party.

In the fourth quarter of 2017, we decided to apply the nano-encapsulation technology to AmiKet and develop Amiket Nano as a next generation, improved formulation of AmiKet. Previously, we had considered developing Amiket Nano but temporarily abandoned the project to focus on other development programs. Current management has decided to renew AmiKet Nano development activities based on the results of the BNS research. Additionally, the incorporation of the nano technology with AmiKet provides significant new patent protection for AmiKet Nano.

## Segment Information

We operate in one reportable segment: acquiring, developing and commercializing prescription drug products. Accordingly, we report the accompanying consolidated financial statements in the aggregate, including all of our activities in one reportable segment. Approximately 8% and 9% of our assets were located outside of the United States as of December 31, 2017 and 2016, respectively.

## 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 the 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.

## Reverse Stock Split

On April 12, 2017, we announced a reverse stock split (the “Reverse Split”) of our shares of common stock (“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”). Every twenty shares of issued and outstanding Common Stock were automatically combined into one issued and outstanding share of Common Stock. Our shareholders ratified the effectiveness of the Reverse Split at our Annual Meeting of Stockholders, held and adjourned on February 15, 2018, and reconvened on February 23, 2018.

The Reverse Split affected all issued and outstanding shares of Common Stock, as well as Common Stock underlying stock options, warrants and convertible instruments outstanding immediately prior to the effectiveness of the Reverse Split. The Reverse Split reduced the total number of shares of Common Stock outstanding from approximately 194.3 million to approximately 9.7 million and was reflected on our Statement of Financial Position by a reduction in Common Stock of approximately \$15.6 million and a corresponding increase in Additional Paid-in Capital of the same amount because the par value per share of our Common Stock did not change.

No fractional shares were issued in connection with the Reverse Split. Any fractional share of common stock that would otherwise have resulted from the Reverse Split was rounded up to the nearest whole share.

All share and per share amounts in the financial statements have been retroactively adjusted for all periods presented to give effect to the Reverse Split, including reclassifying an amount equal to the reduction in par value to Additional Paid-in Capital.

### **Income Taxes**

We account for income taxes in accordance with ASC 740 "Income Taxes." We are required to file income tax returns in the appropriate foreign, U.S. federal, state and local jurisdictions, including New Jersey, New York State, New York City and Israel. Since we had losses in the past, all prior years that generated net operating loss carry-forwards are open and subject to audit examination.

Income taxes are accounted for under the asset and liability method. Under the asset and liability method, deferred tax assets and liabilities are recognized based upon the differences arising from carrying amounts of our assets and liabilities for tax and financial reporting purposes using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect on the deferred tax assets and liabilities of a change in tax rates is recognized in the period when the change in tax rates is enacted. A valuation allowance is established when it is determined that it is more likely than not that some portion or all of the deferred tax assets will not be realized. A full valuation allowance has been applied against our net deferred tax assets as of December 31, 2017 and 2016, due to projected losses and because it is not more likely than not that we will realize future benefits associated with these deferred tax assets. Our policy is to recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. ASC 740 prescribes how a company should recognize, measure, present and disclose in its financial statements uncertain tax positions that a company has taken or expects to take on a tax return. Additionally, for tax positions to qualify for deferred tax benefit recognition under ASC 740, the position must have at least a "more likely than not" chance of being sustained upon challenge by the respective taxing authorities, which criteria is a matter of significant judgment. We had gross liabilities recorded of \$70,000 and \$60,000 for the years ended December 31, 2017 and 2016, respectively, to account for potential state income tax exposure. Our policy is to record interest and penalty related to the underpayment of income taxes or unrecognized tax benefits as a component of its income tax provision, of which such amounts were immaterial for the years ended December 31, 2017 and 2016.

### **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**

#### *New accounting standards which have been adopted*

In March 2016, the FASB issued **Accounting Standards Update No. 2016-09, "Compensation-Stock Compensation"** (ASU 2016-09). The new standard was effective for us on January 1, 2017. Among other provisions, the new standard requires that excess tax benefits and tax deficiencies that arise upon vesting or exercise of share-based payments be recognized as income tax benefits and expenses in the income statement. Previously, such amounts were recorded to additional paid-in-capital. This aspect of the new guidance was required to be adopted prospectively. Adoption of ASU 2016-09 did not have a material impact on the income tax provision for the year ended December 31, 2017.

In January 2017, the FASB issued **Accounting Standards Update No. 2017-01, "Business Combinations"** (ASU 2017-01). ASU 2017-01 provides guidance for evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The guidance provides a screen to determine when an integrated set of assets and activities (a "set") does not qualify to be a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in an identifiable asset or a group of similar identifiable assets, the set is not a business. If the screen is not met, the guidance requires a set to be considered a business to include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs and removes the evaluation as to whether a market participant could replace the missing elements. During the year ended December 31, 2017, we early adopted ASU 2017-11. The acquisition of the Ceplene rights, did not meet the definition of a business in accordance with ASU 2017-01 (see Note 7).

In July 2017, the FASB issued **Accounting Standards Update ("ASU") No. 2017-11, Earnings Per Share** (Topic 260), **Distinguishing Liabilities from Equity** (Topic 480), **Derivatives and Hedging** (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features, II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception ("ASU 2017-11"). ASU 2017-11 revises the guidance for instruments with down round features in Subtopic 815-40, Derivatives and Hedging - Contracts in Entity's Own Equity, which is considered in determining whether an equity-linked financial instrument qualifies for a scope exception from derivative accounting. An entity still is required to determine whether instruments would be classified in equity under the guidance in Subtopic 815-40 in determining whether they qualify for that scope exception. If they do qualify, freestanding instruments with down round features are no longer classified as liabilities. ASU 2017-11 is effective for annual and interim periods beginning after December 15, 2018, and early adoption is permitted, including adoption in an interim period. During the year ended December 31, 2017, we early adopted ASU 2017-11. The impact of this adoption is that the down-round provisions within our warrants issued with the April 2017 Convertible Notes qualify for a scope exception from derivative accounting and were recorded in equity. ASU 2017-11 provides that upon adoption, an entity may apply this standard retrospectively to outstanding financial instruments with a down round feature by means of a cumulative-effect adjustment to the opening balance of retained earnings in the fiscal year and interim period of adoption. We did not have any other outstanding instruments with down round provisions and therefore no cumulative-effect adjustment was made to retained earnings.

*New accounting standards which have not yet 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 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 will be effective for us beginning in the first quarter of 2018. We do not expect the adoption of ASU 2016-01 to have a material effect on our consolidated financial statements as we do not hold any publicly traded equity investments.

In February 2016, the FASB issued **Accounting Standards Update No. 2016-02, "Leases"** (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 implementation of this standard to have an impact on our consolidated financial statements and related disclosures as we expect to have aggregate future minimum lease payments under future non-cancelable leased office space.

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 is effective for us in our first quarter of fiscal 2018. We do not expect 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 is effective for us in our first quarter of fiscal 2018. We do not expect the adoption of ASU 2016-16 to have a material effect on our consolidated financial statements as we do not anticipate 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"**. 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 would require 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 is effective for us in our first quarter of fiscal 2018. We expect the adoption of ASU 2016-18 to result in reclassification of restricted cash in the consolidated statements of cash flows for the year ended December 31, 2017.

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 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.

#### **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.

##### ***Hercules Warrants***

On July 29, 2015, the Company and Immune Pharmaceuticals USA Corp., a wholly-owned subsidiary of the Company entered into a Loan and Security Agreement ("Loan Agreement") with Hercules Capital ("Hercules") pursuant to which we borrowed \$4.5 million from Hercules. In connection with the execution of the Loan Agreement, we issued to Hercules five-year warrants ("Hercules Warrants") to purchase an aggregate of 10,743 shares of our common stock at an exercise price of \$34.00 per share, subject to certain adjustments, including, the effective price of any financing occurring six months after the issuance date at a price lower than the strike price of the Hercules Warrants.

We determined the fair value of the Hercules Warrants to be \$0.3 million on July 29, 2015 using the Binomial Lattice pricing model and recorded that amount as part of debt discount in our consolidated balance sheets because the Hercules Warrants were considered part of the cost of the financing. We amortized the debt discount over the life of the Loan Agreement using the effective interest method. The Hercules Warrants were re-measured at each balance sheet date until the expiration of the anti-dilution provision on January 29, 2016. For the year ended December 31, 2016, we recorded a gain on the change in the estimated fair value of the Hercules Warrants of \$38,000, which was recorded as non-operating income in our consolidated statements of operations. Upon the expiration of the anti-dilution provision on January 29, 2016, the remaining balance of \$46,000 of the derivative liability associated with the Hercules Warrant was reclassified to additional paid-in-capital in our consolidated balance sheets.

### ***Discover Series D Convertible Preferred Stock***

In 2015, we issued Series D Redeemable Convertible Preferred Stock (“Series D Preferred Stock”) to Discover Growth Fund (“Discover”), with a conversion price of \$50.00 per share. We received total gross proceeds of \$12.0 million in connection with the issuance of the Series D Preferred Stock to Discover after taking into account a 5% original issue discount.

Discover could convert at any time and at conversion Discover receives a conversion premium equal to the amount of dividends it would have received with respect to the Series D Preferred Stock if the Series D Preferred Stock had been held to the term of agreement of 6.5 years. The Series D Preferred Stock dividend rate included an adjustment feature that fluctuated inversely to the changes in the value of our common stock price. The conversion premium and dividends are redeemed upon conversion of the Series D Preferred Stock. We determined that the conversion premium and dividends with the features described above required liability accounting. Accordingly, the conversion premium and the dividend feature were bifurcated from the Series D Preferred Stock on our consolidated balance sheet and were recorded as a derivative liability at fair value. Changes in the fair value of the derivative liability are recognized in our consolidated statement of operations for each reporting period. For the year ended December 31, 2016, Discover converted its remaining 963 shares of our Series D Preferred Stock outstanding.

We recorded a loss of \$8.7 million on the change in the estimated fair value of the Discover derivative liability for the year ended December 31, 2016. The loss was recorded as a non-operating expense in our consolidated statements of operations. The fair value of the Discover derivative liability as of December 31, 2016 was \$0.

### **2017 Derivative Liabilities**

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”) (See Note 9). 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 December 31, 2017, the fair value of these shares was \$42,750 based on the closing price of our shares and we recorded the change in fair value of \$165,000.

On October 27, 2017, we entered into an agreement with a consultant in which the consultant is entitled to receive 50,000 shares. We accounted for the obligation as a derivative because the issuance of the shares were subject to approval by our board of directors and were not issued as of December 31, 2017. We recorded the derivative liability of \$40,500 at inception based on the closing price of our shares on that date. As of December 31, 2017, the fair value of these shares was \$28,500 based on the closing price of our shares and we recorded the change in fair value of \$12,000.

### **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, restricted 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 \$4.7 million as it related to the long-term portion of the Ceplene asset acquisition payable which was recorded at its present value using our borrowing rates (see Notes 7 and 9). We had no other financial liabilities or assets that were measured at fair value as of December 31, 2017 or 2016.

#### *Hercules Warrants*

The following table sets forth a summary of changes in the estimated fair value of our Hercules Warrant derivative liability for the periods presented (\$ in thousands):

	<b>Fair Value Measurements of Hercules Common Stock Warrants Using Significant Unobservable Inputs (Level 3)</b>	
Balance at January 1, 2016	\$	84
Change in estimated fair value of liability classified warrants		(38)
Reclassification from liability to additional paid-in capital		(46)
Balance at December 31, 2016	<u>\$</u>	<u>-</u>

#### *Series D Preferred Stock*

The following table sets forth a summary of changes in the estimated fair value of our Series D Preferred Stock derivative liability for the periods presented (\$ in thousands):

	<b>Fair Value Measurements of Series D Preferred Stock Derivative Liability Using Significant Unobservable Inputs (Level 3)</b>	
Balance at January 1, 2016	\$	6,529
Change in estimated fair value of Series D Preferred Stock derivative liability		8,694
Series D Preferred Stock conversions		(15,223)
Balance at December 31, 2016	<u>\$</u>	<u>-</u>

### **Note 6. Licensing Agreements**

#### **Bertilimumab**

##### *iCo Therapeutics Inc.*

In December 2010, iCo Therapeutics Inc. (“iCo”) granted Immune Ltd. an option to sub-license the use of bertilimumab from iCo, which obtained certain exclusive license rights to intellectual property relating to bertilimumab pursuant to a license agreement with Cambridge Antibody Technology Group Plc, and to which Immune Ltd. became a party. In June 2011, Immune Ltd. exercised its option and obtained a worldwide license from iCo for the use and development of bertilimumab for all human indications, other than ocular indications, pursuant to a product sub-license agreement (the “iCo License”). iCo retained the worldwide exclusive right to the use of bertilimumab for all ocular applications.

Under the agreement, Immune Ltd. paid an initial consideration of \$1.7 million comprised of (i) \$0.5 million in cash, (ii) 30,000 ordinary shares issued by Immune Ltd, which were valued at approximately \$1.0 million and (iii) 10,000 warrants, which were valued at approximately \$0.2 million.

Pursuant to the iCo License, iCo is entitled to receive up to \$32.0 million in development and commercialization milestones plus sales based royalties. The license term with respect to each separate Licensed Product, expires, on a country-by-country basis, on the later to occur of (a) the tenth anniversary of the First Commercial Sale of such Licensed Product in the applicable country or (b) the expiration date in such country of the last to expire of any issued iCo Patent that includes at least one Valid Claim that claims the particular Licensed Product or its manufacture or use (aa capitalized terms as defined in the iCo License”).

No milestones triggering a payment obligation were reached during the years ended December 31, 2017 or 2016.

#### ***Lonza Sales AG***

On May 2, 2012, Lonza Sales AG (“Lonza”) granted us a sub-licensable, non-exclusive worldwide license under certain know-how and patent rights to use, develop, manufacture, market, sell, offer, distribute, import and export bertilimumab, as it is produced through the use of Lonza’s system of cell lines, vectors and know-how. We are not obligated to manufacture bertilimumab through the use of Lonza’s system.

We agreed to pay Lonza (i) a royalty of 1% of the net selling price of bertilimumab manufactured by Lonza; or (ii) an annual payment of approximately \$0.1 million (first payable upon commencement of phase 2 clinical trials) plus a royalty of 1.5% of the net selling price of bertilimumab if it is manufactured by us or one of our strategic partners; or (iii) an annual payment of approximately \$0.5 million (first payable upon commencement of the relevant sublicense) plus a royalty of 2% of the net selling price of bertilimumab if it is manufactured by any party other than Lonza, us or one of our strategic partners. The royalties are subject to a 50% reduction based on the lack of certain patent protections, including the expiration of patents, on a country-by-country basis. Unless earlier terminated, the license agreement continues until the expiration of the last enforceable valid claim to the licensed patent rights, which began to expire in 2014 and continued to expire between 2015 and 2016, or for so long as the System Know How (as defined in the License) is identified and remains secret and substantial, whichever is later. We considered the System Know How as secret and substantial as of December 31, 2017 and accordingly, the license remains in effect as of that date.

For the year ended December 31, 2017 there were no payments due related to this license.

#### ***NanoCyclo - BioNanoSim Ltd***

In January 2016, we, through our wholly owned subsidiary, Immune Ltd., entered into a definitive research and license agreement with BioNanoSim Ltd. (“BNS”), a Yissum spin-off company. We obtained from BNS an exclusive worldwide sublicense, with a right to further sublicense, for the development, manufacturing and commercialization of certain inventions and research results regarding Yissum’s patents in connection with nanoparticles for topical delivery of cyclosporine-A (Nanocyclo) for all topical skin indications. As consideration for the grant of the license, we are required to pay the following consideration:

- an annual maintenance fee of \$30,000, commencing on January 1, 2021, which will increase by 30% each year up to a maximum annual maintenance fee of \$0.1 million and may be credited against royalties or milestone payments payable in the same calendar year;
- a license fee in the amount of \$0.5 million, paid in 2016;
- royalties on net sales of products (as such term is defined in the License) by us of up to 5%, subject to certain possible reductions in certain jurisdictions;
- sublicense fees in the amount of 18% of any non-sales related consideration received by us from a sublicense or an option to receive a sublicense for the products and/or the licensed technology (as such terms are defined in the license); and
- milestone payments of up to approximately \$4.5 million and 250,000 shares of our common stock (12,500 shares after giving effect to the April 2017 Reverse Stock Split) upon the achievement of certain regulatory, clinical development and commercialization milestones. In the event that we receive consideration from a sublicensee for any such milestones, we will pay to BNS the higher of either (a) the amount of the particular milestone payment or (b) the amount of the sublicense fees that are due for such sublicensee consideration paid to us.

In addition, we are obligated to reimburse BNS within 60 days for expenses relating to patent fees and will sponsor a 12-month research program to prepare the program for IND submission.

In November 2017, we issued 250,000 shares valued at \$225,000 to BNS without giving effect to the impact of the April 2017 Reverse Stock Split because we decided that the importance of the NanoCyclo program and the need to maintain a positive working relationship with BNS warranted ignoring the impact of the Reverse Split and instead issuing 250,000 Shares to BNS as if the Reverse Split had not occurred.

For the year ended December 31, 2016, we paid a license fee of \$0.5 million and approximately \$0.2 million in research fees. For the year ended December 31, 2017, we paid approximately \$0.3 million in research fees.

#### **Amiket and AmiKet Nano**

##### ***Yissum***

In June 2015, we entered into a definitive research and license agreement with Yissum. We obtained an exclusive, worldwide license from Yissum, with certain sublicensing rights, to make commercial use of certain of Yissum's patents and know-how in connection with a topical nano-formulated delivery of AmiKet for the development, manufacturing, marketing, distribution and commercialization of products based on the technology. As consideration for the grant of the license, we are required to pay the following consideration:

- an annual maintenance fee of \$30,000 commencing on June 25, 2020, which maintenance fee shall increase by 30% each year, up to a maximum annual maintenance fee of \$0.1 million and may be credited against royalties or milestone payments payable in the same calendar year;
- royalties on net sales of products (as such term is defined in the license) by us in the amount of up to 3%, subject to certain possible reductions in certain jurisdictions;
- milestones payments of up to approximately \$4.5 million upon the achievement of certain regulatory, clinical development and commercialization milestone; and
- reimbursement of related patent fees

In addition, we agreed to fund an annual research program in the amount of approximately \$0.4 million annually, plus VAT and any applicable taxes, commencing on October 1, 2015 (or such other time as mutually agreed between the parties). The results of the research, including any patents or patent applications will automatically be licensed to us.

For the year ended December 31, 2016, we paid research fees of approximately \$0.1 million. As of December 31, 2017, \$250,000 is due to Yissum for research fees.

##### ***Dalhousie University***

In July 2007, we entered into a license agreement with Dalhousie University ("Dalhousie") under which we obtained an exclusive license to certain patents for the topical use of tricyclic anti-depressants and N-methyl-D-aspartate ("NMDA") receptor antagonists as topical analgesics for neuralgia. These and other patents cover the combination treatment consisting of amitriptyline and ketamine in AmiKet. We obtained worldwide rights to make, use, develop, sell and market products utilizing the licensed technology in connection with passive dermal applications. We are obligated to make payments to Dalhousie upon achievement of specified milestones and royalties based on annual net sales derived from the products incorporating the licensed technology. In April 2014, we entered into a Waiver and Amendment to the license agreement pursuant to which Dalhousie agreed to irrevocably waive our obligation to pay maintenance fees. In exchange, we agreed to pay Dalhousie royalties of 5% of net sales of licensed technology in countries in which patent coverage is available and 3% of net sales in countries in which data protection is available. Also, we agreed to amend the timing and increase the amounts of the milestone payments payable under the license agreement.

## Oncology

### ***Ceplene - Pint Pharma International S.A.***

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”, as more fully defined in the Licensing Agreement) through Pint and one or more of its affiliates. Pursuant to the Licensing Agreement, Cytovia is entitled to (i) 35% of Ceplene net sales in the Territory (ii) a milestone payment of \$0.5 million when net sales of Ceplene in the Territory 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 reach \$25.0 million in any calendar year (collectively, the “Ceplene Payments”). Cytovia further granted Pint and its affiliates certain sublicensing 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 product(s).

Additionally, in connection with the Licensing Agreement, the parties agreed that Pint GmbH, an affiliate of Pint, will separately enter into an investment agreement, pursuant to which Pint GmbH will make an investment of \$4.0 million at series A valuation into Cytovia in exchange for an equity interest in Cytovia. Dr. Massimo Radaelli, Executive Chairman of Pint, will also join the board of Cytovia upon completion of the investment and effective spin off of Cytovia from us, if and as consummated.

### ***NanomAbs - Yissum***

In April 2011, We entered into a license agreement with Yissum, which includes patents, research results and know-how developed by Professor Simon Benita related to the NanomAbs technology. Yissum granted us an exclusive license, with a right to sub-license, to make commercial use of the licensed technology in order to develop, manufacture, market, distribute or sell products derived from the license. As consideration for the grant of the license, we are required to pay the following consideration:

- royalties in the amount of up to 4.5% of net sales;
- beginning on the sixth anniversary, an annual license maintenance fee between \$30,000 for the first year and up to a maximum of \$0.1 million thereafter;
- research fees of at least \$0.3 million for the first year and at least \$0.1 million from the second year through the sixth year (but, not to exceed \$1.8 million in the aggregate);
- milestone payments of up to \$8.6 million, based on the attainment of certain milestones, including IND application submission, patient enrollment in clinical trials, regulatory approval and commercial sales;
- sub-license fees in amounts up to 18% of any sub-license consideration; and
- equity consideration in the amount of 8% of our shares of common stock on a fully diluted basis.

The license expires, on a country-by-country basis, upon the later of the expiration of (i) the last valid licensed patent, (ii) any exclusivity granted by a governmental or regulatory body on any product developed through the use of the licensed technology or (iii) the 15-year period commencing on the date of the first commercial sale of any product developed through the use of the licensed technology. Upon the expiration of the license, we will have a fully paid, non-exclusive license to the licensed technology.

For the year ended December 31, 2017 we paid research fees of approximately \$0.1 million.

### **Bispecific Antibodies - SATT Sud-Est**

In January 2017, we entered into an exclusive patent sub-license agreement with SATT Sud-Est, (“SATT”) a French technology transfer office of the five universities of the Provence-Alpes-Cote-d’Azur and Corsica regions in France, relating to certain patents covering the development, use, manufacture and commercialization of monoclonal and bispecific antibodies targeting components of the tumor microenvironment and angiogenic factors. In addition, SATT agreed to grant us an exclusive option relating to the pro-angio vascular endothelial growth factor (“VEGF”) invention to be filed as a patent application during the term of the agreement. We will have a month after the filing of the patent to exercise the option. In consideration of the sub-license and option agreement, we agreed to pay an upfront payment of approximately \$0.2 million, with \$0.1 million payable in January 2017 and the remainder payable in three equal quarterly payments thereafter beginning in March 2017. As of December 31, 2017, we have not made any payments. In addition, we agreed to certain milestone and royalty payments for each monoclonal and bispecific product developed.

### **Bispecific Antibodies - Atlante Biotech SAS**

In December 2015, we entered into an exclusive license with Atlante Biotech SAS (“Atlante”) relating to the patents and know-how for a new format of bispecific antibody platform. The technology, the result of a collaborative European consortium led by Dr. Jean Kadouche and funded by a European grant, developed the novel platform for the production of tetravalent IgG1-like bispecific antibodies. A prototype bispecific antibody utilizing the platform was shown to retain effector functions and mediate redirect killing of target cells by cytokine induced killer T cells. Moreover, the bispecific antibody demonstrated direct in-vitro and in-vivo anti-cancer effects in tumor models and improved survival in a mouse xenograft model of disseminated leukemia.

### **MabLife SAS**

In March 2012, we acquired from MabLife SAS (“MabLife”), a biotechnology company specializing in research and development of antibody-based therapeutics for the treatment of cancers, autoimmune and inflammatory disorders. We acquired all rights, title and interest in and to the patent rights, technology and deliverables related to the anti-Ferritin monoclonal antibody (“AMB8LK”), including its nucleotide and protein sequences, its ability to recognize human acid and basic ferritins, or a part of its ability to recognize human acid and basic ferritins. The consideration was: \$0.6 million payable in six equal installments (total payments to date totaled \$0.2 million) and 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. We are required to assign the foregoing rights back to MabLife if we fail to make any of the required payments, are declared insolvent or bankrupt or terminate the agreement.

In February 2014, we acquired from MabLife all rights, titles and interests in and to the secondary patent rights 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.

### **Shire BioChem Inc.**

In connection with the Merger, we acquired a license agreement for the rights to the MX2105 series of apoptosis inducer anti-cancer compounds from Shire BioChem Inc. (“Shire BioChem”), (formerly known as BioChem Pharma, Inc.). Under the license agreement, we are required to pay Shire BioChem a portion of any sublicensing payments we receive if we relicense the series of compounds or make milestone payments to Shire BioChem totaling up to \$26.0 million and pay a royalty on product sales if we develop the compounds internally for the treatment of a cancer indication.

### **Dr. Jean Kadouche and Alan Razafindrastita**

In December 2011, Dr. Jean Kadouche sold, assigned and transferred to us the entire right, title and interest for all countries, in and to any and all patents and inventions related to mice producing human antibodies and a method of preparation of human antibodies (the “Human Antibody Production Technology Platform”) for 40,000 shares of our common stock and \$20,000 (paid to Dr. Kadouche and Alan Razafindrastita). Through the Human Antibody Production Technology Platform and additional laboratory work, human immune systems and specific cell lines were introduced in mice, enabling the mice to produce human monoclonal antibodies.

## LidoPAIN - Endo Pharmaceuticals Inc.

In December 2003, EpiCept entered into a license agreement (“License Agreement”) with Endo Pharmaceuticals Inc. (“Endo”) under, which EpiCept granted Endo (and its affiliates) the exclusive (including as to EpiCept and its affiliates) worldwide right to commercialize LidoPAIN, adhesive-backed, lidocaine-based patch for the treatment of acute lower back pain. EpiCept also granted Endo worldwide rights to use certain of EpiCept’s patents for the development of certain other non-sterile, topical lidocaine patches, including Lidoderm, Endo’s non-sterile topical lidocaine-containing patch for the treatment of chronic lower back pain. We assumed the License Agreement upon the Merger.

Under the License Agreement, we are entitled to receive milestone payments of up to \$52.5 million upon the achievement of various milestones relating to product development, regulatory approval and sales based royalties on sales of LidoPAIN and Endo’s own back pain product, if covered by our patents. Royalties are payable until generic equivalents to the LidoPAIN product are available or until expiration of the patents covering LidoPAIN, whichever is sooner. Also, we are eligible to receive milestone payments from Endo of up to \$30 million upon the achievement of specified regulatory and net sales milestones of Lidoderm, Endo’s chronic lower back pain product candidate, if covered by our patents. The License Agreement terminates upon the later of the conclusion of the royalty term, on a country-by-country basis, and the expiration of the last applicable EpiCept patent covering licensed Endo product candidates on a country-by-country basis. Either party may terminate the agreement upon an uncured material breach by the other or, subject to the relevant bankruptcy laws, upon a bankruptcy event of the other.

In July 2015, we amended the License Agreement. We transferred to Endo its previously licensed patents related to the use of topical lidocaine in acute and chronic back pain and Endo granted to us a royalty-free, non-exclusive, fully transferable license to those patents. Endo will make undisclosed milestone payments to us if Endo receives approval for a back pain indication for a lidocaine-based product. We regained full exclusive rights to develop, commercialize and license LidoPAIN.

### Note 7. 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. 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 is determined by using our current borrowing rate of 15% as the relevant discount rate for present value calculations. As of December 31, 2017, the amount due to Meda on a present value basis, classified as current and long term notes and loans payable is \$3.0 million and \$1.4 million, respectively. The estimated useful life of these intangible assets is seven years.

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
<b>Balance as of January 1, 2016</b>	\$ 1,753	\$ 475	\$ 475	\$ 408	\$ -	\$ 3,111
Amortization	(167)	(46)	(47)	(45)	-	(305)
<b>Balance as of December 31, 2016</b>	\$ 1,586	\$ 429	\$ 428	\$ 363	\$ -	\$ 2,806
Additions	-	-	-	-	4,310	4,310
Amortization	(167)	(46)	(47)	(45)	(334)	(639)
<b>Balance, December 31, 2017</b>	<u>\$ 1,419</u>	<u>\$ 383</u>	<u>\$ 381</u>	<u>\$ 318</u>	<u>\$ 3,976</u>	<u>\$ 6,477</u>
<b>Gross asset value</b>	\$ 2,509	\$ 694	\$ 700	\$ 547	\$ 4,310	\$ 8,760
Accumulated Amortization	(1,090)	(311)	(319)	(229)	(334)	(2,283)
<b>Balance, December 31, 2017</b>	<u>\$ 1,419</u>	<u>\$ 383</u>	<u>\$ 381</u>	<u>\$ 318</u>	<u>\$ 3,976</u>	<u>\$ 6,477</u>

Management determined that our amortizable intangible assets have a useful life of between 7 and 15 years. Amortization expense amounted to \$639,000 and \$305,000 for the years ended December 31, 2017 and 2016, respectively.

Estimated amortization expense for each of the five succeeding years, based upon intangible assets owned at December 31, 2017 is as follows (\$ in thousands):

<b>Period Ending December 31,</b>	<b>Amount</b>
2018	\$ 921
2019	921
2020	921
2021	907
2022	905
Thereafter	1,902
<b>Total</b>	<b>\$ 6,477</b>

#### **Note 8. Accrued Expenses**

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

	<b>December 31, 2017</b>	<b>December 31, 2016</b>
Professional fees	\$ 284	\$ 414
Consulting fees	691	-
License fees	421	-
Dividends	216	-
Salaries and employee benefits	105	930
Advances and fees	-	340
Financing costs	-	616
Other	403	320
<b>Total</b>	<b>\$ 2,120</b>	<b>\$ 2,620</b>

## Note 9. Notes and Loans Payable

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

	December 31, 2017	December 31, 2016
Loan Agreement, net of original issue discount of \$0 and \$0.4 million, respectively <sup>(1)</sup>	\$ —	\$ 2,857
July 2017 Senior Secured Convertible Promissory Note, net of original issue discount, debt issuance cost and debt discount <sup>(2)</sup>	—	—
April 2017 Convertible Notes <sup>(3)</sup>	—	—
May 2017 Convertible Notes, net of original issue discount, debt issuance cost and debt discount <sup>(4)</sup> (11)	—	—
July 2017 Convertible Notes, net of original issue discount, debt issuance cost and debt discount <sup>(5)</sup> (11)	—	—
August 2017 Convertible Notes, net of original issue discount, debt issuance cost and debt discount <sup>(6)</sup> (11)	—	—
September 2017 Convertible Notes, net of original issue discount, debt issuance cost and debt discount (7) (11)	—	—
Mablife Notes Payable <sup>(8)</sup>	394	387
Asset Acquisition Payable, net of discount of \$0.6 million <sup>(9)</sup>	4,359	—
Convertible Notes, net of original issue discount, debt issuance cost and debt discount of \$0 and \$0.1 million <sup>(10)</sup>	—	937
<b>Total notes and loans payable</b>	<b>\$ 4,753</b>	<b>\$ 4,181</b>
Notes and loans payable, net of debt discount, current portion	\$ 3,296	\$ 2,739
Notes and loans payable, noncurrent portion	1,457	1,442
<b>Total notes and loans payable, net of original issue discount, debt issuance cost and debt discount of \$0.6 million and \$0.5 million</b>	<b>\$ 4,753</b>	<b>\$ 4,181</b>

Repayments under our existing debt agreements consist of the following (\$ in thousands):

Period Ending December 31,	Amount
2018	\$ 3,367
2019	1,000
2020	1,020
<b>Total</b>	<b>\$ 5,387</b>

### Loan and Security Agreement (1)

On July 29, 2015, the Company and Immune Pharmaceuticals USA Corp., a wholly-owned subsidiary of the Company, entered into a Loan and Security Agreement (“Loan Agreement”) pursuant to which Hercules agreed to lend \$4.5 million to us with an option to borrow an additional \$5.0 million prior to June 15, 2016, subject to the achievement of certain clinical milestones and other conditions. As of June 15, 2016, we had not met certain of the milestones described in the Loan Agreement required in order to borrow an additional \$5.0 million and as a result the option expired. The Loan Agreement is collateralized by a first priority perfected security interest in all tangible and intangible assets of the Company and its subsidiaries. The Loan Agreement is senior in priority to all other Company indebtedness. The interest rate on the Hercules Loan is calculated at the greater of 10% or the prime rate plus 5.25%. We may prepay the Hercules Loan at any time, subject to certain prepayment penalties. Hercules may optionally convert up to \$1.0 million of the unpaid principal balance of the loan in any subsequent institutionally led Company financing on the same terms, conditions and pricing applicable to such subsequent financing. This option to convert the loan to equity would be at the then fair value of our equity. Because the option to convert will be at the same terms and pricing as the new investors will be paying in the subsequent Company financing, the option is deemed to have minimal value for financial reporting purposes. The Hercules Loan’s matures on September 1, 2018 and includes an interest-only payment period for the first nine months following initial funding of the loan, after which escalating principal payments of \$0.1 million per month began on April 1, 2016. Interest expense for the year ended December 31, 2016 was \$0.4 million. As of December 31, 2016, we had made \$1.2 million in principal repayments.

The Loan Agreement includes an end of term charge of \$0.5 million payable on the earliest to occur of (i) the Term Loan Maturity Date, (ii) the date that Borrower prepays the outstanding secured obligations under the Loan Agreement in full, or (iii) the date that the secured obligations under the Loan Agreement become due and payable in full (as described in the Loan Agreement). We accrue a portion of the end of term charge for each reporting period and will accrue up to the full \$0.5 million charge over the 37-month term of the Hercules Loan because this charge is deemed a cost of the debt. For the year ended December 31, 2016, we had recorded a charge of approximately \$0.2 million, in interest expense in our consolidated statements of operations related to the Loan Agreement.

We recorded \$1.3 million in debt issuance costs relating to placement agent fees, legal fees, closing costs and the fair value of the placement agent warrants in its consolidated balance sheets upon execution of the Loan Agreement. We early adopted ASU 2015-03 Simplifying the Presentation of Debt Issuance Costs, ASU 2015-03 amends existing guidance to require the presentation of debt issuance costs in the balance sheet as a deduction from the carrying amount of the related debt liability instead of a deferred charge. We amortized the debt issuance costs over the term of the Loan Agreement. For the year ended December 31, 2016, we recorded \$0.6 million in interest expense related to the amortization of the debt issuance costs. At December 31, 2016, we had approximately \$0.4 million in debt issuance costs remaining to be amortized which is presented net of the debt balance in our consolidated balance sheets.

We repaid \$1.2 million in principal through December 31, 2016 and another \$0.9 million in principal in 2017. As more fully described below (see Note 9 (2)), pursuant to an Assignment and Exchange Agreement that we executed in July 2017, we repaid the full principal balance of the Hercules Loan of \$2.4 million and early termination fees of \$0.6 million and the Hercules Loan was extinguished.

For the year ended December 31, 2017, interest expense was \$423,000 related to the Loan Agreement, of which \$143,000 was based on the interest rate, \$202,000 was for the amortization of debt issuance costs and \$78,000 was for the end of term charge.

***Assignment and Exchange Agreement (July 2017 Senior Secured Convertible Promissory Note) (2)***

On July 7, 2017, Immune and Immune Pharmaceuticals USA Corp. (together, the “Borrower”), Hercules and certain subsidiaries of our subsidiaries, as guarantors, entered into an Assignment Agreement (the “Assignment Agreement”) with MEF I, L.P. (the “Investor”) whereby Hercules assigned to the Investor the existing amount outstanding under the Loan Agreement. Also on the Closing Date, we entered into an Exchange Agreement with the Investor (the “Exchange Agreement”) whereby we issued to the Investor a senior secured convertible promissory note with a principal amount of \$2,974,159 (the “Exchange Note”) in exchange for the Hercules Loan.

The Exchange Note is convertible, at the option of the holder, into shares of our common stock, par value \$0.001 per share, at a per share price of \$2.95 (the “Fixed Conversion Price”) subject to adjustment as provided in the Exchange Note, but in no event to a conversion price lower than \$1.00 per share and subject to a total beneficial ownership limitation of 4.99% of our issued and outstanding common stock. The Exchange Note is due one year from the issue date.

The Exchange Note is repayable through equal monthly amortization payments during the term of the Exchange Note, in cash or in shares of common stock at the Amortization Conversion Price (as defined in the Exchange Note). The holder has the option to accelerate each amortization payment in up to three separate payments and demand such payments in shares of our common stock.

We concluded that the assignment and debt exchange should be accounted for as an extinguishment of debt because we were released of our obligation to Hercules and issued new debt to the Investor. We calculated the fair value of the new debt at the date of assignment of July 7, 2017 to be \$3.4 million based on the principal of the new debt of approximately \$3.0 million plus guaranteed interest of \$0.4 million. The conversion price is equal to the lower of \$2.80 per share or 83.5% of the lowest trading price of our common stock during the 15 trading days immediately preceding conversion. The fair value of the conversion discount was calculated to be \$0.6 million, which was recorded as loss on extinguishment and additional paid in capital. We recorded the difference between the fair value of the new debt of \$3.4 million and the net carrying amount of the extinguished debt of \$2.5 million as a loss on extinguishment of \$0.9 million in the consolidated statements of operations during the year ended December 31, 2017.

During the year ended December 31, 2017, the Investor converted approximately \$2.2 million of aggregate principal and accrued interest into 1,991,864 shares of our common stock. In October 2017, we paid the Investor \$1.4 million in cash, representing the remaining aggregate principal and accrued interest on the Exchange Note of \$1.2 million and a cash redemption fee of \$0.2 million.

For the year ended December 31, 2017, interest expense was \$236,000 related to the July 2017 Senior Secured Convertible Promissory Note for the amortization of original issue discount.

### *April 2017 Convertible Notes (3)*

On April 10, 2017, we entered into a securities purchase agreement with EMA Financial, LLC (“EMA”) pursuant to which EMA purchased an aggregate principal amount of \$525,000 of Convertible Notes for an aggregate purchase price of \$450,000 (the “April 2017 Convertible Notes”). The April 2017 Convertible Notes included a 5% origination fee of \$25,000 and a 10% original issue discount of \$50,000 that was added to the face amount of the April 2017 Convertible Notes.

The April 2017 Convertible Notes bear interest at a rate of 6.0% per annum, payable in arrears on the maturity date of April 10, 2018 (the “Maturity Date”). The April 2017 Convertible Notes are convertible into shares of our common stock, after the effectiveness of a Registration Statement, at a conversion price equal to the lower of \$2.80 or seventy-five percent (75%) of the lowest trading price of our common stock during 15 trading days immediately preceding conversion (“Conversion Date”). We calculated the fair value of this conversion feature as \$175,000 and recorded that amount as interest expense with an offset to additional paid-in capital.

We issued to EMA 83,333 warrants with an exercise price of \$4.00 per share (subject to adjustment) which may be exercisable on a cashless basis in accordance with the terms of the warrants. The warrants contain a provision whereby if we complete a transaction with an effective price per share lower than the exercise price of the warrants, then the exercise price is reduced and the number of warrant shares issuable is increased such that the aggregate exercise price payable after taking into account the decrease in the exercise price is equal to the aggregate exercise price prior to such adjustment. We calculated the fair value of these warrants using the Monte Carlo model. We allocated the proceeds from the issuance of the April 2017 Convertible Notes between the debt and the warrants using the allocated fair value method and the value assigned to the warrants of \$180,000 was recorded as interest expense with an offset to additional paid-in capital.

On May 3, 2017, we signed a Waiver Letter with EMA whereby we agreed to prepay a portion of the April 2017 Convertible Notes and EMA agreed to participate in the May 2017 Convertible Notes financing transaction described below. Additionally, we amended the April 2017 Convertible Notes to provide that the notes are convertible into shares of our common stock after the effectiveness of the Registration Statement at a conversion price equal to the lower of \$2.80 or sixty-five percent (65%) of the lowest trading price of our common stock during 15 trading days immediately preceding a Conversion Date. On May 4, 2017, EMA converted outstanding notes with a principal balance of \$123,000 plus a prepayment premium of \$31,000, for a total of \$154,000, and applied that amount to the purchase of May 2017 Convertible Notes (see below). We determined that the amendment of the April 2017 Convertible Notes constituted an extinguishment of debt and reissuance. We calculated a fair value of \$105,000 for the conversion feature inherent in the amended April 2017 Convertible Notes and recorded that amount as interest expense with an offset to additional paid-in capital. Additionally, the unamortized debt discount associated with the April 2017 Notes prior to the amendment was written off and charged to interest expense.

On May 30, 2017, we amended the Registration Rights Agreement with EMA dated as of April 10, 2017 to change the filing date of the registration statement to June 30, 2017 and we agreed to prepay \$97,000 towards the principal amount outstanding on the April 2017 Convertible Notes at a prepayment price of \$122,000, which included a prepayment premium of \$25,000. We recorded the premium as interest expense. We filed the S-1 Registration Statement on June 30, 2017.

In July 2017, EMA assigned the April 2017 Convertible Notes to the Investor described above for approximately \$0.4 million. We concluded that the EMA assignment should be accounted for as an extinguishment of debt because we were released of our obligation to EMA and issued new debt to the Investor. We calculated the fair value of the new debt on the date of the assignment based on the purchase price of \$0.4 million paid by the Investor for the April 2017 Convertible Notes. We recorded \$0.1 million as expense from extinguishment of debt, which is the difference between the fair value of the assigned debt of \$0.4 million and the net carrying amount of the extinguished debt of \$0.3 million.

On August 24, 2017, we agreed to reduce the minimum Conversion Price of the April 2017 Convertible Notes from \$1.00 to \$0.75 in exchange for the waiver of certain rights held by the Investor and the consent of the Investor to allow us to issue and sell the August 2017 Convertible Notes (described below). In 2017, the remaining principal balance of the April 2017 Convertible Notes were converted into 462,323 shares of our common stock.

For the year ended December 31, 2017, interest expense was \$607,000 related to the April 2017 Convertible Notes, of which \$280,000 was for the conversion premium, \$180,000 was for the fair value of the warrants, \$85,000 was for the original issue discount, origination fees and attorney's fees, \$55,000 for the prepayment premium of 25% and interest expense of approximately \$7,000 was based on the 6% per annum interest rate.

#### ***May 2017 Convertible Notes (4)***

On May 4, 2017, we entered into a securities purchase agreement (the "May 2017 Purchase Agreement"), with several institutional investors (the "Investors") regarding a multi-tranche private placement of up to \$3.4 million of principal amount of convertible notes (the "May 2017 Convertible Notes"). The first tranche, consisting of the sale of convertible notes with a principal balance of \$2.0 million and the issuance of 361,455 shares of our common stock closed on May 9, 2017. The second tranche, consisting of the sale of convertible notes with a principal balance of \$360,000 and the issuance of 60,000 shares of our common stock closed on May 22, 2017.

The May 2017 Convertible Notes are due and payable upon the earlier of (a) November 9, 2017 and (b) the closing of one or more subsequent financings with gross proceeds equal to at least \$5,000,000 in the aggregate. The holders of the May 2017 Convertible Notes have the option to extend the maturity date of the notes through February 7, 2018.

We recorded the issuance of the shares as original issue discount relating to the convertible notes and used the allocated fair value method to determine the amount of discount. The fair value of the shares of common stock at time of issuance was \$0.6 million.

On June 29, 2017, we entered into a letter agreement with the Investors whereby we waived the right to issue the remaining May 2017 Convertible Notes issuable in the subsequent tranches and the Investors agreed to amend the May 2017 Convertible Notes to provide that the Issuable Maximum (as defined in the May 2017 Convertible Notes) shall not exceed 9.99% (rather than 19.99%) of the number of shares of common stock outstanding on the trading day immediately preceding the date of the May 2017 Purchase Agreement.

Pursuant to the May 2017 Purchase Agreement, the May 2017 Convertible Notes are 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 we have not filed a S-1 registration statement for a follow-on offering by June 3, 2017. Additionally, interest on the May 2017 Convertible Notes would accrue daily at an interest rate of 2% per month on the then outstanding principal amount. Also, the holder may elect to convert all or any portion of the remaining principal amount into shares of common stock at 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 \$1.00. We filed the S-1 Registration Statement on June 30, 2017 and recorded the Mandatory Default Amount of \$1.0 million as interest expense, of which \$0.9 million represents an additional 40% of principal and \$60,000 represents interest at a rate of 2% per month on the outstanding principal balance (including the additional 40%).

On August 24, 2017, we agreed to reduce the conversion price of the May 2017 Convertible Notes from \$2.89 to \$1.30 in exchange for the waiver of certain rights held by the holders and their consent to our sale of the August 2017 Convertible Notes described below. We concluded that the amendment should be accounted for as an extinguishment of debt and reissuance. We calculated the fair value of the new debt on the date of the amendment based on a fair value determination of \$3.8 million and recorded the difference between the fair value of the new debt and the net carrying amount of 3.1 million of the May 2017 Convertible Notes as a loss on extinguishment of \$0.7 million

During the year ended December 31, 2017, the holders of the May 2017 Convertible Notes converted approximately \$1.86 million of aggregate principal and accrued interest into 1,409,946 shares of our common stock. In November 2017, we paid the holders of the May 2017 Convertible Notes \$0.5 million in cash, representing the remaining aggregate principal and accrued interest on the May 2017 Convertible Notes.

For the year ended December 31, 2017, interest expense was \$1,186,000 related to the May 2017 Convertible Notes for the amortization of original issue discount. An additional \$938,000 was paid in liquidated damages for the Mandatory Default Amount noted above.

#### **July 2017 Convertible Notes (5)**

On July 17, 2017, we entered into an agreement in principle with Carmelit 9 Nehassim Ltd (“Carmelit”) for the sale of \$0.3 million of original issue discount convertible notes (the “Carmelit Notes”) for net proceeds of \$0.25 million (\$50,000 original issue discount) which are convertible into shares of our common stock upon shareholder approval. The proposed terms of the notes are as follows: the notes are convertible into an aggregate of 101,695 shares of our common stock based upon a conversion price of \$2.95 per share, subject to adjustment but in no event below \$1.00 per share. The Carmelit Notes are due and payable upon the earlier of (a) January 17, 2018 and (b) the closing of one or more subsequent financings with gross proceeds equal to at least \$5,000,000 in the aggregate. The holder has the option to extend the maturity date of the notes through October 17, 2018. Also, the holder is entitled to receive 75,000 shares of our common stock subject to approval by our shareholders. The transaction was consummated on August 24, 2017. We repaid the Carmelit Notes in full in November 2017.

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, we classified the obligation as a 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. The 75,000 shares had a fair value of \$0.2 million on July 17, 2017 based on the closing price of our shares on that date. As of December 31, 2017, the 75,000 shares had a fair value of \$43,000 based on the closing price of our shares.

For the year ended December 31, 2017, interest expense was \$263,000 related to the July 2017 Convertible Notes for the amortization of original issue discount.

#### **August 2017 Convertible Notes (6)**

On August 24, 2017, we entered into a securities purchase agreement with certain institutional investors for the sale of \$858,000 in aggregate principal amount of original issue discount convertible notes (the “August 2017 Convertible Notes”) with net proceeds of \$515,000 (original issue discount of \$343,000) which are convertible into shares of our common stock upon shareholder approval. The notes are convertible into shares of our common stock at a conversion price of \$1.75 per share, subject to adjustment, subject to adjustment but in no event below \$1.00 per share. The transaction was consummated on August 30, 2017. The August Convertible Notes are due and payable upon the earlier of (a) February 28, 2018 and (b) the closing of one or more subsequent financings with gross proceeds equal to at least \$3.0 million in the aggregate. The holder has the option to extend the maturity date through May 28, 2018. We repaid the August 2017 Convertible Notes in full in October 2017.

For the year ended December 31, 2017, interest expense was \$343,000 related to the August 2017 Convertible Notes for the amortization of original issue discount.

#### **September 2017 Convertible Notes (7)**

In September 2017, we entered into a securities purchase agreement with certain institutional investors for the sale of \$149,500 in aggregate principal amount of original issue discount convertible notes (the "September 2017 Convertible Notes") with net proceeds of \$115,000 (original issue discount of \$34,500) which are convertible into shares of our common stock upon shareholder approval. The notes are convertible into shares of our common stock at a conversion price of \$1.75 per share, subject to adjustment, but in no event below \$1.00 per share. We repaid the September 2017 Convertible Notes in full in October 2017.

For the year ended December 31, 2017, interest expense was \$35,000 related to the September 2017 Convertible Notes for the amortization of original issue discount.

#### **MabLife Notes Payable (8)**

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.

For the years ended December 31, 2017 and 2016, interest expense was \$0 and \$49,000, respectively.

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 are awaiting confirmation by the commercial court.

#### **Asset Acquisition Note Payable (9)**

In conjunction with the Asset Purchase Agreement with Meda described in Note 7, 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 \$3.0 million and \$1.4 million, respectively, representing the amount due to Meda calculated on a present value basis. For the year ended December 31, 2017, interest expense was \$141,000. See Note 15 for discussion of our default on this debt.

## **HLHW Convertible Notes (10)**

On November 17, 2016, we entered into a securities purchase agreement with HLHW IV, LLC (“HLHW”), pursuant to which HLHW purchased an aggregate principal amount of \$1,050,000 of Subordinated Convertible Notes for an aggregate purchase price of \$1,000,000 (“Convertible Notes”), representing a principal amount of the Notes of \$1,000,000 plus an original issue discount of 5% which is \$50,000.

The Convertible Notes bear interest at a rate of 7.0% per annum, payable in arrears on the maturity date of November 17, 2017. The Notes are convertible into shares of our common stock at any time from the date of issuance of the Notes, at a conversion price equal to eighty percent (80%) of the lowest intraday bid price on the date of conversion (“conversion date”); provided the lowest intraday bid price on such conversion date is above the lowest closing bid price on the closing date (“Market Price”). In the event on the conversion date, the lowest intraday bid price is less than the Market Price, then in that instance, the conversion price on that conversion date will be equal to the lowest intraday bid price.

On the maturity date, we have the option to pay the amount being redeemed; including accrued but unpaid interest, in cash, shares or any combination of cash and shares of our common stock. In addition, if at any time the lowest intraday bid price falls below \$5.00 per share, the holder may elect to redeem up to \$350,000 of the outstanding principal, interest and any amounts due under the Convertible Notes; provided, however, we may only use the proceeds from the sale of common stock pursuant to the terms of the Common Stock Purchase Agreement, dated November 17, 2016 (“CS Purchase Agreement”) entered into with HLHW to redeem the Convertible Notes. The Convertible Notes are subordinated to the Loan Agreement with Hercules Capital. This redemption process may be repeated once every five business days, at the election of Holder, until the Convertible Notes are fully satisfied. The foregoing notwithstanding, HLHW may convert any or all of these Convertible Notes into shares of our common stock at any time.

The Convertible Notes also includes certain events of defaults which at any time after HLHW becomes aware of may require the redemption of all or any portion of the Convertible Notes by delivery of a written notice to us. Each portion of the Convertible Notes subject to redemption shall be redeemed at a price equal to the greater of 18% per annum or the maximum rate permitted under applicable law of the conversion amount being redeemed, together with liquidated damages of \$250,000. As part of the agreement, we paid approximately \$0.1 million in debt issuance costs and discount.

On December 16, 2016, we entered into Amendment No. 1 to the Purchase Agreement, which amended the Purchase Agreement to provide that in no circumstance shall the conversion price be lower than \$2.00 per share of our common stock. As of December 31, 2016, the principal outstanding on the Convertible Notes was approximately \$1.0 million. We incurred \$0.1 million in transaction costs. For the year ended December 31, 2016, we recognized \$25,000 in interest expense, amortization of debt discount and debt issuance costs which was recorded in interest expense in our consolidated statement of operations.

On February 3, 2017, we entered into Amendment No. 2 to the Purchase Agreement, which amended the Convertible Notes to provide that we would redeem the Convertible Notes for \$1.35 million by March 1, 2017, reflecting a redemption premium of 120% of the face amount of the HLHW Convertible Notes plus accrued interest. We recorded \$0.3 million in interest expense as the redemption premium during the first quarter of 2017 related to Amendment No. 2 to the Convertible Note. We repaid the HLHW Convertible Notes in full in the second quarter of 2017.

For the year ended December 31, 2017, interest expense was \$404,000 related to the HLHW Convertible Notes, of which \$300,000 was for the redemption premium during the first quarter of 2017 related to Amendment No. 2 to the Convertible Note and \$104,000 was for the amortization of debt discount, debt issuance costs and original issue discount. We also paid \$825,000 of liquidated damages.

### ***Revolving Line of Credit***

In April 2014, we entered into a three-year, \$5.0 million revolving line of credit with Melini Capital Corp., a stockholder related to Daniel Kazado, our former Chairman of the Board until October 19, 2016 and a member of our Board of Directors. Borrowings under the revolving line of credit incur interest at a rate of 12% per year, payable quarterly. The revolving line of credit is unsecured and subordinated to the Hercules Loan Agreement. On November 30, 2016, the revolving line of credit expired with no amounts having been drawn.

**Note 10. Stockholders' Equity**

*(a) Stock options and stock award activity*

The following table illustrates the common stock options granted for the years ended December 31, 2017 and 2016:

<b>Title</b>	<b>Grant date</b>	<b>No. of options</b>	<b>Weighted average exercise price</b>	<b>Weighted average grant date fair value</b>	<b>Vesting terms</b>	<b>Assumptions used in Black-Scholes option pricing model</b>
Management, Directors and Employees	January – December 2017	366,500	\$ 2.60	\$ 2.40	0 to 3.0 years	Volatility 109.42% - 114.20% Risk free interest rate 2.01%-2.53% Expected term, in years 6.00-10.00 Dividend yield 0.00%

<b>Title</b>	<b>Grant date</b>	<b>No. of options</b>	<b>Weighted average exercise price</b>	<b>Weighted average grant date fair value</b>	<b>Vesting terms</b>	<b>Assumptions used in Black-Scholes option pricing model</b>
Management, Directors and Employees	January – December 2016	138,500	\$ 11.20	\$ 7.20	0 to 3.0 years	Volatility 91.55% - 107.35% Risk free interest rate 1.35%-2.06% Expected term, in years 6.00-10.00 Dividend yield 0.00%

Consultants	January – December 2016	24,250	\$ 6.20	\$ 4.60	0 to 1.0 years	Volatility 91.55% - 102.12% Risk free interest rate 1.39% -1.56% Expected term, in years 10.00 Dividend yield 0.00%
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The following table illustrates the stock awards granted for the years ended December 31, 2017 and 2016:

<b>Title</b>	<b>Grant date</b>	<b>No. of stock awards</b>	<b>Weighted average grant date fair value</b>	<b>Vesting terms</b>
Consultant	January - December 2017	250,000	\$ 0.90	Immediately
Consultant	January - December 2016	45,000	\$ 8.80	Immediately

The following table summarizes information about stock option activity for the years ended December 31, 2017 and 2016:

	<b>Options</b>				
	<b>Number of Options</b>	<b>Weighted Average Exercise Price</b>	<b>Exercise Price Range</b>	<b>Weighted Average Grant Date Fair Value</b>	<b>Aggregate Intrinsic Value (000)s</b>
<b>Outstanding at January 1, 2016</b>	249,450	\$ 31.20	\$0.80-80.00	\$ 39.40	\$ -
Granted	162,750	\$ 9.20	\$5.40-14.60	\$ 6.80	-
Exercised	(23,835)	\$ 0.80	\$0.80	\$ 33.60	-
Forfeited/Expired	(17,608)	\$ 24.60	\$8.00-71.60	\$ 21.20	-
<b>Outstanding at December 31, 2016</b>	<b>370,757</b>	<b>\$ 23.80</b>	<b>\$0.80-80.00</b>	<b>\$ 27.60</b>	<b>-</b>
Granted	366,500	2.60	\$1.10-4.00	\$ 2.40	-
Exercised	-	-	-	-	-
Forfeited/Expired	(218,243)	\$ 23.20	\$0.80-71.60	\$ 21.20	-
<b>Outstanding at December 31, 2017</b>	<b>519,014</b>	<b>\$ 9.80</b>	<b>\$0.80-80.00</b>	<b>\$ 9.40</b>	<b>-</b>
<b>Exercisable at December 31, 2017</b>	<b>345,638</b>	<b>\$ 13.40</b>	<b>\$0.80-80.00</b>	<b>\$ 13.20</b>	<b>\$ -</b>

Stock-based compensation expense for the years ended December 31, 2017 and 2016 was \$0.5 million and \$2.0 million, respectively, which has not been tax-effected due to the recording of a full valuation allowance against net deferred tax assets. As of December 31, 2017, unamortized stock-based compensation for stock options and stock awards was \$0.3 million, with a weighted-average recognition period of approximately 1.7 years, respectively.

**(b) Warrants**

The following table summarizes information about warrants outstanding at December 31, 2017 and 2016:

	<b>Number of Warrants</b>	<b>Weighted Average Exercise Price</b>	<b>Exercise Price Range</b>
<b>Warrants outstanding at January 1, 2016</b>	<b>534,607</b>	<b>\$ 78.60</b>	<b>\$ 33.20-1,312</b>
Warrants issued (1)	64,911	\$ 14.80	\$ 9.40-20.00
Expired	(19,128)	\$ 404.40	\$ 28.00-1,312
<b>Warrants outstanding at December 31, 2016</b>	<b>580,390</b>	<b>\$ 60.80</b>	<b>\$ 9.40-200.00</b>
Warrants issued (2)	18,116,507	\$ 1.20	\$ 4.00-10.00
Expired	(1,220)	\$ 188.40	\$ 170-200
<b>Warrants outstanding at December 31, 2017</b>	<b>18,695,677</b>	<b>\$ 3.00</b>	<b>\$ 9.40-200.00</b>
<b>Warrants exercisable at December 31, 2017</b>	<b>18,695,577</b>	<b>\$ 3.00</b>	<b>\$ 9.40-200.00</b>

- 1) Includes warrants to purchase an aggregate of 25,000 shares of our common stock, at an exercise price of \$20.00 per share, exercisable immediately and expiring five years after the issuance date, issued in connection with the July 29, 2016 securities purchase agreement with certain institutional investors for issuance and sale of 158,730 shares of our common stock, for aggregate gross proceeds of \$1.0 million as discussed below.
- 2) Includes the 83,333 warrants issued with the April 2017 Convertible Notes 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 we complete 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.

### ***(c) Capital Access Agreements***

#### ***April 19, 2016 Capital Access Agreement***

On April 19, 2016, we entered into a Capital Access Agreement (“April 2016 Agreement”) with Regatta Select Healthcare, LLC (“Regatta”) providing for the purchase up to 175,000 shares of our common stock over a twelve month term beginning on the date of the agreement. The purchase price per share is equal to 83% of the lowest trading price of our common stock on NASDAQ during the five consecutive trading days immediately following the date of such Put Notice (the “Put Date”) (all as defined in the April 2016 Agreement). The number of shares that may be purchased under each Put Notice was subject to a ceiling of the lesser of (a) \$250,000 in market value of Purchase Shares or (b) 200% of average daily volume of our shares traded on NASDAQ, computed using the 10 business days prior to the Put Date multiplied by the average of the daily closing price for the 10 business days immediately preceding the Put Date. The Purchase Price was additionally subject to a floor price equal to 75% of the average closing bid price for our common stock for the 10 trading days prior to the Put Date. We sold all 175,000 shares to Regatta during the year ended December 31, 2016 for aggregate gross proceeds of \$0.8 million. We incurred approximately \$0.1 million in transaction fees related to this transaction.

#### ***June 10, 2016 Capital Access Agreement***

On June 10, 2016, we entered into a second Capital Access Agreement (“June 2016 Agreement”) with Regatta providing for the purchase of up to 185,000 shares of our common stock over a twelve month term beginning on the date of the agreement. The purchase price per share is equal to 83% of the lowest trading price of our common stock on NASDAQ during the five consecutive trading days immediately following the date of such Put Notice (the “Put Date”) (all as defined in the June 2016 Agreement). The number of shares that may be purchased under each Put Notice was subject to a ceiling of the lesser of (a) \$250,000 in market value of Purchase Shares or (b) 200% of average daily volume of our shares traded on NASDAQ, computed using the 10 business days prior to the Put Date multiplied by the average of the daily closing price for the 10 business days immediately preceding the Put Date. The Purchase Price was additionally subject to a floor price equal to 75% of the average closing bid price for our common stock for the 10 trading days prior to the Put Date. We sold all 185,000 shares to Regatta during the year ended December 31, 2016 for aggregate gross proceeds of \$1.1 million. We incurred approximately \$0.1 million in transaction fees related to this transaction.

### ***(d) Share Purchase Agreements and Amendments to Share Purchase Agreements***

During the second quarter of 2016, we entered into share purchase agreements with two investors, CrystalClear Group, Inc. (“Crystal”) and Dr. Jean-Marc Menat to sell a total of 48,333 restricted shares of our common stock at a price of \$7.20 per share for aggregate gross proceeds of \$0.3 million.

On December 16, 2016, we entered into amendment to the securities purchase agreement (the “SPA Amendment”) with Crystal, effective as of December 14, 2016. The SPA Amendment amends the Securities Purchase Agreement to adjust the per share purchase price paid by Crystal to \$8.50 per share. Pursuant to the SPA Amendment, the Investor returned 4,248 shares to us in the first quarter of fiscal 2017.

In consideration of the entering into the SPA Amendment by Crystal, we agreed to issue to the Crystal a five-year warrant to purchase an aggregate of 9,259 shares at an exercise price of \$10.00 per share, which Warrant shall not be exercisable until six months after the date of issuance.

On December 27, 2016, the Company and Dr. Jean-Marc Menat (“Dr. Menat”) entered into Amendment No. 1 to the Securities Purchase Agreement which amends the securities purchase agreement to adjust the per share price paid by Dr. Menat to \$8.82 per share. Pursuant to the SPA Amendment, Dr. Menat returned 3,776 shares to us in the first quarter of fiscal 2017. In consideration of the entering into of the SPA Amendment with Dr. Menat, we agreed to issue to Dr. Menat a five-year warrant to purchase an aggregate of 6,852 shares at an exercise price of \$10.00 per share, which warrant shall not be exercisable until six months after the date of issuance the warrant.

On July 29, 2016, we entered into a securities purchase agreement with certain institutional investors for issuance and sale of 158,730 shares of our common stock, for aggregate gross proceeds of \$1.0 million. Under this securities purchase agreement, we also agreed to issue to the institutional investors warrants to purchase 25,000 shares of common stock. The warrants were sold concurrently with the sale of the shares of common stock, pursuant to the securities purchase agreement, in a concurrent private placement. The warrants are exercisable for a period of five years from the date of issuance at an exercise price equal to \$20.00 per share. Pursuant to this securities purchase agreement, we also agreed to pay to the institutional investors a commitment fee of \$100,000, in cash or alternatively, 17,500 shares of common stock. We incurred an additional \$40,000 in transaction fees related to this transaction. The proceeds received for the issuance of the common stock was recorded in stockholder’s equity in our consolidated balance sheet. Transaction fees and the value of the consideration paid to the institutional investors were recorded as a reduction to additional paid in capital in our consolidated balance sheets. On January 10, 2017, the Company and the institutional investors signed an amendment to the securities purchase agreement whereby the institutional investors agreed to give us an additional \$238,095, in exchange for five year warrants to purchase 52,910 shares of common stock at an exercise price of \$10.00

On September 6, 2016, we entered into a stock purchase agreement with an existing stockholder for the sale of 200,000 shares of our common stock for gross proceeds of \$2.0 million. These shares of common stock were issued in a registered direct offering pursuant to a prospectus supplement filed with the SEC on September 7, 2016, in connection with a takedown from the Registration Statement on Form S-3 (File No. 333-198647).

*(e) Equity Lines*

November 2016 Equity Line

On November 17, 2016, we entered into a Common Stock Purchase Agreement (“CS Purchase Agreement”) with HLHW (“Buyer”), which provides that, upon the terms and subject to the conditions and limitations set forth therein, we have the right to sell to Buyer up to \$10.0 million in shares of our common stock.

Beginning on the day following November 17, 2016, the date that certain closing conditions in the CS Purchase Agreement were satisfied (the “Commencement Date”), we shall have the right, but not the obligation, to direct Buyer via written notice (a “Purchase Notice”) to purchase up to a specific number of shares of our common stock (the “Purchase Shares”). The per share purchase will be equal to: (i) from 9:30am to 4:00pm Eastern Time of the regular session of any trading day, lowest intra-day bid price or (ii) if after the close of the regular session on any trading day, then such trading day’s closing bid price on Nasdaq. We shall have the obligation to sell and Buyer shall have the obligation to purchase at the Purchase Price a number of Purchase Shares with an aggregate value of \$2.0 million of Purchase Shares on or before December 31, 2016 which we had met prior to December 31, 2016.

We shall not issue, and the Buyer shall not purchase any shares of common stock under the CS Purchase Agreement, if such shares proposed to be issued and sold, when aggregated with all other shares of common stock then owned beneficially (as calculated pursuant to Section 13(d) of the 1934 Act and Rule 13d-3 promulgated thereunder) by the Buyer and its affiliates would result in the beneficial ownership by the Buyer and its affiliates of more than 4.99% of the then issued and outstanding shares of common stock of the Company, unless waived in writing by Buyer. Shares of Common Stock were issued pursuant to our “shelf” registration statement on Form S-3 (File No. 333-198647), previously filed with the U.S. Securities and Exchange Committee (“SEC”) on September 8, 2014, as amended on October 3, 2014, and that was declared effective by the SEC on October 28, 2014.

At any time after the Commencement Date, the CS Purchase Agreement may be terminated by the mutual written consent of us and Buyer and upon the meeting of certain conditions as defined in the CS Purchase Agreement. In addition, at any time after the Commencement Date, we shall have the option to terminate the CS Purchase Agreement for any reason or for no reason by delivering notice to Buyer electing to terminate the CS Purchase Agreement without any liability whatsoever except that we must transmit to Buyer a termination fee of \$250,000 in cash or shares, at Buyer’s election with such shares to be valued at the Purchase Price, within two (2) Business Days following delivery of such notice of termination. Net proceeds to us will depend on the Purchase Price and the frequency of the our sales of Purchase Shares to Buyer.

As part of the CS Purchase Agreement, we paid \$0.7 million in commitment fees through delivery of shares of its common stock and recorded the fees as a reduction to additional paid in capital during the fourth quarter of 2016. We also agreed to pay Buyer legal fees related to the CS Purchase Agreement of \$35,000. In addition, we also agreed to pay on each Purchase Date and on each Additional Purchase Date (each as defined in the CS Purchase Agreement) 1.75% of such aggregate proceeds representing the fees and expenses of Buyer’s advisers, counsel, accountants and other experts. As of December 31, 2016, the Company sold 625,000 shares of its common stock to Buyer for gross proceeds of \$2.4 million.

During the first quarter of 2017, we sold 1,100,000 shares of common stock to Buyer for gross proceeds of \$4.0 million, of which \$0.2 million was received as an advance during the fourth quarter of 2016, and we paid \$70,000 in financing related fees. In June 2017, Buyer returned the shares of our common stock received as commitment fees and the CS Purchase Agreement was terminated.

February 2017 Equity Line

On February 3, 2017, we entered into a second Common Stock Purchase Agreement with HLHW (the “February 2017 CS Purchase Agreement”) providing for the purchase by HLHW of up to \$3,057,100 of shares of our common stock. Purchase of stock were contingent on the effectiveness of a registration statement covering the shares. On March 22, 2017, we filed a prospectus supplement which amended, supplemented and superseded our prospectus supplement dated February 3, 2017 and its accompanying prospectus dated October 28, 2014 related to the February 2017 CS Purchase Agreement, dated February 3, 2017 to register the shares to be issued under the February 2017 CS Purchase Agreement.

In March 2017, we were advised that NASDAQ rules required us to obtain shareholder approval prior to issuing any stock to HLHW pursuant to the February 2017 CS Purchase Agreement because the issuance was “below market” and represented an aggregate amount of shares greater than 20% of the total number of our common shares outstanding. Accordingly, effective March 22, 2017, we halted all future offers and sales of common stock under the February 2017 CS Purchase Agreement and reduced the amount of potential future offers and sales under the February CS Purchase Agreement to zero.

#### March 2017 Equity Line

On March 22, 2017, we entered into another Common Stock Purchase Agreement with HLHW (the “March 2017 CS Purchase Agreement”) providing for the purchase by HLHW of up to \$1.6 million of shares of our common stock. We paid HLHW a cash commitment fee of \$1.0 million.

The number of shares that may be purchased under each “Purchase Notice” is subject to a ceiling of up to 25,000 shares or an aggregate purchase price of \$250,000, at a price not below the closing bid price of our common stock on the day preceding the date of execution of the March 2017 CS Purchase Agreement (“Floor Price”), subject to certain exceptions to the ceiling specified in the agreement. The shares of common stock were issued pursuant to our “shelf” registration statement on Form S-3 (File No. 333-198647) filed with the United States Securities and Exchange Committee (“SEC”) on September 8, 2014, as amended on October 3, 2014, and declared effective by the SEC on October 28, 2014.

We issued a total of 496,895 shares of our common stock for gross proceeds of \$1.6 million to HLHW during the year ended December 31, 2017 and paid \$48,000 in financing related fees. Also, we agreed to pay on each Purchase Date and on each Additional Purchase Date (each as defined in the November 2016 CS Purchase Agreement) 1.75% of the aggregate proceeds as reimbursement to HLHW of professional fees.

#### **(f) Convertible Preferred Stock**

##### Series E Convertible Preferred Stock

On October 23, 2017, we consummated a public offering of units for gross proceeds of \$18,000,000, which excludes underwriting discounts and commissions and offering expenses. The units, priced at a public offering price of \$1,000 per unit, consists of one share of Series E Convertible Preferred Stock (the “Series E Stock”) and 982 warrants (the “Warrants”) for a total of 18,000 units. Each Warrant entitles the holder to purchase one share of our common stock for a total of 17,676,000 shares of our common stock. The Warrants are initially exercisable at an exercise price of \$1.10 per share and expire 7 years from the date of issuance.

The Series E Stock is convertible into shares of common stock by dividing the stated value of the Series E Stock (\$1,080) by the Conversion Price. The “Conversion Price” is as follows: (i) for the first 40 trading days following the closing of the offering, \$1.10 per share of common stock (the “Set Price”), and (ii) after such 40 trading days, the lesser of (a) the Set Price and (b) 87.5% of the lowest volume weighted average price for our common stock during the five trading days prior to the date of the notice of conversion. The Conversion Price is subject to a floor of \$0.66, except in the event of anti-dilution adjustments. The Conversion Price is subject to appropriate adjustment in the event of recapitalization events, stock dividends, dilutive issuances, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock. Further, the Set Price is subject to full ratchet adjustment if we issue or are deemed to issue additional shares of our common stock at a price per share less than the then effective Set Price.

Holders of Series E Stock are entitled to receive cumulative dividends at the rate of 8.0% per annum, payable quarterly on January 1, April 1, July 1 and October 1, beginning on the first such date after the original issue date and continuing for a period of twenty four (24) months thereafter.

The securities were offered pursuant to a registration statement on Form S-1 (File No. 333-220413), which was declared effective by the United States Securities and Exchange Commission (“SEC”) on October 18, 2017.

We accounted for the Series E Stock and Warrants as permanent equity in accordance with ASC 480 “Distinguishing Liabilities from Equity”. We performed a valuation of the Series E Stock and Warrants. The Warrants were valued using a Black-Scholes model. Based upon that valuation, we allocated the net proceeds between the Series E Stock and Warrants of approximately \$8,690,000 and \$7,355,000, respectively, based on their relative fair value. In addition, we evaluated the conversion feature of the Series E Stock to assess whether it met the definition of a beneficial conversion feature (“BCF”). Assuming all 18,000 shares of Series E Stock will convert into common stock at the \$1.10 price, and taking the 8% original issue discount into consideration, we will issue 17,672,727 shares of common stock, which provides an effective conversion price of \$0.28 for accounting purposes. As the fair value of a share of common stock of \$0.94 exceeded the effective conversion price of approximately \$0.55 at the issuance date, the Series E Stock contained a BCF. The intrinsic value of the BCF of approximately \$6,864,000 was recorded as a discount to the Series E Stock and a credit to additional paid in capital. The BCF was immediately recorded as a deemed dividend.

For the year ended December 31, 2017, 5,809 shares of Series E Stock were converted into 6,922,992 shares of our common stock and dividends of \$864 were converted into 786 shares of our common stock.

For the year ended December 31, 2017, we recorded dividends of \$231,698.

#### Discover Series D Preferred Stock

During 2015, we entered into Stock Purchase Agreements (the “Purchase Agreements”) with Discover Growth Fund (“Discover”) pursuant to which we agreed to issue and sell up to an aggregate of 1,263 shares of our Series D Redeemable Convertible Preferred Stock (“Series D Preferred Stock”), par value \$0.0001 per share, which were convertible into shares of our common stock, at a purchase price of \$10,000 per share, for total gross proceeds of \$12.0 million after taking into account a 5% original issue discount which was received in two tranches of \$9.0 million on July 28, 2015 and \$3.0 million on September 29, 2015.

The Series D Preferred Stock was convertible at a price of \$50.00 per share (“Conversion Price”) and had a six and one half year maturity term, at which time it would have converted automatically into shares of common stock based on the Conversion Price. The Series D Preferred Stock bore an accrued annual dividend rate which ranged from 0% to 15%, based on certain adjustments and conditions, including changes in the volume weighted average price of the our common stock. Upon conversion, we were obligated to pay the holders of the Series D Preferred Stock being converted a conversion premium equal to the amount of dividends that such shares would have otherwise been issued if they had been held through the entire 6.5-year term.

The dividends and conversion premium was payable at our option in shares of common stock with the number of shares issued calculated as follows: (i) if there was no triggering event (as such term is defined in the Certificate of Designations), 90.0% of the average of the five lowest individual daily volume weighted average prices during the applicable measurement period, which may be non-consecutive, less \$1.00 per share of common stock, not to exceed 100% of the lowest sales price on the last day of such measurement period, less \$1.00 per share of common stock, or (ii) following a triggering event, 80.0% of the lowest daily volume weighted average price during any measurement period, less \$1.00 per share of common stock, not to exceed 80.0% of the lowest sales price on the last day of any measurement period, less \$1.00 per share of common stock. In addition, in a triggering event the dividend rate would adjust upwards by 10%.

We accounted for the Series D Preferred Stock as mezzanine equity in accordance with ASC 480 “Distinguishing Liabilities from Equity,” because upon liquidation, we are required to redeem the outstanding Series D Preferred Stock for cash. The conversion premium and the dividends associated with the Series D Preferred Stock contained an anti-dilution feature within the dividend rate, which fluctuated inversely to the changes in the value of our stock price. The conversion premium and dividends with the features noted above were to be redeemed upon conversion of the Series D Preferred Stock. We analyzed the conversion premium and dividends with the features noted and had determined that liability treatment was appropriate. Therefore, we bifurcated the conversion premium and the dividends from the Series D Preferred Stock for financial reporting purposes. Initial and subsequent measurements of this derivative liability were at fair value, with changes in fair value recognized in our consolidated statement of operations on a quarterly basis.

Upon closing of the \$9.0 million financing, the two co-placement agents received an aggregate of \$0.6 million and each received warrants to purchase 13,750 shares of our common stock at an exercise price of \$50.00 per share, exercisable commencing six months following the issuance date and ending five years following the issuance date. We valued the warrants issued to the placement agents using the Black-Scholes options-pricing model and calculated a fair value of \$0.6 million, which we recorded as a reduction to the Series D Preferred Stock in the consolidated balance sheet. Upon closing of the additional \$3.0 million financing, the co-placement agents received an aggregate of \$0.2 million in cash and each received warrants to purchase 5,700 shares of our common stock at an exercise price of \$50.00 per share, exercisable six months following the issuance date and ending five years following the issuance date. We valued the warrants issued to placement agents using the Black-Scholes options-pricing model and calculated a fair value of \$0.2 million.

We paid legal fees of \$0.1 million, which were recorded as a reduction of the Series D Preferred Stock in the consolidated balance sheets. Total Series D Preferred Stock issuance costs of approximately \$1.7 million were recorded as a reduction of the Series D Preferred Stock in the consolidated balance sheets as of December 31, 2015.

During 2015, Discover converted 300 shares of Series D Preferred Stock into 60,000 of our common stock and the Company issued an additional 165,586 of common stock to Discover as payment of dividends and conversion premium. We recorded a proportionate amount of the Series D Preferred Stock as a deemed dividend of \$2.4 million upon conversion, which was charged to additional paid-in capital. In addition, during 2015, \$3.0 million was credited to additional paid-in capital from the conversion of the 300 shares of Series D Preferred Stock.

During 2016, a triggering event occurred resulting in an upward adjustment to the dividend rate from 15% to 25%. We recorded a loss on the change in the estimated fair value of the derivative liability associated with the Series D Preferred Stock of \$8.7 million for the year ended December 31, 2016, which was recorded in non-operating expense in our consolidated statements of operations.

During 2016, Discover converted all of its remaining 963 shares of Series D Preferred Stock into a total of 192,600 shares of our common stock and we issued an additional 4,542,989 shares of common stock as payment of dividends and conversion premium. We recorded a proportionate amount of the Series D Preferred Stock as a deemed dividend of approximately \$8.0 million upon conversion, which was charged to additional paid-in capital in the consolidated balance sheets. As of December 31, 2016, we had no Series D Preferred Stock outstanding as we had met our obligations under the Purchase Agreements.

Below is the activity for the Company's Series D Preferred Stock issuances for the periods presented (\$ in thousands, except share amounts):

	<u>Shares</u>	<u>Amount</u>
<b>Balance at January 1, 2016</b>	<b>963</b>	<b>\$ 1,659</b>
Accretion of Series D Preferred Stock	-	7,973
Conversion of Series D Preferred Stock	(963)	(9,632)
<b>Balance at December 31, 2016</b>	<b>-</b>	<b>\$ -</b>

***(g) Nasdaq Listing Compliance Matters***

On December 1, 2017, we received a letter from the Listing Qualifications Department of The NASDAQ Stock Market LLC ("NASDAQ") notifying us that our 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"). The notice has no immediate effect on the listing or trading of our common stock and the common stock will continue to trade on The NASDAQ Capital Market under the symbol "IMNP" at this time.

In accordance with NASDAQ Listing Rule 5810(c)(3)(A), we have a grace period of 180 calendar days, or until June 2, 2018, to regain compliance with NASDAQ Listing Rule 5550(a)(2). Compliance can be achieved automatically and without further action if the closing bid price of our stock is at or above \$1.00 for a minimum of 10 consecutive business days at any time during the 180-day compliance period, in which case NASDAQ will notify us of our compliance and the matter will be closed.

We may be eligible for additional time to comply if we do not achieve compliance with the Minimum Bid Price Requirement by June 2, 2018. In order to be eligible for such additional time, we will be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The NASDAQ Capital Market, with the exception of the Minimum Bid Price Requirement, and must notify NASDAQ in writing of our intention to cure the deficiency during the second compliance period.

On February 7, 2018, the Disciplinary Board of NASDAQ Stockholm informed us that it decided to delist our shares from trading eligibility on NASDAQ First North effective March 29, 2017. The delisting does not affect our trading status on the NASDAQ Capital Market in the United States.

The Nasdaq First North Disciplinary Board noted that we were not in compliance with certain of the regulations of First North Premier over a prolonged period. The Disciplinary Board acknowledged that we have recently taken measures to insure compliance. However, these measures are insufficient to rectify the numerous prior breaches of the Rule Book. Consequently, the Disciplinary Committee has decided to remove our shares from trading on NASDAQ Stockholm.

***(h) Performance Based Options***

On May 6, 2015, our Board of Directors, pursuant to the recommendation of the Compensation Committee of the Board of Directors of the Company (“Compensation Committee”), granted an option to purchase up to 12,500 shares of our common stock to Dr. Daniel G. Teper, our former Chief Executive Officer, as performance-based compensation. The performance-based options were granted at an exercise price of \$37.40 per share and will vest upon achievement of certain operational, financing and partnership objectives. We recorded a charge to stock compensation expense of \$0.2 million for the year ended December 31, 2016 because we determined that the achievement of the performance options vesting criteria was deemed to be probable. In April 2017, these options were forfeited in connection with Dr. Teper’s resignation as Chief Executive Officer as the performance targets were not met.

***(i) Equity Incentive Plan***

Shareholders approved our 2015 Equity Incentive Plan (the “2015 Plan”) on December 9, 2015 at our Annual Meeting of Stockholders. The 2015 Plan provides for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code, to our employees and for the grant of non-statutory stock options, restricted stock, restricted stock units, performance-based awards and cash awards to our employees, directors and consultants. Our Board of Directors determines the terms of grants under the 2015 Plan. A total of 250,000 shares of our common stock is reserved for issuance pursuant to the 2015 Plan. No 2015 Plan participant may be granted an option to purchase more than 37,500 shares in any fiscal year. Options issued pursuant to the 2015 Plan have a maximum maturity of 10 years. The 2015 Plan will expire on November 12, 2025. On December 24, 2015, we filed a Registration Statement on Form S-8 (Registration No. 333-208754), which registered the 250,000 common shares that may be issued or sold under the plan. On December 20, 2016, an Amended and Restated 2015 Plan was approved at our 2016 Annual Meeting of Stockholders increasing the amount of shares authorized under the 2015 Plan from 250,000 shares to 750,000 shares.

In May 2017, our Board of Directors approved a resolution to increase the amount of shares authorized under our 2015 Equity Incentive Plan from 750,000 to 1,250,000 and to increase the share limit on annual awards to any single participant (whether an employee, director or consultant) in any fiscal year.

On February 15, 2018, our shareholders approved an amendment to the 2015 Plan to increase the number of shares issuable under the plan to 3,500,000 and to eliminate the share limit on annual awards to any single participant (whether an employee, director or consultant) in any fiscal year.

***(j) Employee Stock Purchase Plan***

The Employee Stock Purchase Plan (the “ESPP”) is implemented by offerings of rights to all eligible employees from time to time. Unless otherwise determined by our Board of Directors, common stock is purchased for accounts of employees participating in the ESPP at a price per share equal to the lower of (i) 85% of the fair market value of a share of our common stock on the first day of offering or (ii) 85% of the fair market value of a share of the our common stock on the last trading day of the purchase period. Each offering period will have six-month duration. There were no shares issued under the ESPP during the years ended December 31, 2017 and 2016, and no expense has been recorded. A total of 49,902 shares are available for issuance under the ESPP as of December 31, 2017.

## 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 years ended December 31, 2017 and 2016 excludes shares underlying stock options and warrants and convertible preferred stock, since the effects would be anti-dilutive. Accordingly, basic and diluted loss per share is the same. Such excluded shares are summarized as follows:

	Year Ended December 31,	
	2017	2016
Common stock options	519,014	370,757
Common shares issuable upon conversion of Series E Preferred Stock (not including dividends)	19,948,582	-
Warrants	18,695,677	580,390
Total shares excluded from calculation	<u>39,163,273</u>	<u>951,147</u>

## Note 12. Commitments and Contingencies

### (a) Leases

In February 2015, we signed a lease agreement with ARE-EAST RMR Science Park, LLC, New York, NY, for corporate headquarters space at the Alexandria Center in New York City. In August 2015, we signed an amendment to the Alexandria Center lease agreement for an additional 1,674 square feet to be used for lab space and additional offices. Effective May 1, 2017, we terminated the lease agreement with ARE-EAST RMR Science Park, LLC, and forfeited a security deposit in the amount of \$177,000 and relocated our headquarters to 550 Sylvan Avenue, Englewood Cliffs, NJ 07632 under a lease agreement with 550 Sylvan Avenue, LLC. Lease expense is \$2,950 per month. The lease may be terminated upon two months' written notice to the landlord.

Cytovia occupies shared office space on a month to month basis at 12 E 49th Street, New York, NY 10017 for rent expense of approximately \$3,500 per month. Immune Ltd. occupies shared office space on a month to month basis in offices in Tel-Aviv and Jerusalem, Israel for a combined rent expense of approximately \$2,900 per month.

We recorded rent expense of \$0.1 million and \$0.6 million for the years ended December 31, 2017 and 2016, respectively.

### (b) Licensing Agreements

We are a party to a number of research and licensing agreements, including iCo, BNS, Yissum, Dalhousie, MabLife, Lonza, Atlante and Shire Biochem, which may require us to make payments to the other party upon the other party attaining certain milestones or royalties as defined in the agreements. We may be required to make future milestone royalty payments under these agreements (see Note 6).

### (c) Litigation

Immune Pharmaceuticals Inc. was the defendant in litigation involving a dispute with the plaintiffs Kenton L. Cowley and John A. Flores. The complaint alleges breach of contract, breach of covenant of good faith and fair dealing, fraud and rescission of contract with respect to the development of a topical cream containing ketamine and butamben, known as EpiCept NP-2. A summary judgment in Immune's favor was granted in January 2012 and the plaintiffs filed an appeal in the United States Court of Appeals for the Ninth Circuit in September 2012. A hearing on the motion occurred in November 2013. In May 2014, the court scheduled the trial in November 2014 and a mandatory settlement conference in July 2014. In July 2014, the parties failed to reach a settlement at the mandatory settlement conference. The case was tried by a jury, which rendered a decision on March 23, 2015, in favor of us on all causes of action.

In April 2015, the plaintiffs filed a motion for a new trial, which was heard by the Court on June 8, 2015. In October 2015, the court denied the plaintiff's motion for a new trial. On October 9, 2015, the plaintiffs filed a notice of appeal to the United States Court of Appeals for the Ninth Circuit. On February 13, 2018, the Appellate Court affirmed the district court's judgment in favor of us.

During the years ended December 31, 2017 and 2016, in connection with this litigation matter, we incurred legal costs of approximately \$0.1 million and \$0.1 million, respectively.

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. Income Taxes

The Tax Cuts and Jobs Act (the "Act") was enacted in December 2017. Among other things, the Act reduces the U.S. federal corporate tax rate from 34 percent to 21 percent, eliminates the alternative minimum tax ("AMT") for corporations, and creates a one-time deemed repatriation of profits earned outside of the U.S. The reduction of the corporate tax rate resulted in a write-down of the deferred tax liability of approximately \$1.8 million, resulting in a deferred income tax benefit. The tax rate reduction also resulted in a write-down of the gross deferred tax asset of approximately \$6.4 million, and a corresponding write-down of the valuation allowance.

We recorded a deferred tax liability of \$4.1 million and \$5.9 million as of December 31, 2017 and 2016, respectively, 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. 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. As such, this deferred tax liability cannot be used to offset the valuation allowance. During the year ended December 31, 2016, the AmiKet IPR&D was written down to \$15.0 million resulting in a reduction of the deferred tax liability by \$4.9 million (see Note 3).

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. Our deferred tax assets relate primarily to its net operating loss carryforwards and other balance sheet basis differences. In accordance with ASC 740, "Income Taxes," we recorded a valuation allowance to fully offset the gross deferred tax asset, because it is not more likely than not that we will realize future benefits associated with these deferred tax assets at December 31, 2017 and 2016.

At December 31, 2017 and 2016, we had deferred tax assets of \$27.5 million and \$31.1 million, respectively, against which a full valuation allowance of \$27.5 million and \$31.1 million, respectively, had been recorded. The determination of this valuation allowance did not take into account our deferred tax liability for IPR&D assigned an indefinite life for book purposes, also known as a "naked credit" in the amount of \$4.1 million and \$5.9 million at December 31, 2017 and 2016, respectively. The change in the valuation allowance for the year ended December 31, 2017 was a decrease of \$3.6 million. The decrease in the valuation allowance for the year ended December 31, 2017 was mainly attributable to the decrease in the gross deferred tax assets caused by the decrease in the corporate tax rate, net of increases in net operating losses and accrued liabilities. Significant components of our deferred tax assets at December 31, 2017 and 2016 are as follows (\$ in thousands):

	December 31,	
	2017	2016
Deferred tax assets:		
Property, plant & equipment	\$ 81	\$ 5
Accrued liabilities	2,619	3,894
Losses on debt extinguishment	458	45
Net operating loss carryforwards - U.S.	13,591	13,420
Net operating loss carryforwards - Israel	6,766	6,766
Stock-based compensation	4,014	5,435
Gross deferred tax assets	27,529	29,565
Valuation allowance	(27,529)	(29,565)
Gross deferred tax assets after valuation allowance	-	-
Deferred tax liability - AmiKet IPR&D assets	(4,142)	(5,933)
Net deferred tax liability	\$ (4,142)	\$ (5,933)

A reconciliation of the federal statutory tax rate and the effective tax rates for the years ended December 31, 2017 and 2016 is as follows:

	<b>For the Year Ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
U.S. federal statutory tax rate	34.0%	34.0%
State income taxes, net of federal benefit	(5.0)	4.9
U.S. vs. foreign tax rate differential	(1.3)	(1.0)
Impact of tax law change	(32.5)	-
Deferred tax adjustments	(2.5)	-
Other	(1.1)	(2.1)
Change in valuation allowance	18.3	(22.9)
Effective tax rate	<u>9.9%</u>	<u>12.9%</u>

We had approximately \$127.9 million and \$95.0 million of available gross net operating loss (“NOL”) carryforwards (federal, state and Israel) as of December 31, 2017 and 2016, respectively. Sections 382 and 383 of the Internal Revenue Code, and similar state regulations, contain provisions that may limit the NOL carryforwards available to be used to offset income in any given year upon the occurrence of certain events, including changes in the ownership interests of significant stockholders. In the event of a cumulative change in ownership in excess of 50% over a three-year period, the amount of the NOL carryforwards that we may utilize in any one year may be limited. We reduced our tax attributes (NOLs and tax credits) as a result of our ownership changes in 2007, 2009, 2013, 2015, and 2016 and the limitation placed on the utilization of its tax attributes, as a substantial portion of the NOLs and tax credits generated prior to the ownership changes will likely expire unused. The most significant reduction in tax attributes occurred in 2013 as a result of the Merger with Epiccept. We do not have any material foreign earnings, due to a history of losses in its foreign subsidiary.

A reconciliation of our NOLs for the years ended December 31, 2017 and 2016 is as follows (\$ in thousands):

	<b>December 31,</b>	
	<b>2017</b>	<b>2016</b>
U.S. Federal NOLs	\$ 49,157	\$ 33,953
U.S. State NOLs	49,341	33,940
Israel NOLs	29,417	27,066
Total NOLs	<u>\$ 127,915</u>	<u>\$ 94,959</u>

Our federal and state NOLs of approximately \$49.2 million and \$49.3 million, respectively, begin to expire from 2030 through 2037. Our Israel NOL of \$29.4 million does not expire.

We have adopted guidance on accounting for uncertainty in income taxes which clarified the accounting for income taxes by prescribing the minimum threshold a tax position is required to meet before being recognized in the financial statements as well as guidance on de-recognition, measurement, classification and disclosure of tax positions. We have gross liabilities recorded of \$70,000 and \$60,000 for the years ended December 31, 2017 and 2016, respectively, to account for potential income tax exposure. We are obligated to file income tax returns in the U.S. federal jurisdiction, Israel and various U.S. states. However, because we had losses in the past, all prior years that generated NOLs are open and subject to audit examination in relation to the NOL generated from those years. A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (\$ in thousands):

	<b>2017</b>	<b>2016</b>
Balance at January 1,	\$ 60	\$ 50
Additions related to tax positions	10	10
Reductions related to tax positions	-	-
Balance at December 31,	<u>\$ 70</u>	<u>\$ 60</u>

Our evaluation of uncertain tax positions was performed for the tax years ended December 31, 2013 and forward, the tax years which remain subject to examination by major taxing jurisdictions as of December 31, 2017.

#### **Note 14. Related-Party Transactions**

##### ***(a) Promissory Notes issued to Certain Related Parties***

###### ***Daniel Kazado***

On July 15, 2016, our Board of Directors approved and we issued a \$0.3 million promissory note to Daniel Kazado in exchange for advances made to us. The note bears interest at a rate of 5% per year and matures one year from the date of issuance. The outstanding balance of the note may be paid in cash or, at the option of either party, converted into shares of our common stock at a conversion rate of 9.00 per share, the last bid price of our common stock on the date of approval. On August 4, 2016, we exercised our option to pay off the promissory note in full by issuing 33,333 restricted shares of our common stock. Pursuant to applicable securities laws these restricted shares may not be transferred or sold at least for a period of six months or unless they have been registered for sale pursuant to the Securities Act of 1933, as amended.

###### ***Daniel Teper***

On June 24, 2016, our Board of Directors approved and we issued a \$0.4 million promissory note to Daniel G. Teper, a director and our Chief Executive Officer at the time. The note bears interest at a rate of 5.0% per year and matures one year from the date of issuance. The outstanding balance of the note may be paid in cash or, at the option of either party, converted into shares of our common stock at a conversion rate of \$8.20 per share, the last bid price of our common stock on the date of approval. On August 4, 2016, we exercised our option to pay off the promissory note in full by issuing 43,445 restricted shares of our common stock. Pursuant to applicable securities laws these restricted shares may not be transferred or sold at least for a period of six months and unless they have been registered for sale pursuant to the Securities Act of 1933, as amended.

###### ***Monica Luchi***

On July 15, 2016, our Board of Directors approved and we issued a \$0.4 million promissory note to Monica Luchi, our Chief Medical Officer at the time in exchange for an advance made to us. The note bears interest at a rate of 5.0% per year and matures one year from the date of issuance. The outstanding balance of the note may be paid in cash or, at the option of either party, converted into shares of our common stock at a conversion rate of \$9.00 per share, the last bid price of our common stock on the date of approval. On August 4, 2016, we exercised our option to pay off the promissory note in full by issuing 38,889 restricted shares of our common stock. Pursuant to applicable securities laws these restricted shares may not be transferred or sold at least for a period of six months and unless they have been registered for sale pursuant to the Securities Act of 1933, as amended.

##### ***(b) Daniel Kazado and Melini Capital Corp.***

Daniel Kazado was our Chairman of the Board until October 19, 2016 and is a member of the Board of Directors. In April 2014, we entered into a \$5.0 million revolving line of credit with Melini Capital Corp (“Melini”), an existing stockholder who is related to Mr. Kazado. Borrowings under the revolving line of credit incur interest at a rate of 12% per year, payable quarterly. The revolving line of credit was unsecured and subordinated to the Loan Agreement with Hercules. The revolving line of credit expired on November 30, 2016. No amounts have been drawn from the revolving line of credit.

##### ***(c) Other Related-Party Transactions***

During 2016, Dr. Teper, advanced a total of \$0.9 million to us of which we had repaid \$0.7 million prior to December 31, 2016 including \$0.4 million which was paid in shares of our common stock as discussed above. The balance of \$0.2 million owed to Dr. Teper as of December 31, 2017 has been reflected in advances from related parties in the consolidated balance sheets.

During the first quarter of 2017, we issued 3,825 shares in settlement of the fourth quarter of 2016 board fees of \$14,000 for Daniel Kazado, a member of our board of directors.

On June 15, 2017, substantially contemporaneous with the entry into the Asset Purchase Agreement (see Note 9), 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 the our capital stock. Currently, we intend to finance the \$5.0 million financial obligations contemplated by the Asset Purchase Agreement through Cytovia on a basis that is on terms that are acceptable to our board of directors and without recourse to us. The Standby Financer will 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 Cytovia has not obtained funding on terms reasonably acceptable to us (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, at or prior to each installment date, 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 15. Subsequent Events**

We have evaluated events and transactions subsequent to December 31, 2017 through the date the consolidated financial statements were included in this Form 10-K and filed with the SEC.

#### **Asset Purchase Agreement with Meda**

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 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.

**Subsidiaries of Immune Pharmaceuticals Inc.**

The following are the subsidiaries of Immune Pharmaceuticals Inc.:

<b>Name</b>		<b>Jurisdiction of Incorporation</b>
Immune Pharmaceuticals USA Corp.	Delaware	
Immune Pharmaceuticals Ltd.	Israel	
Maxim Pharmaceuticals, Inc.	Delaware	
Cytovia, Inc.	Delaware	
Immune Oncology Pharmaceuticals Inc.	Delaware	

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**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the Registration Statement of Immune Pharmaceuticals Inc. on Form S-3 (File Nos. 333-132613, 333-145133, 333-145561, 333-147589, 333-153256, 333-153895, 333-160571, 333-176512, 333-198309, 333-198647, 333-206587, and 333-214873) and Form S-8 (File Nos. 333-130860, 333-130861, 333-130865, 333-151150, 333-156438, 333-198521, and 333-208754) of our report, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, dated April 2, 2018, with respect to our audit of the consolidated financial statements of Immune Pharmaceuticals Inc. as of December 31, 2017 and for the year ended December 31, 2017, which report is included in this Annual Report on Form 10-K of Immune Pharmaceuticals Inc. for the year ended December 31, 2017.

/s/ Marcum LLP

Marcum LLP  
New Haven, CT  
April 2, 2018

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**Consent of Independent Registered Public Accounting Firm**

Immune Pharmaceuticals Inc.

New York, New York

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-130860, 333-130861, 333-130865, 333-151150, 333-156438, 333-198521, and 333-208754) and Form S-3 (Nos. 333-132613, 333-145133, 333-145561, 333-147589, 333-153256, 333-153895, 333-160571, 333-176512, 333-198309, 333-198647, 333-206587 and 333-214873) of Immune Pharmaceuticals Inc. of our report dated May 17, 2017 relating to the financial statements of Immune Pharmaceuticals Inc., which appears in this Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP

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New York, New York

April 2, 2018

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

I, Elliot M. Maza, certify that:

1. I have reviewed this Annual Report on Form 10-K 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 the Company's 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 the Company's 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 the Company's 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 the Company's 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: April 2, 2018

/s/ Elliot M. Maza

Elliot M. Maza

Chief Executive Officer

(Principal Executive Officer, Principal Financial Officer and

Principal Accounting Officer)

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CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER, PRINCIPAL FINANCIAL OFFICER AND  
PRINCIPAL ACCOUNTING 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 Annual Report of Immune Pharmaceuticals Inc. (the “Company”) on Form 10-K for the year ended December 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Elliot M. Maza, Principal Executive Officer, Principal Financial Officer and Principal Accounting 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/ Elliot M. Maza

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Elliot M. Maza  
Chief Executive Officer  
(Principal Executive Officer, Principal Financial Officer and  
Principal Accounting Officer)

April 2, 2018

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