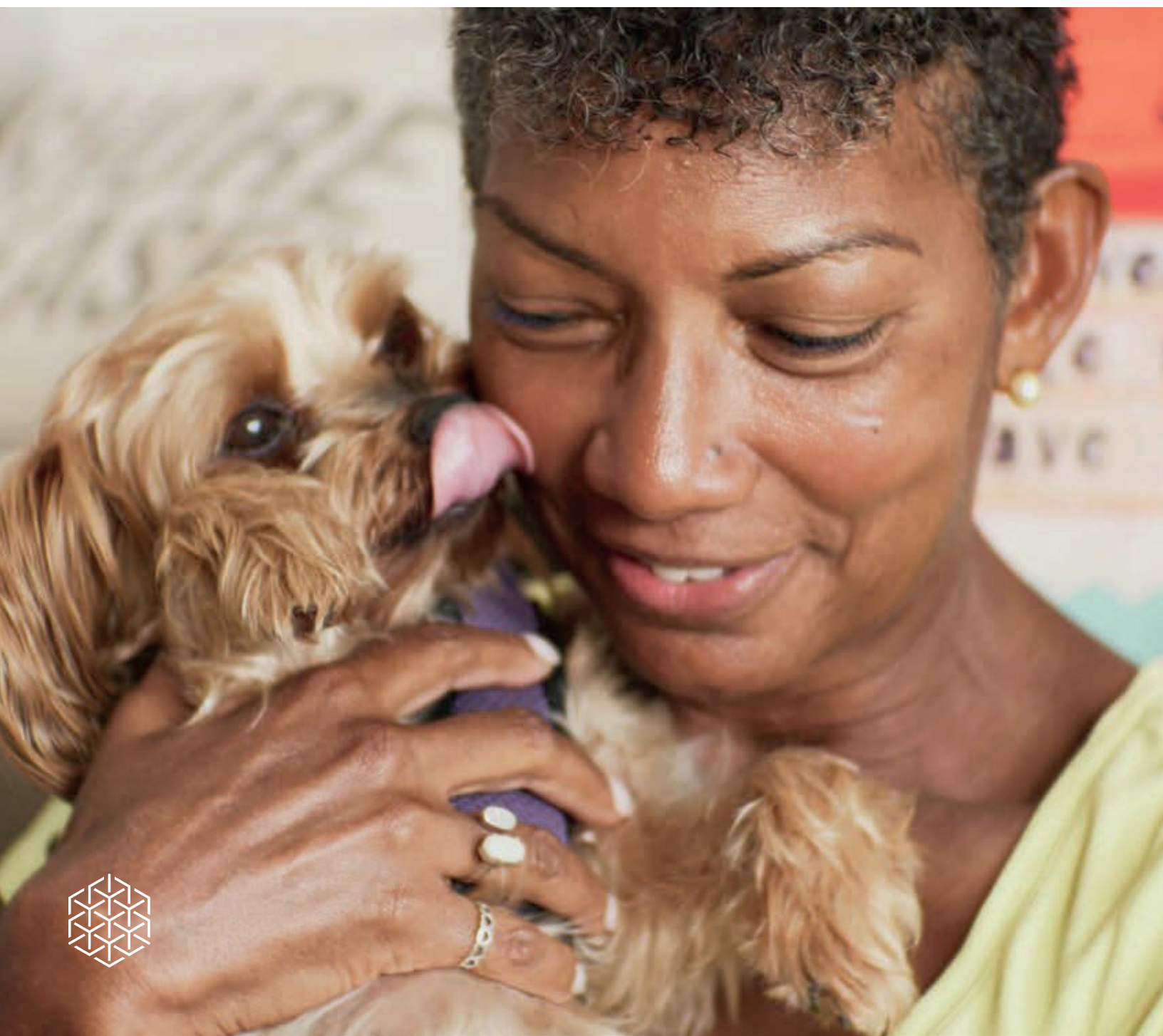


Immunomedics

# 2019 Annual Report



## Dear Fellow Stockholders,

For many, 2020 represents a concept that generally denotes perfect vision. For Immunomedics, 2020 represents the year we have clarified and accelerated our vision of creating and delivering breakthrough therapies that help transform the lives of those with hard-to-treat cancers. A vision we established merely three years ago after winning your vote of support to lead the Company in a new direction.

The approval of Trodelvy by the U.S. Food and Drug Administration (FDA) is our most prominent example of how we are delivering on our mission for all stakeholders: the triple-negative breast cancer (TNBC) community, our employees at Immunomedics, our stockholders, and our business partners and stakeholders. Trodelvy is the first and only antibody-drug conjugate (ADC) FDA approved for adult patients with metastatic TNBC and is the first and only FDA-approved anti-Trop-2 ADC.

More than anything, we are incredibly proud of the fact that people living with previously-treated metastatic TNBC now have a viable therapeutic option to address a hard-to-treat cancer where few alternatives existed. We are grateful to all the patients, their families and healthcare providers who participated in Trodelvy studies for their sacrifices and contributions, as well as to the FDA for its diligence and collaborative support in helping us bring this transformative drug to breast cancer patients.

We would not have reached this monumental milestone without the dedication of our employees and the support of their families. To them, I extend my heartfelt gratitude and appreciation. While we celebrate our collective success in bringing innovation and hope to people with metastatic TNBC, we understand this is only one leg on a longer journey and are mindful that, in many ways, our work is just beginning. Our ambition to become a pioneering leader in next-generation ADC technology continues to grow, as we continue to progress our goal of establishing Trodelvy as a standard of care across lines of TNBC.

To that end, we are executing against a blueprint designed for Trodelvy to address virtually every stage of TNBC treatment, while enhancing our competitive positioning in hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer. In the curative setting, we are working with Dana-Farber/Partners CancerCare, the adult oncology collaboration of Dana-Farber Cancer Institute, Brigham and Women's Hospital and the Massachusetts General Hospital Cancer Center, to evaluate Trodelvy in neoadjuvant TNBC; and with the German Breast Group to assess Trodelvy in post-neoadjuvant HER2-negative breast cancer. Additionally, we are partnering with Roche and AstraZeneca to each combine Trodelvy with their respective immune checkpoint inhibitors in newly-diagnosed metastatic TNBC, and with Clovis Oncology's PARP inhibitor in the second-line setting.

Our next key event is the release of topline data from the Phase 3 confirmatory ASCENT study, expected in mid-2020. Given that this study was stopped early as recommended unanimously by the independent Drug Safety and Monitoring Committee based on compelling efficacy across multiple endpoints, we expect the readout to verify and describe the clinical benefit we observed with Trodelvy in the single-arm Phase 2 study. A positive readout will lead to a full approval in the U.S., while strengthening our registrational and reimbursement pathways in Europe.

A positive ASCENT readout also could bode well for TROPiCS-02, our registrational Phase 3 study in HR-positive/HER2-negative metastatic breast cancer. Although this breast cancer subtype is about three times the size of TNBC population, for patients who failed hormonal and CDK4/6 treatments, and two lines of chemotherapy, the same unmet need exists as in late-line metastatic TNBC, with commonly used single-agent chemotherapy offering response rates in the low teens and progression-free survival (PFS) in the range of 2 to 3 months. In a single-arm Phase 2 study, Trodelvy produced a confirmed overall

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, 2019

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

**Commission file number: 0-12104**

**IMMUNOMEDICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**61-1009366**

(I.R.S. Employer Identification No.)

**300 The American Road, Morris Plains, New Jersey 07950**

(Address of principal executive offices) (Zip Code)

**(973) 605-8200**

(Registrant's Telephone Number, Including Area Code)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, \$0.01 par value	IMMU	Nasdaq Stock Market LLC

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the 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 requirement for the past 90 days. Yes ☒ No ☐

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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. (Check one):

Large Accelerated Filer	<input checked="" type="checkbox"/>	Accelerated Filer	<input type="checkbox"/>
Non-Accelerated Filer	<input type="checkbox"/>	Smaller Reporting Company	<input type="checkbox"/>
		Emerging Growth Company	<input type="checkbox"/>

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 Exchange Act Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the registrant's common stock held by non-affiliates computed by reference to the price at which the common stock was last sold on the Nasdaq Global Select Market as of June 30, 2019 was \$2,660,996,949. The number of shares of the registrant's common stock outstanding as of February 21, 2020 was 213,929,505.

### **Documents Incorporated by Reference:**

Specified portions of the registrant's proxy statement, which will be filed with the Commission pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2019 in connection with the registrant's 2020 Annual Meeting of Stockholders, are incorporated by reference into Part III of this annual report on Form 10-K.

In this Form 10-K, we use the words "Immunomedics, Inc." to refer to Immunomedics, Inc., a Delaware corporation, and we use the words the "Company," "Immunomedics," "Immunomedics, Inc.," "we," "us" and "our" to refer to Immunomedics, Inc. and its subsidiaries.

**Immunomedics, Inc.**  
**Annual Report on Form 10-K**  
**Table of Contents**

Part I			
	Item 1.	Business . . . . .	4
	Item 1A.	Risk Factors . . . . .	19
	Item 1B.	Unresolved Staff Comments . . . . .	39
	Item 2.	Properties . . . . .	40
	Item 3.	Legal Proceedings . . . . .	40
	Item 4.	Mine Safety Disclosures . . . . .	42
Part II			
	Item 5.	Market For Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of	43
	Item 6.	Selected Financial Data . . . . .	44
	Item 7.	Management’s Discussion and Analysis of Financial Condition and Results of Operations . . . .	45
	Item 7A.	Quantitative and Qualitative Disclosures About Market Risk . . . . .	54
	Item 8.	Financial Statements and Supplementary Data . . . . .	55
	Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure . . . .	87
	Item 9A.	Controls and Procedures . . . . .	87
	Item 9B.	Other Information . . . . .	87
Part III			
	Item 10.	Directors, Executive Officers, and Corporate Governance . . . . .	88
	Item 11.	Executive Compensation . . . . .	88
	Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder	88
	Item 13.	Certain Relationships and Related Transactions and Director Independence . . . . .	88
	Item 14.	Principal Accounting Fees and Services . . . . .	88
Part IV			
	Item 15.	Exhibits, Financial Statement Schedules . . . . .	88
	Item 16.	Form 10-K Summary . . . . .	91
		Signatures . . . . .	92



## PART I

### Item 1. BUSINESS

#### Transition Period

On December 14, 2018, the Company's Board of Directors approved a change in the Company's fiscal year end from June 30 to December 31. In connection with this change, we previously filed a Transition Report on Form 10-K to report the results of the six-month transition period from July 1, 2018 to December 31, 2018 (which we sometimes refer to as the "Transition Period"). In this Annual Report, the periods presented are the year ended December 31, 2019, the Transition Period ended December 31, 2018 and our fiscal years ended June 30, 2018 and 2017 (which are referred to as "fiscal 2018," and "fiscal 2017", as if we had not changed our fiscal year to a calendar year). For comparison purposes, we have also included unaudited data for the year ended December 31, 2018.

#### Overview

Immunomedics is a clinical-stage biopharmaceutical company developing monoclonal antibody-based products for the targeted treatment of cancer. Our advanced proprietary technologies allow us to create humanized antibodies that can be used either alone in unlabeled or "naked" form, or conjugated with chemotherapeutics, cytokines or toxins. Our most advanced product candidate is sacituzumab govitecan ("IMMU-132"), an antibody-drug conjugate ("ADC") that has received Breakthrough Therapy Designation ("BTD") from the United States Food and Drug Administration for the treatment of patients with metastatic triple-negative breast cancer ("mTNBC") who previously received at least two prior therapies for metastatic disease.

Our current focus is to commercialize sacituzumab govitecan as a third-line therapy for patients with mTNBC in the United States. In May 2018, we submitted a Biologics License Application ("BLA") to the United States Food and Drug Administration ("FDA") for sacituzumab govitecan for the treatment of patients with mTNBC who have received at least two prior therapies for metastatic disease. In July 2018, we received notification from the FDA that the BLA was accepted for filing and the original application was granted Priority Review with a Prescription Drug User Fee Act ("PDUFA") target action date in January 2019. In January 2019, we received a Complete Response Letter ("CRL") from the FDA for the BLA. We subsequently met with the FDA in May 2019 to review the FDA's findings and discussed our BLA resubmission. Since then, we have developed a detailed plan to address the chemistry, manufacturing, and controls ("CMC") matters raised in the CRL and in our pre-approval inspection. We held another meeting with the FDA in September 2019 to update the FDA on our progress in addressing these matters and to receive feedback from the FDA on our approach. On November 30, 2019, we resubmitted our BLA to the FDA and on December 23, 2019 we received notification from the FDA that the BLA was accepted for filing and further assigned a new PDUFA target action date as June 2, 2020. We have dedicated, and continue to commit, significant resources to address the CMC matters identified by the FDA, while, in parallel, preparing our manufacturing facility to be ready for re-inspection by the FDA. Our Phase 3 confirmatory ASCENT study for sacituzumab govitecan has reached its target enrollment for mTNBC patients previously treated with at least two systemic chemotherapy regimens. Top-line data for the ASCENT study is expected to be available around mid-2020.

On March 29, 2019, the Company entered into a sales agreement (the "ATM Agreement") with Cowen and Company, LLC ("Cowen") to issue and sell shares of the Company's common stock, par value \$0.01 per share, having an aggregate offering price of up to \$150.0 million, from time to time during the term of the ATM Agreement, through an "at-the-market" equity offering program at the Company's sole discretion, under which Cowen will act as the Company's agent and/or principal. The Company will pay Cowen a commission up to 3.0% of the gross sales proceeds of any common stock sold through Cowen under the ATM Agreement. During the year ended December 31, 2019, the Company sold 4,432,416 shares of common stock with net proceeds of \$71.6 million at a weighted average price of \$16.40 (excluding commissions) under the ATM Agreement.

On April 5, 2019, the Company entered into a promotion agreement (the "Promotion Agreement") with Janssen Biotech Inc., ("Janssen") pursuant to which the Company will provide non-exclusive product detailing services to Janssen for erdafitinib (the "Product"). Pursuant to the Promotion Agreement, the Company will provide a dedicated sales team to detail the Product to oncologists and other targeted health care providers in the United States. Under the terms of the Promotion Agreement, Janssen maintains ownership of the New Drug Application for the Product as well as legal, regulatory, distribution, commercialization and manufacturing responsibilities for the Product, while the Company will provide product detailing services to Janssen. Following the achievement of certain sales targets in 2019 and 2020, Janssen will pay the Company (a) a service fee equal to a percentage in the low double digits of the portion of Cumulative Net Sales (as defined in the Promotion Agreement) in excess of a baseline amount during each of 2019 and 2020, and (b) potential milestone payments of up to \$15.0 million when Cumulative Net Sales exceed certain thresholds during each of 2019 and 2020. On April 12, 2019, the Company was informed that the FDA granted accelerated approval to Janssen's Balversa® (erdafitinib) for the treatment of adult patients with locally advanced or

metastatic urothelial carcinoma that has a type of susceptible genetic alteration known as FGFR3 or FGFR2, and that has progressed during or following prior platinum-containing chemotherapy. Refer to "Note 2 - Revenue Recognition" for additional information.

On April 29, 2019, we entered into a license agreement (the "License Agreement") with Everest Medicines II Limited, a China limited company ("Everest"). Pursuant to the License Agreement, we granted Everest an exclusive license to develop and commercialize sacituzumab govitecan in the People's Republic of China, Taiwan, Hong Kong, Macao, Indonesia, Philippines, Vietnam, Thailand, South Korea, Malaysia, Singapore and Mongolia (the "Territory"). In consideration for entering into the License Agreement, Everest made a one-time, non-refundable upfront payment to us in the aggregate amount of \$65.0 million which is recorded as deferred revenue on the consolidated balance sheet as of December 31, 2019. The License Agreement contains a development milestone payment of \$60.0 million based upon our achievement of FDA approval for sacituzumab govitecan. The License Agreement also contains additional development milestone payments in a total amount of up to \$180.0 million based upon the achievement of certain other development milestones. In addition, the License Agreement contains sales milestone payments in a total amount of up to \$530.0 million based upon the achievement of certain sales milestones. Everest will make royalty payments to us based upon percentages of net sales of sacituzumab govitecan, ranging from 14% to 20%. Refer to "Note 2 - Revenue Recognition" for additional information.

On December 9, 2019, we closed an underwritten public offering of 14,285,715 shares of common stock at a public offering with a price of \$17.50 per share, representing gross proceeds of approximately \$250.0 million. In addition, the Company granted the underwriters a 30-day option to purchase up to 2,142,857 additional shares of common stock for a total of 16,428,572 shares. We received gross proceeds of \$287.5 million and net proceeds of \$273.0 million after deducting the underwriting discounts and commissions and expenses related to the offering. We intend to use the net proceeds from this offering primarily to accelerate commercial launch readiness, pending FDA approval, of sacituzumab govitecan in the United States in mTNBC, continue to expand the clinical development programs for sacituzumab govitecan, invest in the broader clinical development of the platform (including IMMU-130 and IMMU-140), continued scale-up of manufacturing and manufacturing process improvements, as well as for working capital and general corporate purposes.

As of December 31, 2019, we had \$613.2 million in cash, cash equivalents and marketable securities. We believe our projected financial resources are adequate to (i) accelerate commercial launch readiness, pending FDA approval, of sacituzumab govitecan in the United States in mTNBC, (ii) continue to expand the clinical development programs for developing sacituzumab govitecan in mTNBC, metastatic urothelial cancer ("mUC"), hormone receptor-positive ("HR+") /human epidermal growth factor receptor 2-negative ("HER2-") metastatic breast cancer ("mBC"), and other indications of high medical need, (iii) invest in the broader clinical development of the platform (including IMMU-130 and IMMU-140), (iv) continued scale up of manufacturing and manufacturing process improvements, and (v) general working capital requirements. However, in case of regulatory delays or other unforeseen events, we may require additional funding. Potential sources of funding in such a case could include (i) the entrance into potential development and commercial partnerships to advance and maximize our full pipeline for mTNBC and beyond in the United States and globally, and (ii) potential private and public capital markets financing. Refer to "Note 9 - Stockholders' Equity" for additional information.

For 2020, our strategic priorities for sacituzumab govitecan include:

1. FDA approval of sacituzumab govitecan for the treatment of patients with mTNBC who have received at least two prior therapies for metastatic disease under the FDA's Accelerated Approval Pathway;
2. Commercial launch of sacituzumab govitecan, pending FDA approval, in the United States;
3. Execution of our clinical development plan, which includes:
  - a. Complete patient enrollment into registrational Phase 3 TROPiCS-02 study in HR+/HER2- mBC;
  - b. Complete enrolling cisplatin-ineligible patients into cohort 2 of the pivotal Phase 2 TROPHY U-01 study in mUC and report top-line results from full 100 cohort 1 patients with prior platinum-based and immune checkpoint inhibitor therapies;
  - c. Include an additional exploratory cohort of patients who have relapsed or are refractory to platinum-based therapies but naïve to immuno-oncology therapies to evaluate sacituzumab govitecan in combination with pembrolizumab in the ongoing TROPHY U-01 study;

- d. Report initial results in non small cell lung cancer ("NSCLC") from the TROPiCS-03 study, a Trop-2-enriched Phase 2 multi-cohort study in refractory adeno- and squamous NSCLC, head and neck cancer, and endometrial cancer; and
  - e. Report top-line results from the confirmatory Phase 3 ASCENT study in mTNBC.
- 4. Establishing Samsung BioLogics Co., Ltd. as our primary source of commercial antibody in the supply chain for sacituzumab govitecan, while also investing in the scale up of our global supply chain.

## **Our Clinical and Preclinical Programs**

We believe that our antibodies have therapeutic potential, in some cases as a naked antibody or when conjugated with chemotherapeutics, cytokines or other toxins to create unique and potentially more effective treatment options. The attachment of effective anti-tumor compounds to antibodies is intended to allow the delivery of these therapeutic agents to tumor sites with better specificity than conventional chemotherapy. This treatment method is designed to optimize the therapeutic window through reducing the systemic exposure of the patient to the therapeutic agents, which ideally minimizes debilitating side effects while maximizing the concentration of the therapeutic agent at the tumor, potentially leading to better efficacy.

Our portfolio of investigational products includes ADCs that are designed to deliver a specific payload of a chemotherapeutic directly to the tumor while reducing overall toxicities that are usually associated with conventional administration of these chemotherapeutic agents. Sacituzumab govitecan is our most advanced ADC and our lead product candidate that has received Breakthrough Therapy Designation from the FDA for the treatment of patients with mTNBC who have received at least two prior therapies for metastatic disease.

To accelerate the clinical and preclinical development of sacituzumab govitecan, we have entered into the following clinical collaborations: with AstraZeneca PLC ("AstraZeneca") to investigate sacituzumab govitecan in combination with the checkpoint inhibitor, durvalumab (Imfinzi<sup>®</sup>), in earlier lines of therapy for mTNBC, advanced urothelial cancer ("UC") and metastatic NSCLC ("mNSCLC"); with Clovis Oncology, Inc. ("Clovis") to combine sacituzumab govitecan with its poly (ADP-ribose) polymerase (PARP) inhibitor, rucaparib (Rubraca<sup>®</sup>), in mTNBC, advanced UC and ovarian cancer; and with Roche to initiate a Phase 1b/2 study (MORPHEUS) comparing the safety and efficacy of the combination of atezolizumab (Tecentriq<sup>®</sup>) and sacituzumab govitecan as a frontline treatment for patients with metastatic or inoperable locally advanced mTNBC versus atezolizumab plus nab-paclitaxel as standard of care. Additionally, we have entered into a collaboration with the German Breast Group ("GBG") to conduct a multinational, post-neoadjuvant registrational Phase 3 study (SASCIA) that will evaluate sacituzumab govitecan as a treatment for newly-diagnosed breast cancer patients who do not achieve a pathological complete response ("pCR") following standard neoadjuvant therapy.

We are also working with (i) Massachusetts General Hospital ("MGH") on a Phase 1b/2 study of sacituzumab govitecan combining with Pfizer's PARP inhibitor, talazoparib (TALZENNA<sup>®</sup>), in patients with mTNBC previously treated with no more than one prior therapeutic regimen for metastatic disease; (ii) Yale University on a Phase 2 study of sacituzumab govitecan in patients with persistent and recurrent endometrial cancer; and (iii) the University of Wisconsin in patients with metastatic castration-resistant prostate cancer who have progressed on second generation androgen receptor-directed therapy on a Phase 2 study. Refer to "Corporate Collaboration" and "Other Collaborations" below for additional information.



Below is our development timeline for sacituzumab govitecan across indications:

Compound	Indication	Designation	Phase 1	Phase 2	Phase 3	Approval
Sacituzumab govitecan	mTNBC (>Third Line)		Under FDA Review			
	mTNBC (Third Line)	ASCENT	Topline Readout Expected around mid-2020			
	HR+/HER2- mBC	TROPICS-02				
	Urothelial (Third Line)	TROPY-U-01	Cohort 1 enrollment completed			
	Urothelial (Third Line) (Pending FDA Discussion)					
	mNSCLC / H&N / Endometrial (Trop-2-enriched)	TROPICS-03				
	mTNBC (First Line) (+ Tecentriq)	MORPHEUS				
	mTNBC / mUC / Ovarian (+ Rubraca)	SEASTAR				
	mTNBC / mUC / mNSCLC (+ Imfinzi)					
	HER2- BC (Post-neoadjuvant)	SASCIA				
IMMU-130	Colorectal Cancer					
IMMU-140	Hematological Cancers					

Sacituzumab govitecan has been studied in over 1,000 cancer patients in more than 15 types of solid cancers. Sacituzumab govitecan received BTB from the FDA for the treatment of patients with mTNBC who have received at least two prior therapies for metastatic disease. The FDA has also granted sacituzumab govitecan fast track designation, designed to expedite the development and review of applications for products intended for the treatment of a serious or life-threatening disease or condition, for the same indication and for patients with NSCLC or small-cell lung cancer ("SCLC"). Sacituzumab govitecan has also been designated an orphan drug by the FDA for the treatment of patients with SCLC or pancreatic cancer and by the European Medicines Agency ("EMA") for the treatment of patients with pancreatic cancer.

In February 2019, updated data from the Phase 1/2 trial of sacituzumab govitecan in patients with mTNBC were published in the New England Journal of Medicine. The data (from 108 subjects with mTNBC) showed an overall response rate of 33% and continue to support a favorable benefit/risk profile of the ADC in the mTNBC cohort. The confirmatory Phase 3 ASCENT study in patients with mTNBC with at least two prior therapies for metastatic disease has completed enrollment. Top-line data for the ASCENT study is expected to be available around mid-2020.

HR+/HER2- mBC is another breast cancer indication that is a key strategic focus for the Company. Phase 1/2 results of sacituzumab govitecan in this treatment-refractory cohort, a population with the distinct need for better treatment options, showed a confirmed overall response rate of 31%. Median duration of response was 7.4 months, the clinical benefit rate was 48% and median progression-free survival was 6.8 months. The safety profile in this cohort was consistent with previous reports.

Updated results from the Phase 1/2 study of sacituzumab govitecan in the cohort of patients with previously treated mUC was presented in an oral presentation at the 2019 Genitourinary Cancers Symposium. The results showed an overall response rate of 31% and a median duration of response of 12.9 months in 45 relapsed/refractory patients. Further supportive clinical data was reported in the interim analysis of the first 35 patients from cohort 1 of the pivotal TROPY-U-01 study and confirmed the safety and efficacy profile of sacituzumab govitecan with an overall response rate of 29% in mUC patients who progressed after both platinum-based chemotherapy and immune checkpoint inhibitor therapy.

The February 2019, New England Journal of Medicine publication also provided additional information on safety from 420 patients with a variety of epithelial cancers from the Phase 1/2 study. The adverse event profile from this overall safety population of the trial was generally consistent with those observed from various cohorts at earlier stages with low discontinuation rates and key adverse events of neutropenia, nausea and diarrhea.

With the promising efficacy and safety findings, the Company has strategically decided to broaden the development of sacituzumab govitecan beyond mTNBC by launching a Trop-2-enriched Phase 2 basket study in refractory NSCLC, head and neck cancer, and endometrial cancer.

We have an extensive intellectual property portfolio protecting sacituzumab govitecan. Specifically, 57 patents were issued in the United States and 35 foreign patents were issued covering composition of matter, synthesis and uses. Certain patents relating to the protein sequence of the hRS7 antibody used in sacituzumab govitecan expired in 2017 in the United States and will expire in 2023 overseas. Patents to compositions and use of the CL2A linker incorporated in sacituzumab govitecan expire between 2023 and 2029 in the United States and overseas. Other patents relating to methods of cancer therapy with the SN-38 conjugated form of hRS7 used in sacituzumab govitecan extend to 2033. Additionally, we are entitled to extend the term of our key patent for up to five more years in the United States and certain foreign countries. Outside the United States, patents were issued in Australia, Canada, China, Europe, Israel, Japan, Mexico, South Korea and other key global markets.

## Our Platform Technologies

In our drive to improve targeted therapies of diseases, we have built significant expertise in antibody engineering, particularly proprietary complementarity determining region (CDR)-grafting (antibody humanization) methods, antibody production and formulation, immunochemistry, molecular biology, antibody conjugation, peptide chemistry, synthetic organic chemistry, and protein engineering.

Beginning with our unique grafting technique to engineer humanized antibodies, our antibody humanization platform has produced a diverse portfolio of therapeutic agents that are well tolerated and also have a low incidence of immunogenicity.

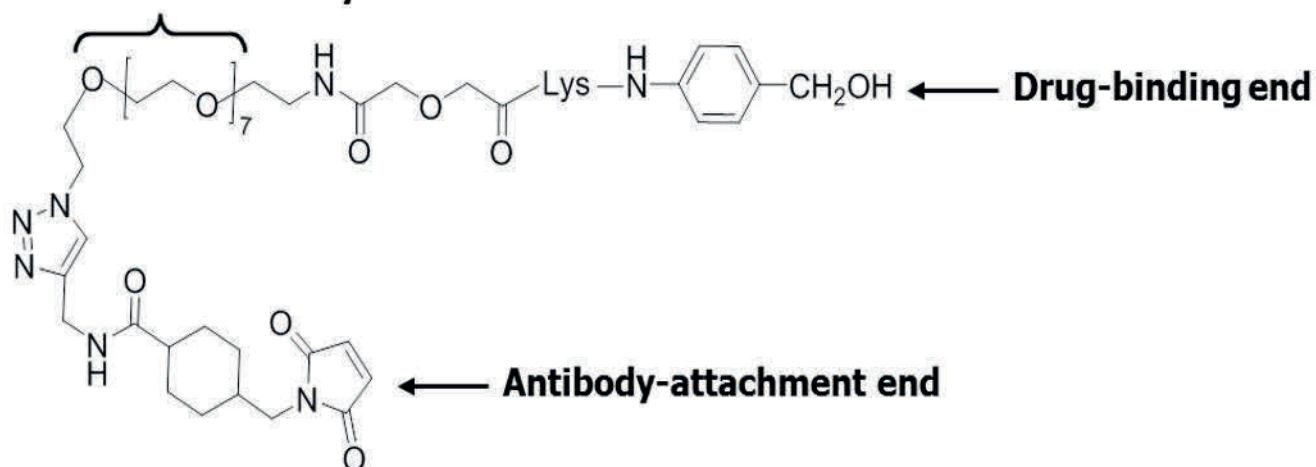
With the successful humanized antibody platform as a foundation, we have built a robust ADC program using our own proprietary ADC linker technology.

### ADC Linker Technology

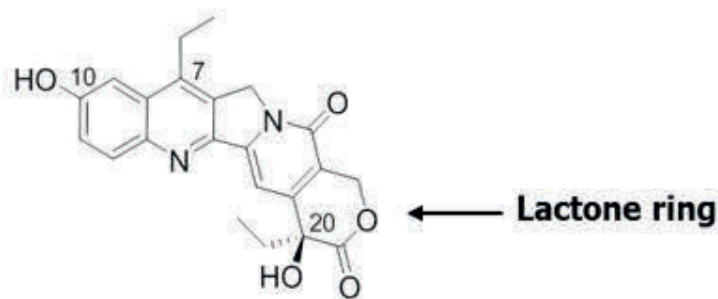
We developed a novel ADC platform using our proprietary linker, CL2A, which was designed with targeted delivery of SN-38 in mind. SN-38 is about 3 orders of magnitude (100 to 1,000 times) more potent than irinotecan, its parent drug, but it cannot be administered systemically to patients because of its poor water solubility and toxicity. Our linker, CL2A, allows us to produce SN-38 conjugates that are soluble in water with excellent yields while preserving antibody binding and drug activity.

CL2A contains an antibody coupling group on one end and a chemical group on the other for binding with a drug. We have also added a short polyethylene glycol to improve the solubility of CL2A.

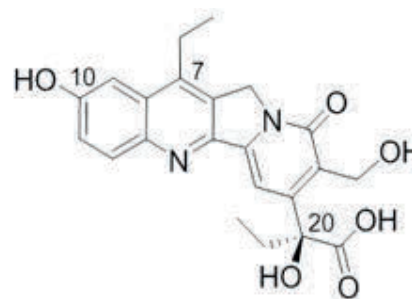
### Short PEG for solubility



Furthermore, because SN-38 can be converted from its active lactone form to the inactive carboxylate form, CL2A was designed to attach close to the lactone ring to prevent it from opening up, thereby maintaining the activity of SN-38. Another key feature of our ADC platform is that the linkage between CL2A and SN-38 is hydrolyzable and will allow the detachment of SN-38 at a rate of about 50% per day *in vivo*.

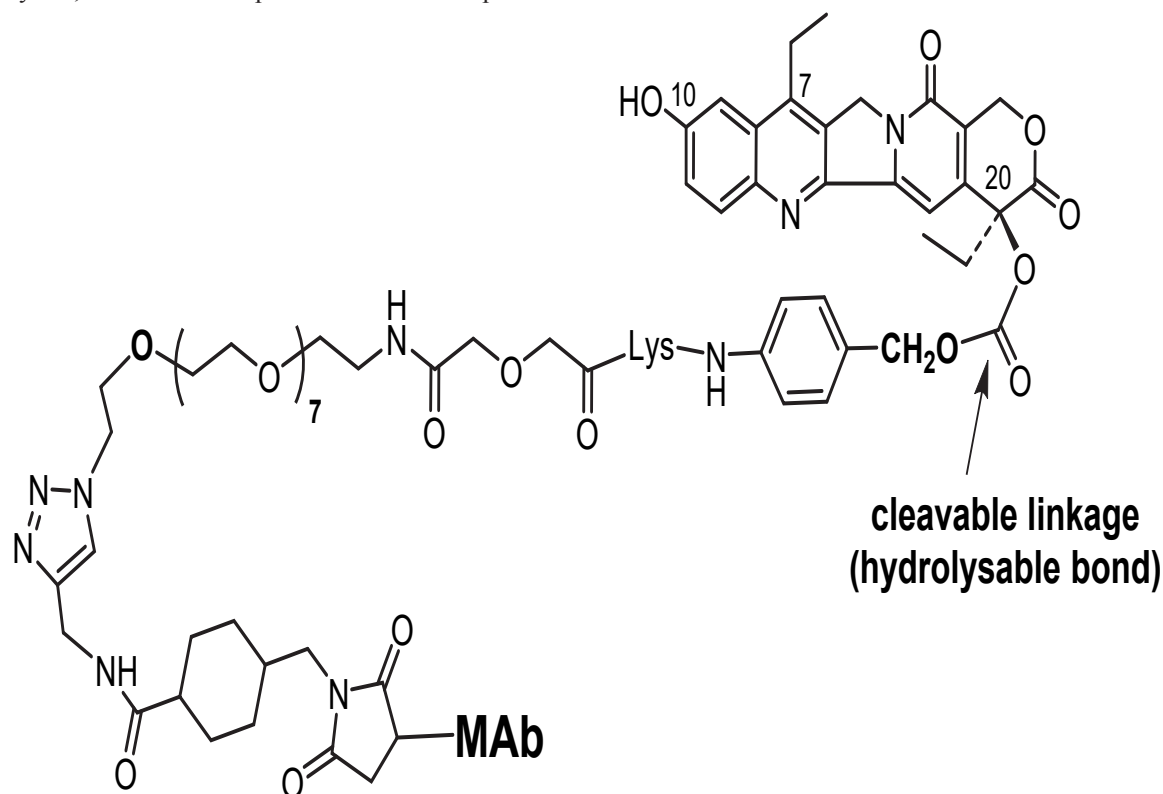


### Active lactone form



### Inactive carboxylate form

The final structure of our ADC is depicted below, with the hydrolysable linker indicated. What differentiates our ADC platform from those of other companies is the high drug-to-antibody ratio of about seven to eight molecules of drug per antibody. That is to say, when our ADCs bind to their targets on cancer cells, they are delivering up to eight molecules of SN-38 per antibody molecule into the blood or at the vicinity of the tumor, which may explain why our ADCs can deliver more than 120-times the amount of SN-38 to the tumor when studied in an animal model, as compared to irinotecan, the parent compound. We can deliver this drug concentration because our drug is not supertoxic, thus permitting us to give higher antibody doses, in repeated therapy cycles, that we believe provide a better therapeutic index.



## Patents and Proprietary Rights

### Our Patents

We have accumulated a sizable portfolio of patents and patent applications in the course of our research, which we believe constitutes a valuable business asset. Our key patents relate primarily to our therapeutic product candidates as well as our technologies and other discoveries for which no product candidate has yet been identified. As of December 31, 2019, our portfolio included approximately 285 active United States patents. In addition, as of such date, the portfolio included approximately 384 foreign patents, with a number of United States and foreign patent applications pending.

The chart below highlights our material patents and product groups as of December 31, 2019, the major jurisdictions, and relevant expiration periods. Additional patents have been filed to extend the patent life on some of these products, but there can be no assurance that these will be issued as filed.

Program & Product Group	Targeted Antigen/Description	Patent Expiration	Major Jurisdictions
Antibody-Drug Conjugates	Trop-2, CEA/CEACAM5 and HLA-DR	2023-2033	U.S., Europe, Japan
Subcutaneous Formulation	All Antibodies	2032	U.S., Europe, Japan
Epratuzumab	CD22	2020	U.S., Europe
Veltuzumab	CD20	2023-2029	U.S., Europe, Japan
Milatuzumab	CD74	2023-2032	U.S., Europe, Japan
IMMU-114	HLA-DR	2026-2027	U.S., Europe, Japan
DNL <sup>®</sup> Program - (E1)-3s	Trop-2	2033	U.S., Japan <sup>+</sup>

<sup>+</sup> pending in Europe

## ***License***

On April 4, 2018, we entered into a license agreement with The Scripps Research Institute ("TSRI"). Pursuant to the license agreement, TSRI granted to us an exclusive, worldwide, sub-licensable, royalty-bearing license to use certain patent rights relating to our ADC sacituzumab govitecan. The license agreement expires on a country-by-country basis on the expiration date of the last to expire licensed patent rights in such country covering a licensed product. The license agreement may be terminated by the mutual written consent of us and TSRI, and TSRI may terminate the license agreement upon the occurrence of certain events, including, but not limited to, if we do not make a payment due pursuant to the license agreement and fail to cure such non-payment within 30 days after the date of TSRI's written notice of such non-payment. As consideration for the license granted, we made a cash payment of \$250,000 to TSRI. Additionally, we will pay TSRI (i) product development milestone payments that range from the mid-six digit dollar figure to the low-seven digit dollar figure and (ii) royalties on net sales of licensed products in the low-single digit percentage figure range capped at an annual amount. We have agreed to use reasonable efforts to develop and market the licensed products. During the year ended December 31, 2019, we recognized a \$0.5 million milestone payment expense.

## ***Our Trademarks***

The mark "IMMUNOMEDICS" is registered in the United States and 21 foreign countries and a European Community Trademark has been granted. Our logo is also registered in the United States and in one foreign country. The mark "IMMUSTRIP" is registered in the United States and Canada. The mark "LEUKOSCAN" is registered in eight foreign countries, and a European Community Trademark has been granted. In addition, we have applied for registration in the United States for several other trademarks for use on products now in development or testing, and for corresponding foreign and/or European Community Trademarks for certain of those marks. The marks "EPRATUCYN," "VELTUCYN" and "MILATUCYN" have been registered in the United States and International Trademark Registrations which claim priority to the respective United States applications have been filed for "EPRATUCYN" and "VELTUCYN." The International Registrations request registration in China, Japan and the European Union. The marks "DOCK-AND-LOCK," "DNL," and "PANCRI" have been registered in the United States. Registrations for "SCIGOV," "TRODELVY" and "HUMANLY" have been filed in the United States and internationally and for "TUMIMI" in the United States. The U.S. Patent and Trademark Office has issued Notices of Allowance for the marks "TRODELVY," "SCIGOV," "HUMANLY" and "TUMIMI".

## ***Our Trade Secrets***

We also rely upon unpatented trade secrets, and there is no assurance that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technology, or that such rights can be meaningfully protected. We require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisers to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of our employees, the agreement provides that all inventions conceived by such employees shall be our exclusive property. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

## ***Third Party Rights***

Our success also depends in part on our ability to gain access to third party patent and proprietary rights and to operate our business without infringing on third party patent rights. We may be required to obtain licenses to patents or other proprietary rights from third parties to develop, manufacture and commercialize our product candidates. Licenses required under third-party patents or proprietary rights may not be available on terms acceptable to us, if at all. If we do not obtain the required licenses, we could encounter delays in product development while we attempt to redesign products or methods or we could be unable to develop, manufacture or sell products requiring these licenses at all.

## Corporate Collaborations

### *AstraZeneca/MedImmune*

In June 2018, we entered into a clinical collaboration with AstraZeneca and its global biologics research and development arm, MedImmune, to evaluate in Phase 1/2 studies the safety and efficacy of combining AstraZeneca's Imfinzi® (durvalumab), a human monoclonal antibody directed against programmed cell death ligand 1 ("PD-L1"), with sacituzumab govitecan as a treatment of patients with TNBC and UC, which was broadened in October 2018 to include second-line mNSCLC.

Part one of the two-part Phase 1/2 studies will be co-funded by the two companies. Immunomedics will supply the study drug and AstraZeneca will utilize its existing clinical trial infrastructure to accelerate the enrollment of the sacituzumab govitecan and durvalumab combination. The trial design allows for rapid transition into randomized Phase 2 studies should the first part of these studies show promising data and the companies agree to proceed based on efficacy and safety results obtained.

### *Clovis Oncology*

In June 2018, we signed a letter of intent with Clovis, and in December 2018, we entered into a clinical collaboration to investigate the combination of Clovis' Rubraca® (rucaparib), a poly (ADP ribose) polymerase inhibitor (PARPi), and sacituzumab govitecan as a second-line treatment of patients with mTNBC and mUC in a phase 1/2 study (SEASTAR), which has been expanded to include platinum resistant ovarian cancer. The dose escalation phase of the study is currently enrolling patients.

### *GBG Forschungs GmbH*

In September 2019, we entered into a clinical collaboration with GBG, Neu-Isenburg, Germany, to develop sacituzumab govitecan as a treatment for newly-diagnosed breast cancer patients who do not achieve a pCR following standard neoadjuvant therapy.

The multinational, post-neoadjuvant Phase 3 SASCIA study developed by GBG will be conducted under the sponsorship of GBG. Approximately 1,200 high-risk patients with newly-diagnosed HER2- breast cancer not achieving a pCR following standard neoadjuvant therapy will be randomized to receive either sacituzumab govitecan or treatment of physician's choice. Primary endpoint is invasive disease-free survival with overall survival, patient reported outcome/quality of life, circulating tumor DNA clearance, and safety serving as secondary endpoints.

Under the terms of the agreement, GBG is eligible to receive up to €33.0 million in potential clinical and regulatory milestone payments over a span of approximately six years, of which €0.5 million was paid during the year ended December 31, 2019.

### *F. Hoffman-La Roche Ltd*

In September 2019, we entered into a clinical collaboration with F. Hoffman-La Roche Ltd ("Roche") to compare the safety and efficacy of the combination of atezolizumab (Tecentriq®), a programmed cell death ligand 1 blocking checkpoint inhibitor, and sacituzumab govitecan, as a frontline treatment of patients with metastatic or inoperable locally advanced TNBC versus atezolizumab plus nab-paclitaxel as standard of care. Roche will be responsible for conducting the randomized trial.

## Other Collaborations

In breast cancer, we are collaborating with MGH on a Phase 1b/2 study of sacituzumab govitecan combining with Pfizer's PARP inhibitor, TALZENNA®, in patients with mTNBC previously treated with no more than one prior therapeutic regimens for metastatic disease. In endometrial cancer, we are collaborating with Yale University on a Phase 2 study of sacituzumab govitecan in patients with persistent and recurrent endometrial cancer. Through an agreement with The Prostate Cancer Clinical Trials Consortium, we are collaborating with the University of Wisconsin Carbone Cancer Center to investigate sacituzumab govitecan in a Phase 2 study to assess whether targeting Trop-2 with sacituzumab govitecan is promising in prostate cancer patients. In addition to the Phase 2 study, Dr. Lang, the lead investigator at the University of Wisconsin, is also leading a broad translational program integrated into the clinical study to further validate the expression and importance of Trop-2 as a therapeutic target in various stages of prostate cancer.

A separate research collaboration was also established with Fred Hutchinson Cancer Research Center to investigate sacituzumab govitecan and IMMU-130 as a single agent and in combination in prostate cancer xenograft models.



## **Funding Agreement**

On January 7, 2018, we entered into a funding agreement (the “Funding Agreement”) with RPI Finance Trust, a Delaware statutory trust (“RPI”). Pursuant to the Funding Agreement, we granted RPI the right to receive certain royalty amounts, subject to certain reductions, based on the net sales of the antibody-drug conjugate IMMU-132 (sacituzumab govitecan) (the “Product”), for each calendar quarter during the term of the Funding Agreement (“Revenue Participation Right”), in exchange for \$175,000,000 in cash (the “Purchase Price”). Specifically, the royalty rate commences at 4.15 percent on net annual sales of up to \$2 billion, declining step-wise based on sales tiers to 1.75 percent on net global annual sales exceeding \$6 billion. In addition, after the seventh anniversary of the First Commercial Sale (as defined in the Funding Agreement) in the United States and following a change of control of the Company, we shall have the option to repurchase fifty percent (50%) of the Revenue Participation Right from RPI, at the net present value (calculated using a 5% discount rate) of the projected royalty payments based upon the then projected sales of the Product.

## **Government Regulation**

### ***Regulatory Compliance***

Our research and development activities, including testing in laboratory animals and in humans, our manufacture of antibodies and oversight of suppliers and contract manufacturers involved in the production of our product candidates, as well as the design, manufacturing, safety, efficacy, handling, labeling, storage, record-keeping, advertising, promotion and marketing of the product candidates that we are developing, are all subject to stringent regulation, primarily by the FDA in the United States under the Federal Food, Drug, and Cosmetic Act (the “FDCA”) and its implementing regulations, and the Public Health Service Act (“PHS Act”) and its implementing regulations, and by comparable authorities under similar laws and regulations in other countries. If, for any reason, we do not comply with applicable requirements, such noncompliance can result in various adverse consequences, including one or more delays in approval of, or even the refusal to approve, product licenses or other applications, the suspension or termination of clinical investigations, the revocation of approvals previously granted, as well as fines, criminal prosecution, recall or seizure of products, injunctions against shipping products and total or partial suspension of production and/or refusal to allow us to enter into or termination of governmental supply contracts.

### ***Product Approval***

In the United States, our product candidates are regulated as biologic pharmaceuticals, or biologics. The FDA's regulatory authority for the approval of biologics resides in the PHS Act. However, biologics are also subject to regulation under the FDCA because most biological products also meet the FDCA's definition of “drugs.” Most pharmaceuticals or “conventional drugs” consist of pure chemical substances and their structures are known. Most biologics, however, are complex mixtures that are not easily identified or characterized. Biological products differ from conventional drugs in that they tend to be heat-sensitive and susceptible to microbial contamination, thus requiring sterile manufacturing processes. The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA’s current Good Laboratory Practices regulations;
- submission to the FDA of an Investigational New Drug Application (“IND”), which must become effective before human clinical trials may begin and must be updated annually;
- approval by an independent Institutional Review Board (“IRB”) ethics committee at each clinical site before the trial is initiated;
- performance of adequate and well-controlled clinical trials to establish the safety, purity and potency of the proposed biologic, and its safety and efficacy for each indication;
- preparation of and submission to the FDA of a BLA for a new biologic, after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities to assess compliance with current Good Manufacturing Practice (“cGMP”) regulations; and

- FDA review and approval of a BLA for a new biologic, prior to any commercial marketing or sale of the product in the United States.

Preclinical tests assess the potential safety and efficacy of a product candidate in animal models. Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with current Good Clinical Practices (“cGCPs”), which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical trial site’s IRB before the trials may be initiated, and the IRB must monitor the study until completed. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

The clinical investigation of a pharmaceutical, including a biologic, is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined.

- Phase 1 studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational product in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness.
- Phase 2 includes controlled clinical trials conducted to preliminarily or further evaluate the effectiveness of the investigational product for a particular indication(s) in patients with the disease or condition under study, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the product.
- Phase 3 clinical trials are generally controlled clinical trials conducted in an expanded patient population generally at geographically dispersed clinical trial sites, and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational product, and to provide an adequate basis for product approval.

The FDA may place clinical trials on hold at any point in this process if, among other reasons, it concludes that clinical subjects are being exposed to an unacceptable health risk. Trials may also be terminated by IRBs, which must review and approve all research involving human subjects. Side effects or adverse events that are reported during clinical trials can delay, impede or prevent marketing authorization.

The results of the preclinical and clinical testing, along with information regarding the manufacturing of the product and proposed product labeling, are evaluated and, if determined appropriate, submitted to the FDA through a BLA. The application includes all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product’s chemistry, manufacturing, controls and proposed labeling, among other things. Once the BLA submission has been accepted for filing, the FDA’s standard goal is to review applications within ten months of the filing date or, if the application relates to a drug that treats a serious condition and would provide a significant improvement in safety or effectiveness qualifying for Priority Review, six months from the filing date. The review process is often significantly extended by FDA requests for additional information or clarification.

The FDA offers certain programs, such as BTB and Fast Track designation, designed to expedite the development and review of applications for products intended for the treatment of a serious or life-threatening disease or condition. For BTB, preliminary clinical evidence of the product indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If BTB or Fast Track designation is obtained, the FDA may initiate review of sections of a BLA before the application is complete, and the product may be eligible for accelerated approval. However, receipt of BTB or Fast Track designation for a product candidate does not ensure that a product will be developed or approved on an expedited basis, and such designation may be rescinded if the product candidate is found to no longer meet the qualifying criteria.

The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, pure and potent, which includes determining whether it is effective for its intended use, and whether the product is being manufactured in accordance with cGMP, to assure and preserve the product’s identity, strength, quality, potency and purity. The FDA may refer an application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved, and applications for new molecular entities and original BLAs are generally discussed at advisory committee meetings unless the FDA determines that this type of consultation is not needed under the circumstances. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations.

After the FDA evaluates the BLA and conducts inspections of manufacturing facilities, it may issue an approval letter or a CRL. An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete, and the application is not ready for approval. A CRL may require additional inspections, and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. The FDA could approve the BLA with a Risk Evaluation and Mitigation Strategy ("REMS") to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") created an abbreviated pathway for the approval of biosimilar and interchangeable biologic products. The abbreviated pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. In March 2015, the FDA approved Novartis's Zarxio as a biosimilar product to Amgen's Neupogen. Since then, as of January 2019, twenty-six biosimilar drugs have received FDA approval. In 2020, the FDA and FTC announced collaborative regulatory efforts to support the adoption of biosimilars and interchangeable products and indicated that they will take measures to discourage anti-competitive behavior and promotional statements that they deem false and misleading.

### ***Expedited Review and Approval***

The FDA has four program designations/approval pathways — Fast Track, BTB, Accelerated Approval, and Priority Review — to facilitate and expedite development and review of new drugs and biologics to address unmet medical needs in the treatment of serious or life-threatening conditions. The Fast Track designation provides pharmaceutical manufacturers with opportunities for frequent interactions with FDA reviewers during the product's development and the ability for the manufacturer to do a rolling submission of the BLA. A rolling submission allows completed portions of the application to be submitted and reviewed by the FDA on an ongoing basis. The BTB provides manufacturers with all of the features of the Fast Track designation as well as intensive guidance on implementing an efficient development program for the product and a commitment by the FDA to involve senior managers and experienced review staff in the review. The Accelerated Approval designation allows the FDA to approve a product based on an effect on a surrogate or intermediate endpoint that is reasonably likely to predict a product's clinical benefit and generally requires the manufacturer to conduct required post-approval confirmatory trials to verify the clinical benefit. The Priority Review designation means that the FDA's goal is to take action on the BLA within six months, compared to ten months under standard review. The BLA submitted in 2018 for sacituzumab govitecan in patients with mTNBC was accepted by the FDA and the original application was granted Priority Review. On January 17, 2019, we received a CRL from the FDA for the sacituzumab govitecan BLA. We requested a meeting with the FDA to gain a full understanding of its requirements and the resulting timelines for preparation of the resubmission, agency review, and an agency decision on the resubmission. On November 30, 2019 we resubmitted our BLA to the FDA and on December 23, 2019 we received notification from the FDA that the BLA was accepted for filing and further assigned a new PDUFA target action date as June 2, 2020. Refer to "Overview" above for additional information.

### ***Post-Approval Requirements***

Any products manufactured or distributed by us or on our behalf pursuant to FDA approvals are subject to continuing regulation by the FDA and certain state agencies, including requirements for record-keeping, reporting of adverse experiences with the biologic, submitting biological product deviation reports to notify the FDA of unanticipated changes in distributed products, establishment registration, compliance with cGMP standards (including investigation and correction of any deviations from cGMP), and certain state licensing requirements. Additionally, any significant change in the approved product or in how it is manufactured, including changes in formulation or the site of manufacture, generally require prior FDA approval, and even changes that may seem less significant must be evaluated under change control procedures to assess their potential impact on product quality and relative to the specifications on file with the FDA, and whether they trigger notification or approval requirements. The packaging and labeling of all products developed by us are also subject to FDA approval and ongoing regulation. Noncompliance with any regulatory requirements can result in, among other things, issuance of warning letters, civil and criminal penalties, seizures, and injunctive action. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The commercial distribution of prescription drugs is subject to the Drug Supply Chain Security Act ("DSCSA"), which regulates the distribution of the products at the federal level, and sets certain standards for federal or state registration and compliance of entities in the supply chain (manufacturers and packagers, wholesale distributors, third-party logistics providers, and dispensers). The DSCSA preempts certain previously enacted state laws and the pedigree requirements of the Prescription Drug Marketing Act ("PDMA"). Trading partners within the drug supply chain must now ensure certain product tracing requirements are met, and are required to exchange transaction information, transaction history, and transaction statements. Further, the DSCSA limits the distribution of prescription biopharmaceutical products and imposes requirements to ensure overall accountability and security in the drug supply chain. Product identifier information (an aspect of the product tracing scheme) is also now required. The DSCSA requirements, development of standards, and the system for product tracing have been and will continue to be phased in over a period of years through 2023, and subject companies will need to continue their implementation efforts. The distribution of product samples continues to be regulated under the PDMA, and some states also impose regulations on drug sample distribution.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations, guidance documents, and policies are often revised or reinterpreted by the agency in ways that may significantly affect our business and our product candidates. It is impossible to predict whether further legislative or FDA regulation or policy changes will be enacted or implemented and what the impact of such changes, if any, may be.

### ***Orphan Drug Act***

We have successfully obtained Orphan Drug designation by the FDA under the Orphan Drug Act of 1983 for sacituzumab govitecan for SCLC and pancreatic cancer. Under the Orphan Drug Act, FDA may grant Orphan Drug designation to drugs intended to treat a rare disease or condition, which is generally defined as a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan Drug designation must be requested before submitting a BLA. In the United States, Orphan Drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. Orphan Drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first BLA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA Orphan Drug designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, FDA may not approve any other applications to market the same drug for the same orphan indication, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or where the manufacturer of the approved product cannot assure sufficient quantities. As a result, there can be no assurance that our competitors will not receive approval of drugs or biologics that have a different active ingredient for treatment of the diseases for which our products and product candidates are targeted.

### ***Foreign Regulation***

In addition to regulations in the United States, we are subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our product candidates being developed, and products being marketed outside of the United States. We must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of our products in those countries. The approval process varies from country to country, and the time may be longer or shorter than required by the FDA for BLA licensure. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. As in the United States, we are subject to post-approval regulatory requirements, such as those regarding product manufacturing, marketing, or distribution.

### ***Other Regulatory Considerations***

We are also subject to regulation under the Occupational Safety and Health Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, The Clean Air Act, New Jersey Department of Environmental Protection and other current and potential future federal, state, or local regulations. Our research and development activities involve the controlled use of hazardous materials, chemicals, biological materials and various radioactive compounds. We believe that our procedures comply with the standards prescribed by state and federal regulations; however, the risk of injury or accidental contamination cannot be completely eliminated.

We may also be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments where we may market our products and product candidates, if approved. These laws and regulations include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, data privacy and security, aggregate spend reporting, and product price advertising.



The federal Anti-Kickback Statute, which prohibits, among other things, persons and entities including pharmaceutical manufacturers from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, overtly or covertly, in case or in kind, to induce or reward, or in return for, or either the referral of an individual for, or the purchase, lease or order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted broadly to apply to, among other things, arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. The term “remuneration” expressly includes kickbacks, bribes or rebates and also has been broadly interpreted to include anything of value. There are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions; however, the exceptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exception or safe harbor may be subject to scrutiny. The failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not meet all of the criteria for safe harbor protection from federal Anti-Kickback Statute liability in all cases. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. In addition, Patient Protection and Affordable Care Act of 2010, as amended (“ACA”) codified cash law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

The federal civil False Claims Act prohibits individuals or entities from, among other things, knowingly presenting or causing the presentation of a claims payment to, or approval by, the federal government that are false, fictitious or fraudulent, or knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the federal government. Although we do not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to “cause” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers, promoting a product for unapproved uses (also known as “off-label promotion”), marketing products of sub-standard quality, or, as noted above, paying a kickback that results in a claim for items or services in violation of the Anti-Kickback Statute. In addition, our activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under the False Claims Act. For example, several pharmaceutical and other healthcare companies have faced enforcement actions under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal healthcare programs for the product. The federal civil False Claims Act also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery. In addition, certain marketing practices, including off-label promotion, may also implicate the False Claims Act. Although the False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes.

In addition to the Anti-Kickback Statute and False Claims Act, there are state statutes and regulations equivalent or substantially similar to the federal laws which may extend to items and services reimbursed by commercial insurers and/or by patients directly. State law equivalents to the Anti-Kickback Statute and False Claims Act may not have adopted exceptions and safe harbors available at the federal level and therefore, may implicate a broader range of activities.

To the extent we obtain coverage for our products by state Medicaid programs, we may be required to pay a rebate to each state Medicaid program for any covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program, and to comply with all Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Healthcare Act of 1992. Moreover, federal law requires that any company participating in the Medicaid Drug Rebate program also participate in the Public Health Service’s 340B Program, which impose additional reporting requirements and price concessions. Manufacturer compliance with 340B Program requirements can be costly. In addition, if our products are made available to authorized users of the Federal Supply Schedule of the General Services Administration or to low income patients of certain hospitals, additional laws and requirements may apply.

The federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud or obtain, by any means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.



There has also been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The federal physician payment transparency requirements, sometimes referred to as the “Physician Payments Sunshine Act,” created under the ACA, and its implementing regulations, which requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the State Children’s Health Insurance Program (with certain exceptions) to annually report to the United States Department of Health and Human Services, or HHS, information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Under recent legislation, the Sunshine Act will extend to payments and transfers of value to physician assistants, nurse practitioners, and other mid-level healthcare providers (with reporting requirements going into effect in 2022 for payments and transfers made in 2021). Centers for Medicare and Medicaid Services (“CMS”) has the potential to impose penalties of up to \$1.15 million per year for violations of the Sunshine Act, depending on the circumstances, and payments reported under the Sunshine Act also have the potential to draw scrutiny on payments to and relationships with physicians and teaching hospitals, which may have implications under the Anti-Kickback Statute and other healthcare laws.

We may also be subject to data privacy and security regulation by both the federal government and the state governments in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act of 2009 (“HITECH”) and their respective implementing regulations, including the Final Omnibus Rule published on January 25, 2013, imposes, among other things, obligations, including mandatory contractual terms with respect to safeguarding the privacy, security and transmission of individually identifiable health information held by certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, and business associates. Among other things, HITECH made certain aspects of HIPAA’s rules (notably the Security Rule) directly applicable to business associates, defined as independent contractors or agents of covered entities that receive or obtain individually identifiable health information in connection with providing a service for or on behalf of a covered entity. HITECH created four tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal court to enforce the federal HIPAA laws and seek attorney’s fees and costs associated with pursuing federal civil actions. The Department of Health and Human Services Office of Civil Rights (“OCR”) has increased its focus on compliance and continues to train state attorneys general for enforcement purposes. The OCR has recently increased both its efforts to audit HIPAA compliance and its level of enforcement, with one recent penalty exceeding \$5.0 million.

Even where HIPAA does not apply, according to the United States Federal Trade Commission (“FTC”), failing to take appropriate steps to keep consumers’ personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act (“FTCA”), 15 United States C § 45(a). The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC’s guidance for appropriately securing consumers’ personal information is similar to what is required by the HIPAA Security Rule.

There are numerous other laws and legislative and regulatory initiatives at the federal and state levels addressing privacy and security concerns, and some state privacy laws apply in broader circumstances than HIPAA. California recently enacted legislation – the California Consumer Privacy Act (“CCPA”), which took effect January 1, 2020. The CCPA, among other things, created new data privacy obligations for covered companies and provided new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also created a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. The California Attorney General will issue clarifying regulations. Although the law, as initially enacted, included certain limited exceptions, including for information collected as part of clinical trials as specified in the law, it remains unclear what language the final Attorney General regulations will contain or how the statute and regulations will be interpreted.

We are subject to the United States Foreign Corrupt Practices Act (“FCPA”), which prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. Under this act, it is illegal to pay, offer to pay, or authorize the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. Our present and future business has been and will continue to be subject to various other laws and regulations.

## **Marketing, Sales and Distribution**

As noted above, we intend to bring sacituzumab govitecan to the United States market on our own for patients with mTNBC. In anticipation of bringing sacituzumab govitecan to market, we have built a commercial operation with a total sales force of approximately 56 colleagues. We also have maintained a core commercial infrastructure preparing for launch readiness.

In April 2019, we entered into the Promotion Agreement with Janssen pursuant to which we will provide non-exclusive product detailing services to Janssen. Pursuant to the Promotion Agreement, we will provide a dedicated sales team to market Janssen's Balversa (erdafitinib) to oncologists and other targeted health care providers in the United States. Under the terms of the Promotion Agreement, Janssen maintains ownership of the New Drug Application for the product as well as legal, regulatory, distribution, commercialization and manufacturing responsibilities for the product, while we will provide product detailing services to Janssen. Refer to "Note 2 - Revenue Recognition" for additional information.

## **Manufacturing**

We operate a cGMP manufacturing facility in Morris Plains, New Jersey for the production of ADC product candidates for clinical trials, as well as, potentially, for commercial use.

Presently, we believe our Morris Plains facility has enough capacity to produce sufficient quantities of hRS7, the anti-Trop-2 antibody used in sacituzumab govitecan, to support the initial commercial launch of sacituzumab govitecan in the United States, pending FDA approval. To meet our projected future demand of sacituzumab govitecan, we have contracted with Samsung Biologics Co., Ltd. for commercial-scale antibody production. Our global supply chain also includes two outside contract manufacturing organizations: Johnson Matthey Pharma Services of Devens, Massachusetts for the manufacture of the linker-drug payload, and BSP Pharmaceuticals of Latina Scalo, Italy for the conjugation of the antibody with the linker-drug and fill/finish of the sacituzumab govitecan drug product. Together, our end-to-end supply chain has capacity to support the potential commercial launch of sacituzumab govitecan in the United States, as well as the multitude of clinical development programs globally.

## **Manufacturing Regulatory Considerations**

In addition to regulating and auditing human clinical trials, the FDA regulates and inspects equipment, facilities and processes used in the manufacturing of such products prior to providing approval to market a product. If, after receiving approval from the FDA, a material change is made in manufacturing equipment, location, or process related to an approved product, additional regulatory review may be required. We must also adhere to cGMP and product-specific regulations enforced by the FDA through its facilities inspection program. The FDA also conducts regular, periodic visits to re-inspect equipment, facilities, and processes following the initial approval. If, as a result of these inspections, the FDA determines that our equipment, facilities or processes do not comply with applicable FDA regulations and conditions of product approval, the FDA may seek civil, criminal or administrative sanctions and/or remedies against us, including the suspension of our manufacturing operations.

## **Employees**

As of December 31, 2019, we employed 366 persons on a full-time basis, 71 of whom were engaged in research, clinical research and regulatory affairs, 182 of whom were engaged in operations and manufacturing and quality control, and 113 of whom were engaged in finance, administration, sales and marketing. We believe that while we have been successful to date in attracting skilled and experienced scientific personnel, competition for such personnel continues to be intense and there can be no assurance that we will continue to be able to attract and retain the professionals we will need to grow our business. Our employees are not covered by a collective bargaining agreement and we believe that our relationship with our employees is excellent.

## **Corporate Information**

We were incorporated in Delaware in 1982. Our principal offices are located at 300 The American Road, Morris Plains, New Jersey 07950 and 410 The American Road, Morris Plains, New Jersey 07950. Our telephone number is (973) 605-8200. In addition, to our majority-owned subsidiary, IBC Pharmaceuticals, Inc. ("IBC"), we also have one foreign subsidiary, Immunomedics GmbH in Rodermark, Germany, to assist us in managing sales and marketing efforts, coordinating clinical trials in Europe, and providing related regulatory affairs support. Immunomedics has incurred expenses on behalf of the IBC operations, including interest, over the past fifteen years. As of December 31, 2019, IBC has a liability to Immunomedics Inc. of approximately \$18.1 million, which is eliminated in consolidation. Our web address is [www.immunomedics.com](http://www.immunomedics.com). We have not incorporated by reference into this Annual Report on Form 10-K the information on our website and you should not consider it to be a part of this document.

Our reports that have been filed with the Securities and Exchange Commission ("SEC"), are available on our website free of charge, including our transition report and annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, Forms 3, 4 and 5 filed on behalf of directors and executive officers and any amendments to such reports filed pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Copies of this Annual Report on Form 10-K may also be obtained without charge electronically or by paper by contacting Investor Relations, Immunomedics, Inc., 300 The American Road, Morris Plains, New Jersey 07950 or by calling (973) 605-8200.

In addition, we make available on our website (i) the charters for the committees of the Board of Directors, including the Audit Committee, Compensation Committee and Governance and Nominating Committee, and (ii) the Company's Code of Business Conduct (the "Code of Conduct") governing our directors, officers and employees. Within the time period required by the SEC, we will post on our website any modifications to the Code of Conduct, as required by the Sarbanes-Oxley Act of 2002, ("Sarbanes-Oxley Act"). The SEC maintains a web site at <http://www.sec.gov> that contains reports, proxy and information statements and other information regarding companies that file electronically with the SEC.

## **Item 1A. RISK FACTORS**

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10-K, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations

### **Risks Relating to Our Business, Operations and Product Development**

***We have a long history of operating losses and it is likely that our operating expenses will continue to exceed our revenues for the foreseeable future.***

We have incurred significant operating losses since our formation in 1982. We continue to spend our cash resources to fund our research and development programs and, subject to adequate funding, we expect these expenses to increase for the foreseeable future. There can be no assurance that we will be profitable in future quarters or other periods. Further, we have made the strategic decision to focus on our therapeutic pipeline. We have never had product sales of any therapeutic product. We expect to experience significant operating losses as we invest further in our research and development activities while simultaneously attempting to develop and commercialize our other therapeutic product candidates. Even if we are able to develop commercially viable therapeutic products, certain obligations the Company has to third parties, including, without limitation, our obligation to pay RPI Finance Trust, a Delaware statutory trust ("RPI"), royalties on certain sacituzumab govitecan revenues pursuant to the Royalty Agreement may erode profitability of such products. If we are unable to develop commercially viable therapeutic products or to license them to third parties, it is likely that we will never achieve significant revenues or become profitable, either of which would jeopardize our ability to continue as a going concern.

***We have significant future capital needs and may be unable to raise capital when needed, which could force us to delay or reduce our clinical development efforts.***

We believe our projected financial resources are adequate to (i) accelerate commercial launch readiness, pending FDA approval, of sacituzumab govitecan in the United States in mTNBC, (ii) continue to expand the clinical development programs for developing sacituzumab govitecan in mTNBC, metastatic urothelial cancer ("mUC"), hormone receptor-positive ("HR+") / human epidermal growth factor receptor 2-negative ("HER2-") metastatic breast cancer ("mBC"), and other indications of high medical need, (iii) invest in the broader clinical development of the platform (including IMMU-130 and IMMU-140), (iv) continued scale up of manufacturing and manufacturing process improvements, and (v) general working capital requirements. However, in case of regulatory delays or other unforeseen events, we may require additional funding.

We may require additional funding in the future to complete our clinical trials currently planned or underway, continue research and new development programs, and continue operations. Potential sources of funding include (i) the entrance into various potential strategic partnerships targeted at advancing and maximizing our full pipeline for mTNBC and beyond, (ii) the sales and marketing of sacituzumab govitecan as a third-line therapy for mTNBC in the United States (pending FDA approval), and (iii) potential equity and debt financing transactions. Refer to "Note 9 - Stockholders' Equity" for additional information.

Until we can generate significant cash through (i) the entrance into various potential strategic partnerships towards advancing and maximizing our full pipeline for mTNBC and beyond, or (ii) the sales and marketing of sacituzumab govitecan as a third-line therapy for mTNBC in the United States (pending FDA approval), we expect to continue to fund our operations with our current financial resources. In the future, if we cannot obtain sufficient funding through the above methods, we could be required to finance future cash needs through the sale of additional equity and/or issuance of debt. However, there can be no assurance that we will be able to raise the additional capital needed to complete our pipeline of research and development programs on commercially acceptable terms, if at all. The capital markets have experienced volatility in recent years, which has resulted in uncertainty with respect to availability of capital and hence the timing to meet an entity's liquidity needs. Our existing debt may also negatively impact our ability to raise additional capital. If we are unable to raise capital on acceptable terms, our ability to continue our business would be materially and adversely affected.

***Other than our pending BLA resubmission for sacituzumab govitecan for patients with metastatic triple-negative breast cancer, our other most advanced therapeutic product candidates are still only in the clinical development stage, and may require us to raise capital in the future in order to fund further expensive and time-consuming studies before they can even be submitted for final regulatory approval. A failure of a clinical trial could severely harm our business and results of operations.***

Clinical trials involve the administration of a product candidate to patients who are already extremely ill, making patient enrollment often difficult and expensive. Moreover, even in ideal circumstances where the patients can be enrolled and then followed for the several months or more required to complete the study, the trials can be suspended, terminated, delayed or otherwise fail for any number of reasons, including:

- later-stage clinical trials may raise safety or efficacy concerns not readily apparent in earlier trials or fail to meet the primary endpoint;
- unforeseen difficulties in manufacturing the product candidate in compliance with all regulatory requirements and in the quantities needed to complete the trial which may become cost-prohibitive;
- we or any of our collaboration partners may experience delays in obtaining, or be unable to obtain, agreement for the conduct of our clinical trials from the FDA, IRBs, or other reviewing entities at clinical sites selected for participation in our clinical trials;
- while underway, the continuation of clinical trials may be delayed, suspended or terminated due to modifications to the clinical trial's protocols based on interim results obtained or changes required or conditions imposed by the FDA, an IRB, a data and safety monitoring board ("DSMB"), or any other regulatory authority;
- our third-party contractors may fail to meet their contractual obligations to us in a timely manner;
- the FDA or other regulatory authorities may impose a clinical hold, for example based on an inspection of the clinical trial operations or trial sites;
- we or any of our collaboration partners may suspend or cease trials in our or their sole discretion;
- during the long trial process alternative therapies may become available which make further development of the product candidate impracticable; and
- if we are unable to obtain the additional capital we need to fund all of the clinical trials we foresee, we may be forced to cancel or otherwise curtail such trials and other studies.

Any substantial delay in successfully completing clinical trials for our product candidates, sacituzumab govitecan and labetuzumab govitecan, could severely harm our business and results of operations.

***Our clinical trials may not adequately show that our drugs are safe or effective, and a failure to achieve the planned endpoints could result in termination of product development.***

Progression of our drug products through the clinical development process is dependent upon our trials indicating our drugs have adequate safety and efficacy in the patients being treated by achieving pre-determined safety and efficacy endpoints according to the trial protocols. Failure to achieve either of these endpoints could result in delays in our trials; require the performance of additional unplanned trials or require termination of any further development of the product for the intended indication.



These factors could result in delays in the development of our product candidates and could result in significant unexpected costs or the termination of programs.

***Information obtained from our Expanded Access Program launched in January 2020 may not reliably predict the efficacy of our product candidates in company-sponsored clinical trials and may lead to adverse events that could limit approval.***

In January 2020, we instituted an Expanded Access Program for mTNBC patients. Expanded access studies conducted under this program are uncontrolled, carried out by individual investigators and not typically conducted in strict compliance with cGCPs, all of which can lead to a treatment effect which may differ from that in placebo-controlled trials. These studies provide only anecdotal evidence of efficacy for regulatory review. These studies contain no control or comparator group for reference and these patient data are not designed to be aggregated or reported as study results. Moreover, data from such small numbers of patients may be highly variable.

Expanded access programs provide supportive safety information for regulatory review. Physicians conducting these studies may use sacituzumab govitecan in a manner inconsistent with the protocol. Any adverse events or reactions experienced by subjects in the expanded access program may be attributed to sacituzumab govitecan and may limit our ability to obtain regulatory approval with labeling that we consider desirable, or at all.

***Should the clinical development process be successfully completed, our ability to derive revenues from the sale of therapeutics will depend upon our first obtaining FDA as well as foreign regulatory approvals, all of which are subject to a number of unique risks and uncertainties.***

Even if we are able to demonstrate the safety and efficacy of our product candidates in clinical trials, if we fail to gain timely approval to commercialize our product candidates from the FDA and other foreign regulatory authorities, we will be unable to generate the revenues we will need to build our business. The FDA or comparable regulatory authorities in other countries may delay, limit or deny approval of our product candidates for various reasons. For example, such authorities may disagree with the design, scope or implementation of our clinical trials; or with our interpretation of data from our preclinical studies or clinical trials; or may otherwise take the position that our product candidates fail to meet the requirements and standards for regulatory approval. There is limited FDA precedent or guidance on ADCs, and ADC product candidates may present more complex review considerations than conventional drugs, given their biologic (antibody), drug, and linker components. There are numerous FDA personnel assigned to review different aspects of a BLA, and uncertainties can be presented by their ability to exercise judgment and discretion during the review process. During the course of review, the FDA may request or require additional preclinical, clinical, chemistry, manufacturing, and controls ("CMC"), or other data and information, and the development and provision of these data and information may be time consuming and expensive. Regulatory approvals may not be granted on a timely basis, if at all, and even if and when they are granted, they may not cover all the indications for which we seek approval. On May 21, 2018, we submitted a Biologics License Application ("BLA") to the FDA for sacituzumab govitecan for the treatment of patients with mTNBC who have received at least two prior therapies for metastatic disease. On July 18, 2018, we received notification from the FDA that the BLA was accepted for filing and the original application was granted Priority Review with a PDUFA target action date of January 18, 2019. In January 2019, we received a Complete Response Letter ("CRL") from the FDA for the BLA, which identified CMC matters for the Company to address to place our application in condition for approval. In February 2019, we received a written communication from the FDA enclosing the Establishment Inspection Report ("EIR") from the chemistry, manufacturing and controls BLA pre-approval inspection conducted by the FDA at the Company's Morris Plains, New Jersey antibody manufacturing facility for our ADC product candidate sacituzumab govitecan, which took place from August 6, 2018 through August 14, 2018. The FDA also notified the Company that the FDA will be conducting a re-inspection of the Company's Morris Plains, New Jersey antibody manufacturing facility as part of the BLA resubmission process. The Company met with the FDA on May 2, 2019 to review the FDA's findings and discussed the Company's BLA resubmission and held another meeting with the FDA in September 2019 to update the FDA on our progress in addressing the items identified in the CRL and in our pre-approval inspection and to receive feedback from FDA on our approach. On November 30, 2019 we resubmitted our BLA to the FDA and on December 23, 2019 we received notification from the FDA that the BLA was accepted for filing and further assigned a new PDUFA target action date as June 2, 2020. The Company has developed a detailed plan and has dedicated, and continues to commit, significant resources to addressing the CMC matters identified by the FDA, while, in parallel, preparing our manufacturing facility to be ready for re-inspection by the FDA. If the FDA determines that these actions were not sufficient, or based on the re-inspection FDA officials do not recommend approval relative to our manufacturing facility, or if information deemed necessary by the FDA cannot be provided as part of our BLA submission or during the review period as deemed appropriate on a timely basis, such events could further delay the progress of our BLA and could require additional Company actions that cannot be completed during the review period which may adversely impact our business. Further, while we may develop a product candidate with the intention of addressing a large, unmet medical need, the FDA may only approve the use of the drug for indications affecting a relatively small number of patients, thus greatly reducing the market size and our potential revenues. The approvals



may also contain significant limitations in the form of warnings, precautions or contraindications with respect to conditions of use, which could further narrow the size of the market. In certain countries, even if the health regulatory authorities approve a drug, it cannot be marketed until pricing for the drug is also approved. Finally, even after approval can be obtained, we may be required to recall or withdraw a product as a result of newly discovered safety or efficacy concerns, either of which would have a materially adverse effect on our business and results of operations.

***In order to fund future operations, we will need to raise significant amounts of additional capital. Because it can be difficult for a mid-cap company like ours to raise equity capital on acceptable terms, we cannot assure you that we will be able to obtain the necessary capital when we need it, or on acceptable terms, if at all.***

Even if our technologies and product candidates are superior, if we lack the capital needed to bring our future products to market, we may not be successful. We have obtained the capital necessary to fund our research and development programs to date primarily from the following sources:

- upfront payments, milestone payments, and payments for limited amounts of our antibodies received from licensing partners;
- proceeds from the public and private sale of our equity or debt securities; and
- licenses and interest income from our investments.

Over the long term, we expect to commercialize sacituzumab govitecan in mTNBC in the United States and globally, to expand sacituzumab govitecan to treat patients with other solid tumors, including UC, HR+/HER2- mBC, NSCLC and other serious cancers, to expand research and development activities to continue to expand and we do not believe we will have adequate cash to continue commercial expansion and development of sacituzumab govitecan, or to complete development of product candidates in line with our pipeline included in our long term corporate strategy. Our capital requirements are dependent on numerous factors, including:

- the rate of progress of commercialization of sacituzumab govitecan in mTNBC and our ability to develop it for other cancers;
- the rate at which we progress our research programs and the number of product candidates we have in preclinical and clinical development at any one time;
- the cost of conducting clinical trials involving patients in the United States, Europe and possibly elsewhere;
- our need to establish the manufacturing capabilities necessary to produce the quantities of our product candidates we project we will need;
- the time and costs involved in obtaining FDA and foreign regulatory approvals;
- the cost of first obtaining, and then defending, our patent claims and other intellectual property rights; and
- our ability to enter into licensing and other collaborative agreements to help offset some of these costs.

There may be additional cash requirements for many reasons, including, but not limited to, changes in our commercial expansion plans, our research and development plans, the need for unexpected capital expenditures or costs associated with any acquisitions of other businesses, assets or technologies that we may choose to undertake and marketing and commercialization of our product candidates. If we deplete our existing capital resources, we will be required to either obtain additional capital quickly, or significantly reduce our operating expenses and capital expenditures, either of which could have a material adverse effect on us.

Until we can generate significant cash through either (i) the entrance into various potential strategic partnerships targeted at advancing and maximizing the Company's full pipeline for mTNBC and beyond, or (ii) the sales and marketing of sacituzumab govitecan as a third-line therapy for mTNBC We believe our projected financial resources are adequate to (i) accelerate commercial launch readiness, pending FDA approval, of sacituzumab govitecan in the United States in mTNBC, (ii) continue to expand the clinical development programs for developing sacituzumab govitecan in mTNBC, metastatic urothelial cancer ("mUC"), hormone receptor-positive ("HR+") / human epidermal growth factor receptor 2-negative ("HER2-") metastatic breast cancer ("mBC"), and other indications of high medical need, (iii) invest in the broader clinical development of the platform (including IMMU-130 and

IMMU-140), (iv) continued scale up of manufacturing and manufacturing process improvements, and (v) general working capital requirements. However, in case of regulatory delays or other unforeseen events, we may require additional funding. If, however, we cannot obtain sufficient funding through the entrance into various potential strategic partnerships targeted at advancing and maximizing the Company's full pipeline for mTNBC and beyond, we could be required to finance future cash needs through the sale of additional equity securities and/or the issuance of debt. However, there can be no assurance that we will be able to raise the additional capital needed to complete our pipeline of research and development programs on commercially acceptable terms, if at all. The capital markets have experienced volatility in recent years, which has resulted in uncertainty with respect to availability of capital and hence the timing to meet an entity's liquidity needs. The Company's existing debt will also negatively impact the Company's ability to raise additional capital. If the Company is unable to raise capital on acceptable terms, its ability to continue its business would be materially and adversely affected. Having insufficient funds may require us to delay, scale-back, or eliminate some or all of our programs, or renegotiate less favorable terms than we would otherwise choose. Failure to obtain adequate financing also may adversely affect our ability to operate as a going concern.

Additionally, if we raise funds by issuing equity securities, dilution to existing stockholders would result; and if we raise funds by incurring additional debt financing, the terms of the debt may involve future cash payment obligations and/or conversion to equity as well as restrictions that may limit our ability to operate our business.

***If we, or any of our collaboration partners, or our or their contract manufacturers, cannot successfully and efficiently manufacture the compounds that make up our products and product candidates, our ability, and the ability of our collaboration partners, to sell products and conduct clinical trials will be impaired.***

Our ability to conduct our preclinical and clinical research and development programs depends, in large part, upon our ability to manufacture our proprietary compounds in accordance with the FDA and other regulatory requirements. We have limited historical experience in manufacturing these compounds in significant quantities, and we may not be able to do so in the quantities required to commercialize these products. Any interruption in manufacturing across the supply chain, whether by natural disasters, global disease outbreaks such as COVID-19 (coronavirus) or otherwise, could significantly and adversely affect our operations, and delay our research and development programs.

We and our collaboration partners also depend on third parties to provide certain raw materials, and contract manufacturing and processing services. All manufacturers of biopharmaceutical products must comply with current cGMP standards, required by the FDA and other regulatory agencies. Such regulations address, among other matters, controls in manufacturing processes, quality control and quality assurance requirements and the maintenance of proper records and documentation. The FDA and other regulatory agencies routinely inspect manufacturing facilities, including in connection with the review of a BLA. The FDA generally will issue a notice on Form 483 if it finds issues with respect to its inspections, to which the facility must adequately respond in order to avoid escalated regulatory concerns. If our manufacturing facility or those facilities of our collaboration partners and our respective contract manufacturers or processors do not comply with applicable cGMP standards and other regulatory requirements, in addition to regulatory enforcement, we may be subject to product liability claims, we may be unable to meet clinical demand for our products, and we could suffer delays in the progress of clinical trials for products under development and of potential approval and commercialization.

***Although historically we have been a research and development company, we currently plan to commercialize our lead product candidate internally rather than license such asset. There can be no assurance that we will be successful in developing and expanding commercial operations or balancing our research and development activities with our commercialization activities.***

We have historically been engaged primarily in research and development activities, but plan to commercialize our lead product candidate, sacituzumab govitecan, ourselves. There can be no assurance that we will be able to successfully manage the balance of our research and development operations with our planned commercialization activities. Potential investors should be aware of the problems, delays, expenses and difficulties frequently encountered by companies balancing development of product candidates, which can include problems such as unanticipated issues relating to clinical trials and receipt of approvals from the FDA and foreign regulatory bodies, with commercialization efforts, which can include problems relating to managing manufacturing and supply, reimbursement, marketing problems and additional costs. Our product candidates will require significant additional research and clinical trials, and we will need to overcome significant regulatory burdens prior to commercialization in the United States and other countries. In addition, we may be required to spend significant funds on building out our commercial operations.

Factors that may impact our efforts to commercialize our current or future product candidates and generate product revenues include:

- the need to recruit, train, manage, and retain adequate numbers of effective sales and marketing personnel over a large geographic area;
- the costs and time associated with the initial and ongoing training of sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions;
- the clinical indications for which the products are approved and the claims that we may make for the products;
- limitations or warnings, including distribution or use restrictions, contained in the products' approved labeling;
- any distribution and use restrictions imposed by the FDA or to which we agree;
- understanding and training relevant personnel on the limitations on, and the transparency and reporting requirements applicable to, remuneration provided to actual and potential referral sources; and
- liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements.

Additionally, commercial products must now meet the requirements of the DSCSA, which imposes obligations on manufacturers of prescription drug products for commercial distribution, regulating the distribution of the products at the federal level, and sets certain standards for federal or state registration and compliance of entities in the supply chain (manufacturers and repackagers, wholesale distributors, third-party logistics providers, and dispensers). The DSCSA preempts previously enacted state pedigree laws and the pedigree requirements of the PDMA. Trading partners within the drug supply chain must now ensure certain product tracing requirements are met that they are doing business with other authorized trading partners; and they are required to exchange transaction information, transaction history, and transaction statements. Further, the DSCSA limits the distribution of prescription pharmaceutical products and imposes requirements to ensure overall accountability and security in the drug supply chain. Product identifier information (an aspect of the product tracing scheme) is also now required. The DSCSA requirements, development of standards, and the system for product tracing have been and will continue to be phased in over a period of years through 2023, and subject companies will need to continue their implementation efforts. The distribution of product samples continues to be regulated under the PDMA, and some states also impose regulations on drug sample distribution.

If we are unable to develop commercially viable therapeutic products, certain obligations the Company has to third parties, including, without limitation, our obligation to pay RPI royalties on certain sacituzumab govitecan revenues pursuant to the funding agreement may also erode profitability of this product. There can be no assurance that after the expenditure of substantial funds and efforts, we will successfully develop and commercialize any of our product candidates, generate any significant revenues or ever achieve and maintain a substantial level of sales of our products.

***We may not successfully establish and maintain collaborative and licensing arrangements, which could adversely affect our ability to develop and commercialize certain of our product candidates. Any of our collaboration partners may not adequately perform their responsibilities under our agreements, which could adversely affect our development and commercialization program.***

A key element of our business strategy has been to develop, market and commercialize our product candidates through collaborations with more established pharmaceutical companies, including, but not limited to, our collaborations with Everest, Clovis, Roche and AstraZeneca. To the extent we continue to rely on this business strategy, we may not be able to maintain or expand these licenses and collaborations or establish additional licensing and collaboration arrangements necessary to develop and commercialize any of our product candidates. Even if we are able to maintain or establish licensing or collaboration arrangements, these arrangements may not be on favorable terms and may contain provisions that will restrict our ability to develop, test and market our product candidates. Any failure to maintain or establish licensing or collaboration arrangements on favorable terms could adversely affect our business prospects, financial condition or ability to develop and commercialize our product candidates.

We expect to rely at least in part on third party collaborators to perform a number of activities relating to the development and commercialization of certain of our product candidates, including the manufacturing of product materials, the design and conduct of clinical trials for certain of our product candidates, and potentially the obtaining of regulatory approvals and marketing and distribution of any successfully developed products. Our collaborative partners may also have or acquire rights to control aspects of our product development and clinical programs. As a result, we may not be able to conduct these programs in the manner or on the time schedule we currently contemplate. In addition, if any of these collaborative partners withdraw support for our programs or product candidates or otherwise impair their development, our business could be negatively affected. Our expenses may also increase as a result of our plan to undertake these activities internally to commercialize sacituzumab govitecan.

In addition, our success depends on the performance of our collaborators of their responsibilities under these arrangements. Some potential collaborators may not perform their obligations in a timely fashion or in a manner satisfactory to us. Because such agreements may be exclusive, we may not be able to enter into a collaboration agreement with any other company covering the same product field during the applicable collaborative period. In addition, our collaborators' competitors may not wish to do business with us at all due to our relationship with our collaborators. If we are unable to enter into additional product discovery and development collaborations, our ability to sustain or expand our business will be significantly diminished.

***Our future success will depend upon our ability to first obtain and then adequately protect our patent and other intellectual property rights, as well as avoiding the infringement of the rights of others.***

Our future success will be highly dependent upon our ability to first obtain and then defend the patent and other intellectual property rights necessary for the commercialization of our product candidates. We have filed numerous patent applications on the technologies and processes that we use in the United States and certain foreign countries. Although we have obtained a number of issued United States patents to date, the patent applications owned or licensed by us may not result in additional patents being issued. Moreover, these patents may not afford us the protection we need against competitors with similar technologies or products. A number of jurisdictions where we have sought, or may in the future choose to seek, intellectual property protection, have intellectual property laws and patent offices which are still developing. Accordingly, we may have difficulty obtaining intellectual property protection in these markets, and any intellectual property protections which we do obtain may be less protective than in the United States, which could have an adverse effect on our operations and financial prospects.

The successful development of therapeutic products frequently requires the application of multiple technologies that may be subject to the patent or other intellectual property rights of third parties. Although we believe it is likely we will need to license technologies and processes from third parties in the ordinary course of our business, we are not currently aware of any material conflict involving our technologies and processes with any valid patents or other intellectual property rights owned or licensed by others that would affect commercial sales of sacituzumab govitecan or other products starting in 2020. In the event that a third party was to claim such a conflict existed, they could sue us for damages as well as seek to prevent us from commercializing our product candidates. It is possible that a third party could successfully claim that our products infringe on their intellectual property rights. Uncertainties resulting from the litigation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Any patent litigation or other proceeding, even if resolved in our favor, would require significant financial resources and management time.

Some of our competitors may be able to sustain these costs more effectively than we can because of their substantially greater financial and managerial resources. If a patent litigation or other proceeding is resolved unfavorably to us, we may be enjoined from manufacturing or selling our products without a license from the other party, in addition to being held liable for significant damages. We may not be able to obtain any such license on commercially acceptable terms, if at all.

In addition to our reliance on patents, we attempt to protect our proprietary technologies and processes by relying on trade secret laws, nondisclosure and confidentiality agreements and licensing arrangements with our employees and other persons who have access to our proprietary information. These agreements and arrangements may not provide meaningful protection for our proprietary technologies and processes in the event of unauthorized use or disclosure of such information. In addition, our competitors may independently develop substantially equivalent technologies and processes or otherwise gain access to our trade secrets or technology, either of which could materially and adversely affect our competitive position.

***Expiry of our intellectual property rights could lead to increased competition.***

Even where we are able to obtain and then defend patent and other intellectual property rights necessary for research, development and commercialization of our product candidates, such intellectual property rights will be for a limited term. Where patents which we own or license expire, the technology comprising the subject of the patent may be utilized by third parties in research and development or competing products (for example, biosimilars of a patented product may be manufactured by third parties once the patent expires). While we endeavor to maintain robust intellectual property protection, as our existing issued patents expire, it may materially and adversely affect our competitive position.

***We face substantial competition in the biotechnology industry and may not be able to compete successfully against one or more of our competitors.***

The biotechnology industry is highly competitive, particularly in the area of therapeutic oncology products. In recent years, there have been extensive technological innovations achieved in short periods of time, and it is possible that future technological changes and discoveries by others could result in our products and product candidates quickly becoming uncompetitive or obsolete. A number of companies, including ADC Therapeutics, AbbVie, Astellas Pharma, AstraZeneca, Bristol-



Myers Squibb, Daiichi Sankyo, GlaxoSmithKline, Immunogen, Merck, Novartis, Pfizer, Roche, Sanofi, Seattle Genetics, and Zyme Works, are engaged in the development of therapeutic ADC and/or oncology products. Many of these companies have significantly greater financial, technical and marketing resources than we do. In addition, many of these companies have more established positions in the pharmaceutical industry and are therefore better equipped to develop, commercialize and market oncology products. Even some smaller competitors may obtain a significant competitive advantage over us if they are able to discover or otherwise acquire patentable inventions, form collaborative arrangements or merge with larger pharmaceutical companies. Further, even if we are able to successfully develop and commercialize products, other manufacturers operating in emerging markets may also have a competitive advantage over us with respect to competing products due to their ability to manufacture with a lower cost base.

We expect to face increasing competition from universities and other non-profit research organizations. These institutions carry out a significant amount of research and development in the field of antibody-based technologies and they are increasingly aware of the commercial value of their findings. As a result, they are demanding greater patent and other proprietary rights, as well as licensing and future royalty revenues. It is possible that such competition could come from universities with which we have, or have previously had, collaborative research and development relationships, notwithstanding our efforts to protect our intellectual property in the course of such relationships.

***We may be liable for contamination or other harm caused by hazardous materials that we use in the operations of our business.***

In addition to laws and regulations enforced by the FDA, we are also subject to regulation under various other foreign, federal, state and local laws and regulations. Our manufacturing and research and development programs involve the controlled use of viruses, hazardous materials, chemicals and various radioactive compounds. The risk of accidental contamination or injury from these materials can never be completely eliminated, and if an accident occurs we could be held liable for any damages that result, which could exceed our available resources.

***The nature of our business exposes us to significant liability claims, and our insurance coverage may not be adequate to cover any future claims.***

The use of our compounds in clinical trials and any future sale exposes us to liability claims that could be substantial. These claims might be made directly by healthcare providers, medical personnel, patients, consumers, pharmaceutical companies, and others selling or distributing our compounds. While we currently have product liability insurance that we consider adequate for our current needs, we may not be able to continue to obtain comparable insurance in the future at an acceptable cost, if at all. If for any reason we cannot maintain our existing or comparable liability insurance, our ability to clinically test and market products could be significantly impaired. Moreover, the amount and scope of our insurance coverage, as well as the indemnification arrangements with third parties upon which we rely, may be inadequate to protect us in the event of a successful product liability claim. Any successful claim in excess of our insurance coverage could materially and adversely affect our financial condition and operating results.

***Certain potential for conflicts of interest, both real and perceived, exist which could result in expensive and time-consuming litigation.***

Certain of our former officers and directors have relationships and agreements, both with us as well as among themselves and their respective affiliates, which create the potential for both real, as well as perceived, conflicts of interest. These include Dr. David M. Goldenberg, our former Chairman of our Board of Directors, our former Chief Scientific Officer and our former Chief Patent Officer, and Ms. Cynthia L. Sullivan, a former Director and our former President and Chief Executive Officer (who is also the wife of Dr. Goldenberg). Dr. Goldenberg is also a minority stockholder of our majority-owned subsidiary, IBC. Dr. Goldenberg was the primary inventor of new intellectual property for Immunomedics and IBC and was largely responsible for allocating ownership between the two companies. Immunomedics has incurred expenses on behalf of the IBC operations, including interest, over the past fifteen years. As of December 31, 2019, IBC has a liability to Immunomedics Inc. which is eliminated in consolidation.

On January 8, 2018, Morris Rosenberg joined the Company as Chief Technology Officer and became a full-time employee and was permitted to continue to provide certain limited outside consulting services through M Rosenberg BioPharma Consulting LLC.

On March 5, 2019, we entered into a Letter Agreement with Scott Canute, a member of our Board of Directors, in connection with his appointment as Executive Director of the Company.



On November 19, 2019, pursuant to the Plan, the Board of Directors approved a stock option grant to Behzad Aghazadeh, Executive Chairman of the Board of Directors of the Company, to purchase 150,000 shares of the Company's common stock (the "Performance-Based Option") for certain duties performing this role; including providing consulting and advisory services to the Company. The Performance-Based Option will be a nonqualified stock option and one third vested upon FDA acceptance of the BLA resubmission, and two thirds shall vest upon approval from the FDA for the Company's BLA for sacituzumab govitecan.

As a result of these and other relationships, the potential for both real and perceived conflicts of interest exist and disputes could arise over the allocation of funds, research projects and ownership of intellectual property rights. In addition, in the event that we become involved in stockholder litigation regarding these potential conflicts, we might be required to devote significant resources and management time defending the Company from these claims, which could adversely affect our results of operations.

***The commercial success of our product candidates depends on the availability and sufficiency of third-party payor coverage and reimbursement. Given that recent cancer therapeutics for solid cancers such as the ones we are developing can cost approximately in the range of \$13,000 to \$30,000 a month, even if our product candidates become available for sale it is likely that federal and state governments, insurance companies and other payors of health care costs will try to first limit the use of these drugs to certain patients, and may be reluctant to provide a level of reimbursement that permits us to earn a significant profit on our investment, if any.***

Our ability to successfully commercialize therapeutic products will depend, in significant part, on the extent to which hospitals and physicians can obtain appropriate reimbursement levels for the cost of our products and related treatment. Third-party payors are increasingly challenging the prices charged for diagnostic and therapeutic products and related services. Many commercial payors employ "new-to-market blocks" for newly launched medications and other products until the payors have the opportunity to make a coverage decision based upon their internal review of such products. When a medication or other product is not covered, the patient is responsible to pay the full price, which can significantly limit utilization. In addition, legislative proposals to reform health care or reduce government insurance programs may result in lower prices or the actual inability of prospective customers to purchase our products. Furthermore, even if reimbursement is available, it may not be available at price levels sufficient for us to realize a positive return on our investment.

The United States government, state legislatures and foreign governmental entities have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and coverage and requirements for substitution of generic products for branded prescription drugs. Adoption of government controls and measures and tightening of restrictive policies in jurisdictions with existing controls and measures, could exclude or limit our product candidates from coverage and limit payments for pharmaceuticals. We continue to monitor the potential impact of proposals to lower prescription drug costs at the federal and state level. For example, on May 11, 2018, President Trump laid out his administration's "Blueprint" to lower drug prices and reduce out of pocket costs of drugs, as well as additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, and incentivize manufacturers to lower the list price of their products. Although some proposals related to the administration's Blueprint require additional authorization to become effective, may ultimately be withdrawn, or may face challenges in the courts, the U.S. Congress and the Trump administration have indicated that they will continue to seek new legislative and administrative measures to control drug costs. Drug pricing remains a key bipartisan issue and drug pricing legislation has been introduced in both the Senate and the House. The Senate Finance Committee released "The Prescription Drug Pricing Reduction Act of 2019" in late July 2019 which includes changes to Medicare and Medicaid drug pricing and targets certain pharmacy benefit manager ("PBM") and pharmaceutical manufacturer pricing practices such as: (i) revisions to Medicare Part D benefit design and capping beneficiary out-of-pocket costs at \$3,100; (ii) an inflationary rebate policy that would require pharmaceutical manufacturers to pay rebates when the price of their drug or biologic increases faster than inflation; (iii) manufacturer reporting requirement to HHS for certain drug price increases; and (iv) PGM transparency requirements and a ban on spread pricing in Medicaid. In December 2019, the House passed a drug pricing bill, "Lower Drug Costs Now Act of 2019), which features Medicare Parts B and D direct negotiation with manufacturers, inflationary rebates and a restructuring of the Part D benefit. Direct price negotiations would occur for at least 50 of the most costly drugs to Medicare and would target drugs without a comparable generic or biosimilar on the market. Negotiated prices under the House bill could be used by any payor, both governmental and commercial. Republicans in both chambers have opposed the drug pricing bills but the Trump administration has expressed support for the Senate bill and continues to push for drug pricing controls. If drug pricing reform is not meaningfully addressed before the 2020 election, policies to be pursued in the future may be more aggressive, regardless of which party controls the White House.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

In addition, we expect that increased emphasis on managed care and cost containment measures in the United States by third-party payors and government authorities to continue and will place pressure on pharmaceutical pricing and coverage. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

If we are unable to obtain and maintain sufficient third-party coverage and adequate reimbursement for our product candidates, the commercial success of our product candidates may be greatly hindered, and our financial condition and results of operations may be materially and adversely affected.

***Our products may not achieve market acceptance.***

If any of our product candidates fail to achieve sufficient market acceptance, we may not be able to generate sufficient revenue to become profitable. The degree of market acceptance of our product candidates, if and when they are approved for commercial sale, will depend on a number of factors, including but not limited to:

- the timing of our receipt of marketing approvals, the terms of such approvals and the countries in which such approvals are obtained;
- the safety, efficacy, reliability and ease of administration of our product candidates;
- the prevalence and severity of undesirable side effects and adverse events;
- the extent of the limitations or warnings required by the FDA or comparable regulatory authorities in other countries to be contained in the labeling of our product candidates;
- the clinical indications for which our product candidates are approved;
- the availability and perceived advantages of alternative therapies;
- any publicity related to our product candidates or those of our competitors;
- the quality and price of competing products;
- our ability to obtain third-party payor coverage and sufficient reimbursement;
- the willingness of patients to pay out of pocket in the absence of third-party payor coverage; and
- the selling efforts and commitment of our commercialization collaborators.

If our approved product candidates fail to receive a sufficient level of market acceptance, our ability to generate revenue from sales of our product candidates will be limited, and our business and results of operations may be materially and adversely affected.

***A portion of our funding has come from federal government grants and research contracts. Due to reductions in funding, we may not be able to rely on these grants or contracts as a continuing source of funds.***

During the last few years, we have generated revenues from awards made to us by the National Institutes of Health and the Department of Defense to partially fund some of our programs. We cannot rely on grants or additional contracts as a continuing source of funds. Funds available under these grants and contracts must be applied by us toward the research and development programs specified by the government rather than for all our programs generally. The government's obligation to make payments under these grants and contracts is subject to appropriation by the United States Congress for funding in each year. It is possible that Congress or the government agencies that administer these government research programs will continue to scale back these programs or terminate them due to their own budgetary constraints, as they have recently been doing. Additionally, these grants and research contracts are subject to adjustment based upon the results of periodic audits performed on behalf of the granting authority. Consequently, the government may not award grants or research contracts to us in the future, and any amounts that we derive from existing awards may be less than those received to date. In those circumstances, we would need to provide funding on our own, obtain other funding, or scale back or terminate the affected program. In particular, we cannot assure you that any

currently-contemplated or future efforts to obtain funding for our product candidate programs through government grants or contracts will be successful, or that any such arrangements which we do conclude will supply us with sufficient funds to complete our development programs without providing additional funding on our own or obtaining other funding. Where funding is obtained from government agencies or research bodies, our intellectual property rights in the research or technology funded by the grant are typically subject to certain licenses to such agencies or bodies, which could have an impact on our utilization of such intellectual property in the future.

***We face a number of risks relating to the maintenance of our information systems and our use of information relating to clinical trials.***

In managing our operations, we rely on computer systems and electronic communications, including systems relating to record keeping, financial information, sourcing, and back-up and the Internet ("Information Systems"). Our Information Systems include the electronic storage of financial, operational, research, patient and other data. Our Information Systems may be subject to interruption or damage from a variety of causes, including power outages, computer and communications failures, system capacity constraints, catastrophic events (such as fires, tornadoes and other natural disasters), cyber risks, computer viruses and security breaches. If our Information Systems cease to function properly, are damaged or are subject to unauthorized access, we may suffer interruptions in our operations, be required to make significant investments to fix or replace systems and/or be subject to fines, penalties, lawsuits, or government action. The realization of any of these risks could have a material adverse effect on our business, financial condition and results of operations. Our clinical trials information and patient data (which may include personally identifiable information) is part of our Information Systems and is therefore subject to all of the risks set forth above, notwithstanding our efforts to code and protect such information.

## **Risks Related to Government Regulation of Our Industry**

***Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably.***

In recent years, there have been numerous initiatives on the federal and state levels in the United States for comprehensive reforms affecting the payment for, the availability of, and reimbursement for, healthcare services. As discussed above, there have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States. For example, the Patient Protection and Affordable Care Act ("ACA") and the Health Care and Education Reconciliation Act of 2010, which amends the ACA, collectively, the United States Health Reform Laws, were signed into law in the United States in March 2010.

Among the provisions of the ACA of importance to the pharmaceutical industry are the following:

- the Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition of Medicare Part B and Medicaid coverage of the manufacturer's outpatient drugs furnished to Medicaid patients. Effective in 2010, the ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP, establishing new methodologies by which AMP is calculated and rebates owed by manufacturers under the Medicaid Drug Rebate Program are collected for drugs that are inhaled, infused, instilled, implanted or injected, adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, expanding the universe of Medicaid utilization subject to drug rebates to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, and expanding the population potentially eligible for Medicaid drug benefits;
- the expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in April 2010 and by adding new mandatory eligibility categories for certain individuals with income at or below 133.0% of the federal poverty level beginning in 2014, thereby potentially increasing both the volume of sales and manufacturers' Medicaid rebate liability;
- in order for a pharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to United States government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. Effective in 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs

when used for the orphan indication. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase. Proposed guidance from the United States Department of Health and Human Services Health Resources and Services Administration, if adopted in its current form, may affect manufacturers' rights and liabilities in conducting audits and resolving disputes under the 340B program;

- the ACA imposed a requirement on manufacturers of branded drugs to provide a 50%, which increased to 70% on January 1, 2019, discount off the negotiated price of branded drugs dispensed to Medicare Part D patients in the coverage gap (i.e., the "donut hole");
- the ACA imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications;
- the ACA implemented the Physician Payments Sunshine Act;
- the ACA requires annual reporting of drug samples that manufacturers and distributors provide to physicians;
- the ACA expanded healthcare fraud and abuse laws in the United States, including the False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance;
- the ACA established a licensing framework for follow-on biologics;
- the ACA established the Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with the funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products by influencing decisions relating to coverage and reimbursement rates; and
- the ACA established the Center for Medicare & Medicaid Innovation within the Centers for Medicare & Medicaid Services ("Innovation Center"), to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. The Innovation Center was funded through 2019, and funding will be automatically renewed for each 10-year budget window thereafter.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 ("TCJA"), includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. Congress may consider additional legislation to repeal or repeal and replace other elements of the ACA. On December 14, 2018, the U.S. District Court for the Northern District of Texas struck down the ACA in *Texas v. Azar*, deeming it unconstitutional given that Congress repealed the individual mandate in 2017; on July 9, 2019, the U.S. Court of Appeals for the Fifth Circuit heard arguments on appeal in this matter. On December 18, 2019, the Fifth Circuit ruled that the ACA's individual mandate is unconstitutional. In concluding that the individual mandate is unconstitutional, the question remains whether, or how much of, the rest of the ACA is severable from that constitutional defect. The Fifth Circuit further remanded the case to the U.S. District Court for the Northern District of Texas to further analyze whether the other provisions of the ACA are severable as they currently exist under the law. It is unclear how the eventual decision from this appeal, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.



In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2.0% per fiscal year, which went into effect in 2013, and due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. In January 2013, then-President Barack Obama signed into law the American Taxpayer Relief Act of 2012 ("ATRA"), which, among other things, delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. The ATRA also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover over-payments to providers from three to five years. Moreover, CMS has promulgated or amended a number of cost containment and value based reimbursement measures in the ordinary course of business, and it is expected to continue revising its regulations and policies in response to market conditions and administration directives. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material and adverse effect on our customers and accordingly, our financial operations.

Further, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent United States Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

In addition, there have been a number of other policy, legislative, and regulatory proposals aimed at changing the pharmaceutical industry. For instance, on May 11, 2018, President Trump laid out his administration's "Blueprint" to lower drug prices and reduce out of pocket costs of drugs, as well as additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, and incentivize manufacturers to lower the list price of their products. Although some proposals related to the administration's Blueprint may require additional authorization to become effective, may ultimately be withdrawn, or may face challenges in the courts, the U.S. Congress and the Trump administration have indicated that they will continue to seek new legislative and administrative measures to control drug costs, including by addressing the role of pharmacy benefit managers in the supply chain.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The ACA and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations.

On May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or Right to Try Act, was signed into law. The law, among other things, provides a federal framework for patients to access certain investigational new product candidates that have completed a Phase I clinical trial. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA approval under the FDA expanded access program. The Right to Try Act did not establish any new entitlement or positive right to any party or individual, nor did it create any new mandates, directives, or additional regulations requiring a manufacturer or sponsor of an eligible investigational new product candidates to provide expanded access.

We are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The United States Health Reform Laws and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations.

***Healthcare laws and regulations may affect the pricing of our product candidates and may affect our profitability.***

In certain countries, the government may provide healthcare at a subsidized cost to consumers and regulate prices, patient eligibility or third-party payor reimbursement policies to control the cost of product candidates. Such a system may lead to inconsistent pricing of our product candidates from one country to another. The availability of our product candidates at lower prices in certain countries may undermine our sales in other countries where our product candidates are more expensive. In addition, certain countries may set prices by reference to the prices of our product candidates in other countries. Our inability to secure



adequate prices in a particular country may adversely affect our ability to obtain an acceptable price for our product candidates in existing and potential markets. If we are unable to obtain a price for our product candidates that provides an appropriate return on our investment, our profitability may be materially and adversely affected.

***Our industry and we are subject to intense regulation from the United States Government and other governments and quasi-official authorities regulating where our products are and product candidates may be sold.***

Both before and after regulatory approval to market a particular product candidate, including our biologic product candidates, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and record keeping related to the product are subject to extensive, ongoing regulatory requirements, including, without limitation, submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP requirements and good clinical practice requirements for any clinical trials that we conduct post-approval. As a result, we are subject to a number of governmental and other regulatory risks, which include:

- clinical development is a long, expensive and uncertain process; delay and failure can occur at any stage of our clinical trials;
- our clinical trials are dependent on patient enrollment and regulatory approvals; we do not know whether our planned trials will begin on time, or at all, or will be completed on schedule, or at all;
- the FDA or other regulatory authorities may not approve a clinical trial protocol or may place a clinical trial on hold;
- we rely on third parties, such as consultants, contract research organizations, medical institutions, and clinical investigators, to conduct clinical trials for our drug candidates and if we or any of our third-party contractors fail to comply with applicable regulatory requirements, such as cGCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials;
- if the clinical development process is completed successfully, our ability to derive revenues from the sale of therapeutics will depend on our first obtaining FDA or other comparable foreign regulatory approvals, each of which is subject to unique risks and uncertainties;
- there is no assurance that we will receive FDA or corollary foreign approval for any of our product candidates for any indication; we are subject to government regulation for the commercialization of our product candidates;
- we have not received regulatory approval in the United States for the commercial sale of any of our biologic product candidates;
- even if one or more of our product candidates does obtain approval, regulatory authorities may approve such product candidate 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 with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate;
- undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities;
- later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with the regulatory requirements of FDA and other applicable United States and foreign regulatory authorities could subject us to administrative or judicially imposed sanctions;
- although several of our product candidates have received orphan drug designation in the United States and the European Union ("EU"), for particular indications, we may not receive orphan drug exclusivity for any or all of those product candidates or indications upon approval, and even if we do obtain orphan drug exclusivity, that exclusivity may not effectively protect the product from competition; and

- even if one or more of our product candidates is approved in the United States, it may not obtain the 12 years of exclusivity from biosimilars for which innovator biologics are eligible, and even if it does obtain such exclusivity, that exclusivity may not effectively protect the product from competition; the FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates, and if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained; and we may be liable for contamination or other harm caused by hazardous materials used in the operations of our business.

Healthcare providers, physicians and third-party payors often play a primary role in the recommendation and prescription of any currently marketed products and product candidates for which we may obtain marketing approval. Our current and future arrangements with healthcare providers, physicians, third-party payors and customers, and our sales, marketing and educational activities, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations (at the federal and state level) that may constrain our business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. In addition, our operations are also subject to various federal and state fraud and abuse, physician payment transparency and privacy and security laws, including, without limitation:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons and entities including pharmaceutical manufacturers from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, overtly or covertly, in case or in kind, to induce or reward, or in return for, or either the referral of an individual for, or the purchase, lease, order or recommendation of, an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare or Medicaid programs. This statute has interpreted broadly to apply to, among other things, arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. The term "remuneration" expressly includes kickbacks, bribes or rebates and also has been broadly interpreted to include anything of value, including, for example, gifts, discounts, waivers of payment, ownership interest and providing anything at less than its fair market value. There are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, however, the exceptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exception or safe harbor may be subject to scrutiny. The failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not meet all of the criteria for safe harbor protection from federal Anti-Kickback Statute liability in all cases. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. In addition, the ACA codified case law supporting that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.
- Federal enforcement agencies and private whistleblowers recently have shown interest in pharmaceutical companies' product and patient assistance programs (PAPs), including reimbursement support, co-pay support, nursing, adherence and educational services, referrals to other providers, donations to independent patient assistance charities, and relationships with specialty pharmacies. Co-pay assistance programs are intended to assist qualified patients with private insurance with any out-of-pocket financial obligations but must exclude any government healthcare program beneficiaries. Several investigations into patient assistance practices have resulted in significant civil and criminal settlements. Recently, the HHS-Office of the Inspector General has released several industry guidance documents, special bulletins, and advisory opinions addressing PAPs. Failure to implement certain measures and safeguards may be found by government agencies to courts to be evidence of intent to induce the purchase of drugs paid for by federal programs, in violations of the Anti-Kickback Statute. PAPs have also been the subject of recent Congressional review.
- The federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment to, or approval by, the federal government that are false, fictitious or fraudulent or knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the federal government. Although we do not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers, promoting a product off-label, marketing products of sub-standard quality, or, as noted above, paying a kickback that results in a claim for items or services in violation of the Anti-Kickback Statute. In addition, our activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products,

and the sale and marketing of our products, are subject to scrutiny under this law. For example, several pharmaceutical and other healthcare companies have faced enforcement actions under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. The False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery. In addition, certain marketing practices, including off-label promotion, may also implicate the False Claims Act. Although the False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes.

- The Federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, including the Final Omnibus Rule published on January 25, 2013, impose, among other things, obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information held by certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, and business associates. Among other things, HITECH made certain aspects of HIPAA's rules (notably the Security Rule) directly applicable to business associates - independent contractors or agents of covered entities that receive or obtain individually identifiable health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal court to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. The Department of Health and Human Services Office of Civil Rights ("OCR"), has increased its focus on compliance and continues to train state attorneys general for enforcement purposes. The OCR has recently increased both its efforts to audit HIPAA compliance and its level of enforcement, with one recent penalty exceeding \$5 million.
- The federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act," created under the United States Patient Protection and Affordable Care Act of 2010, as amended, or the ACA, and its implementing regulations, which requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program (with certain exceptions) to annually report to the United States Department of Health and Human Services ("HHS"), information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. In 2022, the Sunshine Act will be extended to payments and transfers of value to physician assistants, nurse practitioners, and other mid-level practitioners (with reporting requirements going into effect in 2022 for payments made in 2021). In addition, Section 6004 of the ACA requires annual reporting of information about drug samples that manufacturers and authorized distributors provide to healthcare providers.
- On October 25, 2018, President Trump signed into law the "Substance Use-Disorder Prevention that Promoted Opioid Recovery and Treatment for Patients and Communities Act." This law, in part (under a provision entitled "Fighting the Opioid Epidemic with Sunshine"), will extend the Sunshine Act to payments and transfers of value to physician assistants, nurse practitioners, and other mid-level healthcare providers (with reporting requirements going into effect in 2022 for payments made in 2021).
- According to the United States Federal Trade Commission ("FTC"), failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA, 15 USC § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers'

personal information is similar to what is required by the HIPAA Security Rule.

- To the extent we obtain coverage for our products by state Medicaid programs, we may be required to pay a rebate to each state Medicaid program for any covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program, and to comply with all Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Healthcare Act of 1992. Moreover, federal law requires that any company participating in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B Program, which impose additional reporting requirements and price concessions. Manufacturer compliance with 340B Program requirements can be costly. In addition, if our products are made available to authorized users of the Federal Supply Schedule of the General Services Administration or to low income patients of certain hospitals, additional laws and requirements may apply.
- Analogous state laws and regulations, such as state anti-kickback and false claims laws, and other states laws addressing the pharmaceutical and healthcare industries, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and in some cases that may apply regardless of payor, i.e., even if reimbursement is not available; some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines (the PhRMA Code) and the relevant compliance program guidance promulgated by the federal government (HHS-OIG) in addition to requiring drug manufacturers to report pricing and marketing information, including, among other things, information related to gifts, payments, or other remuneration to physicians and other healthcare providers, state and local laws that require the registration of pharmaceutical sales representatives, and state laws governing the privacy and security of health information and the use of prescriber-identifiable data in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. For example, California enacted legislation - the California Consumer Privacy Act ("CCPA") - which goes into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. The California Attorney General will issue clarifying regulations. Although the law includes limited exceptions, including for certain information collected as part of clinical trials as specified in the law and for protected health information collected by covered entities or business associates subject to HIPAA as specified in the law, it may regulate or impact our processing of personal information depending on the context. It remains unclear what language the final Attorney General regulations will contain or how the statute and regulations will be interpreted.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, it is possible that certain business activities could be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that business arrangements with third parties comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert management's attention from the business.

If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in government healthcare programs, injunctions, private qui tam actions brought by individual whistleblowers in the name of the government and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our results of operations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business, and damage our reputation.

Many aspects of these laws have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of subjective interpretations that increases the risk of potential violations. In addition, these laws and their interpretations are subject to change. In addition, from time to time in the future, we may become subject to additional laws or regulations administered by the FDA, the FTC, HHS, or by other federal, state, local, or foreign regulatory authorities, or the repeal of laws or regulations that we generally consider favorable, or to more stringent interpretations of current laws or regulations. We are not able to predict the nature of such future laws, regulations, repeals, or interpretations, and we cannot predict what effect additional governmental regulation, if and when it occurs, would have on our business in the future.



***Our failure to comply with foreign data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.***

EU member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. Moreover, the collection and use of personal health data in the EU, which was formerly governed by the provisions of the European Union Data Protection Directive, was replaced with the European Union General Data Protection Regulation ("GDPR"), in May 2018. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EU to the United States, provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the non-compliant company, whichever is greater. The recent implementation of the GDPR has increased our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may in the future be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EU and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

***Our employees and our independent contractors, principal investigators, consultants or commercial collaborators, as well as their respective sub-contractors, if any, may engage in misconduct or fail to comply with certain regulatory standards and requirements, which could expose us to liability and adversely affect our reputation.***

Our employees and our independent contractors, principal investigators, consultants or commercial collaborators, as well as their respective sub-contractors, if any, may engage in fraudulent conduct or other illegal activity, which may include intentional, reckless or negligent conduct that violates, among others, (a) FDA laws and regulations, or those of comparable regulatory authorities in other countries, including those laws that require the reporting of true, complete and accurate information to the FDA, (b) manufacturing standards, (c) healthcare fraud and abuse laws (d) anti-bribery and anti-corruption laws, including the FCPA, or (e) laws that require the true, complete and accurate reporting of financial information or data. For example, such persons may improperly use or misrepresent information obtained in the course of our clinical trials, create fraudulent data in our preclinical studies or clinical trials or misappropriate our drug products, which could result in regulatory sanctions being imposed on us and cause serious harm to our reputation. It is not always possible for us to identify or deter misconduct by our employees and third parties, and any precautions we may take to detect or prevent such misconduct may not be effective. Any misconduct or failure by our employees and our independent contractors, principal investigators, consultants or commercial collaborators, as well as their respective sub-contractors, if any, to comply with the applicable laws or regulations may expose us to governmental investigations, other regulatory action or lawsuits. If any action is instituted against us as a result of the alleged misconduct of our employees or other third parties, regardless of the final outcome, our reputation may be adversely affected, and our business may suffer as a result. If we are unsuccessful in defending against any such action, we may also be liable to significant fines or other sanctions, which could have a material and adverse effect on us.

***Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including from December 22, 2018 until January 25, 2019, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company,



future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

## **Risks Related to Our Securities**

### ***Our indebtedness and debt service obligations may adversely affect our cash flow.***

We intend to fulfill our current debt service obligations, including repayment of the principal from our existing cash and investments, as well as the proceeds from potential licensing agreements and any additional financing from equity or debt transactions. However, our ability to make scheduled payments of the principal of, to pay interest on, or to refinance, our indebtedness, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow to meet these obligations, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive, or delaying or curtailing research and development programs. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

### ***We may add lease lines to finance capital expenditures and may obtain additional long-term debt and lines of credit. If we issue other debt securities in the future, our debt service obligations will increase further.***

Our indebtedness could have significant additional negative consequences, including, but not limited to:

- requiring the dedication of a substantial portion of our existing cash and marketable securities balances and, if available, future cash flow from operations to service our indebtedness, thereby reducing the amount of our expected cash flow available for other purposes, including capital expenditures;
- increasing our vulnerability to general adverse economic and industry conditions;
- limiting our ability to obtain additional financing;
- limiting our ability to sell assets if deemed necessary;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a possible competitive disadvantage to less leveraged competitors and competitors that have better access to capital resources.

### ***Shares eligible for future sale may adversely affect our ability to sell equity securities.***

Sales of our common stock (including the issuance of shares upon conversion of convertible debt) in the public market could materially and adversely affect the market price of shares. As of December 31, 2019 we had 212,529,313 shares of common stock issued, plus (1) outstanding options to purchase 5,900,099 shares of common stock with a weighted-average exercise price of \$16.54 per share, (2) 58,002 outstanding restricted stock units held by certain directors of the Company, (3) 836,769 outstanding performance stock options held by certain executive officers and employees of the Company, (4) 4,588,632 shares of common stock reserved for potential future grant under the Plan, and (5) \$7.1 million of principal amount of Convertible Senior Notes convertible into approximately 1,393,160 shares of common stock at the conversion rate of \$5.11 subject to adjustment as described in the indenture. Of the 250,000,000 shares of common stock authorized under our Certificate of Incorporation, there are 24,694,025 shares of common stock that remain available for future issuance.

### ***Our outstanding options may adversely affect our ability to consummate future equity-based financings due to the dilution potential to future investors.***

Due to the number of shares of common stock we are obligated to issue pursuant to outstanding options, potential investors may not purchase our future equity offerings at market price because of the potential dilution such investors may suffer as a result of the exercise of the outstanding options.

### ***The market price of our common stock has fluctuated widely in the past and is likely to continue to fluctuate widely based on a number of factors, many of which are beyond our control.***

The market price of our common stock has been, and is likely to continue to be, highly volatile. Furthermore, the stock market and the market for stocks of comparable biopharmaceutical companies like ours have from time to time experienced, and likely will again experience, significant price and volume fluctuations that are unrelated to actual operating performance.

From time to time, stock market analysts publish research reports or otherwise comment upon our business and future prospects. Due to a number of factors, we may fail to meet the expectations of securities analysts or investors and our stock price would likely decline as a result. These factors include:

- Announcements by us, any collaboration partners, any future alliance partners or our competitors of pre-clinical studies and clinical trial results, regulatory developments, technological innovations or new therapeutic products, product sales, new products or product candidates and product development timelines;
- The formation or termination of corporate alliances;
- Developments in patent or other proprietary rights by us or our respective competitors, including litigation;
- Developments or disputes concerning our patent or other proprietary rights, and the issuance of patents in our field of business to others;
- Government regulatory action;
- Period-to-period fluctuations in the results of our operations; and
- Developments and market conditions for emerging growth companies and biopharmaceutical companies, in general.

In addition, Internet “chat rooms” have provided forums where investors make predictions about our business and prospects, oftentimes without any real basis in fact, that readers may trade on.

In the past, following periods of volatility in the market prices of the securities of companies in our industry, securities class action litigation has often been instituted against those companies. Refer to “Legal Proceedings” for more information. If we face such litigation in the future, it would result in substantial costs and a diversion of management’s attention and resources, which could negatively impact our business.

***Our principal stockholders can significantly influence all matters requiring the approval by our stockholders.***

As of December 31, 2019, Avoro Capital Advisors LLC, (“Avoro”) is the beneficial owner of approximately 11.5% of our outstanding common stock. Avoro is our largest stockholder, and Dr. Behzad Aghazadeh, the portfolio manager and controlling person of Avoro, serves as Executive Chairman of our Board of Directors.

As a result of this voting power, Avoro has the ability to significantly influence the outcome of substantially all matters that may be put to a vote of our stockholders, including the election of our directors.

***There are limitations on the liability of our directors, and we may have to indemnify our officers and directors in certain instances.***

Our certificate of incorporation limits, to the maximum extent permitted under Delaware law, the personal liability of our directors for monetary damages for breach of their fiduciary duties as directors. Our bylaws provide that we will indemnify our officers and directors and may indemnify our employees and other agents to the fullest extent permitted by law. These provisions may be in some respects broader than the specific indemnification provisions under Delaware law. The indemnification provisions may require us, among other things, to indemnify such officers and directors against certain liabilities that may arise by reason of their status or service as directors or officers (other than liabilities arising from willful misconduct of a culpable nature), to advance their expenses incurred as a result of certain proceedings against them as to which they could be indemnified and to obtain directors’ and officers’ insurance. Section 145 of the Delaware General Corporation Law provides that a corporation may indemnify a director, officer, employee or agent made or threatened to be made a party to an action by reason of the fact that he or she was a director, officer, employee or agent of the corporation or was serving at the request of the corporation, against expenses actually and reasonably incurred in connection with such action if he or she acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. Delaware law does not permit a corporation to eliminate a

director's duty of care and the provisions of our certificate of incorporation have no effect on the availability of equitable remedies, such as injunction or rescission, for a director's breach of the duty of care.

We believe that our limitation of officer and director liability assists us to attract and retain qualified employees and directors. However, in the event an officer, a director or the board of directors commits an act that may legally be indemnified under Delaware law, we will be responsible to pay for such officer(s) or director(s) legal defense and potentially any damages resulting there from. Furthermore, the limitation on director liability may reduce the likelihood of derivative litigation against directors and may discourage or deter stockholders from instituting litigation against directors for breach of their fiduciary duties, even though such an action, if successful, might benefit our stockholders and us. Given the difficult environment and potential for incurring liabilities currently facing directors of publicly-held corporations, we believe that director indemnification is in our and our stockholders' best interests because it enhances our ability to attract and retain highly qualified directors and reduce a possible deterrent to entrepreneurial decision-making.

Nevertheless, limitations of director liability may be viewed as limiting the rights of stockholders, and the broad scope of the indemnification provisions contained in our certificate of incorporation and bylaws could result in increased expenses. Our board of directors believes, however, that these provisions will provide a better balancing of the legal obligations of, and protections for, directors and will contribute positively to the quality and stability of our corporate governance. Our board of directors has concluded that the benefit to stockholders of improved corporate governance outweighs any possible adverse effects on stockholders of reducing the exposure of directors to liability and broadened indemnification rights.

***We are exposed to potential risks from legislation requiring companies to evaluate controls under Section 404 of the Sarbanes-Oxley Act.***

The Sarbanes-Oxley Act requires that we maintain effective internal controls over financial reporting and disclosure controls and procedures. Among other things, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on, and our independent registered public accounting firm to attest to, our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act ("Section 404"). Compliance with Section 404 requires substantial accounting expense and significant management efforts. Our testing, or the subsequent review by our independent registered public accounting firm, may reveal deficiencies in our internal controls that would require us to remediate in a timely manner so as to be able to comply with the requirements of Section 404 each year. If we are not able to comply with the requirements of Section 404 in a timely manner each year, we could be subject to sanctions or investigations by the SEC, the Nasdaq Stock Market or other regulatory authorities that would require additional financial and management resources and could adversely affect the market price of our common stock.

***We do not intend to pay dividends on our common stock. Until such time as we pay cash dividends, our stockholders, must rely on increases in our stock price for appreciation.***

We have never declared or paid dividends on our common stock. We intend to retain future earnings to develop and commercialize our product candidates and therefore we do not intend to pay cash dividends in the foreseeable future. Until such time as we determine to pay cash dividends on our common stock, our stockholders must rely on increases in the market price of our common stock for appreciation of their investment.

**Item 1B. Unresolved Staff Comments**

None.

## Item 2. Properties

Our corporate headquarters is located in Morris Plains, New Jersey. Summarized below are the locations, primary usage and approximate square footage of the facilities we lease. Under these lease agreements, we may be required to reimburse the lessors for real estate taxes, insurance, utilities, maintenance and other operating costs. All leases are with unaffiliated parties.

Location	Primary Usage	Approximate Square Feet
300 The American Road, Morris Plains, New Jersey	Office space, research, manufacturing and clinical trial management	85,000
400 The American Road, Morris Plains, New Jersey	Office space, warehouse, research and clinical trial management	45,700

## Item 3. Legal Proceedings

The following is a summary of legal matters that are outstanding.

### Stockholder Complaints:

#### *Class Action Stockholder Federal Securities Cases*

Two purported class action cases were filed in the United States District Court for the District of New Jersey; namely, *Fergus v. Immunomedics, Inc., et al.*, filed June 9, 2016; and *Becker v. Immunomedics, Inc., et al.*, filed June 10, 2016. These cases arise from the same alleged facts and circumstances and seek class certification on behalf of purchasers of our common stock between April 20, 2016 and June 2, 2016 (with respect to the Fergus matter) and between April 20, 2016 and June 3, 2016 (with respect to the Becker matter). These cases concern the Company's statements in press releases, investor conference calls, and filings with the U.S. Securities and Exchange Commission (the "SEC") beginning in April 2016 that the Company would present updated information regarding its IMMU-132 breast cancer drug at the 2016 American Society of Clinical Oncology ("ASCO") conference in Chicago, Illinois. The complaints allege that these statements were false and misleading in light of June 2, 2016 reports that ASCO had canceled the presentation because it contained previously reported information. The complaints further allege that these statements resulted in artificially inflated prices for our common stock, and that the Company and certain of its officers are thus liable under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). An order of voluntary dismissal without prejudice was entered on November 10, 2016 in the Becker matter. An order granting motion to consolidate cases, appoint lead plaintiff, and approve lead and liaison counsel was entered on February 7, 2017 in the Fergus matter. A consolidated complaint was filed on October 4, 2017. The Company filed a motion to dismiss the consolidated complaint on January 26, 2018. On March 31, 2019, the court granted the Company's motion to dismiss, without prejudice, and left plaintiffs with the ability to file an amended complaint within thirty (30) days. Counsel for the Company has consented to an extension of time for plaintiffs to file the proposed amended complaint for an additional thirty (30) days. On May 30, 2019, plaintiffs filed an amended complaint alleging many of the same allegations that were set forth in the previously filed complaints, and the Company has filed a motion to dismiss.

A third purported class action case was filed in the United States District Court for the District of New Jersey; namely, *Odeh v. Immunomedics, Inc., et al.*, filed December 27, 2018. The complaint in this action alleges that the Company failed to disclose the results of observations made by the FDA during an inspection of the Company's manufacturing facility in Morris Plains, New Jersey in August 2018. The complaint alleges that Immunomedics misled investors by failing to disclose the Form 483 inspection report issued by the FDA which set forth the observations of the FDA inspector during the inspection. Such observations purportedly included, inter alia, manipulated bioburden samples, misrepresentation of an integrity test procedure in the batch record, and backdating of batch records. The complaint further alleges that the Company's failure to disclose the Form 483 resulted in an artificially inflated price for our common stock, and that the Company and certain of its officers are thus liable under Sections 10(b) and 20(a) of the Exchange Act.

On February 8, 2019, a purported class action case was filed in the United States District Court for the District of New Jersey; namely, *Choi v. Immunomedics, Inc., et al.* The complaint asserts violations of the federal securities laws based on claims that the Company violated the federal securities laws by making alleged misstatements in various press releases and securities filings from February 8, 2018 to November 7, 2018 and by failing to disclose the substance of its interactions with the FDA in connection with the Company's submission of its BLA for sacituzumab govitecan.

Motions for the appointment of a lead plaintiff and lead counsel and to consolidate the Odeh and Choi actions were granted on September 10, 2019. Pursuant to a scheduling order entered by the court on October 7, 2019, the plaintiffs filed an

amended complaint on November 18, 2019. The Company filed a motion to dismiss the consolidated, amended complaint on January 17, 2020. The motion has a return date of April 20, 2020.

On April 8, 2019, a putative stockholder of the Company filed a derivative action purportedly on behalf of the Company and against the Company's board of directors and certain Company current and former officers, in the Superior Court of New Jersey, Law Division (Morris County); namely, *Crow v. Aghazadeh, et al.* The Crow complaint alleges that the individual defendants breached their fiduciary duties and committed other violations of law based on the same core allegations in the Odeh and Choi actions. The Crow complaint was served on the Company and other defendants on July 18, 2019. On August 13, 2019, the parties submitted to the court a stipulation and proposed order to stay the action until either the entry of an order denying all motions to dismiss the now-consolidated federal actions or the entry of an order dismissing the federal actions with prejudice. That stipulation is currently pending court approval.

#### *Stockholder Claim in the Court of Chancery of the State of Delaware*

On February 13, 2017, venBio commenced an action captioned *venBio Select Advisor LLC v. Goldenberg, et al., C.A. (Del. Ch.)* (the "venBio Action"), alleging that Company's Board breached their fiduciary duties when the Board (i) amended the Company's Amended and Restated By-laws (the "By-Laws") to call for a plurality voting regime for the election of directors instead of majority voting, and providing for mandatory advancement of attorneys' fees and costs for the Company's directors and officers, (ii) rescheduled the Company's 2016 Annual Meeting of Stockholders (the "2016 Annual Meeting") from December 14, 2016 to February 16, 2017, and then again to March 3, 2017, and (iii) agreed to the proposed Licensing Transaction with Seattle Genetics. venBio also named Seattle Genetics as a defendant and sought an injunction preventing the Company from closing the licensing transaction with Seattle Genetics. On March 6, 2017, venBio amended its complaint, adding further allegations. The Court of Chancery entered a temporary restraining order on March 9, 2017, enjoining the closing of the Licensing Transaction. venBio amended its complaint a second time on April 19, 2017, this time adding Greenhill & Co. Inc. and Greenhill & Co. LLC (together "Greenhill"), the Company's financial advisor on the Licensing Transaction, as an additional defendant. On May 3, 2017, venBio and the Company and individual defendants Dr. Goldenberg, Ms. Sullivan and Mr. Brian A. Markison, a director of the Company (collectively, the "Individual Defendants") entered into the Initial Term Sheet. On June 8, 2017, venBio the Company and Greenhill entered into the Greenhill Term Sheet. On February 9, 2018, the Court of Chancery approved the Settlement, and entered an order and partial judgment releasing all claims that were asserted by venBio against the Individual Defendants and Greenhill in the venBio Action and awarding venBio fees and expenses. On May 24, 2018 the remaining parties to the venBio Action participated in a mediation of the claims against Geoff Cox, Robert Forrester, Bob Oliver, and Jason Aryeh (the "Remaining Defendants"). The mediation was unsuccessful. The Remaining Defendants filed submitted motions to dismiss the claims against them in the venBio Action. On March 18, 2019, venBio amended its complaint, adding further allegations. The Remaining Defendants filed a motion to dismiss the claims against them on May 1, 2019. The Court of Chancery held oral arguments for the motion to dismiss on November 13, 2019 and following arguments, denied Defendants' motion to dismiss on that same date. The parties are now engaged in discovery activities.

#### **Insurance Coverage Arbitration:**

The Company has initiated an arbitration with two of its management liability insurers: Starr Indemnity & Liability Company ("Starr"), and Liberty Insurance Underwriters Inc. ("Liberty") (collectively, "Insurers"). The arbitration arises from the 2015 Insurers' refusal to cover \$3.4 million in attorneys' fees and expenses paid to venBio pursuant to a December 1, 2017, settlement agreement between venBio, the Company, Dr. Goldenberg, Ms. Sullivan, Mr. Markison, and Greenhill to partially settle the venBio Action and fully settle the Federal Action and the Delaware Section 225 Action (the "venBio Fee Award").

The Insurers argue that the venBio Fee Award does not satisfy their policies' definitions of covered "loss" because the policies only cover defense costs incurred by the Company. The Company counters that the venBio Fee Award is a covered settlement, not a claim for defense costs. Insurers also argue that they have no obligation to pay any defense costs or settlement incurred in the Federal Action or 225 Action because Immunomedics initiated those lawsuits. The Company's position is that the Federal Action and 225 Action were defensive in nature and therefore covered because they were initiated to further the defense of the venBio Action. Additionally, Insurers argue the venBio Fee Award is not covered because the Company was required to obtain Insurers' consent to enter into a binding term sheet in the venBio Action and to agree to pay the venBio Fee Award and that the Company failed to do so. The Company takes the position that Insurers at all times were aware of the developments in the venBio Action, that they sought consent to enter into the settlement, and that Insurers cannot show they were prejudiced by an any alleged failure to obtain Insurers' consent.

The Insurers argue that the venBio Fee Award does not satisfy their policies' definitions of covered "loss" because the policies only cover defense costs incurred by the Company. The Company counters that the venBio Fee Award is a covered settlement, not a claim for defense costs. Insurers also argue that they have no obligation to pay any defense costs or settlement



incurred in the Federal Action or 225 Action because Immunomedics initiated those lawsuits. The Company's position is that the Federal Action and 225 Action were defensive in nature and therefore covered because they were initiated to further the defense of the venBio Action. Additionally, Insurers argue the venBio Fee Award is not covered because the Company was required to obtain Insurers' consent to enter into a binding term sheet in the venBio Action and to agree to pay the venBio Fee Award and that the Company failed to do so. The Company takes the position that Insurers at all times were aware of the developments in the venBio Action, that they sought consent to enter into the settlement, and that Insurers cannot show they were prejudiced by an any alleged failure to obtain Insurers' consent.

In the event Insurers prevail on their argument that the venBio Fee Award is covered by a subsequent policy year, the Company will pursue coverage under its other insurance policies.

Starr is presently advancing the costs to defend the remaining claims in the venBio Action, *i.e.*, those against the Company as Nominal Defendant and individual defendants Aryeh, Cox, Forrester, and Oliver. However, all Insurers have reserved their rights to contest coverage for any potential settlement of those claims.

#### **Arbitration of Disputed Matters:**

On January 15, 2019, the Company received an Arbitrator's Findings of Fact and Conclusions of Law and Final Award (the "Final Award") in the arbitration matter in which Dr. David M. Goldenberg, the Company's former Chief Scientific Officer, Chief Patent Officer and Chairman of the Company's Board of Directors, claimed entitlement to certain equity awards and severance payments, and Dr. Goldenberg and Ms. Cynthia Sullivan, a former director of the Company and former President and Chief Executive Officer, claimed rights to certain bonus payments. The Final Award (i) denied Dr. Goldenberg's claim that he was entitled to an award of 1.5 million restricted stock units, (ii) denied each of Dr. Goldenberg's and Ms. Sullivan's claims that they were entitled to certain discretionary cash bonuses relating to the Company's 2017 fiscal year, and (iii) granted Dr. Goldenberg an award of approximately \$1 million relating to certain claimed severance payments which was paid in March 2019. The arbitration took place pursuant to the Delaware Rapid Arbitration Act. Although the Delaware Rapid Arbitration Act permits challenges to arbitration awards in limited circumstances, pursuant to that certain stipulation and agreement of settlement, compromise, and release dated November 2, 2017, the Company, Dr. Goldenberg and Ms. Sullivan agreed that the Final Award would be the sole and exclusive final and binding remedy between and among the parties with respect to the matters disputed in the arbitration.

#### **Other Matters:**

Immunomedics is also a party to various claims and litigation arising in the normal course of business.

#### **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 Price and Dividend Information

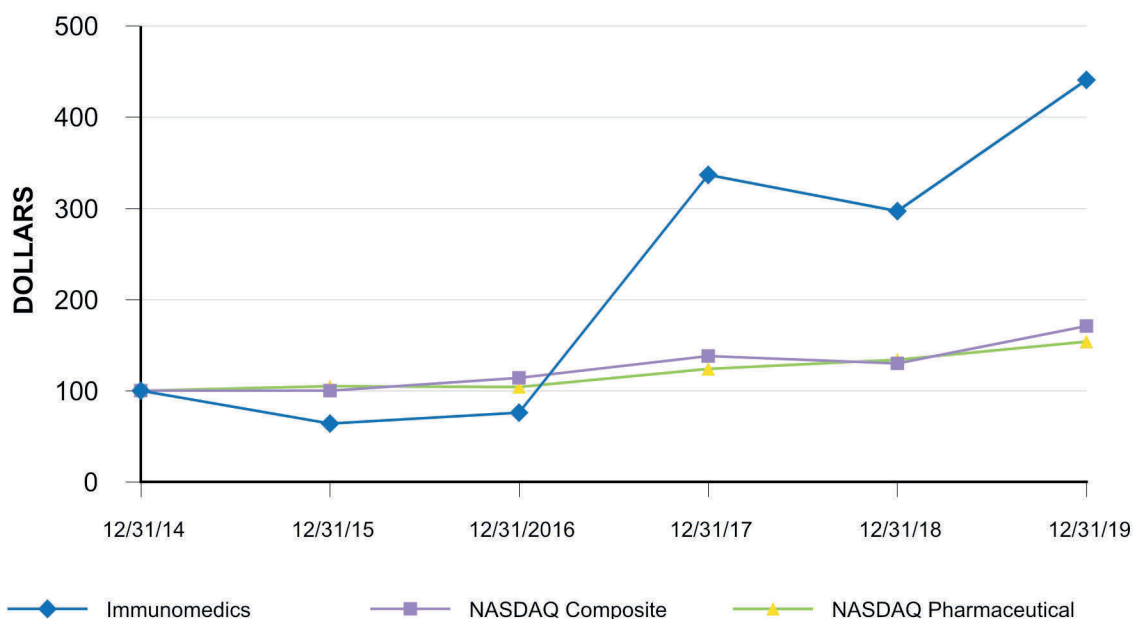
Our common stock is quoted on the Nasdaq Global Market under the symbol "IMMU." As of February 21, 2020, the closing sales price of our common stock on the Nasdaq Global Market was \$18.03 and there were approximately 328 stockholders of record of our common stock. We have not paid dividends on our common stock since inception and do not plan to pay cash dividends in the foreseeable future.

#### Stock Performance Graph

This graph is not "soliciting material," and is not deemed filed with the SEC and not to be incorporated by reference in any filing by our Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing. The total return values data is prepared by the Nasdaq OMX Global Index Group. Total Return Indexes are posted on Nasdaq Online on a monthly basis.

The following graph compares the yearly change in cumulative total stockholder return on the Company's common stock for the prior five years with the total cumulative return of the Nasdaq Composite Index and the Nasdaq Pharmaceutical Index. The returns are indexed to a value of \$100.00 at December 31, 2014.

#### COMPARISON OF FIVE YEAR CUMULATIVE TOTAL RETURN AMONG IMMUNOMEDICS, INC., THE NASDAQ STOCK MARKET - US INDEX AND THE NASDAQ PHARMACEUTICAL INDEX



Company/Index	Indexed Returns (years ending)					
	12/31/14	12/31/15	12/31/16	12/31/17	12/31/18	12/31/19
Immunomedics	100	64	76	337	297	441
Nasdaq Composite	100	100	114	138	130	171
Nasdaq Pharmaceutical	100	105	104	124	134	154

## Item 6. Selected Financial Data

The following table sets forth our consolidated financial data for the year ended December 31, 2019, the Transition Period ended December 31, 2018 as well as for each of the four fiscal years ended June 30, 2018, 2017, 2016 and 2015, which has been derived from our audited consolidated financial statements. The audited consolidated financial statements for the year ended December 31, 2019, the Transition Period ended December 31, 2018, as well as the two fiscal years ended June 30, 2018 and 2017, are included elsewhere in this Annual Report on Form 10-K. The information below should be read in conjunction with the consolidated financial statements (and notes thereon) and Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations.

(\$ in thousands, except per share amounts)	Year Ended December 31, 2019	Transition Period Ended December 31, 2018	Fiscal Years Ended June 30,			
			2018	2017	2016	2015
Total revenues	\$ 295	\$ —	\$ 2,156	\$ 3,091	\$ 3,233	\$ 5,653
Total costs and expenses	325,133	144,535	143,203	82,241	62,241	51,873
Operating loss	(324,838)	(144,535)	(141,047)	(79,150)	(59,008)	(46,220)
Changes in fair market value of warrant liabilities	—	1,404	(108,636)	(61,074)	—	—
Warrant related expenses	—	—	—	(7,649)	—	—
Interest expense <sup>(1)</sup>	(40,337)	(20,017)	(23,255)	(5,480)	(5,480)	(2,091)
Interest and other income	7,856	6,106	5,493	431	338	246
Loss on induced exchanges of debt	—	(897)	(13,005)	—	—	—
Other financing expenses	—	—	—	(347)	—	—
Insurance reimbursement	—	190	6,638	—	—	—
Foreign currency transaction gain (loss), net	—	—	81	23	(40)	(1)
Loss before income tax	(357,319)	(157,749)	(273,731)	(153,246)	(64,190)	(48,066)
Income tax (expense) benefit	—	—	(156)	(20)	5,054	(58)
Net loss	(357,319)	(157,749)	(273,887)	(153,266)	(59,136)	(48,124)
Net loss attributable to noncontrolling interest	(129)	(81)	(50)	(60)	(99)	(122)
Net loss attributable to Immunomedics, Inc. stockholders	\$ (357,190)	\$ (157,668)	\$ (273,837)	\$ (153,206)	\$ (59,037)	\$ (48,002)
Loss per common share attributable to Immunomedics, Inc. stockholders (basic and diluted):	\$ (1.84)	\$ (0.84)	\$ (1.78)	\$ (1.47)	\$ (0.62)	\$ (0.51)
Weighted average shares used to calculate loss per common share (basic and diluted)	193,617	188,554	153,475	104,536	94,770	93,315

(\$ in thousands)	As of December 31, 2019	For the Transition Period As of December 31, 2018	As of June 30,			
			2018	2017	2016	2015
Total cash, cash equivalents and marketable securities	\$ 613,178	\$ 497,801	\$ 638,802	\$ 154,902	\$ 50,628	\$ 99,618
Total assets	\$ 671,722	\$ 528,040	\$ 664,173	\$ 162,573	\$ 56,950	\$ 105,780
Liability related to sale of future royalties	\$ 261,224	\$ 221,295	\$ 202,007	\$ —	\$ —	\$ —
Convertible senior notes, net	\$ 7,106	\$ 7,055	\$ 19,763	\$ 98,084	\$ 97,354	\$ 96,625
Warrant liabilities	\$ —	\$ —	\$ 8,973	\$ 90,706	\$ —	\$ —
Total stockholders' equity <sup>(2)</sup>	\$ 267,230	\$ 265,849	\$ 399,686	\$ (59,464)	\$ (57,527)	\$ (4,525)

- (1) Interest expense represents interest on liability related to sale of future royalties of \$39.9 million for the year ended December 31, 2019, \$19.3 million for the Transition Period ended December 31, 2018, \$19.8 million for fiscal 2018, the Convertible Senior Notes interest expense (\$0.3 million, \$0.3 million, \$1.8 million, and \$4.8 million for the year ended December 31, 2019, the Transition Period, fiscal 2018, and fiscal 2017, respectively) and amortized debt issuance costs (\$0.1 million, \$0.2 million, \$1.7 million, and \$0.7 million for the year ended December 31, 2019, the Transition Period ended December 31, 2018, fiscal 2018, and fiscal 2017, respectively).
- (2) We have never paid cash dividends on our common stock. Stockholders' equity represents Immunomedics, Inc. stockholders' equity and the non-controlling interest in our subsidiary.

## **Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations***

### **Cautionary Note Regarding Forward-Looking Statements**

The SEC encourages companies to disclose forward-looking information so that investors can better understand a company's future prospects and make informed investment decisions. This Annual Report on Form 10-K contains such "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be made directly in this Annual Report, and they may also be made a part of this Annual Report by reference to other documents filed with the SEC, which is known as "incorporation by reference."

Words such as "may," "anticipate," "estimate," "expects," "projects," "intends," "plans," "believes" and words and terms of similar substance used in connection with any discussion of future operating or financial performance are intended to identify forward-looking statements. All forward-looking statements are management's present expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include, among other things: expectations for the outcome of our resubmission of our BLA for sacituzumab govitecan for the treatment of patients with mTNBC who have received at least two prior therapies for metastatic disease; the FDA re-inspection of the Company's manufacturing facility where we manufacture the monoclonal antibody for further manufacture into our ADC candidate sacituzumab govitecan; potential approval and commercial launch of sacituzumab govitecan for that indication and the Company's development of sacituzumab govitecan for additional indications; clinical trials (including the funding therefor, anticipated patient enrollment, trial outcomes, timing or associated costs); regulatory applications and related timelines, including the filing and approval timelines for BLAs, BLA resubmissions, and BLA supplements; out-licensing arrangements; forecasts of future operating results, potential collaborations, capital raising activities, and the timing for bringing any product candidate to market; our inability to further identify, develop and achieve commercial success for new products and technologies; the possibility of delays in the research and development necessary to select drug development candidates and delays in clinical trials; the risk that clinical trials may not result in marketable products; the risk that we may be unable to obtain additional capital through strategic collaborations, licensing, convertible debt securities or equity financing in order to continue our research and development programs as well as secure regulatory approval of and market our drug candidates; our dependence upon pharmaceutical and biotechnology collaborations; the levels and timing of payments under our collaborative agreements; uncertainties about our ability to obtain new corporate collaborations and acquire new technologies on satisfactory terms, if at all; the development of competing products; our ability to protect our proprietary technologies; patent infringement claims; and risks of new, changing and competitive technologies and regulations in the United States and internationally, as well as the risks discussed in the Company's filings with the SEC. The Company is not under any obligation, and the Company expressly disclaims any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise. Refer to Item 1A "Risk Factors" in this Annual Report on Form 10-K for more information.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this Annual Report on Form 10-K or in any document incorporated by reference might not occur. Stockholders are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K or the date of the document incorporated by reference in this Annual Report on Form 10-K, as applicable. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise except as may be required by applicable law. All subsequent forward-looking statements attributable to the Company or to any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

Historically, our fiscal years ended on June 30. On December 14, 2018, the Company's Board of Directors approved a change in the Company's fiscal year end from June 30 to December 31. In connection with this change, we previously filed a Transition Report on Form 10-K to report the results of the six-month transition period from July 1, 2018 to December 31, 2018 (which we sometimes refer to as the "Transition Period"). In this Annual Report, the periods presented are the year ended December 31, 2019, the Transition Period ended December 31, 2018 and our fiscal years ended June 30, 2018 and 2017 (which are referred

to as “fiscal 2018,” and “fiscal 2017,” as if we had not changed our fiscal year to a calendar year). For comparison purposes, we have also included unaudited data for the year ended December 31, 2018.

The following Management’s Discussion and Analysis (“MD&A”) provides a narrative of our results of operations for the year ended December 31, 2019 and unaudited data for the comparable period ended December 31, 2018. The MD&A should be read together with our consolidated financial statements and related notes included in Item 8 in this Annual Report on Form 10-K.

## Overview

We are a clinical-stage biopharmaceutical company developing monoclonal antibody-based products for the targeted treatment of cancer. Our advanced proprietary technologies allow us to create humanized antibodies that can be used either alone in unlabeled or “naked” form, or conjugated with chemotherapeutics, cytokines or toxins.

We believe that our antibodies have therapeutic potential, in some cases as a naked antibody or when conjugated with chemotherapeutics, cytokines or other toxins to create unique and potentially more effective treatment options. The attachment of effective anti-tumor compounds to antibodies is intended to allow the delivery of these therapeutic agents to tumor sites with better specificity than conventional chemotherapy. This treatment method is designed to optimize the therapeutic window through reducing the systemic exposure of the patient to the therapeutic agents, which ideally minimizes debilitating side effects while maximizing the concentration of the therapeutic agent at the tumor, potentially leading to better efficacy.

Our portfolio of investigational products includes ADCs that are designed to deliver a specific payload of a chemotherapeutic directly to the tumor while reducing overall toxicities that are usually associated with conventional administration of these chemotherapeutic agents. Sacituzumab govitecan is our most advanced ADC and our lead product candidate that has received Breakthrough Therapy Designation from the FDA for the treatment of patients with mTNBC who have received at least two prior therapies for metastatic disease.

Our corporate strategy is to become a fully-integrated biopharmaceutical company and a leader in the field of ADCs. In May 2018, we submitted a Biologics License Application (“BLA”) to the United States Food and Drug Administration (“FDA”) for sacituzumab govitecan for the treatment of patients with mTNBC who have received at least two prior therapies for metastatic disease. In July 2018, we received notification from the FDA that the BLA was accepted for filing and the original application was granted Priority Review with a Prescription Drug User Fee Act (“PDUFA”) target action date in January 2019. In January 2019, we received a Complete Response Letter (“CRL”) from the FDA for the BLA. We subsequently met with the FDA in May 2019 to review the FDA’s findings and discussed our BLA resubmission. Since then, we have developed a detailed plan to address the chemistry, manufacturing, and controls (“CMC”) matters raised in the CRL and in our pre-approval inspection. We held another meeting with the FDA in September 2019 to update the FDA on our progress in addressing these matters and to receive feedback from the FDA on our approach. On November 30, 2019, we resubmitted our BLA to the FDA and on December 23, 2019 we received notification from the FDA that the BLA was accepted for filing and further assigned a new PDUFA target action date as June 2, 2020. We have dedicated, and continue to commit, significant resources to address the CMC matters identified by the FDA, while, in parallel, preparing our manufacturing facility to be ready for re-inspection by the FDA. Our Phase 3 confirmatory ASCENT study for sacituzumab govitecan has reached its target enrollment for mTNBC patients previously treated with at least two systemic chemotherapy regimens. Top-line data for the ASCENT study is expected to be available around mid-2020.

On March 29, 2019, the Company entered into the ATM Agreement with Cowen to issue and sell shares of the Company’s common stock, par value \$0.01 per share, having an aggregate offering price of up to \$150.0 million, from time to time during the term of the ATM Agreement, through an “at-the-market” equity offering program at the Company’s sole discretion, under which Cowen will act as the Company’s agent and/or principal. The Company will pay Cowen a commission up to 3.0% of the gross sales proceeds of any common stock sold through Cowen under the ATM Agreement. During the year ended December 31, 2019, the Company sold 4,432,416 shares of common stock with net proceeds of \$71.6 million at a weighted average price of \$16.40 (excluding commissions) under the ATM Agreement.

On April 5, 2019, the Company entered into the Promotion Agreement with Janssen pursuant to which the Company will provide non-exclusive product detailing services to Janssen for the product. Pursuant to the Promotion Agreement, the Company will provide a dedicated sales team to detail the Product to oncologists and other targeted health care providers in the United States. Under the terms of the Promotion Agreement, Janssen maintains ownership of the New Drug Application for the product as well as legal, regulatory, distribution, commercialization and manufacturing responsibilities for the product, while the Company will provide product detailing services to Janssen. Following the achievement of certain sales targets in 2019 and 2020, Janssen will pay the Company (a) a service fee equal to a percentage in the low double digits of the portion of Cumulative Net Sales (as defined in the Promotion Agreement) in excess of a baseline amount during each of 2019 and 2020, and (b) potential milestone payments



of up to \$15.0 million when Cumulative Net Sales exceed certain thresholds during each of 2019 and 2020. On April 12, 2019, the Company was informed that the FDA granted accelerated approval to Janssen's Balversa® (erdafitinib) for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma that has a type of susceptible genetic alteration known as FGFR3 or FGFR2, and that has progressed during or following prior platinum-containing chemotherapy. Refer to "Note 2 - Revenue Recognition" for additional information.

On April 29, 2019, we entered into the License Agreement with Everest. Pursuant to the License Agreement, we granted Everest an exclusive license to develop and commercialize sacituzumab govitecan in the People's Republic of China, Taiwan, Hong Kong, Macao, Indonesia, Philippines, Vietnam, Thailand, South Korea, Malaysia, Singapore and Mongolia (the "Territory"). In consideration for entering into the License Agreement, Everest made a one-time, non-refundable upfront payment to us in the aggregate amount of \$65.0 million which is recorded as deferred revenue on the consolidated balance sheet as of December 31, 2019. The License Agreement contains a development milestone payment of \$60.0 million based upon our achievement of FDA approval for sacituzumab govitecan. The License Agreement also contains additional development milestone payments in a total amount of up to \$180.0 million based upon the achievement of certain other development milestones. In addition, the License Agreement contains sales milestone payments in a total amount of up to \$530.0 million based upon the achievement of certain sales milestones. Everest will make royalty payments to us based upon percentages of net sales of sacituzumab govitecan, ranging from 14% to 20%. Refer to "Note 2 - Revenue Recognition" for additional information.

On December 9, 2019, we closed an underwritten public offering of 14,285,715 shares of common stock at a public offering with a price of \$17.50 per share, representing gross proceeds of approximately \$250.0 million. In addition, the Company granted the underwriters a 30-day option to purchase up to 2,142,857 additional shares of common stock for a total of 16,428,572 shares. We received gross proceeds of \$287.5 million and net proceeds of \$273.0 million after deducting the underwriting discounts and commissions and expenses related to the offering. We intend to use the net proceeds from this offering primarily to accelerate commercial launch readiness, pending FDA approval, of sacituzumab govitecan in the United States in mTNBC, continue to expand the clinical development programs for sacituzumab govitecan, invest in the broader clinical development of the platform (including IMM-130 and IMM-140), continued scale-up of manufacturing and manufacturing process improvements, as well as for working capital and general corporate purposes.

As of December 31, 2019, we had \$613.2 million in cash, cash equivalents and marketable securities. We believe our projected financial resources are adequate to (i) accelerate commercial launch readiness, pending FDA approval, of sacituzumab govitecan in the United States in mTNBC, (ii) continue to expand the clinical development programs for developing sacituzumab govitecan in mTNBC, metastatic urothelial cancer ("mUC"), hormone receptor-positive ("HR+") / human epidermal growth factor receptor 2-negative ("HER2-") metastatic breast cancer ("mBC"), and other indications of high medical need, (iii) invest in the broader clinical development of the platform (including IMM-130 and IMM-140), (iv) continued scale up of manufacturing and manufacturing process improvements, and (v) general working capital requirements. However, in case of regulatory delays or other unforeseen events, we may require additional funding. Potential sources of funding in such a case could include (i) the entrance into potential development and commercial partnerships to advance and maximize our full pipeline for mTNBC and beyond in the United States and globally, and (ii) potential private and public capital markets financing. Refer to "Note 9 - Stockholders' Equity" for additional information.

As part of our commitment to invest in and scale our global supply capacity with world-class partners in each component of its supply-chain, on September 11, 2018, we entered into a Master Services Agreement (the "MSA") with Samsung BioLogics Co., Ltd. ("Samsung"), pursuant to which Samsung provides the Company with certain biologics manufacturing and development services in accordance with one or more product specific agreements. In connection with the MSA, on September 11, 2018, we also entered into a product specific agreement with Samsung for the production of hRS7, the antibody used in the Company's lead antibody drug conjugate candidate, sacituzumab govitecan. In addition, on December 26, 2018, we expanded our long-term master supply agreement with Johnson Matthey who will continue to scale the manufacturing of CL2A-SN-38, the drug-linker that is a key component of sacituzumab govitecan.

To accelerate the clinical development of sacituzumab govitecan, we are collaborating with Roche to evaluate the safety and efficacy of the combination of its programmed cell death ligand 1 blocking checkpoint inhibitor and sacituzumab govitecan in frontline mTNBC. In the post-neoadjuvant setting in HER2- mBC, we are collaborating with the German Breast Group to assess sacituzumab govitecan as a single agent. We are also collaborating with AstraZeneca to investigate our ADC in earlier lines of therapy for mTNBC, advanced UC and mNSCLC in combination with its checkpoint inhibitor, and with Clovis, Inc. to combine with its PARP inhibitor in mTNBC, advanced UC and ovarian cancer. In addition, Massachusetts General Hospital is working on a study combining sacituzumab govitecan with Pfizer's PARP inhibitor in patients with mTNBC, University of Wisconsin is working on a clinical study of sacituzumab govitecan as a monotherapy in prostate cancer, and Yale University has a Phase 2 study of sacituzumab govitecan in patients with persistent and recurrent endometrial cancer.

We also have a number of other product candidates, which target solid tumors and hematologic malignancies in various stages of clinical and preclinical development. They include other ADCs such as labetuzumab govitecan, which binds the CEACAM5 antigen expressed on CRC and other solid cancers, and IMMU-140 that targets HLA-DR for the potential treatment of hematologic malignancies. We believe that our portfolio of intellectual property provides commercially reasonable protection for our product candidates and technologies.

The development and commercialization of successful therapeutic products is subject to numerous risks and uncertainties including, without limitation, the following:

- the time and expense required for us to comply with all applicable federal, state and foreign legal requirements, including, without limitation, our receipt of the necessary approvals of the FDA (which receipt is uncertain);
- the time and expense required for us to establish and maintain compliant operations for commercial manufacturing, sale, and distribution of products (if approved) under FDA and healthcare law requirements, and risks of non-compliance;
- we may be unable to obtain additional capital through strategic collaborations, licensing, or potential private and public capital markets financings, including the use of the ATM Agreement, in order to continue our research and secure regulatory approval of and market our lead drug candidate;
- challenges based on the type of therapeutic compound under investigation and nature of the disease in connection with which the compound is being studied;
- our ability, as well as the ability of our partners, to conduct and complete clinical trials on a timely basis;
- the financial resources available to us during any particular period; and
- many other factors associated with the commercial development of therapeutic products outside of our control.

(Refer to "Risk Factors" under Item 1A in this Annual Report on Form 10-K for more information.)

### **Critical Accounting Policies and Accounting Estimates**

A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operation and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain.

Our critical accounting estimates and assumptions impacting the consolidated financial statements relate to stock-based compensation expenses, the fair value for the liability related to sale of future royalties and related interest expense. Refer to "Note 1 - Business Overview and Summary of Significant Accounting Policies", "Note 4 - Debt", and "Note 6 - Estimated Fair Value of Financial Instruments", respectively, for more information.

## Results of Operations

### Revenues

		(\$ in thousands)		
		(Decrease)/Increase		
For the Year Ended December 31,	2019	(unaudited 2018)	2019 vs (unaudited 2018)	
Product sales	\$ —	\$ 450	\$ (450)	nm
License fee and other revenues	295	265	30	11.3%
Research and development	—	153	(153)	nm
Total revenues	\$ 295	\$ 868	\$ (573)	nm
nm - not meaningful				

Total revenue for the year ended December 31, 2019 decreased compared to the comparable period ended December 31, 2018, primarily due to the discontinued sale of LeukoScan<sup>®</sup> during February 2018 to focus on our ADC business. Revenues for the year ended December 31, 2019 are service fee revenues earned related to the Janssen Promotion Agreement.

### Costs and Expenses

The following table summarizes our costs and expenses for the year ended December 31, 2019 and the comparable period ended December 31, 2018:

		(\$ in thousands)		
		Increase/(Decrease)		
For the Year Ended December 31,	2019	(unaudited 2018)	2019 vs (unaudited 2018)	
Costs of goods sold	\$ —	\$ 47	\$ (47)	nm
Research and development	254,871	150,333	104,538	69.5 %
Sales and marketing	26,459	25,239	1,220	4.8 %
General and administrative	43,803	59,807	(16,004)	(26.8)%
Total costs and expenses	\$ 325,133	\$ 235,426	\$ 89,707	38.1 %
nm - not meaningful				

Total costs and expenses for the year ended December 31, 2019 increased compared to the comparable period ended December 31, 2018, primarily due to an increase in research and development expenses and an increase in sales and marketing expenses. The increase was partially offset by a decrease in general and administrative expenses.

### Research and Development

We do not track expenses on the basis of each individual compound under investigation and therefore we do not provide a breakdown of such historical information in that format. We evaluate projects under development from an operational perspective, including such factors as results of individual compounds from laboratory/animal testing, patient results and enrollment statistics in clinical trials. It is important to note that multiple product candidates are often tested simultaneously. It is not possible to calculate each antibody's supply costs. There are many different development processes and test methods that examine multiple product candidates at the same time. We have, historically, tracked our costs in the categories discussed below, specifically "research costs" and "product development costs" and by the types of costs outlined below.

Our research costs consist of outside costs associated with animal studies and costs associated with research and testing of our product candidates prior to reaching the clinical stage. Such research costs primarily include personnel costs, facilities, including depreciation, lab supplies, funding of outside contracted research and license fees. Our product development costs consist of costs from preclinical development (including manufacturing), conducting and administering clinical trials and patent expenses.

The following table summarizes our research and development costs for the year ended December 31, 2019 and the comparable period ended December 31, 2018:

For the Year Ended December 31,	2019	(unaudited) 2018	(\$ in thousands)	
			Increase/(Decrease)	
			2019 vs (unaudited) 2018	
Labor	\$ 48,285	\$ 27,026	\$ 21,259	78.7 %
Manufacturing and quality costs	154,249	77,772	76,477	98.3 %
Clinical development and operations	40,627	24,011	16,616	69.2 %
Other	11,710	21,524	(9,814)	(45.6)%
Total research and development costs	<u>\$ 254,871</u>	<u>\$ 150,333</u>	<u>\$ 104,538</u>	<u>69.5 %</u>

Research and development costs increased for the year ended December 31, 2019 by approximately \$104.5 million to \$254.9 million compared to the comparable period ended December 31, 2018. The increase in research and development costs relate primarily to preparations for the approval and launch of sacituzumab govitecan in the United States for patients with mTNBC, CRL remediation costs including outside manufacturers' organizations services costs, and outside consulting services to improve our manufacturing and regulatory functions.

Completion of clinical trials may take several years or more. The length of time varies according to the type, complexity and the disease indication of the product candidate. We estimate that clinical trials of the type we generally conduct are typically completed over the following periods:

Clinical Phase	Estimated Completion Period (Years)
I	0-1
II	1-2
III	1-4

The duration and cost of clinical trials through each of the clinical phases may vary significantly over the life of a particular project as a result of, among other things, the following factors:

- the length of time required to recruit qualified patients for clinical trials;
- the duration of patient follow-up in light of trial results;
- the number of clinical sites required for trials; and
- the number of patients that ultimately participate.

### Sales and Marketing

The following table summarizes our sales and marketing expenses for the year ended December 31, 2019 and the comparable period ended December 31, 2018:

For the Year Ended December 31,	2019	(unaudited) 2018	(\$ in thousands)	
			Increase/(Decrease)	
			2019 vs (unaudited) 2018	
Labor costs	\$ 21,928	\$ 7,825	\$ 14,103	nm
Marketing and promotions	1,440	10,821	(9,381)	(86.7)%
Consulting services	208	2,626	(2,418)	(92.1)%
Other	2,883	3,967	(1,084)	(27.3)%
Total sales and marketing	<u>\$ 26,459</u>	<u>\$ 25,239</u>	<u>\$ 1,220</u>	<u>4.8 %</u>

nm- not meaningful

Sales and marketing expenses increased during the year ended December 31, 2019 by approximately \$1.2 million compared to the comparable period ended December 31, 2018, primarily due to an increase in labor costs due to a full year of expenses relating to our sales force, offset by a decrease in marketing and promotions as well as consulting services.



## General and Administrative Expenses

The following table summarizes our general and administrative expenses for the year ended December 31, 2019 and the comparable period ended December 31, 2018:

For the Year Ended December 31,	2019	(unaudited) 2018	(\$ in thousands)	
			(Decrease)/Increase 2019 vs (unaudited) 2018	
Labor costs	\$ 19,393	\$ 17,397	\$ 1,996	11.5 %
Legal and advisory fees	7,839	16,824	(8,985)	(53.4)%
Consulting services	5,064	8,177	(3,113)	(38.1)%
Other	11,507	17,409	(5,902)	(33.9)%
Total general and administrative	\$ 43,803	\$ 59,807	\$ (16,004)	(26.8)%

General and administrative expenses for the year ended December 31, 2019 decreased by approximately \$16.0 million compared to the comparable period ended December 31, 2018, primarily due to decreased legal and advisory expenses due to reduced reliance on outside legal counsel, as well as a decrease in other and consulting services, partially offset by an increase in labor costs.

## Changes in fair market value of warrant liabilities

We have no non-cash income or expense for the year ended December 31, 2019, compared to \$47.6 million in non-cash expense for the comparable period ended December 31, 2018, as a result of the net appreciation in the fair value of the then outstanding warrants. There were no warrants outstanding at December 31, 2019 and 2018. Refer to "Note 9 - Stockholders' Equity" for more information.

## Interest expense

Interest expense for the year ended December 31, 2019 was \$40.3 million compared to \$40.4 million for the comparable period ended December 31, 2018. The \$0.1 million decrease was due primarily to changes in the fair value of our debt balances as a result of the RPI agreement. Refer to "Note 4 - Debt" for more information.

## Loss on induced exchanges of debt

On October 2, 2018, the Company entered into privately negotiated exchange agreements (the "October 2018 Exchange Agreements"), with a limited number of holders of the Convertible Senior Notes. As a result of the October 2018 Exchange Agreements, the Company recognized a non-cash loss on induced exchanges of debt of \$0.9 million representing the fair value of the incremental consideration paid to induce the holders to exchange their Convertible Senior Notes for equity (i.e., 0.1 million shares of common stock), based on the closing market price of the Company's Common Stock on the date of the October 2018 Exchange Agreements. Refer to "Note 4 - Debt" for more information.

## Insurance reimbursement

We received no insurance reimbursements for the year ended December 31, 2019, compared to \$2.5 million we received for the comparable period ended December 31, 2018, due to insurance reimbursements related to legal costs incurred during our proxy contest during fiscal 2017. Refer to "Note 14 - Commitments and Contingencies" for more information.

## Income tax expense

There was no income tax expense for the year ended December 31, 2019, and \$0.2 million of income tax expense for the comparable period ended December 31, 2018.

## Net Loss Attributable to Immunomedics, Inc. Stockholders

Net loss attributable to Immunomedics, Inc. common stockholders for the year ended December 31, 2019 was \$357.2 million, or \$1.84 per share, compared to a net loss of approximately \$310.2 million, or \$1.74 per share, for the comparable period ended December 31, 2018, an increase in the loss of \$47.0 million due primarily to a \$89.7 million increase in costs and expenses related to preparations for the approval and launch of sacituzumab govitecan in the United States for patients with mTNBC, along

with a reduction of interest and other income of \$2.9 million, a reduction of \$2.5 million in non-recurring insurance reimbursement related to the proxy contest, offset by a decrease in the expense from the change in fair value of warrant liabilities of \$47.6 million, in the comparable period ended December 31, 2018.

***Transition Period Ended December 31, 2018 and the Comparable Period Ended December 31, 2017, and Fiscal Year Ended June 30, 2018 Compared to the Fiscal Year Ended June 30, 2017***

Management's discussion and analysis of our results of operations for the Transition Period ended December 31, 2018, the comparable period ended December 31, 2017, and fiscal year ended June 30, 2018 compared to the fiscal year ended June 30, 2017 may be found in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of our Transition Report on Form 10-K for the transition period ended December 31, 2018, filed with the SEC on February 25, 2019.

**Liquidity and Capital Resources**

Since its inception in 1982, Immunomedics' principal sources of funds have been the private and public sale of equity and debt securities, and revenues from licensing agreements, including up-front and milestone payments, funding of development programs, and other forms of funding from collaborations.

As of December 31, 2019, we had \$613.2 million in cash, cash equivalents and marketable securities. We believe our projected financial resources are adequate to (i) accelerate commercial launch readiness, pending FDA approval, of sacituzumab govitecan in the United States in mTNBC, (ii) continue to expand the clinical development programs for developing sacituzumab govitecan in mTNBC, metastatic urothelial cancer ("mUC"), hormone receptor-positive ("HR+") /human epidermal growth factor receptor 2-negative ("HER2-") metastatic breast cancer ("mBC"), and other indications of high medical need, (iii) invest in the broader clinical development of the platform (including IMMU-130 and IMMU-140), (iv) continued scale up of manufacturing and manufacturing process improvements, and (v) general working capital requirements. However, in case of regulatory delays or other unforeseen events, we may require additional funding. Potential sources of funding in such a case could include (i) the entrance into potential development and commercial partnerships to advance and maximize our full pipeline for mTNBC and beyond in the United States and globally, and (ii) potential private and public capital markets financing. Refer to "Note 9 - Stockholders' Equity" for additional information.

Actual results could differ materially from our expectations as a result of a number of risks and uncertainties, including the risks described in Item 1A Risk Factors, "Factors That May Affect Our Business and Results of Operations," and elsewhere in this Annual Report on Form 10-K. Our working capital and working capital requirements are affected by numerous factors and such factors may have a negative impact on our liquidity. Principal among these are the success of product commercialization and marketing products, the technological advantages and pricing of our products, the impact of the regulatory requirements applicable to us, and access to capital markets that can provide us with the resources, when necessary, to fund our strategic priorities.

***Discussion of Cash Flows***

The following table summarizes our cash flows for the years ended December 31, 2019 and 2018:

	(\$ in thousands)	
	<b>For the Year Ended December 31,</b>	
	<b>2019</b>	<b>2018 (unaudited)</b>
Net cash used in operating activities	\$ (222,442)	\$ (200,311)
Net cash (used in)/provided by investing activities	\$ (6,849)	\$ 54,635
Net cash provided by financing activities	\$ 347,181	\$ 579,010

***Cash flows used in operating activities***

Net cash used in operating activities for the year ended December 31, 2019 was approximately \$222.4 million, compared to \$200.3 million in the prior year. The increase in cash of \$22.1 million used in operating for the period was primarily due to increased research and development expenses primarily relate to preparations for the approval and launch of sacituzumab govitecan in the United States for patients with mTNBC, CRL remediation costs including outside manufacturers' organizations services costs, and outside consulting services to improve our manufacturing and regulatory functions.

### *Cash flows (used in)/provided by investing activities*

Net cash used in investing activities for the year ended December 31, 2019 was \$6.8 million, compared to \$54.6 million of cash provided by investing activities in prior year. The decrease of \$61.4 million was due primarily to a decrease in proceeds from sales or maturities of marketable securities of \$73.8 million, offset by purchases of property and equipment of \$12.3 million.

### *Cash flows provided by financing activities*

Net cash provided by financing activities for the year ended December 31, 2019, was \$347.2 million, compared to \$579.0 million of cash provided by financing activities during the year ended December 31, 2018. The decrease of \$231.8 million was primarily due to receipt of approximately \$182.2 million in net proceeds from the issuance of non-recourse debt, warrant exercises of \$29.4 million, and lower proceeds from the sale of our common stock of \$22.6 million in the comparable period ended December 31, 2018.

### ***Working Capital and Cash Requirements***

Working capital was \$566.9 million as of December 31, 2019 compared to \$472.8 million as of December 31, 2018, a \$94.1 million increase. The increase in cash was primarily due to net proceeds received from public offering and the at-the-marketing offering offset by increased research and development expenses primarily relate to preparations for the approval and launch of sacituzumab govitecan in the United States for patients with mTNBC, CRL remediation costs including outside manufacturers' organizations services costs, and outside consulting services to improve our manufacturing and regulatory functions.

We expect to continue to fund our operations with our current financial resources. Potential sources of funding include (i) the entrance into various potential strategic partnerships targeted at advancing and maximizing our full pipeline for mTNBC and beyond, (ii) the sales and marketing of sacituzumab govitecan as a third-line therapy for mTNBC in the United States (pending FDA approval), and (iii) potential equity and debt financing transactions.

Until we can generate significant cash through (i) the entrance into various potential strategic partnerships towards advancing and maximizing our full pipeline for mTNBC and beyond, or (ii) the sales and marketing of sacituzumab govitecan as a third-line therapy for mTNBC in the United States (pending FDA approval), we expect to continue to fund our operations with our current financial resources. In the future, if we cannot obtain sufficient funding through the above methods, we could be required to finance future cash needs through the sale of additional equity and/or debt securities in capital markets. However, there can be no assurance that we will be able to raise the additional capital needed to complete our pipeline of research and development programs on commercially acceptable terms, if at all. The capital markets have experienced volatility in recent years, which has resulted in uncertainty with respect to availability of capital and hence the timing to meet an entity's liquidity needs. Our existing debt may also negatively impact our ability to raise additional capital. If we are unable to raise capital on acceptable terms, our ability to continue our business would be materially and adversely affected. Actual results could differ materially from our expectations as a result of a number of risks and uncertainties, including the risks described in Item 1A Risk Factors, "Factors That May Affect Our Business and Results of Operations," and elsewhere in our Annual Report on Form 10-K. Our working capital and working capital requirements are affected by numerous factors and such factors may have a negative impact on our liquidity. Principal among these are the success of product commercialization and marketing products, the technological advantages and pricing of our products, the impact of the regulatory requirements applicable to us, and access to capital markets that can provide us with the resources, when necessary, to fund our strategic priorities.

### ***Transition Period Ended December 31, 2018 and the Comparable Period Ended December 31, 2017, and Fiscal Year Ended June 30, 2018 Compared to the Fiscal Year Ended June 30, 2017***

Management's discussion and analysis of our cash flows for the Transition Period ended December 31, 2018, the comparable period ended December 31, 2017, and fiscal year ended June 30, 2018 compared to the fiscal year ended June 30, 2017 may be found in the "Management's Discussion and Analysis of Financial Condition and Results of Operations—Cash Flows—section of our Transition Report on Form 10-K for the transition period ended December 31, 2018, filed with the SEC on February 25, 2019.

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

We did not have during the periods presented in this Annual Report on Form 10-K, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

## Contractual Commitments

The following table summarizes our outstanding contractual obligations as of the year ended December 31, 2019:

(\$ in thousands)

Contractual Obligations	2020	2021	2022	2023	2024	Thereafter	Total
Convertible senior notes	\$ 7,106	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 7,106
Interest on long-term debt	453	—	—	—	—	—	453
Total long-term debt	7,559	—	—	—	—	—	7,559
Purchase obligations <sup>(1)</sup>	90,015	59,765	40,796	40,796	33,026	33,026	297,424
Other <sup>(2)</sup>	1,958	592	100	26	24	23	2,723
Total	\$ 99,532	\$ 60,357	\$ 40,896	\$ 40,822	\$ 33,050	\$ 33,049	\$ 307,706

- (1) Purchase obligations are primarily to purchase commercial manufacturing services including minimum purchase commitments related to product supply contracts and e-sourcing software.
- (2) Other contractual commitments represent vehicles, printers, clinical supply agreements, facility and maintenance agreements, and other equipment.

Effective January 1, 2019, operating lease obligations are presented on our consolidated balance sheet as a right-of-use asset and lease liability for leases with a duration of greater than one year. See Note 1 of Notes to Consolidated Financial Statements contained elsewhere in this report for additional details related to adoption of this change in accounting standard. For more information on the facilities that we occupy under lease arrangements refer to Part I, Item 2. "Properties" of this report.

The above amounts exclude potential payments related to the sale of future royalties pursuant to our agreement with RPI, under which we are required to make certain royalty payments based on estimated future sales of sacituzumab govitecan. Due to the nature of this arrangement, the future potential payments related to the attainment of regulatory approval and sales-based milestones over a period of several years are inherently uncertain, and accordingly, no amounts have been presented for these future potential payments.

### Item 7A. Quantitative and Qualitative Disclosures About Market Risk

The following discussion about our exposure to market risk of financial instruments contains forward-looking statements under the Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those described due to a number of factors, including uncertainties associated with general economic conditions and conditions impacting our industry.

As of the year ended December 31, 2019, we had \$613.2 million in cash, cash equivalents and marketable securities. Such interest-earning instruments carry a degree of interest rate risk. We do not invest for trading or speculative purposes. We do not have any derivative financial instruments to manage our interest rate risk exposure. A hypothetical 1% change in interest rates at December 31, 2019, would not result in a significant change in the fair market value of our portfolio.

We may be exposed to fluctuations in foreign currencies with regard to certain agreements with service providers. Depending on the strengthening or weakening of the United States dollar, realized and unrealized currency fluctuations could be significant.

## Item 8. Financial Statements and Supplementary Data

### Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors  
Immunomedics, Inc.:

#### *Opinion on the Consolidated Financial Statements*

We have audited the accompanying consolidated balance sheets of Immunomedics, Inc. and subsidiaries (the Company) as of December 31, 2019 and 2018, the related consolidated statements of comprehensive loss, changes in stockholders' equity, and cash flows for the year ended December 31, 2019, the six-month transition period ended December 31, 2018, and each of the years in the two-year period ended June 30, 2018, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for the year ended December 31, 2019, the six-month transition period ended December 31, 2018 and each of the years in the two-year period ended June 30, 2018, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated February 27, 2020 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

#### *Basis for Opinion*

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the 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 audits 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 consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

#### *Critical Audit Matter*

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgment. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

#### *Evaluation of liability related to the sale of future royalties*

As discussed in Notes 1, 4, and 6 to the consolidated financial statements, on January 7, 2018, the Company entered into a funding agreement with RPI Finance Trust. The Company accounts for the liability related to the sale of future royalties as a debt financing. The Company estimates the amount of future royalty payments and expected interest expense using the effective interest rate method over the life of the agreement. The carrying value of the liability related to the sale of future royalties at December 31, 2019 was \$261.2 million.

We identified the evaluation of the liability related to the sale of future royalties as a critical audit matter because evaluating the estimates of future royalties involved challenging auditor judgment. These estimates involve significant judgment and inherent uncertainties as it relates to the Company's estimate of future sales for which royalties will be paid. Specifically,



the date of planned commercialization, anticipated pricing and the patient population assumptions used to calculate the revenue projections involved significant estimation uncertainty.

The primary procedures we performed to address this critical audit matter included the following. We tested certain internal controls over the measurement of the liability related to the sale of future royalties, including controls related to the Company's estimate of future sales and use of third party analysis in developing underlying assumptions. We evaluated the amount recorded for the liability, including classification between current and non-current. In addition, we evaluated the Company's estimate of future sales, including the date of planned commercialization, anticipated pricing and the patient population, by comparing to available peer data and market research. We recalculated the current year interest expense based on the amortization schedule and estimate of royalties using the effective interest method.

/s/KPMG LLP

We have served as the Company's auditor since 2013.

New York, NY

February 27, 2020

## **Report of Independent Registered Public Accounting Firm**

To the Stockholders and Board of Directors  
Immunomedics, Inc.:

### *Opinion on Internal Control Over Financial Reporting*

We have audited Immunomedics, Inc.'s and subsidiaries (the Company) internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2019 and 2018, the related consolidated statements of comprehensive loss, changes in stockholders' equity, and cash flows for the year ended December 31, 2019, the six-month transition period ended December 31, 2018, and each of the years in the two-year period ended June 30, 2018, and the related notes (collectively, the consolidated financial statements), and our report dated February 27, 2020 expressed an unqualified opinion on those consolidated financial statements.

### *Basis for Opinion*

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

### *Definition and Limitations of Internal Control Over Financial Reporting*

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's 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. Also, 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.

/s/ KPMG LLP

New York, NY  
February 27, 2020

**IMMUNOMEDICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**  
(Dollars in thousands, except per share amounts)

	December 31,	
	2019	2018
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 608,628	\$ 492,860
Marketable securities	4,550	4,941
Accounts receivable, net of allowances of \$0 at December 31, 2019	295	—
Prepaid expenses	21,818	5,354
Other current assets	3,413	1,348
Total current assets	638,704	504,503
Property and equipment, net of accumulated depreciation and amortization of \$7,925 and \$4,316 at December 31, 2019 and 2018, respectively	32,762	23,469
Other long-term assets	256	68
Total Assets	\$ 671,722	\$ 528,040
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 60,860	\$ 31,722
Liability related to sale of future royalties - current	3,455	—
Lease liability - current	337	—
Convertible senior notes, net	7,106	—
Total current liabilities	71,758	31,722
Convertible senior notes, net	—	7,055
Liability related to sale of future royalties - non-current	257,769	221,295
Deferred revenues	65,000	—
Other long-term liabilities	9,965	2,119
Total Liabilities	404,492	262,191
Commitments and Contingencies (Note 14)		
Stockholders' Equity:		
Convertible preferred stock, \$0.01 par value; authorized 10,000,000 shares; no shares issued and outstanding at December 31, 2019 and 2018	—	—
Common stock, \$0.01 par value; authorized 250,000,000 shares; issued 212,529,313 shares and outstanding 212,409,692 shares at December 31, 2019; issued 190,445,795 shares and outstanding 190,411,070 shares at December 31, 2018	2,125	1,905
Capital contributed in excess of par	1,579,205	1,219,237
Treasury stock, at cost: 119,621 shares at December 31, 2019 and 34,725 shares at December 31, 2018	(2,095)	(824)
Accumulated deficit	(1,310,406)	(953,216)
Accumulated other comprehensive loss	(568)	(351)
Total Immunomedics, Inc. stockholders' equity	268,261	266,751
Noncontrolling interest in subsidiary	(1,031)	(902)
Total Stockholders' Equity	267,230	265,849
Total Liabilities and Stockholders' Equity	\$ 671,722	\$ 528,040

See accompanying notes to consolidated financial statements.

**IMMUNOMEDICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF**  
**COMPREHENSIVE LOSS**  
(Dollars in thousands, except per share amounts)

	Year Ended December 31, 2019	For the Transition Period Ended December 31, 2018	Years Ended June 30,	
			2018	2017
<b>Revenues:</b>				
Product sales	\$ —	\$ —	\$ 1,501	\$ 2,443
License fee and other revenues	295	—	330	284
Research and development	—	—	325	364
Total revenues	295	—	2,156	3,091
<b>Costs and expenses:</b>				
Costs of goods sold	—	—	613	483
Research and development	254,871	93,887	99,283	51,776
Sales and marketing	26,459	19,834	6,822	873
General and administrative	43,803	30,814	36,485	29,109
Total costs and expenses	325,133	144,535	143,203	82,241
Operating loss	(324,838)	(144,535)	(141,047)	(79,150)
Changes in fair market value of warrant liabilities	—	1,404	(108,636)	(61,074)
Warrant related expenses	—	—	—	(7,649)
Interest expense	(40,337)	(20,017)	(23,255)	(5,480)
Interest and other income	7,856	6,106	5,493	431
Loss on induced exchanges of debt	—	(897)	(13,005)	—
Other financing expenses	—	—	—	(347)
Insurance reimbursement	—	190	6,638	—
Foreign currency transaction gain, net	—	—	81	23
Loss before income tax	(357,319)	(157,749)	(273,731)	(153,246)
Income tax expense	—	—	(156)	(20)
Net loss	(357,319)	(157,749)	(273,887)	(153,266)
Net loss attributable to noncontrolling interest	(129)	(81)	(50)	(60)
Net loss attributable to Immunomedics, Inc. stockholders	\$ (357,190)	\$ (157,668)	\$ (273,837)	\$ (153,206)
Loss per common share attributable to Immunomedics, Inc. stockholders (basic and diluted):	\$ (1.84)	\$ (0.84)	\$ (1.78)	\$ (1.47)
Weighted average shares used to calculate loss per common share (basic and diluted)	193,617	188,554	153,475	104,536
<b>Other comprehensive (loss) income, net of tax:</b>				
Foreign currency translation adjustments	174	(8)	(105)	(62)
Unrealized gain (loss) on securities available for sale	(391)	10	55	(109)
Other comprehensive income (loss), net of tax:	(217)	2	(50)	(171)
Comprehensive loss	(357,536)	(157,747)	(273,937)	(153,437)
Comprehensive loss attributable to noncontrolling interest	(129)	(81)	(50)	(60)
Comprehensive loss attributable to Immunomedics, Inc. stockholders	\$ (357,407)	\$ (157,666)	\$ (273,887)	\$ (153,377)

See accompanying notes to consolidated financial statements.

**IMMUNOMEDICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**  
(in thousands)

**Immunomedics, Inc. Stockholders' Equity**

	Convertible Preferred Stock		Common Stock		Capital Contributed in Excess of Par		Treasury Stock		Accumulated Deficit		Accumulated Other Comprehensive Income (Loss)		Noncontrolling Interest		Total
	Shares	Amount	Shares	Amount											
Balance at June 30, 2016	—	\$ —	95,868	\$ 958	\$ 311,320	\$ (458)	\$ (368,505)	\$ (132)	\$ (711)	\$ (57,528)	121,782				
Issuance of preferred stock, net	1,000	10	—	—	121,772	—	—	—	—	—	28,578				
Issuance of common stock in public offering, net	—	—	10,000	100	28,478	—	—	—	—	—	(6,966)				
Proceeds of public offering allocated to warrant liability	—	—	—	—	(6,966)	—	—	—	—	—	—				
Issuance of common stock to Seattle Genetics, Inc.	—	—	3,000	30	14,670	—	—	—	—	—	—				
Proceeds of share issuance to Seattle Genetics, Inc. allocated to warrant liability	—	—	—	—	(14,670)	—	—	—	—	—	—				
Exercise of stock options, net	—	—	1,279	13	4,277	—	—	—	—	—	—				
Stock-based compensation	—	—	198	2	3,785	—	—	—	—	—	—				
Other comprehensive loss	—	—	—	—	—	—	—	—	—	(171)	—				
Net loss	—	—	—	—	—	—	(153,206)	—	(60)	—	—				
Balance at June 30, 2017	1,000	\$ 10	110,345	\$ 1,103	\$ 462,666	\$ (458)	\$ (521,711)	\$ (303)	\$ (771)	\$ (59,464)	190,369				
Reclassification of warrant liability to equity	—	—	—	—	190,369	—	—	—	—	—	—				
Exercise of common stock warrants	—	—	18,206	182	78,044	—	—	—	—	—	—				
Exercise of stock options, net	—	—	586	6	2,255	—	—	—	—	—	—				
Issuance of common stock to RPI Finance Trust	—	—	4,373	44	67,740	—	—	—	—	—	—				
Issuance of common stock in public offering, net	—	—	13,225	132	299,335	—	—	—	—	—	—				
Conversion of preferred stock	(1,000)	(10)	23,105	231	(221)	—	—	—	—	—	—				
Issuance of common stock due to debt conversion	—	—	16,800	168	92,307	—	—	—	—	—	—				
Stock-based compensation	—	—	331	3	4,024	—	—	—	—	—	—				
Conversion of RSU's for tax withholding payments	—	—	(170)	(1)	(1,521)	—	—	—	—	—	—				
Other comprehensive loss	—	—	—	—	—	—	—	—	—	(50)	—				
Net loss	—	—	—	—	—	—	(273,837)	—	(50)	—	—				
Balance at June 30, 2018	—	\$ —	186,801	\$ 1,868	\$ 1,194,998	\$ (458)	\$ (795,548)	\$ (353)	\$ (821)	\$ 399,686	7,569				
Reclassification of warrant liability to equity	—	—	—	—	7,569	—	—	—	—	—	—				
Exercise of common stock warrants	—	—	450	5	1,683	—	—	—	—	—	—				
Exercise of stock options, net	—	—	706	7	2,619	(2,450)	—	—	—	—	—				
Retirement of treasury stock	—	—	(106)	(1)	(2,083)	2,084	—	—	—	—	—				
Issuance of common stock due to debt conversion	—	—	2,568	26	13,757	—	—	—	—	—	—				
Stock-based compensation	—	—	36	—	886	—	—	—	—	—	—				
Conversion of RSU's for tax withholding payments	—	—	(9)	—	(192)	—	—	—	—	—	—				
Other comprehensive income	—	—	—	—	—	—	—	—	—	2	—				
Net loss	—	—	—	—	—	—	(157,668)	—	(81)	—	—				
Balance at December 31, 2018	—	\$ —	190,446	\$ 1,905	\$ 1,219,237	\$ (824)	\$ (953,216)	\$ (351)	\$ (902)	\$ 265,849	2,553				
Exercise of stock options, net	—	—	1,207	12	3,812	(1,271)	—	—	—	—	—				
Issuance of common stock in public offering, net	—	—	16,429	164	272,867	—	—	—	—	—	—				
Stock-based compensation	—	—	15	—	11,736	—	—	—	—	—	—				
Issuance of common stock in at-the-market offering, net	—	—	4,432	44	71,553	—	—	—	—	—	—				
Other comprehensive loss	—	—	—	—	—	—	—	—	—	(217)	—				
Net loss	—	—	—	—	—	—	(357,190)	—	(129)	—	—				
Balance at December 31, 2019	—	\$ —	212,529	\$ 2,125	\$ 1,579,205	\$ (2,095)	\$ (1,310,406)	\$ (568)	\$ (1,031)	\$ 267,230	—				

See accompanying notes to consolidated financial statements.



**IMMUNOMEDICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(Dollars in thousands)

	Year Ended December 31, 2019	For the Transition Period Ended December 31, 2018	Years Ended June 30, 2018	2017
<b>Cash flows from operating activities:</b>				
Net loss	\$ (357,319)	\$ (157,749)	\$ (273,887)	\$ (153,266)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>				
Changes in fair value of warrant liabilities	—	(1,404)	108,636	61,074
Warrant related expense	—	—	—	7,649
Depreciation and amortization	3,822	2,099	1,297	923
Loss on disposal of property and equipment	1,003	—	—	—
Interest on non-recourse debt	39,929	19,288	19,791	—
Loss on induced exchanges of debt	—	897	13,005	—
Amortization of deferred revenue	—	(94)	(77)	(64)
Amortization of bond premiums	—	3	31	218
Amortization of debt issuance costs	50	179	1,679	730
Amortization of deferred rent	—	132	279	10
Non-cash lease expense	264	—	—	—
Loss on sale of marketable securities	—	—	—	16
Decrease in allowance for doubtful accounts	—	—	(9)	(62)
Non-cash expense related to stock-based compensation	11,736	886	4,024	4,333
Non-cash financing expenses	—	—	—	347
<b>Changes in operating assets and liabilities</b>				
Accounts receivable, net	(295)	46	452	103
Inventories, net	—	—	580	(196)
Other receivables	—	—	(30)	223
Prepaid expenses and other current assets	(16,423)	3,617	(7,679)	(97)
Accounts payable and accrued expenses	29,977	1,436	(1,518)	15,809
Other liabilities	(186)	—	—	—
Deferred revenue	65,000	—	—	—
Net cash used in operating activities	(222,442)	(130,664)	(133,426)	(62,250)
<b>Cash flows from investing activities:</b>				
Purchases of marketable securities	—	—	(10,380)	(131,610)
Proceeds from sales/maturities of marketable securities	—	21,818	95,112	57,183
Purchases of property and equipment	(6,849)	(11,213)	(9,975)	(1,837)
Net cash (used in) provided by investing activities	(6,849)	10,605	74,757	(76,264)
<b>Cash flows from financing activities:</b>				
Exercise of stock options, net	2,553	176	2,261	4,290
Exercise of warrants	—	1,688	78,226	—
Sale of preferred stock, net of related expenses	—	—	—	121,782
Proceeds from public offering of common stock	273,031	—	299,467	28,578
Proceeds from the issuance of common stock in at-the-market offering, net	71,597	—	—	—
Proceeds from private offering of common stock	—	—	67,784	14,700
Proceeds from the issuance of non-recourse debt	—	—	182,216	—
Debt conversion fees	—	—	(530)	—
Tax withholding payments for stock-based compensation	—	(192)	(1,521)	(546)
Net cash provided by financing activities	347,181	1,672	627,903	168,804
Effect of changes in exchange rates on cash, cash equivalents and restricted cash	(22)	(22)	(46)	(100)
Net increase (decrease) in cash, cash equivalents and restricted cash	117,868	(118,409)	569,188	30,190
Cash, cash equivalents, and restricted cash beginning of period	494,173	612,582	43,394	13,204
Cash, cash equivalents, and restricted cash end of period	\$ 612,041	\$ 494,173	\$ 612,582	\$ 43,394
<b>Supplemental disclosure of cash flow information:</b>				
Interest paid	\$ 338	\$ 475	\$ 2,850	\$ 4,750
Income taxes paid	\$ —	\$ —	\$ —	\$ 24
<b>Schedule of non-cash investing and financing activities:</b>				
Issuance of common shares for debt conversion	\$ —	\$ 13,757	\$ 92,307	\$ —
Accrued capital expenditures	\$ 101	\$ 795	\$ 2,173	\$ —
Non-cash component of warrant exercise	\$ —	\$ 7,569	\$ —	\$ —
Shares received in cashless exercise	\$ 1,271	\$ 2,450	\$ —	\$ —

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within our consolidated balance sheets that sum to the total of the same amounts shown in the consolidated statements of cash flows:

	<b>Year Ended December 31, 2019</b>	<b>For the Transition Period Ended December 31, 2018</b>	<b>Year Ended June 30, 2018</b>
Cash and cash equivalents	\$ 608,628	\$ 492,860	\$ 612,057
Restricted cash in other current assets	3,413	1,313	525
Total cash, cash equivalents and restricted cash	<u>\$ 612,041</u>	<u>\$ 494,173</u>	<u>\$ 612,582</u>

See accompanying notes to consolidated financial statements.

# IMMUNOMEDICS, INC. AND SUBSIDIARIES

## Notes to Consolidated Financial Statements

### 1. Business Overview and Summary of Significant Accounting Policies

Immunomedics, Inc., a Delaware corporation, together with its subsidiaries (collectively "we," "our," "us," "Immunomedics", or the "Company"), is a clinical-stage biopharmaceutical company that develops monoclonal antibody-based products for the targeted treatment of cancer. Immunomedics manages its operations as one line of business of researching, developing, manufacturing and marketing biopharmaceutical products, particularly antibody-based products for patients with difficult to treat solid tumor and blood cancers. The Company currently reports as a single industry segment with substantially all business conducted in the United States. Immunomedics conducts its research activities in the United States and runs its development studies in the United States and selected European countries. Our corporate objective is to become a fully-integrated biopharmaceutical company and a leader in the field of antibody-drug conjugates ("ADCs"). To that end, our immediate priority is to commercialize our most advanced ADC product candidate, sacituzumab govitecan ("IMMU-132"), beginning in the United States, with metastatic triple-negative breast cancer ("mTNBC") as the first indication. In May 2018, we submitted a Biologics License Application ("BLA") to the United States Food and Drug Administration ("FDA") for sacituzumab govitecan for the treatment of patients with mTNBC who have received at least two prior therapies for metastatic disease. In July 2018, we received notification from the FDA that the BLA was accepted for filing and the original application was granted Priority Review with a Prescription Drug User Fee Act ("PDUFA") target action date in January 2019. In January 2019, we received a Complete Response Letter ("CRL") from the FDA for the BLA. We subsequently met with the FDA in May 2019 to review the FDA's findings and discussed our BLA resubmission. Since then, we have developed a detailed plan to address the chemistry, manufacturing, and controls ("CMC") matters raised in the CRL and in our pre-approval inspection. We held another meeting with the FDA in September 2019 to update the FDA on our progress in addressing these matters and to receive feedback from the FDA on our approach. On November 30, 2019, we resubmitted our BLA to the FDA and on December 23, 2019 we received notification from the FDA that the BLA was accepted for filing and further assigned a new PDUFA target action date as June 2, 2020. We have dedicated, and continue to commit, significant resources to address the CMC matters identified by the FDA, while, in parallel, preparing our manufacturing facility to be ready for re-inspection by the FDA. Our Phase 3 confirmatory ASCENT study for sacituzumab govitecan has reached its target enrollment for mTNBC patients previously treated with at least two systemic chemotherapy regimens. Top-line data for the ASCENT study is expected to be available around mid-2020.

The Company has a foreign subsidiary, Immunomedics GmbH in Rodermark, Germany, that assists the Company in managing sales and marketing efforts and coordinating clinical trials in Europe. The accompanying consolidated financial statements include results for its foreign subsidiary and its majority-owned United States subsidiary, IBC Pharmaceuticals, Inc. ("IBC").

Immunomedics is subject to significant risks and uncertainties, including, without limitation, the Company's inability to further identify, develop and achieve commercial success for new products and technologies; the possibility of delays in the research and development necessary to select drug development candidates and delays in clinical trials; the risk that clinical trials may not result in marketable products; the risk that the Company may be unable to secure regulatory approval of and market its drug candidates; the development or regulatory approval of competing products; the Company's ability to protect its proprietary technologies; patent infringement claims; and risks of new, changing and competitive technologies, and regulations in the United States and internationally.

Since its inception in 1982, Immunomedics' principal sources of funds have been the private and public sale of equity and debt securities, and revenues from licensing agreements, including up-front and milestone payments, funding of development programs, and other forms of funding from collaborations.

The Company expects to continue to fund its operations with its current financial resources.

## **Summary of Significant Accounting Policies:**

### ***Basis of Presentation***

The consolidated financial statements include the accounts of Immunomedics and its subsidiaries. Noncontrolling interests in consolidated subsidiaries in the consolidated balance sheets represent minority stockholders' proportionate share of the equity (deficit) in such subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. In this Annual Report, the periods presented are the year ended December 31, 2019, the six-month transition period from July 1, 2018 to December 31, 2018 (which we sometimes refer to as the "Transition Period") and our fiscal years ended June 30, 2018 and 2017 (which are referred to as "fiscal 2018," and "fiscal 2017", as if we had not changed our fiscal year to a calendar year).

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

The preparation of consolidated financial statements in conformity with United States generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reported period. Actual results could differ from those estimates. The Company's significant estimates and assumptions relate to stock-based compensation expenses, the fair value for the liability related to sale of future royalties and related interest expense.

### ***Interest Expense on Liability Related to Sale of Future Royalties***

The Company accounts for the liability related to the sale of future royalties as a debt financing. The Company has a significant continuing involvement in the generation of related royalty streams. The Company accretes this liability and recognizes expected interest expense using the effective interest rate method over the life of the related royalty stream, based on our current estimates of future royalty payments. These estimates include projections the Company makes and projections from outside the Company and involves significant judgment and inherent uncertainties. The Company periodically re-assesses the projections and, to the extent our future projections are greater or less than its previous estimates or the estimated timing of such payments is materially different than its previous estimates, the Company will adjust the effective interest calculation.

### ***Foreign Currencies***

For our German subsidiary which operates in a local currency environment, income and expense items are translated to United States dollars at the monthly average rates of exchange prevailing during the year, assets and liabilities are translated at year-end exchange rates and equity accounts are translated at historical exchange rates. Translation adjustments are accumulated in a separate component of stockholders' equity in the consolidated balance sheets and the consolidated statements of changes in stockholders' equity and are included in the determination of comprehensive (loss) income in the consolidated statements of comprehensive loss. Transaction gains and losses are included in the determination of net loss in the consolidated statements of comprehensive loss.

### ***Financial Instruments***

The carrying amount of cash and cash equivalents, prepaid expenses, other current assets and current liabilities approximate fair value due to the short-term maturity of these instruments. The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents.

### ***Marketable Securities***

Marketable securities, all of which are available-for-sale, consist of United States Government sponsored agencies which are carried at fair value, with unrealized gains and losses, net of related income taxes, reported as accumulated other comprehensive loss, except for losses from impairments which are determined to be other-than-temporary. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are included in the determination of net loss and are included in interest and other income (net), at which time the average cost basis of these securities are adjusted to fair value. Fair values are based on quoted market prices at the reporting date. Interest and dividends on available-for-sale securities are included in interest and other income (net).

## ***Property and Equipment***

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation expense is computed using the straight-line method over the estimated useful lives of the assets, including leasehold improvements and capital lease assets that are amortized over the shorter of their useful lives or the terms of the respective leases. The Company generally uses the following range of useful lives for its property and equipment categories: leasehold improvements—7 to 10 years; computer equipment—5 years; machinery and equipment—5 to 10 years; and furniture and fixtures—10 years. Depreciation expense includes amortization of assets related to capital leases. The Company charges repairs and maintenance costs to expense as incurred.

## ***Concentration of Credit Risk***

Cash, cash equivalents, and marketable securities are financial instruments that potentially subject the Company to concentration of credit risk. Our investment policy is to invest only in institutions that meet high credit quality standards and establishes limits on the amount and time to maturity of investments with any individual counterparty. The policy also requires that investments are only entered into with corporate and financial institutions that meet high credit quality standards. Restricted cash represents funds the Company is required to set aside to cover vehicle operating leases and other purposes.

## ***Revenue Recognition***

Pursuant to Topic 606, we recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve this core principle, Topic 606 includes provisions within a five step model that includes i) identifying the contract with a customer, ii) identifying the performance obligations in the contract, iii) determining the transaction price, iv) allocating the transaction price to the performance obligations, and v) recognizing revenue when, or as, an entity satisfies a performance obligation.

At contract inception, we assess the goods or services promised within each contract and assess whether each promised good or service is distinct and determine those that are performance obligations. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when the performance obligation is satisfied.

## ***Research and Development Costs***

Research and development costs are expensed as incurred. Costs incurred for clinical trials for patients and investigators are expensed as services are performed in accordance with the agreements in place with the institutions. Research and development costs include salaries and benefits, costs associated with producing biopharmaceutical compounds, laboratory supplies, the costs of conducting clinical trials, and facilities costs. In addition, the Company uses clinical research organizations and contract manufacturing operations to outsource portions of our research and development activities.

## ***Treasury Shares***

The Company records treasury stock at the cost to acquire it and includes treasury stock as a component of Stockholders' Equity. In determining the cost of the treasury shares when either sold or issued, the Company uses the first-in, first-out method ("FIFO"). If the proceeds from the sale of the treasury shares are greater than the cost of the shares sold, the excess proceeds are recorded as additional paid-in capital. If the proceeds from the sale of the treasury shares are less than the original cost of the shares sold, the excess cost reduces any additional paid-in capital arising from previous sales of treasury shares for that class of stock.

## ***Fair Value Measurements***

The Company categorizes its financial instruments measured at fair value into a three-level fair value hierarchy that prioritizes the inputs used in determining the fair value of the asset or liability. The three levels of the fair value hierarchy are as follows:

- *Level 1* - Financial instruments whose values are based on unadjusted quoted prices for identical assets or liabilities in an active market which the company has the ability to access at the measurement date (examples include active exchange-traded securities and most United States Government and agency securities).
- *Level 2* - Financial instruments whose value are based on quoted market prices in markets where trading occurs infrequently or whose values are based on quoted prices of instruments with similar attributes in active markets.



- *Level 3* - Financial instruments whose values are based on prices or valuation techniques that require inputs that are both unobservable and significant to the overall fair value measurement. These inputs reflect management's own assumptions about the assumptions a market participant would use in pricing the asset.

The Company's financial instruments consist of cash and cash equivalents, marketable securities, prepaid expenses, other current assets, accounts payable and accrued expenses, convertible senior notes, liabilities related to the sale of future royalties and Convertible Senior Notes. The carrying amount of prepaid expenses, other current assets, accounts payable and accrued expenses and certain other liabilities are generally considered to be representative of their respective fair values because of the short-term nature of those instruments.

### ***Income Taxes***

The Company uses the asset and liability method to account for income taxes, including the recognition of deferred tax assets and deferred tax liabilities for the anticipated future tax consequences attributable to differences between financial statements amounts and their respective tax bases. The Company reviews its deferred tax assets for recovery. A valuation allowance is established when the Company believes that it is more likely than not that its deferred tax assets will not be realized. Changes in valuation allowances from period to period are included in the Company's tax provision in the period of change. The Company has recorded a full valuation allowance against its net deferred tax assets as of December 31, 2019 and 2018.

The Tax Cuts and Jobs Act (the "Act") was signed into law on December 22, 2017. Among its numerous changes to the Internal Revenue Code, the Act reduces United States corporate rates from 35% to 21%. Additionally, the Act limits the use of net operating loss carry backs, however any future net operating losses will instead be carried forward indefinitely. Only 80% of current income will be able to be offset with a net operating loss carryforward, with the remainder of the net operating loss continuing to carry forward. As a result of the reduction in the U.S. corporate income tax rate, the Company revalued its ending net deferred tax assets as of June 30, 2018, which resulted in a provisional expense of \$59.5 million which was offset by an associated change in valuation allowance. In the second quarter of the Transition Period, the Company completed its analysis to determine the effect of the Tax Act and recorded no further adjustments.

### ***Net Loss Per Share Allocable to Common Stockholders***

Net loss per basic and diluted common share allocable to common stockholders is based on the net loss for the relevant period, divided by the weighted-average number of common shares outstanding during the period. For purposes of the diluted net loss per common share calculations, the exercise or exchange of all potential common shares is not included because their effect would have been anti-dilutive, due to the net loss recorded for the year ended December 31, 2019, the Transition Period and fiscal years ended June 2018, and 2017, respectively. The common stock equivalents excluded from the earnings per share calculation are 8.2 million, 6.7 million, 10.0 million, and 66.1 million for the year ended December 31, 2019, the Transition Period and the fiscal years ended June 2018, and 2017, respectively.

### ***Net Comprehensive Loss***

Net comprehensive loss consists of net loss, unrealized gain (loss) on available for sale securities and foreign exchange translation adjustments and is presented in the consolidated statements of comprehensive loss.

### ***Stock-Based Compensation***

The Company utilizes stock-based compensation in the form of stock options, stock appreciation rights, stock awards, stock unit awards, performance shares, cash-based performance units and other stock-based awards, each of which may be granted separately or in tandem with other awards.

The grant-date fair value of stock awards is based upon the underlying price of the stock on the date of grant. The grant-date fair value of stock option awards must be determined using an option pricing model. Option pricing models require the use of estimates and assumptions as to (a) the expected term of the option, (b) the expected volatility of the price of the underlying stock and (c) the risk-free interest rate for the expected term of the option. The Company uses the Black-Scholes option pricing formula for determining the grant-date fair value of such awards. The fair value of option awards that vest based on achievement of certain market conditions are determined using a Monte Carlo simulation technique.

The expected term of the option is based upon the contractual term and expected employee exercise and expected post-vesting employment termination behavior. The expected volatility of the price of the underlying stock is based upon the historical volatility of the Company's stock computed over a period of time equal to the expected term of the option. The risk-free interest

rate is based upon the implied yields currently available from the United States Treasury yield curve in effect at the time of the grant. Forfeitures are recorded as incurred.

## ***Recently Issued Accounting Pronouncements***

### *Accounting Pronouncements adopted during the year*

The Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2019-01, "Leases Topic 842," requiring entities to recognize assets and liabilities on the balance sheet for all leases, with certain exceptions. Topic 842 allows for a modified retrospective application and is effective as of the first quarter of 2019. Entities are allowed to apply the new guidance using a modified retrospective approach at the beginning of the year in which new lease standard is adopted, rather than to the earliest comparative period presented in their financial statements. The modified retrospective approach includes a number of optional practical expedients that entities may elect to apply. We elected the modified retrospective approach under the new guidance and elected the available practical expedients on adoption. Upon adoption, we recognized additional operating lease liabilities of \$8.4 million with a corresponding right-of-use assets of \$8.4 million based on the present value of the remaining lease payments under existing operating leases. As of December 31, 2018, we had \$2.1 million in deferred charges related to our real estate leases that were recorded against the lease liability asset as part of the transition, resulting in \$10.5 million included in other long-term liabilities on our consolidated balance sheets. In addition, the new guidance resulted in additional lease-related disclosures in the footnotes to our consolidated financial statements. Our leasing portfolio is comprised entirely of operating leases, and we do not recognize right-of-use assets or related lease liabilities with a lease term of twelve months or less on our consolidated balance sheets. Adoption of Topic 842 has required changes to our business processes and controls to comply with the provisions of the standard. Refer to Note 14 "Commitments and Contingencies" for additional information.

In June 2018, the FASB issued ASU 2018-07, "Compensation-Stock Compensation," to improve the usefulness of information provided to users of financial statements while reducing cost and complexity in financial reporting and provide guidance aligning the measurement and classification for share-based payments to nonemployees with the guidance for share-based payments to employees. Under the guidance, the measurement of equity-classified nonemployee awards will be fixed at the grant date. This standard is effective for fiscal years beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted, but no earlier than an entity's adoption date of ASU 2014-09, "Revenue from Contracts with Customers (Topic 606)." We adopted ASU 2018-07 during the first quarter of 2019 and the adoption did not have a material impact to our consolidated financial statements.

### *Accounting Pronouncements yet to be adopted*

In November 2018, the FASB issued ASU 2018-18, "Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606," to clarify when ASC 606 should be used for collaborative arrangements when the counterparty is a customer. The guidance precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the counterparty is not a customer for that transaction. The guidance is effective for public business entities in fiscal years beginning after December 15, 2019, and interim periods therein. Early adoption is permitted to entities that have adopted ASC 606. We are currently assessing the impact of ASU 2018-18.

In August 2018, the FASB issued ASU 2018-13, "Fair Value measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement," to no longer require public companies to disclose transfers between Level 1 and Level 2 of the fair value hierarchy, and to require disclosure about the range and weighted average used to develop significant unobservable inputs for Level 3 fair value measurements. The guidance is effective for fiscal years beginning after December 15, 2019, and for interim periods within those fiscal years. Entities are permitted to early adopt either the entire standard or only the provisions that eliminate or modify the requirements. We are currently assessing the impact of ASU 2018-13.

## **2. Revenue Recognition**

### **Everest Medicines II Limited**

On April 29, 2019, we entered into a license agreement (the "License Agreement") with Everest Medicines II Limited, a China limited company ("Everest"). Pursuant to the License Agreement, we granted Everest an exclusive license to develop and commercialize sacituzumab govitecan in the People's Republic of China, Taiwan, Hong Kong, Macao, Indonesia, Philippines, Vietnam, Thailand, South Korea, Malaysia, Singapore and Mongolia (the "Territory"). In consideration for entering into the License Agreement, Everest made a one-time, non-refundable upfront payment to us in the aggregate amount of \$65.0 million which is recorded as deferred revenue on the consolidated balance sheet as of December 31, 2019. The License Agreement contains a development milestone payment of \$60.0 million based upon our achievement of FDA approval for sacituzumab govitecan. The

License Agreement also contains additional development milestone payments in a total amount of up to \$180.0 million based upon the achievement of certain other development milestones. In addition, the License Agreement contains sales milestone payments in a total amount of up to \$530.0 million based upon the achievement of certain sales milestones. Everest will make royalty payments to us based upon percentages of net sales of sacituzumab govitecan, ranging from 14% to 20%.

The Company assessed the arrangement in accordance with ASC 606 and concluded that the contract counterparty, Everest, is a customer based on the arrangement structure. The Company identified two material promises to deliver under the contract: (1) grant of license and the (2) clinical and commercial supply of the product. However, given the nature of the manufacturing of the product the license is not considered to be distinct from the clinical and commercial supply promise. The Company therefore concluded that there is one combined performance obligation.

The Company initially deferred and will recognize the \$65.0 million over the performance obligation period of the combined performance obligation. As it relates to the upfront consideration, the \$65.0 million is recorded as deferred revenue and will be recognized over the term of the of the contract performance obligation period, which the Company has concluded to be 15 years after initial sale of the product in the territory. As concluded above, the Company has a combined performance obligation, which includes delivering the license and clinical and commercial supply to Everest. As such, because the clinical and commercial supply obligation occur throughout the period of the License Agreement, the \$65.0 million fixed consideration is recognized over the period in which commercial and clinical supply of product is delivered (over-time).

The future potential milestone payments are excluded from the transaction price, as the achievement of the milestone events require considerable judgment in determining whether it is probable of being achieved, and that a significant revenue reversal would not occur. As such, all milestone payments are fully constrained. The Company will reevaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and, if necessary, adjust its estimate of the transaction price.

#### **Janssen Biotech Inc.**

On April 5, 2019, the Company entered into a promotion agreement (the "Promotion Agreement") with Janssen Biotech Inc., ("Janssen") pursuant to which the Company will provide non-exclusive product detailing services to Janssen for erdafitinib (the "Product"). Pursuant to the Promotion Agreement, the Company will provide a dedicated sales team to detail the Product to oncologists and other targeted health care providers in the United States. Under the terms of the Promotion Agreement, Janssen maintains ownership of the New Drug Application for the Product as well as legal, regulatory, distribution, commercialization and manufacturing responsibilities for the Product, while the Company will provide product detailing services to Janssen. Following the achievement of certain sales targets in 2019 and 2020, Janssen will pay the Company (a) a service fee equal to a percentage in the low double digits of the portion of Cumulative Net Sales (as defined in the Promotion Agreement) in excess of a baseline amount during each of 2019 and 2020, and (b) potential milestone payments of up to \$15.0 million when Cumulative Net Sales exceed certain thresholds during each of 2019 and 2020. On April 12, 2019, the Company was informed that the FDA granted accelerated approval to Janssen's Balversa<sup>®</sup> (erdafitinib) for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma that has a type of susceptible genetic alteration known as FGFR3 or FGFR2, and that has progressed during or following prior platinum-containing chemotherapy. During the year ended December 31, 2019, \$0.3 million of service fee revenues were recorded relating to the Promotion Agreement.

### 3. Marketable Securities

Immunomedics considers all of its current investments to be available-for-sale. Marketable securities are carried at fair value, with unrealized gains and losses, net of related income taxes, reported as accumulated other comprehensive (loss) income, except for losses from impairments which are determined to be other-than-temporary. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are included in the determination of net loss and are included in interest and other income (net), at which time the average cost basis of these securities are adjusted to fair value. Fair values are based on quoted market prices at the reporting date. Interest and dividends on available-for-sale securities are included in interest and other income (net). As of December 31, 2019, and 2018, the carrying value of our current investments due after one year or more are \$4.5 million and \$4.9 million, respectively.

The following table summarizes the marketable securities held as of December 31, 2019 and 2018 (in thousands):

December 31, 2019	Amortized Cost	Gross Unrealized Gain	Gross Unrealized (Loss)	Fair Value
U.S. Government Sponsored Agencies	\$ 4,941	\$ —	\$ (391)	\$ 4,550

December 31, 2018	Amortized Cost	Gross Unrealized Gain	Gross Unrealized (Loss)	Fair Value
U.S. Government Sponsored Agencies	\$ 4,941	\$ —	\$ —	\$ 4,941

### 4. Debt

#### *Liability related to sale of future royalties*

On January 7, 2018, the Company entered into a funding agreement (the "Funding Agreement") with RPI Finance Trust, a Delaware statutory trust ("RPI"). Pursuant to the Funding Agreement, the Company issued to RPI the right to receive certain royalty amounts, subject to certain reductions, based on the net sales of the ADC sacituzumab govitecan, for each calendar quarter during the term of the Funding Agreement ("Revenue Participation Right"), in exchange for \$175.0 million in cash (the "Purchase Price"). Specifically, the royalty rate commences at 4.15 percent on net annual sales of up to \$2.0 billion, declining step-wise based on sales tiers to 1.75 percent on net global annual sales exceeding \$6.0 billion.

On January 7, 2018, in connection with the Funding Agreement, the Company entered into a common stock purchase agreement (the "Purchase Agreement") with RPI, pursuant to which the Company, in a private placement, issued and sold to RPI approximately 4.4 million unregistered shares (the "Shares") of the Company's Common Stock, at a price of \$17.15 per share for gross proceeds to the Company of \$75.0 million before deducting fees and expenses (the "Financing").

The Company concluded that there were two units of accounting in the transaction. The Company allocated the transaction consideration on a relative fair value to the liability and common stock in accordance with ASC 470-10 as follows (in thousands):

Units of Accounting:	Allocated Consideration
Liability related to sale of future royalties	\$ 182,216
Common stock	67,784
	\$ 250,000

Interest will be recognized using the effective interest method over a period of 20 years. The effective interest rate under the Funding Agreement, including issuance costs, is approximately 16.0% as of December 31, 2019. During the year ended December 31, 2019, the Transition Period, and the fiscal year ended June 30, 2018, the Company recognized \$39.9 million, \$19.3 million, and \$19.8 million in interest expense, respectively.

The following table shows the activity within the liability related to sale of future royalties during the year ended December 31, 2019, the Transition Period and at the fiscal year ended June 30, 2018 (in thousands):

Liability related to sale of future royalties at January 7, 2018	\$	182,216
Interest expense recognized		19,791
Carrying value of liability related to sale of future royalties at June 30, 2018	\$	202,007
Interest expense recognized		19,288
Carrying value of liability related to sale of future royalties at December 31, 2018	\$	221,295
Interest expense recognized		39,929
Carrying value of liability related to sale of future royalties at December 31, 2019 (includes current portion of \$3,455)	\$	261,224

### *Convertible Senior Notes*

In February 2015, the Company issued \$100.0 million of Convertible Senior Notes (the "Convertible Senior Notes") (net proceeds of approximately \$96.3 million after deducting the initial purchasers' fees and offering expenses) in a private offering exempt from registration under the Securities Act of 1933, as amended (the "Securities Act"), in reliance upon Rule 144A under the Securities Act. The Convertible Senior Notes had a maturity date of February 15, 2020, unless earlier purchased or converted. The debt issuance costs of approximately \$3.7 million, primarily consisting of underwriting, legal and other professional fees, and are amortized over the term of the Convertible Senior Notes. The Convertible Senior Notes are senior unsecured obligations of the Company. Interest at 4.75% is payable semiannually on February 15 and August 15 of each year. The effective interest rate on the Convertible Senior Notes was 5.48% for the period from the date of issuance through the year ended December 31, 2019.

The Convertible Senior Notes are convertible at the option of holders into approximately 19.6 million shares of common stock at any time prior to the close of business on the day immediately preceding the maturity date. The exchange rate will initially be 195.8336 shares of common stock per \$1,000 principal amount of Convertible Senior Notes (equivalent to an initial conversion price of approximately \$5.11 per share of common stock).

If the Company undergoes a fundamental change (as defined in the indenture governing the Convertible Senior Notes), holders may require Immunomedics to purchase for cash all or part of the Convertible Senior Notes at a purchase price equal to 100% of the principal amount of the Convertible Senior Notes to be purchased, plus accrued and unpaid interest, if any, to, but excluding, the fundamental change purchase date, subject to certain exceptions. In addition, if certain make-whole fundamental changes (as defined in the indenture governing the Convertible Senior Notes) occur, Immunomedics will, in certain circumstances, increase the conversion rate for any Convertible Note converted in connection with such make-whole fundamental change.

The indenture does not limit the amount of debt which may be issued by the Company under the indenture or otherwise, does not contain any financial covenants or restrict the Company from paying dividends, selling or disposing of assets, or issuing or repurchasing its other securities, provided that such event is not deemed to be a fundamental change (as defined in the indenture governing the Convertible Senior Notes). The indenture contains customary terms and covenants and events of default.

If an event of default with respect to the Convertible Senior Notes occurs, holders may, upon satisfaction of certain conditions, accelerate the principal amount of the Convertible Senior Notes plus premium, if any, and accrued and unpaid interest, if any. In addition, the principal amount of the Convertible Senior Notes plus premium, if any, and accrued and unpaid interest, if any, will automatically become due and payable in the case of certain types of bankruptcy or insolvency events of default involving the Company.

On September 21, 2017, the Company entered into separate, privately negotiated exchange agreements, (the "September Exchange Agreements") with certain holders of the Convertible Senior Notes. Under the Exchange Agreements, such holders agreed to convert an aggregate \$80.0 million of Convertible Senior Notes held by them. In total, the Company issued an aggregate 16.8 million shares of common stock in the September Exchange Agreements. The shares represent an aggregate of 1.1 million shares more than the number of shares into which the exchanged Convertible Senior Notes were convertible under their original terms. As a result of the September Exchange Agreements, the Company recognized a loss on induced exchanges of debt of \$13.0 million representing the fair value of the incremental consideration paid to induce the holders to exchange their Convertible Senior Notes for equity (i.e., 1.1 million shares of common stock), based on the closing market price of the Company's Common Stock on the date of the September 2017 Exchange Agreements.



On October 2, 2018, the Company entered into privately negotiated exchange agreements (the "October 2018 Exchange Agreements"), with a limited number of holders of the Convertible Senior Notes. Under the Exchange Agreements, such holders agreed to convert an aggregate \$12.9 million of Convertible Senior Notes held by them. In total, the Company issued an aggregate 2.6 million shares of common stock in the October 2018 Exchange Agreements. The shares represent an aggregate of 0.1 million shares more than the number of shares into which the exchanged Convertible Senior Notes were convertible under their original terms. As a result of the October 2018 Exchange Agreements, the Company recognized a loss on induced exchanges of debt of \$0.9 million representing the fair value of the incremental consideration paid to induce the holders to exchange their Convertible Senior Notes for equity (i.e., 0.1 million shares of common stock), based on the closing market price of the Company's Common Stock on the date of the October 2018 Exchange Agreements. As a result of the October 2018 Exchange Agreements, the balance of the outstanding Convertible Senior Notes was \$7.1 million at December 31, 2019 and 2018. As of February 14, 2020, the remaining \$7.1 million of Convertible Senior Notes converted into 1.4 million shares of common stock based on the initial conversion price of approximately \$5.11 per share of common stock.

Total interest expense for the Convertible Senior Notes were \$0.4 million, \$0.5 million, \$3.5 million, and \$5.5 million, for the year ended December 31, 2019, the Transition Period and the fiscal years ended 2018 and 2017, respectively. Included in interest expense is the amortization of debt issuance costs of \$0.1 million for the year ended December 31, 2019, \$0.2 million in the Transition Period (\$0.1 million of which related to the accelerated amortization of debt issuance costs associated with the October 2018 Exchange Agreements), \$1.7 million in fiscal 2018 (\$1.4 million of which related to the accelerated amortization of debt issuance costs associated with the September Exchange Agreements), and \$0.7 million in fiscal 2017.

## **5. Stock-Based Compensation**

### *Stock Incentive Plan*

The Company has a stock incentive plan, the Immunomedics, Inc. 2014 Long-Term Incentive Plan (the "Plan"). The Plan was established to promote the long-term financial interests and growth of the Company, by attracting and retaining management and other personnel and key service providers with the training, experience and ability to enable them to make a substantial contribution to the success of the Company's business. The Plan is designed to motivate management personnel by means of growth-related incentives to achieve long-range goals and further the alignment of interests with those of the stockholders of the Company through opportunities for increased stock or stock-based ownership in the Company. Toward these objectives, the Company may grant stock options, stock appreciation rights, stock awards, stock units, performance shares, performance options, performance units, and other stock-based awards to eligible individuals on the terms and subject to the conditions set forth in the Plan. There have been no significant modifications to the Plan during the year ended December 31, 2019, the Transition Period or fiscal years ended June 30, 2018, or 2017.

Stock-based compensation expense was \$11.7 million, \$0.9 million, \$4.0 million, and \$4.3 million for the year ended December 31, 2019, the Transition Period, and fiscal years ended June 30, 2018 and 2017, respectively. On January 15, 2019, the Company received a final award finding from an arbitrator that denied Dr. Goldenberg 1.5 million of RSU's. As a result, during the Transition Period, \$3.4 million of the stock-based compensation expense was reversed. Refer to "Note 14 - Commitments and Contingencies" for more information.

### *Stock Options*

Stock option grants provide the right to purchase a specified number of shares of Common Stock from the Company at a specified price during a specified period of time. The stock option exercise price per share is the fair market value of one share of Common Stock on the date of the grant of the stock option and generally have a vesting period of four years.

As of December 31, 2019, there was \$40.6 million of total unrecognized compensation cost related to non-vested stock-based compensation arrangements granted under the plan. That cost is being recognized over a weighted-average period of 3 years.

The weighted average grant date fair value of the stock options granted during the year ended December 31, 2019, the Transition Period, and fiscal years ended June 30, 2018, and 2017 was \$8.81 per share, \$12.90 per share, \$8.76 per share, and \$2.21 per share, respectively. The weighted average grant date fair value of the performance-based stock options granted during the year ended December 31, 2019, the Transition Period, and fiscal years ended June 30, 2018, and 2017 was \$9.50, \$0.00, \$7.29 and \$0.00 per share, respectively. There were no performance-based stock options granted during the Transition Period, or for the fiscal year ended June 30, 2017.

We estimated the fair value of options granted using a Black-Scholes option pricing model with the following assumptions:

	Year Ended December 31, 2019	Transition Period December 31, 2018	Fiscal Years Ended June 30,	
			2018	2017
Expected dividend yield	—%	—%	—%	—%
Expected option term (years)	4.52	4.76	4.84	5.04
Expected stock price volatility	71%	69%	70%	63%
Risk-free interest rate	1.39% - 2.58%	2.69% - 3.06%	1.72% - 2.89%	1.16% - 2.15%

The following table summarizes all stock option activity for the ended December 31, 2019:

	Options (in thousands)	Weighted Average Exercise Price Per Option	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Options outstanding, January 1, 2019	4,757	\$ 14.30	5.42	\$ 18,618
Changes during the year:				
Granted	3,614	15.46		
Exercised	(1,207)	3.17		
Expired or forfeited	(1,263)	17.78		
Options outstanding, end of year	5,901	\$ 16.54	5.90	\$ 30,145
Vested as of December 31, 2019	1,150	\$ 14.72	4.61	\$ 8,276

The following table summarizes all stock option activity for the Transition Period ended December 31, 2018:

	Options (in thousands)	Weighted Average Exercise Price Per Option	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Options outstanding, July 1, 2018	3,549	\$ 7.58	4.43	\$ 57,123
Changes during the year:				
Granted	2,002	22.54		
Exercised	(706)	3.71		
Expired or forfeited	(88)	15.57		
Options outstanding, end of year	4,757	\$ 14.30	5.42	\$ 18,618
Vested as of December 31, 2018	1,504	\$ 4.23	3.41	\$ 15,098

The total fair value of shares vested during the year ended December 31, 2019, the Transition Period, and fiscal years ended June 30, 2018, and 2017 was \$8.9 million, \$1.3 million, \$0.3 million, and \$1.4 million, respectively. The total intrinsic value of stock options exercised during the fiscal year ended December 31, 2019, the Transition Period, and fiscal years ended June 30, 2018, and 2017 was \$14.7 million, \$13.3 million, \$7.8 million, and \$2.6 million, respectively.

### *Restricted Stock Units ("RSU's")*

The Company may grant awards of RSU's to eligible individuals. An RSU represents a contractual obligation by the Company to deliver a number of shares of Common Stock equal to the fair market value of the specified number of shares subject to the award, or a combination of shares of Common Stock and cash. Vesting requirements may include performance goals, the attainment of performance goals with continued service, or both.

Information regarding the Company's RSU's for the year ended December 31, 2019 is as follows:

<b>Non-Vested Restricted Stock Units</b>	<b>Share Equivalent (in thousands)</b>	<b>Weighted Average Grant Date Fair Value</b>
Non-vested at January 1, 2019	15	\$ 14.29
Changes during the period:		
Restricted Units Granted	58	12.93
Vested/Exercised	(15)	14.29
Forfeited	—	—
Non-vested at December 31, 2019	58	\$ 12.93

As of the year ended December 31, 2019, there was \$0.3 million of total unrecognized compensation costs related to the awards. The cost is being recognized over a weighted-average period of 0.4 years.

Information regarding the Company's RSU's for the Transition Period ended December 31, 2018 is as follows:

<b>Non-Vested Restricted Stock Units</b>	<b>Share Equivalent (in thousands)</b>	<b>Weighted Average Grant Date Fair Value</b>
Non-vested at July 1, 2018	1,535	\$ 2.83
Changes during the period:		
Restricted Units Granted	15	14.29
Vested/Exercised	(35)	8.46
Forfeited	(1,500)	2.28
Non-vested at December 31, 2018	15	\$ 14.29

As of December 31, 2018, there was \$0.3 million of total unrecognized compensation costs related to the awards. The cost was being recognized over a weighted-average period of 1.18 years. During the Transition Period, the Company received a final award finding from an arbitrator that denied Dr. Goldenberg 1.5 million of RSU's that are included as forfeited in the table above. Refer to "Note 14 - Commitments and Contingencies" for more information.

### *Performance Stock Options ("PSO's")*

The Company may grant awards of PSO's to eligible individuals. PSO's are shares of Common Stock that vest based on performance measured against predetermined objectives that could include performance goals, continued employment, or a combination of both over a specified performance period. PSO's may be settled in shares of Common Stock, cash, or both as determined on the settlement date.

On March 14, 2019, performance stock options were granted to certain individuals that vest upon the Company's receipt of approval from the FDA for the Company's BLA for sacituzumab govitecan for the treatment of patients with metastatic triple-negative breast cancer who have received at least two prior therapies for metastatic disease under the Prescription Drug User Fee Act. There were additional stock options that were granted to certain eligible individuals that vest on the second anniversary of the date of grant. In addition, on April 17, 2019 performance stock options were granted to certain individuals that vest upon achievement of defined sales performance milestones.

The following table summarizes the Company's performance-based stock option activity for the year ended December 31, 2019 is as follows:

	<b>Options (in thousands)</b>	<b>Weighted Average Exercise Price Per Option</b>	<b>Weighted Average Remaining Contractual Term (Years)</b>	<b>Aggregate Intrinsic Value (in thousands)</b>
Options outstanding, January 1, 2019	538	\$ 13.09	6.04	\$ 772
Changes during the year:				
Granted	800	17.18		
Exercised	—	—		
Expired or forfeited	(501)	13.05		
Options outstanding, end of year	837	\$ 17.03	6.26	\$ 3,456
Vested as of December 31, 2019	50	\$ 18.74	6.88	\$ 121

The total fair value of shares vested during the year ended December 31, 2019 was \$1.1 million. As of the year ended December 31, 2019, there was \$4.9 million of total unrecognized compensation costs related to the awards. The cost is being recognized over a remaining weighted-average period of 0.8 years.

The following table summarizes the Company's performance-based stock option activity for the Transition Period ended December 31, 2018 is as follows:

	<b>Options (in thousands)</b>	<b>Weighted Average Exercise Price Per Option</b>	<b>Weighted Average Remaining Contractual Term (Years)</b>	<b>Aggregate Intrinsic Value (in thousands)</b>
Options outstanding, July 1, 2018	538	\$ 13.09	6.54	\$ 5,688
Changes during the year:				
Granted	—	—		
Exercised	—	—		
Expired or forfeited	—	—		
Options outstanding, end of year	538	\$ 13.09	6.04	\$ 772
Vested as of December 31, 2018	38	\$ 11.86	5.94	\$ 91

As of December 31, 2018, there was \$3.0 million of total unrecognized compensation costs related to the awards. The cost was being recognized over a remaining weighted-average period of 3.05. There were no performance stock options granted during the Transition Period.

## 6. Estimated Fair Value of Financial Instruments

### Cash Equivalents and Marketable Securities

(\$ in thousands)				
As of December 31, 2019	Level 1	Level 2	Level 3	Total
Money Market Funds Note (a)	\$ 550,788	\$ —	\$ —	\$ 550,788
Marketable Securities:				
U.S. Government Sponsored Agencies	4,550	—	—	4,550
Total	<u>\$ 555,338</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 555,338</u>

(\$ in thousands)				
As of December 31, 2018	Level 1	Level 2	Level 3	Total
Money Market Funds Note (a)	\$ 326,239	\$ —	\$ —	\$ 326,239
Marketable Securities:				
U.S. Government Sponsored Agencies	4,941	—	—	4,941
Total	<u>\$ 331,180</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 331,180</u>

(a) The money market funds noted above are included in cash and cash equivalents.

### Convertible Senior Notes

The carrying amounts and estimated fair values (Level 2) of debt instruments are as follows (in thousands):

	As of December 31, 2019		As of December 31, 2018	
	Carrying Amount	Estimated Fair Value	Carrying Amount	Estimated Fair Value
Convertible Senior Notes	<u>\$ 7,106</u>	<u>\$ 28,900</u>	<u>\$ 7,055</u>	<u>\$ 20,100</u>

The fair value of the Convertible Senior Notes, which differs from their carrying values, is influenced by interest rates, the Company's stock price and stock price volatility and is determined by prices for the Convertible Senior Notes observed in market trading which are Level 2 inputs.

### Liability Related to the Sale of Future Royalties

The Company has determined the fair value of the liability related to the sale of future royalties is based on the Company's current estimates of future royalties expected to be paid to RPI, over the life of the arrangement, which are considered Level 3 (See Note 4 - "Debt").

There were no transfers between Level 1, Level 2, and Level 3 during the periods presented.



## 7. Property and Equipment

Property and equipment consisted of the following as of December 31, (in thousands):

	2019	2018
Machinery and equipment	\$ 14,331	\$ 16,048
Leasehold improvements	11,535	6,365
Right-of-use asset	8,368	—
Furniture and fixtures	1,190	291
Computer equipment	2,596	1,850
Construction in progress	2,667	3,231
	<u>40,687</u>	<u>27,785</u>
Accumulated depreciation and amortization	(7,925)	(4,316)
	<u>\$ 32,762</u>	<u>\$ 23,469</u>

Depreciation and amortization expense for the year ended December 31, 2019, the Transition Period, and the fiscal years ended June 30, 2018 and 2017, was \$3.8 million, \$2.1 million, \$1.3 million and \$0.9 million, respectively.

## 8. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following as of December 31, (in thousands):

	2019	2018 <sup>(a)</sup>
Trade accounts payable	\$ 37,758	\$ 20,125
Accrued contract manufacturing expenses	11,663	—
Accrued employee related expenses	7,403	315
Clinical trial accruals	2,225	5,114
Executive severance liabilities	561	2,198
Miscellaneous other current liabilities	1,250	3,970
	<u>\$ 60,860</u>	<u>\$ 31,722</u>

<sup>(a)</sup> Certain 2018 amounts have been reclassified to conform with current year presentation.

## 9. Stockholders' Equity

At the June 29, 2017 Special Meeting, the Company's stockholders approved the amendment and restatement of the Company's Certificate of Incorporation to increase the maximum number of shares of the Company's stock authorized up to 260,000,000 shares of stock consisting of 250,000,000 shares of common stock and 10,000,000 shares of preferred stock. Previously the Company's Certificate of Incorporation authorized up to 165,000,000 shares of capital stock, consisting of 155,000,000 shares of common stock and 10,000,000 shares of preferred stock.

### *Preferred Stock*

The Certificate of Incorporation of the Company authorizes 10,000,000 shares of preferred stock, \$.01 par value per share. The preferred stock may be issued from time to time in one or more series, with such distinctive serial designations, rights and preferences as shall be determined by the Board of Directors.

On May 10, 2017, the Company issued in a private placement 1,000,000 shares (the "Preferred Shares") of the Company's Series A-1 Convertible Preferred Stock at a price of \$125 per share for gross proceeds to the Company of \$125.0 million, before deducting fees and expenses (the "Financing"). Each Preferred Share will be convertible into 23.10536 shares of common stock (or an aggregate of 23,105,348 shares of common stock). The conversion price per share of common stock is \$5.41. At December 31, 2019 and 2018, the Company had no preferred stock outstanding.

Following the June 29, 2017 Special Meeting and filing the Charter Amendment with the State of Delaware, the Company had authorized a sufficient number of unreserved shares of common stock to permit the exchange of the Preferred Shares. On July 31, 2017, the Company filed a registration statement on Form S-3 to register for resale the 23,105,348 shares of the Company's common stock issuable upon the exchange of the Series A-1 Convertible Preferred Stock. The Preferred Shares converted to shares of common stock on August 24, 2017. The registration statement was declared effective on September 19, 2017.

### ***Common Stock***

On October 11, 2016, the Company completed an underwritten public offering of 10,000,000 shares of its common stock and accompanying warrants to purchase 10,000,000 shares of common stock at a purchase price of \$3.00 per unit, comprising of one share of common stock and one warrant. The Company received gross and net proceeds of \$30.0 million and approximately \$28.6 million, respectively after deducting the underwriting discounts and commissions and estimated expenses related to the offering payable. The warrants became exercisable nine months following the date of issuance and will expire on the second anniversary of the date of issuance and have an exercise price of \$3.75. On the date of issuance, the fair value of these warrants was determined to be \$7.3 million and recognized as a liability. The warrants under certain situations require cash settlement by the Company. During fiscal 2018 there were 9,550,000 warrants exercised. The fair value of the 9,550,000 exercised warrants increased \$102.1 million from June 30, 2017 to the dates of exercise which has been recognized in the accompanying consolidated statements of comprehensive loss. As of the fiscal year ended June 30, 2018, there were 450,000 warrants outstanding. During the transition period ended December 31, 2018, the remaining 450,000 warrants were exercised for which we received \$1.7 million in cash. As of December 31, 2019, and 2018, there were no warrants outstanding.

On February 10, 2017, in connection with the execution of a License Agreement, the Company entered into the Securities Purchase Agreement ("SPA") with Seattle Genetics. Under the SPA, Seattle Genetics purchased 3,000,000 shares (the "Common Shares") of the Company's common stock at a price of \$4.90 per share, for aggregate proceeds of \$14.7 million. Concurrently with the sale of the Common Shares, pursuant to the SPA, the Company also agreed to issue the three-year warrant to purchase an aggregate of 8,655,804 shares of common stock. On July 31, 2017, the Company filed a registration statement on Form S-3 to register the 3,000,000 shares of Company's common stock and 8,655,804 shares of common stock issuable upon the exercise of the warrants (in addition to the shares issuable upon the conversion of our Series A-1 Convertible Preferred Stock, as discussed above). The warrant became exercisable for cash on February 16, 2017 and expired on January 31, 2018. The warrant was issued on February 16, 2017 and was originally exercisable until February 10, 2020. On the date of issuance, the fair value of these warrants was determined to be \$22.3 million. The difference between such fair value and the proceeds of \$14.7 million has been recognized as an expense and presented in the consolidated statements of comprehensive loss as a "warrant related expense." On May 4, 2017, the Company and Seattle Genetics entered into the Termination Agreement, pursuant to which the Company and Seattle Genetics relinquished their respective rights under the License Agreement and agreed to amend the terms of the warrant to amend the expiration date from February 10, 2020 to December 31, 2017. On December 5, 2017, Seattle Genetics exercised the Warrants they held in full to acquire 8,655,804 shares of Common Stock for an aggregate purchase price of \$42.4 million.

On June 15, 2018, we announced the closing of our public offering of 11,500,000 shares of our common stock at a price of \$24.00 per share. Pursuant to the underwriter's full exercise of the over-allotment option granted by us, on June 22, 2018, we closed on the sale of an additional 1,725,000 shares of our common stock for a total of 13,225,000 shares. The total net proceeds from the offering, including the exercise of the over-allotment option, were \$299.5 million, after deducting \$17.4 million in underwriting discounts and commissions and other offering expenses payable by the Company.

On December 9, 2019, we closed an underwritten public offering of 14,285,715 shares of its common stock at a public offering price of \$17.50 per share, representing gross proceeds of approximately \$250.0 million. In addition, the Company granted the underwriters a 30-day option to purchase up to 2,142,857 additional shares of common stock for a total of 16,428,572 shares. We received gross proceeds of \$287.5 million and net proceeds of \$273.0 million after deducting the underwriting discounts and commissions and expenses related to the offering.

### ***At-the-Market Offering***

On March 29, 2019, the Company entered into a sales agreement (the "ATM Agreement") with Cowen and Company, LLC ("Cowen") to issue and sell shares of the Company's common stock, par value \$0.01 per share, having an aggregate offering price of up to \$150.0 million, from time to time during the term of the ATM Agreement, through an "at-the-market" equity offering program at the Company's sole discretion, under which Cowen will act as the Company's agent and/or principal. The Company will pay Cowen a commission up to 3.0% of the gross sales proceeds of any common stock sold through Cowen under the ATM Agreement. During the year ended December 31, 2019, the Company sold 4,432,416 shares of common stock with net proceeds of \$71.6 million at a weighted average price of \$16.40 (excluding commissions) under the ATM Agreement.

## Treasury Stock

During the year ended December 31, 2019, there were 84,896 shares received in connection with a non-cash equity transaction related to the Company's Plan. During the Transition Period, there were 105,959 treasury shares received in connection with a non-cash equity transaction related to the Company's Plan and the shares were subsequently retired.

### 10. Accumulated Other Comprehensive (Loss) Income

The components of accumulated other comprehensive (loss) income were as follows (in thousands):

	Currency Translation Adjustments	Net Unrealized Gains (Losses) on Available-for- Sale Securities	Accumulated Other Comprehensive (Loss) Income
Balance at June 30, 2016	\$ (172)	\$ 40	\$ (132)
Other comprehensive loss before reclassifications	(62)	(125)	(187)
Amounts reclassified from accumulated other comprehensive income <sup>(a)</sup>	—	16	16
Net other comprehensive loss for the year	(62)	(109)	(171)
Balance at June 30, 2017	(234)	(69)	(303)
Other comprehensive income (loss) before reclassifications	(105)	55	(50)
Amounts reclassified from accumulated other comprehensive income <sup>(a)</sup>	—	—	—
Net other comprehensive (loss) income for the year	(105)	55	(50)
Balance at June 30, 2018	(339)	(14)	(353)
Other comprehensive income (loss) before reclassifications	(8)	10	2
Amounts reclassified from accumulated other comprehensive income <sup>(a)</sup>	—	—	—
Net other comprehensive (loss) income for the year	(8)	10	2
Balance at December 31, 2018	(347)	(4)	(351)
Other comprehensive loss before reclassifications	(21)	(391)	(412)
Amounts reclassified from accumulated other comprehensive income <sup>(a)</sup>	195	—	195
Net other comprehensive (loss) income for the year	174	(391)	(217)
Balance at December 31, 2019	\$ (173)	\$ (395)	\$ (568)

- (a) For the year ended December 31, 2019, the Transition Period ended December 31, 2018, and the fiscal years ended June 30, 2018 and 2017, \$0.2 million, \$0, \$0, and \$16 thousand, respectively, were reclassified from accumulated other comprehensive (loss) income to interest and other income.

All components of accumulated other comprehensive (loss) income are net of tax, except currency translation adjustments, which exclude income taxes related to indefinite investments in foreign subsidiaries.

## 11. Income Taxes

Income tax expense for income taxes is as follows (in thousands):

	Year Ended December 31, 2019	Transition Period Ended December 31, 2018	Fiscal Year Ended June 30,	
			2018	2017
<b>Federal</b>				
Current	\$ —	\$ —	\$ —	\$ —
Deferred	—	—	—	—
Total Federal	—	—	—	—
<b>State</b>				
Current	—	—	2	1
Deferred	—	—	—	—
Total State	—	—	2	1
<b>Foreign</b>				
Current	—	—	154	19
Deferred	—	—	—	—
Total Foreign	—	—	154	19
Total income tax expense	\$ —	\$ —	\$ 156	\$ 20

A reconciliation of the statutory tax rates and the effective tax rates for the year ended December 31, 2019, the transition period ended December 31, 2018 and fiscal years ended June 30, 2018 and 2017 is as follows:

	Year Ended December 31, 2019	Transition Period Ended December 31, 2018	Fiscal Year Ended June 30,	
			2018	2017
Statutory rate	(21.0)%	(21.0)%	(28.0)%	(34.0)%
Foreign income tax	— %	— %	— %	— %
Change in valuation allowance	29.9 %	34.4 %	21.1 %	21.9 %
State income taxes, (net of federal tax benefit)	(7.5)%	(8.8)%	(4.3)%	(4.8)%
Permanent differences, (primarily warrant-related expenses)	(1.4)%	(4.2)%	11.3 %	15.3 %
Other	— %	(0.4)%	— %	1.6 %
Effective rate	— %	— %	0.1 %	— %

The tax effects of temporary differences that give rise to significant portions of the Company's deferred tax assets and liabilities as of December 31, (in thousands):

	2019	2018
<b>Deferred tax assets:</b>		
NOL carryforwards	\$ 203,928	\$ 132,841
Research and development credits	28,535	23,118
Liability related to sale of future royalties	49,228	49,217
Deferred revenue	18,286	—
Disallowed interest expense	13,474	—
Other	5,807	3,088
Total	319,258	208,264
Valuation allowance	(317,828)	(206,397)
Net deferred assets	\$ 1,430	\$ 1,867
<b>Deferred tax liabilities:</b>		
Property and equipment	\$ (1,430)	\$ (1,867)
Net deferred assets and liabilities	\$ —	\$ —

A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. The valuation allowances for the year ended December 31, 2019, and the Transition Period ended December 31, 2018 have been applied to offset the deferred tax assets in recognition of the uncertainty that such tax benefits will be realized as the Company continues to incur losses. The differences between book income and tax income primarily relate to the temporary differences from depreciation and stock compensation expenses, and deferred book income that is realized for tax.

At December 31, 2019, and the Transition Period ended December 31, 2018, the Company has available net operating loss carry forwards for federal income tax reporting purposes of approximately \$769.1 million and \$516.6 million for state income tax reporting purposes of approximately \$593.6 million and \$343.0 million, respectively, which expire at various dates between 2020 and 2038. For tax years 2018 onward, Federal net operating losses have an indefinite life but are limited to annual utilization by 80% taxable income.

The Company accounts for uncertain tax benefits in accordance with the provisions of section 740-10 of the Accounting for Uncertainty in Income Taxes Topic of the FASB ASC. Of the total unrecognized tax benefits at December 31, 2019 and 2018, approximately \$2.5 million was recorded in both years as a reduction to deferred tax assets, which caused a corresponding reduction in the Company's valuation allowance of \$2.5 million in both years. The Company does not anticipate that the amount of unrecognized tax benefits as of December 31, 2019 will change materially within the 12-month period following December 31, 2019. The change in unrecognized tax benefits are presented below (in thousands):

	Year Ended December 31, 2019	Transition Period Ended December 31, 2018
Change in unrecognized tax benefits		
Balance at beginning of year	\$ 2,521	\$ —
Gross increases related to current period tax positions	—	—
Gross increases related to prior periods tax positions	—	2,521
Gross decreases in tax positions	—	—
Expiration of the statute of limitations	—	—
Balance at end of year	<u>\$ 2,521</u>	<u>\$ 2,521</u>

The Company will recognize potential interest and penalties related to income tax positions as a component of the provision for income taxes on the Consolidated Statements of Comprehensive Loss in any future periods in which the Company must record a liability. The Company is subject to examination for United States Federal and Foreign tax purposes for 2013 and forward and for New Jersey 2015 and forward. The Company conducts business and files tax returns in New Jersey.

For fiscal year 2016, the Company sold certain State of New Jersey State Net Operating Losses ("NOL") and Research and Development ("R&D") tax credits through the New Jersey Economic Development Authority Technology Business Tax Certificate Transfer Program. Pursuant to such sale, for the year ended June 30, 2016, the Company recorded a tax benefit of \$5.1 million, as a result of its sale of approximately \$66.2 million, of New Jersey State NOL and \$1.5 million of New Jersey R&D tax credits. There were no sales of NOL or R&D for the year ended December 31, 2019, the Transition Period or 2018 or 2017 fiscal years.

The Global Intangible Low-tax Income ("GILTI") provisions of the 2017 Tax Act require the Company to include in its United States income tax return foreign subsidiary earnings in excess of an allowable return on the foreign subsidiary's tangible assets. The Company expects that it may be subject to incremental United States tax on GILTI income in the future but not for the year ended December 31, 2019. The Company has elected to account for GILTI tax in the period in which it is incurred, and therefore has not provided any deferred tax impacts of GILTI in its consolidated financial statements.

As a result of U.S. tax reform legislation, distributions of profits from non-U.S. subsidiaries are not expected to cause a significant incremental U.S. tax impact in the future. However, distributions may be subject to non-U.S. withholding taxes if profits are distributed from certain jurisdictions. U.S. federal income taxes have not been provided on undistributed earnings of our international subsidiaries as it is our intention to reinvest any earnings into the respective subsidiaries. It is not practicable to estimate the amount of tax that might be payable if some or all of such earnings were to be repatriated due to the legal structure and complexity of U.S. and local tax laws. As of December 31, 2019, and 2018, there are no undistributed earnings.

As a result of the reduction in the U.S. corporate income tax rate, the Company revalued its ending net deferred tax assets as of June 30, 2018, which resulted in a provisional expense of \$59.5 million which was offset by an associated change in valuation allowance. In the second quarter of the Transition Period, the Company completed its analysis to determine the effect of the Tax Act and recorded no further adjustments.



## **12. Related Party Transactions**

On January 8, 2018, Morris Rosenberg joined the Company as Chief Technology Officer and became a full-time employee. Between May 5, 2017, and January 7, 2018, Mr. Rosenberg was engaged by the Company as an independent consultant pursuant to a consulting agreement between the Company and Mr. Rosenberg's consulting company, M Rosenberg BioPharma Consulting LLC. The Company paid M Rosenberg BioPharma Consulting LLC \$0.6 million during this time and Morris Rosenberg was also granted stock options to purchase 45,000 shares of the Company's common stock pursuant to the Immunomedics, Inc. 2014 Long-Term Incentive Plan. From January 8, 2018, through June 30, 2018, the Company paid M Rosenberg BioPharma \$0.8 million, and from July 1, 2018, through the transition period ending December 31, 2018, the Company paid M Rosenberg BioPharma \$0.3 million for services agreed upon prior to Mr. Rosenberg becoming a full-time employee. As part of his employment contract, 50% of the 45,000 shares granted to Mr. Rosenberg as a consultant were forfeited, the remaining 50% continue to vest. Mr. Rosenberg received 104,389 stock options and was permitted to continue to provide certain limited outside consulting services through M Rosenberg BioPharma Consulting LLC based on certain restrictions outlined in the contract. Additionally, during his employment period, except with the prior written consent of the Board of Directors, Mr. Rosenberg is not permitted to enter into any contract, agreement or other transaction arrangement to provide goods and/or services to the Company through M Rosenberg BioPharma Consulting LLC.

On March 5, 2019, the Company appointed Scott Canute, a member of the Company's Board, as the Company's Executive Director. Upon recommendation of the Compensation Committee, the Board approved that Mr. Canute will be paid \$16,667 per month for his service as Executive Director and was granted a nonqualified stock option to purchase 79,818 shares of the Company's common stock (the "Initial Canute Compensation"). The Compensation Committee determined that in order to reflect the scope of his role and the significant time that Mr. Canute will be devoting to his role as Executive Director, Mr. Canute's cash compensation shall be increased to \$21,372 per month, and Mr. Canute was granted an additional nonqualified stock option to purchase 22,854 shares of the Company's common stock (the "Revised Canute Compensation"). The options have a seven-year term and an exercise price equal to the fair market value of the Company's common stock based on the closing price of the Company's common stock on each date of grant and will be subject to the terms of a nonqualified stock option agreement (the "Canute NQSO Agreement"). Such options will vest in full upon the Company's receipt of approval from the FDA for the Company's BLA resubmission for sacituzumab govitecan for the treatment of patients with mTNBC who have received at least two prior therapies for metastatic disease under the PDUFA. The Company and Mr. Canute entered into a letter agreement (the "Canute Letter Agreement") to memorialize his appointment as the Company's Executive Director, and the Initial Canute Compensation. The Canute Letter Agreement may be terminated by either party at any time upon written notice to the other party. During the year ended December 31, 2019, the Company paid Mr. Canute \$0.4 million for such services.

On November 19, 2019, pursuant to the Plan, the Board of Directors approved a stock option grant to Behzad Aghazadeh, Executive Chairman of the Board of Directors of the Company, to purchase 150,000 shares of the Company's common stock (the "Performance-Based Option") for certain duties performing this role; including providing consulting and advisory services to the Company. The Performance-Based Option will be a nonqualified stock option and one third vested upon FDA acceptance of the BLA resubmission in December 2019, and two thirds shall vest upon approval from the FDA for the Company's BLA for sacituzumab govitecan.

## **13. Collaboration Agreements**

### **AstraZeneca/MedImmune**

In June 2018, we entered into a clinical collaboration with AstraZeneca PLC ("AstraZeneca") and its global biologics research and development arm, MedImmune, to evaluate in Phase 1/2 studies the safety and efficacy of combining AstraZeneca's Imfinzi® (durvalumab), a human monoclonal antibody directed against programmed cell death ligand 1 ("PD-L1"), with sacituzumab govitecan as a treatment of patients with triple-negative breast cancer ("TNBC") and urothelial cancer ("UC"), which was broadened in October 2018 to include second-line metastatic non-small cell lung cancer ("NSCLC").

Part one of the two-part Phase 1/2 studies will be co-funded by the two companies. Immunomedics will supply the study drug and AstraZeneca will utilize its existing clinical trial infrastructure to accelerate the enrollment of the sacituzumab govitecan and durvalumab combination. The trial design allows for rapid transition into randomized Phase 2 studies should the first part of these studies show promising data and the companies agree to proceed based on efficacy and safety results obtained.

## **GBG Forschungs GmbH**

In September 2019, we entered into a clinical collaboration with the German Breast Group Forschungs-GmbH ("GBG"), Neu-Isenburg, Germany, to develop sacituzumab govitecan as a treatment for newly-diagnosed breast cancer patients who do not achieve a pathological complete response ("pCR") following standard neoadjuvant therapy.

The multinational, post-neoadjuvant Phase 3 SASCIA study developed by GBG will be conducted under the sponsorship of GBG. Approximately 1,200 high-risk patients with newly-diagnosed HER2-negative breast cancer not achieving a pCR following standard neoadjuvant therapy will be randomized to receive either sacituzumab govitecan or treatment of physician's choice. Primary endpoint is invasive DFS with overall survival, patient reported outcome/quality of life, circulating tumor DNA clearance, and safety serving as secondary endpoints.

Under the terms of the agreement, GBG is eligible to receive up to €33.0 million in potential clinical and regulatory milestone payments over a span of approximately six years, of which €0.5 million was paid during the year ended December 31, 2019.

### **14. Commitments and Contingencies**

#### ***a. Legal Matters***

##### ***Arbitration of Disputed Matters:***

On January 15, 2019, the Company received an Arbitrator's Findings of Fact and Conclusions of Law and Final Award (the "Final Award") in the arbitration matter in which Dr. David M. Goldenberg, the Company's former Chief Scientific Officer, Chief Patent Officer and Chairman of the Company's Board of Directors, claimed entitlement to certain equity awards and severance payments, and Dr. Goldenberg and Ms. Cynthia Sullivan, a former director of the Company and former President and Chief Executive Officer, claimed rights to certain bonus payments. The Final Award (i) denied Dr. Goldenberg's claim that he was entitled to an award of 1.5 million restricted stock units, (ii) denied each of Dr. Goldenberg's and Ms. Sullivan's claims that they were entitled to certain discretionary cash bonuses relating to the Company's 2017 fiscal year, and (iii) granted Dr. Goldenberg an award of approximately \$1.0 million relating to certain claimed severance payments which was paid in March 2019. The arbitration took place pursuant to the Delaware Rapid Arbitration Act. Although the Delaware Rapid Arbitration Act permits challenges to arbitration awards in limited circumstances, pursuant to that certain stipulation and agreement of settlement, compromise, and release dated November 2, 2017, the Company, Dr. Goldenberg and Ms. Sullivan agreed that the Final Award would be the sole and exclusive final and binding remedy between and among the parties with respect to the matters disputed in the arbitration.

##### ***Stockholder Complaints:***

##### ***Class Action Stockholder Federal Securities Cases***

Two purported class action cases were filed in the United States District Court for the District of New Jersey; namely, *Fergus v. Immunomedics, Inc., et al.*, filed June 9, 2016; and *Becker v. Immunomedics, Inc., et al.*, filed June 10, 2016. These cases arise from the same alleged facts and circumstances and seek class certification on behalf of purchasers of our common stock between April 20, 2016 and June 2, 2016 (with respect to the Fergus matter) and between April 20, 2016 and June 3, 2016 (with respect to the Becker matter). These cases concern the Company's statements in press releases, investor conference calls, and filings with the U.S. Securities and Exchange Commission (the "SEC") beginning in April 2016 that the Company would present updated information regarding its IMMU-132 breast cancer drug at the 2016 American Society of Clinical Oncology ("ASCO") conference in Chicago, Illinois. The complaints allege that these statements were false and misleading in light of June 2, 2016 reports that ASCO had canceled the presentation because it contained previously reported information. The complaints further allege that these statements resulted in artificially inflated prices for our common stock, and that the Company and certain of its officers are thus liable under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). An order of voluntary dismissal without prejudice was entered on November 10, 2016 in the Becker matter. An order granting motion to consolidate cases, appoint lead plaintiff, and approve lead and liaison counsel was entered on February 7, 2017 in the Fergus matter. A consolidated complaint was filed on October 4, 2017. The Company filed a motion to dismiss the consolidated complaint on January 26, 2018. On March 31, 2019, the court granted the Company's motion to dismiss, without prejudice, and left plaintiffs with the ability to file an amended complaint within thirty (30) days. Counsel for the Company has consented to an extension of time for plaintiffs to file the proposed amended complaint for an additional thirty (30) days. On May 30, 2019, plaintiffs filed an amended complaint alleging many of the same allegations that were set forth in the previously filed complaints, and the Company has filed a motion to dismiss.

A third purported class action case was filed in the United States District Court for the District of New Jersey; namely, *Odeh v. Immunomedics, Inc., et al.*, filed December 27, 2018. The complaint in this action alleges that the Company failed to disclose the results of observations made by the FDA during an inspection of the Company's manufacturing facility in Morris Plains, New Jersey in August 2018. The complaint alleges that Immunomedics misled investors by failing to disclose the Form 483 inspection report issued by the FDA which set forth the observations of the FDA inspector during the inspection. Such observations purportedly included, inter alia, manipulated bioburden samples, misrepresentation of an integrity test procedure in the batch record, and backdating of batch records. The complaint further alleges that the Company's failure to disclose the Form 483 resulted in an artificially inflated price for our common stock, and that the Company and certain of its officers are thus liable under Sections 10(b) and 20(a) of the Exchange Act.

On February 8, 2019, a purported class action case was filed in the United States District Court for the District of New Jersey; namely, *Choi v. Immunomedics, Inc., et al.* The complaint asserts violations of the federal securities laws based on claims that the Company violated the federal securities laws by making alleged misstatements in various press releases and securities filings from February 8, 2018 to November 7, 2018 and by failing to disclose the substance of its interactions with the FDA in connection with the Company's submission of its BLA for sacituzumab govitecan.

Motions for the appointment of a lead plaintiff and lead counsel and to consolidate the *Odeh* and *Choi* actions were granted on September 10, 2019. Pursuant to a scheduling order entered by the court on October 7, 2019, the plaintiffs filed an amended complaint on November 18, 2019. The Company filed a motion to dismiss the consolidated, amended complaint on January 17, 2020. The motion has a return date of April 20, 2020.

On April 8, 2019, a putative stockholder of the Company filed a derivative action purportedly on behalf of the Company and against the Company's board of directors and certain Company current and former officers, in the Superior Court of New Jersey, Law Division (Morris County); namely, *Crow v. Aghazadeh, et al.* The *Crow* complaint alleges that the individual defendants breached their fiduciary duties and committed other violations of law based on the same core allegations in the *Odeh* and *Choi* actions. The *Crow* complaint was served on the Company and other defendants on July 18, 2019. On August 13, 2019, the parties submitted to the court a stipulation and proposed order to stay the action until either the entry of an order denying all motions to dismiss the now-consolidated federal actions or the entry of an order dismissing the federal actions with prejudice. That stipulation is currently pending court approval.

#### *Stockholder Claim in the Court of Chancery of the State of Delaware*

On February 13, 2017, venBio commenced an action captioned *venBio Select Advisor LLC v. Goldenberg, et al., C.A. (Del. Ch.)* (the "venBio Action"), alleging that Company's Board breached their fiduciary duties when the Board (i) amended the Company's Amended and Restated By-laws (the "By-Laws") to call for a plurality voting regime for the election of directors instead of majority voting, and providing for mandatory advancement of attorneys' fees and costs for the Company's directors and officers, (ii) rescheduled the Company's 2016 Annual Meeting of Stockholders (the "2016 Annual Meeting") from December 14, 2016 to February 16, 2017, and then again to March 3, 2017, and (iii) agreed to the proposed Licensing Transaction with Seattle Genetics. venBio also named Seattle Genetics as a defendant and sought an injunction preventing the Company from closing the licensing transaction with Seattle Genetics. On March 6, 2017, venBio amended its complaint, adding further allegations. The Court of Chancery entered a temporary restraining order on March 9, 2017, enjoining the closing of the Licensing Transaction. venBio amended its complaint a second time on April 19, 2017, this time adding Greenhill & Co. Inc. and Greenhill & Co. LLC (together "Greenhill"), the Company's financial advisor on the Licensing Transaction, as an additional defendant. On May 3, 2017, venBio and the Company and individual defendants Dr. Goldenberg, Ms. Sullivan and Mr. Brian A. Markison, a director of the Company (collectively, the "Individual Defendants") entered into the Initial Term Sheet. On June 8, 2017, venBio the Company and Greenhill entered into the Greenhill Term Sheet. On February 9, 2018, the Court of Chancery approved the Settlement, and entered an order and partial judgment releasing all claims that were asserted by venBio against the Individual Defendants and Greenhill in the venBio Action and awarding venBio fees and expenses. On May 24, 2018 the remaining parties to the venBio Action participated in a mediation of the claims against Geoff Cox, Robert Forrester, Bob Oliver, and Jason Aryeh (the "Remaining Defendants"). The mediation was unsuccessful. The Remaining Defendants filed submitted motions to dismiss the claims against them in the venBio Action. On March 18, 2019, venBio amended its complaint, adding further allegations. The Remaining Defendants filed a motion to dismiss the claims against them on May 1, 2019. The Court of Chancery held oral arguments for the motion to dismiss on November 13, 2019 and following arguments, denied Defendants' motion to dismiss on that same date. The parties are now engaged in discovery activities.

#### ***Insurance Coverage Arbitration:***

The Company has initiated an arbitration with two of its management liability insurers: Starr Indemnity & Liability Company ("Starr"), and Liberty Insurance Underwriters Inc. ("Liberty") (collectively, "Insurers"). The arbitration arises from

the 2015 Insurers' refusal to cover \$3.4 million in attorneys' fees and expenses paid to venBio pursuant to a December 1, 2017, settlement agreement between venBio, the Company, Dr. Goldenberg, Ms. Sullivan, Mr. Markison, and Greenhill to partially settle the venBio Action and fully settle the Federal Action and the Delaware Section 225 Action (the "venBio Fee Award").

The Insurers argue that the venBio Fee Award does not satisfy their policies' definitions of covered "loss" because the policies only cover defense costs incurred by the Company. The Company counters that the venBio Fee Award is a covered settlement, not a claim for defense costs. Insurers also argue that they have no obligation to pay any defense costs or settlement incurred in the Federal Action or 225 Action because Immunomedics initiated those lawsuits. The Company's position is that the Federal Action and 225 Action were defensive in nature and therefore covered because they were initiated to further the defense of the venBio Action. Additionally, Insurers argue the venBio Fee Award is not covered because the Company was required to obtain Insurers' consent to enter into a binding term sheet in the venBio Action and to agree to pay the venBio Fee Award and that the Company failed to do so. The Company takes the position that Insurers at all times were aware of the developments in the venBio Action, that they sought consent to enter into the settlement, and that Insurers cannot show they were prejudiced by an any alleged failure to obtain Insurers' consent.

Liberty also contends that the Company's insurance claim is not covered by Liberty's 2015-16 insurance policy and should be covered by another company's policy in a later policy period. The Company takes the position that the policies treat the venBio Action as a related claim to the Fergus v. Immunomedics class action stockholder federal securities case, which was filed in 2016 and that because of the similar allegation in the venBio Action and Fergus, the policies deem the venBio Action claim to be made at the same time as Fergus and covered by the 2015-16 policies. In the arbitration, Starr contends it will have the benefit of any finding that the claim is covered in a later policy period, even though Starr had agreed with the Company's position prior to the arbitration.

In the event Insurers prevail on their argument that the venBio Fee Award is covered by a subsequent policy year, the Company will pursue coverage under its other insurance policies.

Starr is presently advancing the costs to defend the remaining claims in the venBio Action, *i.e.*, those against the Company as Nominal Defendant and individual defendants Aryeh, Cox, Forrester, and Oliver. However, all Insurers have reserved their rights to contest coverage for any potential settlement of those claims.

#### ***b. Other Matters***

Immunomedics is also a party to various claims and litigation arising in the normal course of business.

#### ***c. Leases***

Our operating lease assets primarily represent manufacturing and research and development facilities, warehouses, and offices. Our finance leases primarily represent computer equipment and are not significant. For the year ended December 31, 2019, cash payments against operating lease liabilities totaled \$1.3 million. The discount rate used to determine the net present value of the leases at inception was 11.0%. This is the incremental borrowing rate that represents the rate of interest that the Company would expect to pay to borrow an amount equal to the lease payments under similar terms. Our leases both share a remaining lease term of 11.8 years, some of which may include options to extend the leases further. The Company considers these options in determining the lease term used to establish the right-of-use assets and lease liabilities.

Supplemental consolidated balance sheet information related to leases are as follows (in thousands):

<b>Operating leases:</b>	<b>December 31, 2019</b>	
Operating lease right-of-use assets, net	\$	8,105
Current portion of lease liabilities	\$	337
Non-current portion of lease liabilities	\$	9,965
Total operating lease liabilities	\$	10,302
Weighted average remaining lease term (years)		11.8
Weighted average discount rate		11.0%

Operating lease right-of-use asset is a component of property and equipment on the consolidated balance sheet. The non-current portion of lease liabilities is a component of other long-term liabilities on the consolidated balance sheet.

Supplemental cash flow information related to leases are as follows (in thousands):

	Year Ended December 31, 2019	
Non-cash lease expense	\$	264
Change in operating lease liabilities	\$	186

Maturities of lease liabilities as of December 31, 2019 are as follows (in thousands):

Year 1	\$	1,453
Year 2		1,465
Year 3		1,523
Year 4		1,531
Year 5		1,567
Thereafter		11,333
Total lease payments		18,872
Less imputed interest		(8,570)
Total	\$	10,302

Operating lease expense was approximately \$1.4 million, \$0.7 million, \$1.3 million, and \$0.9 million for the year ended December 31, 2019, the transition period ended December 31, 2018 and fiscal years ended June 30, 2018, and 2017, respectively.

#### ***d. Purchase Obligations***

We have several commitments primarily to purchase commercial manufacturing services including minimum purchase commitments related to product supply contracts and e-sourcing software totaling \$90.0 million in 2020, \$59.8 million in 2021, \$40.8 million in 2022, \$40.8 million in 2023, \$33.0 million in 2024 and \$33.0 million thereafter.

#### ***e. License***

On April 4, 2018, we entered into a license agreement with The Scripps Research Institute ("TSRI"). Pursuant to the license agreement, TSRI granted to us an exclusive, worldwide, sub-licensable, royalty-bearing license to use certain patent rights relating to our ADC sacituzumab govitecan. The license agreement expires on a country-by-country basis on the expiration date of the last to expire licensed patent rights in such country covering a licensed product. The license agreement may be terminated by the mutual written consent of us and TSRI, and TSRI may terminate the license agreement upon the occurrence of certain events, including but not limited to if we do not make a payment due pursuant to the license agreement and fail to cure such non-payment within 30 days after the date of TSRI's written notice of such non-payment. As consideration for the license granted, we made a cash payment of \$0.3 million to TSRI. Additionally, we will pay TRSI (i) product development milestone payments that range from the mid-six digit dollar figure to the low-seven digit dollar figure and (ii) royalties on net sales of licensed products in the low-single digit percentage figure range capped at an annual amount. We have agreed to use reasonable efforts to develop and market the licensed products. During the year ended December 31, 2019, we recognized a \$0.5 million milestone payment expense.

#### ***f. Michael Pehl Separation***

On March 13, 2019, the Company entered into a separation agreement (the "Separation Agreement") with Michael Pehl, the Company's former Chief Executive Officer, President and member of the Company's Board. Mr. Pehl resigned as Chief Executive Officer, President and member of the Company's Board effective February 23, 2019. Pursuant to the Separation Agreement, Mr. Pehl will receive cash payments of approximately \$1.0 million over an eighteen-month period. During the year ended December 31, 2019, the Company paid approximately \$0.5 million to Mr. Pehl, and \$0.6 million was accrued for as of December 31, 2019. Mr. Pehl also released the Company from any and all claims with respect to all matters arising out of or related to Mr. Pehl's employment by the Company and his resignation.



## 15. Defined Contribution Plans

Eligible employees are able to participate in the Company's 401(k) plan. Effective January 1, 2019, the Company increased the employer non-discretionary matching contributions in an amount equal to 100% of deferral contributions up to a maximum of 5% of eligible compensation contributed to the 401(k) plan. Company contributions to the 401(k) plan totaled approximately \$1.9 million for the year ended December 31, 2019, and \$0.1 million for the Transition Period and for each of the fiscal years ended June 30, 2018 and 2017.

## 16. Quarterly Results of Operations (Unaudited)

The following table summarizes unaudited quarterly financial data:

(\$ in thousands, except for per share amounts)	Three Months Ended			
	December 31, 2019	September 30, 2019	June 30, 2019	March 31, 2019
Consolidated Statements of Comprehensive Loss Data:				
Revenues	\$ 295	\$ —	\$ —	\$ —
Net loss attributable to Immunomedics, Inc. stockholders	\$ (99,608)	\$ (94,292)	\$ (75,953)	\$ (87,337)
Loss per common share attributable to Immunomedics Inc. stockholders – (basic and diluted)	\$ (0.50)	\$ (0.49)	\$ (0.40)	\$ (0.46)
Weighted average shares used to calculate loss per common share – (basic and diluted)	199,614	191,981	191,745	191,052

(\$ in thousands, except for per share amounts)	Three Months Ended			
	December 31, 2018	September 30, 2018	June 30, 2018	March 31, 2018
Consolidated Statements of Comprehensive Loss Data:				
Revenues	\$ —	\$ —	\$ 387	\$ 482
Net loss attributable to Immunomedics, Inc. stockholders	\$ (93,499)	\$ (64,169)	\$ (117,032)	\$ (35,546)
Loss per common share attributable to Immunomedics Inc. stockholders – (basic and diluted)	\$ (0.50)	\$ (0.34)	\$ (0.68)	\$ (0.21)
Weighted average shares used to calculate loss per common share – (basic and diluted)	190,171	186,937	171,124	166,054

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

**Item 9A. Controls and Procedures:**

*Disclosure Controls and Procedures:* We maintain controls and procedures designed to ensure that we are able to collect the information we are required to disclose in the reports we file with the SEC, and to record, process, summarize and disclose this information within the time periods specified in the rules promulgated by the SEC. Our Chief Financial Officer, who serves as our principal executive officer and principal financial officer, and our Principal Accounting Officer are responsible for establishing and maintaining these disclosure controls and procedures and as required by the rules of the SEC, to evaluate their effectiveness. Based on their evaluation of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K, our Chief Financial Officer and Principal Accounting Officer believe that these procedures are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Securities Exchange Act of 1934 is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our Chief Financial Officer and Principal Accounting Officer, as appropriate to allow timely decisions regarding disclosures.

*Management's Report on Internal Control Over Financial Reporting:* Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. Our internal control over financial reporting is designed 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: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of Immunomedics; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and our directors; and (iii) 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. Also, 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.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2019. In making this assessment, management used the criteria in the *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on its assessment and those criteria, our management has concluded we maintained effective internal control over financial reporting as of December 31, 2019.

Our independent registered public accounting firm has issued an attestation report on the effectiveness of Immunomedics' internal control over financial reporting.

*Changes in internal controls over financial reporting:* There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act), identified in connection with the evaluation of such internal control that occurred during our last fiscal quarter, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

None.

## **PART III**

### **Item 10. *Directors, Executive Officers, and Corporate Governance***

Pursuant to Paragraph G(3) of the General Instructions to Form 10-K, the information required by Part III (Items 10, 11, 12, 13 and 14) is being incorporated by reference herein from our definitive proxy statement to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2019 in connection with our 2020 Annual Meeting of Stockholders.

The text of our Code of Business Conduct, which applies to our directors and employees (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions) is posted in the “Corporate Governance” section of our website, [www.immunomedics.com](http://www.immunomedics.com). A copy of the Code of Business Conduct can be obtained free of charge on our website. We intend to disclose on our website any amendments to, or waivers from, our Code of Business Conduct that are required to be disclosed pursuant to the rules of the SEC and Nasdaq.

### **Item 11. *Executive Compensation***

See Item 10.

### **Item 12. *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

See Item 10.

### **Item 13. *Certain Relationships and Related Transactions and Director Independence***

See Item 10.

### **Item 14. *Principal Accounting Fees and Services***

See Item 10.

## **PART IV**

### **Item 15. *Exhibits, Financial Statement Schedules***

#### **(a) Documents filed as part of this report**

##### **(1) Consolidated Financial Statements**

Index to Consolidated Financial Statements

Consolidated Balance Sheets – as of December 31, 2019 and 2018

Consolidated Statements of Comprehensive Loss for the Year Ended December 31, 2019, the Transition Period Ended December 31, 2018 and the Fiscal Years Ended June 30, 2018 and 2017

Consolidated Statements of Changes in Stockholders’ Equity for the Year Ended December 31, 2019, the Transition Period Ended December 31, 2018 and Fiscal Years Ended June 30, 2018 and 2017

Consolidated Statements of Cash Flows for the Year Ended December 31, 2019, the Transition Period Ended December 31, 2018 and Fiscal Years Ended June 30, 2018 and 2017

Notes to Consolidated Financial Statements

Reports of Independent Registered Public Accounting Firm – KPMG LLP

##### **(b) Financial Statement Schedules**

None.

##### **(3) List of Exhibits**

<b>Exhibit No.</b>	<b>Description</b>
3.(i).1	Amended and Restated Certificate of Incorporation, incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K as filed with the Commission on June 29, 2017.
3.(i).2	Form of Certificate of Designation of Series A-1 Convertible Preferred Stock, incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the Commission on May 5, 2017.
3.(iii).1	By-Laws of Immunomedics, Inc., incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the Commission on April 17, 2019.
4.1*	Description of Securities of the Registrant, dated as of December 31, 2019.
4.2	Indenture, dated as of February 11, 2015, by and between the Company and Wells Fargo Bank, National Association, incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K as filed with the Commission on February 12, 2015.
4.3	Form of 4.75% Convertible Senior Note due 2020 incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K as filed with the Commission on February 12, 2015.
10.1	License Agreement, dated March 5, 1999, between the Company and IBC Pharmaceuticals, incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8-K as filed with the Commission on March 24, 1999.
10.2	Lease Agreement with Baker Properties Limited Partnership, dated January 16, 1992, incorporated by reference from the Exhibits to the Company's Registration Statement on Form S-2 (Commission File No. 33-44750), effective January 30, 1992. (P)
10.3	First Addendum, dated May 5, 1993, of the Lease Agreement with Baker Properties Limited Partnership, dated January 16, 1992, incorporated by reference from Exhibit 10.31 to the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2007.
10.4	Second Addendum, dated March 29, 1995, of the Lease Agreement with Baker Properties Limited Partnership, dated January 16, 1992, incorporated by reference from Exhibit 10.32 to the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2007.
10.5	Letter Amendment, dated October 5, 1998, of the Lease Agreement with Baker Properties Limited Partnership, dated January 16, 1992, incorporated by reference from Exhibit 10.33 to the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2007.
10.6	Fourth Amendment Expansion/Extension Agreement dated August 15, 2001, of the Lease Agreement with Baker Properties Limited Partnership, dated January 16, 1992, incorporated by reference from Exhibit 10.34 to the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2007.
10.7	Fifth Amendment Expansion Agreement dated June 18, 2009 of the Lease with WU/LH 300 American L.L.C. a successor-in-interest to Baker Properties Limited Partnership, incorporated by reference from Exhibit 10.36 to the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2009.
10.8	Sixth Amendment Extension Agreement dated February 11, 2011 of the Lease with WU/LH 300 American L.L.C. a successor-in-interest to Baker Properties Limited Partnership, incorporated by reference from Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2011.
10.9*	Lease Agreement dated October 27, 2017 with WU/LH 400 American L.L.C.
10.10#	Immunomedics, Inc. 2014 Long-Term Incentive Plan, incorporated by reference from Exhibit 99.1 to the Company's Registration Statement on Form S-8 (Commission File Number 333-201470), as filed with the Commission on January 13, 2015.
10.11#	Forms of Incentive Stock Option Notice and Incentive Stock Option Agreement under the Immunomedics, Inc. 2014 Long-Term Incentive Plan, incorporated by reference from Exhibit 99.2 to the Company's Registration Statement on Form S-8 (Commission File Number 333-201470), as filed with the Commission on January 13, 2015.
10.12#	Forms of Nonqualified Stock Option Notice and Nonqualified Stock Option Agreement under the Immunomedics, Inc. 2014 Long-Term Incentive Plan, incorporated by reference from Exhibit 99.3 to the Company's Registration Statement on Form S-8 as filed with the Commission on January 13, 2015.
10.13#	Forms of Restricted Stock Units Notice and Restricted Stock Units Agreement (for Officers/Employees) under the Immunomedics, Inc. 2014 Long-Term Incentive Plan, incorporated by reference from Exhibit 99.4 to the Company's Registration Statement on Form S-8 as filed with the Commission on January 13, 2015.

10.14#	Forms of Restricted Stock Units Notice and Restricted Stock Units Agreement (for Directors) under the Immunomedics, Inc. 2014 Long-Term Incentive Plan, incorporated by reference from Exhibit 99.5 to the Company's Registration Statement on Form S-8 as filed with the Commission on January 13, 2015.
10.15	Form of Indemnification Agreement by and between the Company and each of its directors, executive officers, and certain of its former directors and executive officers, incorporated by reference to exhibit 10.1 to the Company's current report on Form 8-K, as filed with the Commission on February 16, 2017.
10.16	Securities Purchase Agreement between the Company and the Purchasers, dated as of May 4, 2017, incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-3, as filed with the Commission on July 31, 2017 (Commission File No. 333-219594).
10.17 †	Master Services Agreement, dated as of July 3, 2017, by and between the Company and Covance, Inc., incorporated by reference to Exhibit 10.2 to the Company's quarterly report on Form 10-Q, as filed with the Commission on November 9, 2017.
10.18 †	Work Order, dated as of July 3, 2017, by and between the Company and Covance, Inc., incorporated by reference to Exhibit 10.3 to the Company's quarterly report on Form 10-Q, as filed with the Commission on November 9, 2017.
10.19	Stipulation and Agreement of Settlement, Compromise, and Release, dated November 2, 2017, by and among the Company, venBio Select Advisor LLC, Dr. David M. Goldenberg, Cynthia L. Sullivan, Brian A. Markison, Greenhill & Co., Inc., and Greenhill & Co., LLC., incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K, as filed with the Commission on November 8, 2017.
10.20	Form of Indemnification Agreement, incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K, as filed with the Commission on December 6, 2017.
10.21 #	Executive Employment Agreement, dated as of November 8, 2017, between the Company and Brendan Delaney, incorporated by reference to Exhibit 10.5 to the Company's quarterly report on Form 10-Q, as filed with the Commission on February 8, 2018.
10.22 #	Incentive Stock Option Grant, dated as of November 10, 2017, between the Company and Brendan Delaney, incorporated by reference to Exhibit 10.6 to the Company's quarterly report on Form 10-Q, as filed with the Commission on February 8, 2018.
10.23 †	Funding Agreement, dated as of January 7, 2018, between the Company and RPI Finance Trust, incorporated by reference to Exhibit 10.1 to the Company's quarterly report on Form 10-Q, as filed with the Commission on May 9, 2018.
10.24	Common Stock Purchase Agreement, dated as of January 7, 2018, between the Company and RPI Finance Trust, incorporated by reference to Exhibit 10.2 to the Company's quarterly report on Form 10-Q, as filed with the Commission on May 9, 2018.
10.25 †	Letter Agreement, dated as of July 6, 2018, by and between the Company and BSP Pharmaceuticals S.p.A., incorporated by reference to Exhibit 10.55 to the Company's annual report on Form 10K/A, as filed with the Commission on December 6, 2018.
10.26 †	License Agreement, dated as of April 4, 2018, by and between the Company and The Scripps Research Institute, incorporated by reference to Exhibit 10.56 to the Company's annual report on Form 10-K/A, as filed with the Commission on December 6, 2018.
10.27 †	Master Services Agreement, dated as of September 11, 2018, between the Company and Samsung BioLogics Co., Ltd, incorporated by reference to Exhibit 10.59 to the Company's quarterly report on Form 10-Q, as filed with the Commission on November 7, 2018.
10.28 †	Product Specific Agreement, dated as of September 11, 2018, between the Company and Samsung BioLogics Co., Ltd, incorporated by reference to Exhibit 10.60 to the Company's quarterly report on Form 10-Q, as filed with the Commission on November 7, 2018.
10.29	Executive Employment Agreement, dated as of September 24, 2018, between the Company and Jared Freedberg, incorporated by reference to Exhibit 10.61 to the Company's quarterly report on Form 10-Q, as filed with the Commission on November 7, 2018.
10.30	Nonqualified Stock Option Grant, dated as of September 24, 2018, between the Company and Jared Freedberg, incorporated by reference to Exhibit 10.62 to the Company's quarterly report on Form 10-Q, as filed with the Commission on November 7, 2018.
10.31	Executive Employment Agreement, dated as of September 26, 2018, between the Company and Kurt Andrews, incorporated by reference to Exhibit 10.63 to the Company's quarterly report on Form 10-Q, as filed with the Commission on November 7, 2018.
10.32	Nonqualified Stock Option Grant, dated as of July 11, 2018, between the Company and Kurt Andrews, incorporated by reference to Exhibit 10.64 to the Company's quarterly report on Form 10-Q, as filed with the Commission on November 7, 2018.



10.33	Immunomedics, Inc. Annual Cash Bonus Plan, incorporated by reference to Exhibit 10.65 to the Company's quarterly report on Form 10-Q, as filed with the Commission on November 7, 2018.
10.34 †	Manufacturing Services Agreement, dated as of December 17, 2018, by and between the Company and Johnson Matthey Pharmaceutical Materials, Inc., incorporated by reference to Exhibit 10.66 to the Company's annual report on Form 10-K, as filed with the Commission on February 25, 2019.
10.35	Letter Agreement, dated as of March 5, 2019, by and between the Company and Scott Canute, incorporated by reference to Exhibit 10.1 to the Company's quarterly report on Form 10-Q, as filed with the Commission on May 9, 2019.
10.36	Separation Agreement, dated as of March 13, 2019, by and between the Company and Michael Pehl, incorporated by reference to Exhibit 10.2 to the Company's quarterly report on Form 10-Q, as filed with the Commission on May 9, 2019.
10.37	Executive Employment Agreement, dated as of August 7, 2017, by and between the Company and Usama Malik, incorporated by reference to Exhibit 10.3 to the Company's quarterly report on Form 10-Q, as filed with the Commission on May 9, 2019.
10.38 †	Promotion Agreement, dated as of April 5, 2019, by and between Immunomedics, Inc. and Janssen Biotech, Inc., incorporated by reference to Exhibit 10.1 to the Company's quarterly report on Form 10-Q, as filed with the Commission on August 7, 2019.
10.39 †	License Agreement, dated as of April 29, 2019, by and between Immunomedics, Inc. and Everest Medicines II Limited., incorporated by reference to Exhibit 10.2 to the Company's quarterly report on Form 10-Q, as filed with the Commission on August 7, 2019.
10.40	Consulting Agreement, dated as of May 28, 2019, by and between Immunomedics, Inc. and Dr. Robert Iannone, incorporated by reference to Exhibit 10.3 to the Company's quarterly report on Form 10-Q, as filed with the Commission on August 7, 2019.
21.1*	Subsidiaries of the Company.
23.1*	Consent of Independent Registered Public Accounting Firm – KPMG LLP.
31.1*	Certification of the Principal Executive Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of the Principal Financial Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of the Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of the Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following financial information from the Annual Report on Form 10-K for the year ended December 31, 2019, formatted in Inline XBRL (eXtensible Business Reporting Language) and furnished electronically herewith: (i) the Consolidated Balance Sheets; (ii) the Consolidated Statements of Comprehensive Loss; (iii) the Consolidated Statements of Changes in Stockholders' Equity; (iv) the Consolidated Statements of Cash Flows; and (v) the Notes to Consolidated Financial Statements.
104*	The cover page of this Annual Report on Form 10-K for the year ended December 31, 2019, formatted in Inline XBRL, included in the Exhibit 101 Inline XBRL Document Set.

\* Filed herewith.

\*\* Furnished herewith

# Management contract or compensatory plan or arrangement required to be filed as an exhibit to this Annual Report on Form 10-K pursuant to Item 15(a)(3) of Form 10-K.

† Confidential treatment has been granted for certain portions of this exhibit.

P Paper copy only.

(Exhibits available upon request)

## Item 16. Form 10-K Summary

None.

## SIGNATURES

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

IMMUNOMEDICS, INC.

Date: February 27, 2020

By: /s/Usama Malik

\_\_\_\_\_  
Usama Malik

Chief Financial Officer

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

Signature	Title	Date
<u>/s/Dr. Behzad Aghazadeh</u> Dr. Behzad Aghazadeh	Chairman of the Board, Director	February 27, 2020
<u>/s/Charles M. Baum</u> Charles M. Baum, M.D., Ph.D.	Director	February 27, 2020
<u>/s/Barbara G. Duncan</u> Ms. Barbara G. Duncan	Director	February 27, 2020
<u>/s/Dr. Khalid Islam</u> Dr. Khalid Islam	Director	February 27, 2020
<u>/s/Scott Canute</u> Scott Canute	Director	February 27, 2020
<u>/s/Peter Barton Hutt</u> Peter Barton Hutt	Director	February 27, 2020
<u>/s/Usama Malik</u> Usama Malik	Chief Financial Officer (Principal Executive Officer and Principal Financial Officer)	February 27, 2020
<u>/s/William Fricker</u> William Fricker	Corporate Controller (Principal Accounting Officer)	February 27, 2020

## **EXHIBIT 21.1**

### **SUBSIDIARIES OF THE COMPANY AS OF DECEMBER 31, 2019**

- Immunomedics GmbH (Germany)                      Wholly owned subsidiary of Immunomedics, Inc.
- IBC Pharmaceuticals, Inc. (Delaware)                      Majority owned subsidiary of Immunomedics, Inc.

**Consent of Independent Registered Public Accounting Firm**

The Board of Directors  
Immunomedics, Inc.

We consent to the incorporation by reference in the Registration Statements Nos. 333-219594, 333-198766, 333-184377, 333-128310, 333-114810, 333-90338 and 333-225550 on Form S-3 and the Registration Statements Nos. 333-201470, 333-143420 and 333-53224 on Form S-8 of Immunomedics, Inc. of our reports dated February 27, 2020, with respect to the consolidated balance sheets of Immunomedics, Inc. and subsidiaries as of December 31, 2019, December 31, 2018, June 30, 2018 and 2017, the related consolidated statements of comprehensive loss, changes in stockholders' equity and cash flows for the year ended December 31, 2019, six month transition period ended December 31, 2018 and each of the years in the two-year period ended June 30, 2018, and the effectiveness of internal control over financial reporting as of December 31, 2019, which reports appear in the December 31, 2019 annual report on Form 10-K of Immunomedics, Inc.

/s/ KPMG LLP

New York, New York

February 27, 2020

## CERTIFICATION

I, Usama Malik, Principal Executive Officer of Immunomedics, Inc., certify that:

1. I have reviewed the Annual Report on Form 10-K of Immunomedics, 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. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2020

/s/Usama Malik

Usama Malik

Principal Executive Officer



## CERTIFICATION

I, Usama Malik, Chief Financial Officer of Immunomedics, Inc., certify that:

1. I have reviewed the Annual Report on Form 10-K of Immunomedics, 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. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2020

/s/Usama Malik

Usama Malik

Chief Financial Officer

**Certification**

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002  
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Immunomedics, Inc., a Delaware corporation (the “Company”), does hereby certify, to such officer’s knowledge, that:

The Annual Report on Form 10-K for the fiscal year ended December 31, 2019 (the “Form 10-K”) of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 27, 2020

/s/Usama Malik

\_\_\_\_\_  
Usama Malik

Principal Executive Officer

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

Certification  
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002  
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Immunomedics, Inc., a Delaware corporation (the “Company”), does hereby certify, to such officer’s knowledge, that:

The Annual Report on Form 10-K for the fiscal year ended December 31, 2019 (the “Form 10-K”) of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 27, 2020

/s/Usama Malik

Usama Malik

Chief Financial Officer

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







response rate (ORR) of 31 percent, in 54 heavily pre-treated patients, and median duration of response and PFS of 7.4 months and 6.8 months, respectively, offering hope to a significantly larger group of breast cancer patients.

Another pivotal data set we are looking forward to this year is TROPHY U-01, our Phase 2 study in relapsed/refractory metastatic urothelial cancer. Enrollment for the first cohort of 100 patients with prior platinum-based and programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor therapies has been completed, and topline data is expected to be available in the second half of 2020. These data could potentially support a biologics license application submission for accelerated approval to the FDA, which has recently granted Trodelvy Fast Track designation in this indication. Interim results from the initial 35 patients were presented at the 2019 European Society for Medical Oncology (ESMO) Annual Congress and showed an ORR of 29 percent, consistent with previously reported data in this population.

Behind these three late phase clinical programs, we have a multitude of signal seeking studies aimed to explore the effectiveness of Trodelvy in other Trop-2-expressing cancers, including non-small cell lung, head and neck, endometrial, prostate, and ovarian cancers. Taken together, Trodelvy is being developed for eight hard-to-treat solid cancers, either independently or in close collaboration with key opinion leaders and corporate partners.

Following the approval of Trodelvy, we are working towards submitting a prior approval supplement to the FDA to have Samsung BioLogics certified as our second source antibody manufacturer, subject to ongoing dialogue with the agency. We will continue to invest in scaling and securing our global supply chain to meet the anticipated growing demand for Trodelvy in the market and for clinical studies. The Company is well capitalized to implement this and other important strategic initiatives, bolstered by the public equity offering of approximately \$287.5 million in December, 2019.

For 2020 and beyond, we are focused on making Trodelvy available to as many cancer patients globally as possible to improve their quality of life. With the appointments of Harout Semerjian as President and Chief Executive Officer and Dr. Loretta M. Itri as our Chief Medical Officer, and the addition of Robert Azelby to the Board of Directors, we have the right people, the right platform, and the right strategy to launch the Company into the next phase of growth as a commercial enterprise. The future promises to be very exciting for Immunomedics.

On behalf of the Board of Directors and the employees at Immunomedics, I thank you for your continued support.



**Behzad Aghazadeh, Ph.D.**  
**Executive Chairman**

## Management Team

**Behzad Aghazadeh, Ph.D.**  
Executive Chairman of the Board

**Harout Semerjian, M.B.A.**  
President & Chief Executive Officer and Director

**Usama Malik, M.B.A.**  
Chief Financial Officer & Chief Business Officer

**Loretta Itri, M.D.**  
Chief Medical Officer

**Brendan P. Delaney, M.B.A.**  
Chief Commercial Officer

**Morris Rosenberg, Ph.D.**  
Chief Technology Officer

**Kurt Andrews, M.A.**  
Chief Human Resources Officer

**Bryan Ball, M.Sc., M.B.A.**  
Chief Quality Officer

**Jared Freedberg, J.D.**  
General Counsel & Secretary

## Board of Directors

**Behzad Aghazadeh, Ph.D.**  
Executive Chairman of the Board  
Managing Partner & Portfolio Manager  
Avoro Capital Advisors, LLC

**Robert Azelby**  
Former President and Chief Executive Officer  
Alder BioPharmaceuticals, Inc.

**Charles Baum, M.D., Ph.D.**<sup>(1)(3)</sup>  
President & Chief Executive Officer  
Mirati Therapeutics, Inc.

**Scott Canute, M.B.A.**  
Principal and Founder  
Magis Consulting LLC.

**Barbara G. Duncan, M.B.A.**<sup>(1)(2)</sup>  
Former Chief Financial Officer & Treasurer  
Intercept Pharmaceuticals, Inc.

**Peter Barton Hutt, LL.M.**<sup>(2)(3)</sup>  
Senior Counsel  
Covington & Burling LLP

**Khalid Islam, Ph.D.**<sup>(1)(2)(3)</sup>  
Managing Director  
Life Sciences Management GmbH

**Harout Semerjian, M.B.A.**  
President & Chief Executive Officer

### Standing Committees of the Board of Directors

- (1) Audit Committee
- (2) Compensation Committee
- (3) Governance & Nominating Committee

### Independent Registered Public Accounting Firm

KPMG LLP  
51 John F. Kennedy Parkway  
Short Hills, NJ 07078

### Transfer Agent

Philadelphia Stock Transfer, Inc.  
2320 Haverford Rd.  
Ardmore, PA 19003

### Corporate Headquarters

Immunomedics, Inc.  
300 The American Road  
Morris Plains, NJ 07950  
  
Telephone: 973-605-8200  
Fax: 973-605-8282  
<https://immunomedics.com>

### Annual Meeting

Time: 10:00 a.m.  
Date: Thursday, June 18, 2020  
Location: Immunomedics, Inc.  
410 The American Road  
Morris Plains, NJ 07950

The Common Stock of Immunomedics, Inc. (IMMU) is traded on the NASDAQ Global Market.

This annual report, in addition to historical information, contains certain forward-looking statements made pursuant to the Private Securities Litigation Reform Act of 1995. Such statements may involve significant risks and uncertainties and actual results could differ materially from those expressed or implied herein. Factors that could cause such differences include, but are not limited to, risks associated with new product development (including clinical trials outcome, regulatory requirement/actions), competitive risks to marketed products and availability of financing and other sources of capital as well as the risks discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2019.