IMMUNOMEDICS INC
Form 10-Q
November 07, 2018

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

FORM 10-Q
(Mark One)

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

For the quarterly period ended September 30, 2018
or

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

For the transition period from _____ to _____

Commission File Number: 0-12104
Immunomedics, Inc.
(Exact name of Registrant as specified in its charter)

Delaware	61-1009366
(State or other jurisdiction of incorporation or organization)	(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)

Former Name, Former Address and Former Fiscal Year,
If Changed Since Last Report: Not Applicable

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

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

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

Large Accelerated Filer þ Accelerated Filer
Non-Accelerated Filer Smaller Reporting Company Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

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

The number of shares of the registrant's common stock outstanding as of November 5, 2018 was 190,019,435.

-IMMUNOMEDICS, INC.

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PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS (Unaudited)

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

	September 30, 2018	June 30, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 580,594	$612,057
Marketable securities	4,941	26,745
Accounts receivable, net of allowances of $0 at September 30, 2018 and June 30, 2018, respectively	—	46
Other current assets	8,479	9,532
Total current assets	594,014	648,380
Property and equipment, net of accumulated depreciation of $31,449 thousand and $30,858 thousand at September 30, 2018 and June 30, 2018, respectively	18,587	15,733
Other long-term assets	61	60
Total Assets	$ 612,662	$664,173
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 33,710	$31,664
Liability related to sale of future royalties - current	4,482	3,009
Warrant liabilities	5,979	8,973
Deferred revenues	—	94
Total current liabilities	44,171	43,740
Convertible senior notes, net	19,799	19,763
Liability related to sale of future royalties - non-current	207,280	198,998
Other long-term liabilities	2,097	1,986
Total Liabilities	273,347	264,487
Commitments and Contingencies (Note 11)		
Stockholders' Equity:		
Common stock, $0.1 par value; shares authorized 250,000 thousand; shares issued 187,143 thousand and shares outstanding 187,079 thousand at September 30, 2018; shares issued 186,801 thousand and shares outstanding 186,766 thousand at June 30, 2018	1,871	1,868
Capital contributed in excess of par	1,203,025	1,194,998
Treasury stock, at cost: 64 thousand shares at September 30, 2018 and 35 thousand shares at June 30, 2018	(1,092)	(458)
Accumulated deficit	(859,717)	(795,548)
Accumulated other comprehensive loss	(334)	(353)
Total Immunomedics, Inc. stockholders' equity	343,753	400,507
Noncontrolling interest in subsidiary	(4,438)	(821)
Total stockholder's equity	339,315	399,686
Total Liabilities and Stockholders' Equity	$ 612,662	$664,173

See accompanying notes to unaudited condensed consolidated financial statements

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

	Three Months Ended September 30,	
	2018	2017
Revenues:		
Product sales	$—	$526
License fee and other revenues	—	1
Research and development	—	163
Total revenues	—	690
Costs and Expenses:		
Costs of goods sold	—	70
Research and development	38,239	17,342
Sales and marketing	5,799	226
General and administrative	13,131	4,650
Total costs and expenses	57,169	22,288
Operating loss	(57,169)	(21,598)
Changes in fair market value of warrant liabilities	1,218	(86,378)
Loss on induced exchanges of debt	—	(13,005)
Interest expense	(10,142)	(2,647)
Interest and other income	1,694	416
Insurance reimbursement	190	4,366
Foreign currency transaction gain, net	—	84
Loss before income tax	(64,209)	(118,762)
Income tax (expense) benefit	—	—
Net loss	$(64,209)	$(118,762)
Net loss attributable to noncontrolling interest	(40)	(17)
Net loss attributable to Immunomedics, Inc. stockholders	$(64,169)	$(118,745)
Loss per common share attributable to Immunomedics, Inc. stockholders (basic and diluted):	(0.34)	(0.97)
Weighted average shares used to calculated loss per common share (basic and diluted):	186,937	122,550
Other comprehensive income (loss), net of tax:		
Foreign currency translation adjustments	4	(73)
Unrealized gain on securities available for sale	15	32
Other comprehensive income (loss), net of tax:	19	(41)
Comprehensive loss	(64,190)	(118,803)
Comprehensive loss attributable to noncontrolling interest	(40)	(17)
Comprehensive loss attributable to Immunomedics, Inc. stockholders	$(64,150)	$(118,786)

See accompanying notes to unaudited condensed consolidated financial statements

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

	Three Months Ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	$(64,209)	$(118,762)
Adjustments to reconcile net loss to net cash used in operating activities:		
Changes in fair value of warrant liabilities	(1,218)	86,378
Depreciation and amortization	591	213
Loss on induced exchanges of debt	—	13,005
Amortization of deferred revenue	(94)	(17)
Amortization of bond premiums	3	(14)
Amortization of debt issuance costs	36	1,569
Amortization of deferred rent	109	(9)
(Decrease) increase in allowance for doubtful accounts	—	3
Non-cash expense related to stock compensation	1,734	584
Changes in operating assets and liabilities	13,396	(3,520)
Net cash used in operating activities	(49,652)	(20,570)
Cash flows from investing activities		
Purchases of marketable securities	—	(245)
Proceeds from sales/maturities of marketable securities	21,818	15,124
Purchases of property and equipment	(3,184)	(789)
Net cash provided by investing activities	18,634	14,090
Cash flows from financing activities:		
Exercise of stock options	131	612
Exercise of warrants	375	—
Sale of common stock and warrants, net of related expenses	—	5,906
Direct cost of raising equity	—	(419)
Tax withholding payments for stock compensation	(167)	(51)
Net cash provided by financing activities	339	6,048
Effect of changes in exchange rates on cash, cash equivalents and restricted cash	4	(2)
Net decrease in cash, cash equivalents and restricted cash	(30,675)	(434)
Cash, cash equivalents and restricted cash beginning of period	612,582	43,393
Cash, cash equivalents and restricted cash end of period	$581,907	$42,959
Supplemental disclosure of cash flow information:		
Interest paid	$475	$2,375
Schedule for non-cash investing and financing activities:		
Issuance of common shares for debt conversion	$—	$80,000
Accrued capital expenditures	$2,449	$—
Shares received in cashless exercise	$634	$—
Non-cash component of warrant exercise	$1,776	$11,242

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

	September 30, 2018	June 30, 2018

Cash and cash equivalents	$580,594	$612,057
Restricted cash in other current assets	1,313	525
Total cash, cash equivalents and restricted cash	$581,907	$612,582

See accompanying notes to unaudited condensed consolidated financial statements.

IMMUNOMEDICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED
FINANCIAL STATEMENTS

Reference is made to the Annual Report on Form 10-K, as amended, of Immunomedics, Inc., a Delaware corporation (“Immunomedics,” the “Company,” “we,” “our” or “us”), for the fiscal year ended June 30, 2018, which contains our audited consolidated financial statements and the notes thereto.

1. Business Overview, Basis of Presentation and Recent Accounting Pronouncements

Business Overview

Immunomedics, Inc., a Delaware corporation (“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 ("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. 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 Food and Drug Administration ("FDA") that the BLA was accepted for filing and granted Priority Review with a PDUFA target action date of January 18, 2019. If approved, sacituzumab govitecan would be the first and only ADC approved for the treatment of mTNBC.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of Immunomedics, which incorporate our subsidiaries, have been prepared in accordance with United States generally accepted accounting principles (“GAAP”), for interim financial information and the instructions to the Quarterly Report on Form 10 Q and Regulation S X. Accordingly, the statements do not include all of the information and footnotes required by GAAP for complete annual financial statements. With respect to the financial information for the interim periods included in this Quarterly Report on Form 10-Q, which is unaudited, management believes that all adjustments (consisting of normal recurring accruals), considered necessary for a fair presentation of the results for such interim periods have been included. Operating results for the three-month period ended September 30, 2018, are not necessarily indicative of the results that may be expected for the full fiscal year ending June 30, 2019, or any other period. The preparation of the condensed consolidated financial statements requires management to make estimates and assumptions that affect reported amounts and disclosures. Actual results could differ from those estimates.

Recent Accounting Pronouncements

Accounting Pronouncements adopted during the year:

In November 2016, the FASB issued Accounting Standards Update ("ASU") 2016-18 "Statement of Cash Flows (Topic 230): Restricted Cash.” The amendments in this update require that cash and cash equivalent balances in a statement of cash flows include those amounts deemed to be restricted cash and restricted cash equivalents. ASU 2016-18 is effective for annual reporting periods beginning after December 15, 2017, and early adoption is permitted. We adopted the amendments in this accounting standard update in the first quarter of fiscal 2019 on a retrospective basis resulting in an immaterial impact to our condensed consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, “Statement of Cash Flows: Clarification of Certain Cash Receipts and Cash Payments,” which eliminates the diversity in practice related to the classification of certain cash receipts and payments in the statement of cash flows, by adding or clarifying guidance on eight specific cash flow issues. ASU 2016-15 is effective for annual and interim reporting periods beginning after December 15, 2017, and early adoption is permitted. ASU 2016-15 provides for retrospective application for all periods presented. ASU 2016-15 was effective for us in our first quarter of fiscal 2019 and did not result in any changes to the presentation of our Consolidated Statement of Cash Flows upon adoption.

In May 2014, the FASB issued ASU 2014-09, “Revenue from Contracts with Customers (Topic 606),” and has subsequently issued a number of amendments to Topic 606. On July 1, 2018, we adopted Topic 606 using the modified retrospective method. The adoption of Topic 606 did not have a material impact to our condensed consolidated financial statements.

Accounting Pronouncements yet to be adopted:

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.

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 Topic 606. We are currently assessing the impact of ASU 2018-07.

In February 2016, the FASB issued ASU 2016-02, “Leases,” and issued subsequent amendments to the initial guidance contained within ASU 2017-13. This standard requires a lessee to record the assets and liabilities for the rights and obligations created by lease terms of more than 12 months on the balance sheet. The amendments in this update are effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, and early application is permitted. We are currently assessing the impact of ASU 2016-02.

2 . 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.

3. Marketable Securities

Immunomedics considers all of its current investments to be available-for-sale. Marketable securities at September 30, 2018 consisted of the following (in thousands):

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

Maturities of debt securities classified as available-for-sale were as follows at September 30, 2018 (in thousands):

	Fair Value	Net Carrying Amount
Due after one year through five years	$ 4,941	$ 4,954

Marketable securities at June 30, 2018 consisted of the following (in thousands):

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized (Loss)	Fair Value
U.S. Treasury Bonds	$ 9,641	$ —	$ (9)	$ 9,632
Certificate of Deposits	5,610	—	—	5,610
U.S. Government Sponsored Agencies	6,751	—	(2)	6,749
Corporate Debt Securities	4,510	—	(5)	4,505
Commercial Paper	249	—	—	249
	$ 26,761	$ —	$ (16)	$ 26,745

Maturities of debt securities classified as available-for-sale were as follows at June 30, 2018 (in thousands):

	Fair Value	Net Carrying Amount
Due within one year	$ 21,745	$ 21,860
Due after one year through five years	5,000	5,009
	$ 26,745	$ 26,869

4. Debt

Liability related to sale of future royalties:

On January 7, 2018, the Company entered into a funding agreement with RPI Finance Trust, a Delaware statutory trust ("RPI"), under which we sold a portion of our right to receive royalties on potential net sales of the ADC sacituzumab govitecan, in exchange for $175.0 million in cash. Concurrently, we entered into a common stock purchase agreement with RPI through which RPI purchased 4.4 million shares of the Company's common stock for $75.0 million (the "Financing").

The Company concluded that there were two units of accounting in the transaction: (1) the Liability related to the sale of future royalties and (2) the "Financing". We allocated the consideration of $250.0 million on a relative fair value basis to the liability for $182.2 million and the common stock for $67.8 million. We continue to accrete the Liability related to the sale of future royalties using the interest method with an annual interest rate of approximately 19.3%. As of June 30, 2018, we determined the fair value at $202.0 million. During the three months ended September 30, 2018, the Company recognized $9.8 million in interest expense.

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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 will mature on 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, 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 September 30, 2018.

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 2017 Exchange Agreements") with certain holders of the Convertible Senior Notes. Under the September 2017 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 2017 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 2017 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 October 2018 Exchange Agreements, the Company exchanged, in a private placement, $12.9 million in aggregate principal amount of the Convertible Senior Notes held by such holders for 2.6 million newly issued shares of the Company's common stock, par value $0.01 per share.

As a result of the October 2018 Exchange Agreements, the outstanding aggregate principal amount of the Convertible Senior notes was reduced to $7.1 million in the second quarter of fiscal 2019.

Total interest expense for the Convertible Senior Notes for the three months ended September 30, 2018 and 2017 was $0.2 million and $2.6 million, respectively. Included in interest expense was an immaterial amount of amortization of debt issuance costs for the three months ended September 30, 2018, and $1.6 million for the three months ended September 30, 2017 (which included $1.4 million of accelerated amortization of debt issuance costs associated with the $80.0 million exchange of Convertible Senior Notes in September 2017 for the three months ended September 30, 2017).

5. Share-based Compensation

Stock Incentive Plan

The Company has a stock incentive plan, the Immunomedics, Inc. 2014 Long-Term Incentive Plan (the "Plan") that provides for the granting of stock options, restricted stock units (RSUs), performance stock options (PSOs) 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 three months ended September 30, 2018 or 2017.

The following table summarizes the components of share-based compensation expense in the condensed consolidated statements of comprehensive loss (in thousands):

	Three Months Ended September 30,	
	2018	2017
Research and development	$620	$350
Sales and marketing	271	—
General and administrative	843	233
Total share-based compensation expense	$1,734	$583

The following table summarizes the activity for stock options, RSUs and PSOs for the three months ended September 30, 2018 (in thousands):

	Stock Options	RSUs	PSOs
Equity awards outstanding, beginning of year	3,549	1,535	538
Changes during the year:			
Granted	1,279	15	—
Exercised	(219)	(30)	—
Expired or forfeited	(23)	—	—
Equity awards outstanding, end of period	4,586	1,520	538

As of September 30, 2018, total compensation cost related to unvested awards not yet recognized and the weighted-average periods over which the awards are expected to be recognized were as follows ($ in thousands):

	Stock Options	RSUs	PSOs
Unrecognized compensation cost	$25,959	$405	$3,228
Expected weighted-average period in years of compensation cost to be recognized	3.7	1.3	3.3

6. Estimated Fair Value of Financial Instruments

Cash equivalents and marketable securities:

	($ in thousands)			
September 30, 2018	Level 1 [a]	Level 2 [b]	Level 3 [c]	Total
Money Market Funds Note [d]	$324,375	$ —	$ —	$324,375
Marketable Securities:				
U.S. Government Sponsored Agencies	4,941	—	—	4,941
Total	$329,316	$ —	$ —	$329,316

	($ in thousands)			
June 30, 2018	Level 1 [a]	Level 2 [b]	Level 3 [c]	Total
Money Market Funds Note [d]	$300,865	$ —	$ —	$300,865
Marketable Securities:				
U.S. Treasury Bonds	9,632	—	—	9,632
Certificate of Deposits	5,610	—	—	5,610
U.S. Government Sponsored Agencies	6,749	—	—	6,749
Corporate Debt Securities	4,505	—	—	4,505
Commercial Paper	249	—	—	249
Total	$327,610	$ —	$ —	$327,610

[a] 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.

[b] 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.

[c] 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.

[d] 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 September 30, 2018		As of June 30, 2018	
	Carrying Amount	Estimated Fair Value	Carrying Amount	Estimated Fair Value
Convertible Senior Notes	$19,799	$ 79,424	$19,763	$ 89,436

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 (see Note 4).

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Warrant Liabilities

The Company has determined its warrant liabilities to be a Level 2 fair value measurement and used the Black Scholes valuation model to calculate the fair value. At the measurement dates, the Company estimated the fair value for the warrants based on a Black-Scholes valuation model and using the following assumptions:

	September 30, 2018 [2]	June 30, 2018 [2]	June 30, 2017 [1]	June 30, 2017 [2]	February 10, 2017	October 11, 2016
Risk-free interest rate	2.12%	1.95%	1.14%	1.38%	1.47%	0.87%
Expected remaining term	0.03 years	0.3 years	0.5 years	1.3 years	3.0 years	2.0 years
Expected volatility	60.00%	60.00%	69.34%	73.85%	71.42%	75.00%
Dividend yield	—%	—%	—%	—%	—%	—%

[1] Represents the fair value assumptions for the warrants issued in connection with February 10, 2017 stock purchase agreement.

[2] Represents the fair value assumptions for the warrants issued in connection with October 11, 2016 public offering.

The following table sets forth the warrant activity, including transfers of warrant liabilities to equity upon exercise, for the year ended September 30, 2018 (in thousands):

(in thousands)	Number of Warrants	Estimated Fair Value Level 2
Fair value - June 30, 2018	450	$ 8,973
Warrants exercised	(100)	(1,776)
Changes in fair market value of warrant liabilities	—	(1,218)
Fair value - September 30, 2018	350	$ 5,979

7. Stockholders' Equity

Common Stock

On October 11, 2016, the Company completed an underwritten public offering of 10 million shares of its common stock and accompanying warrants to purchase 10 million shares of common stock at a purchase price of $3.00 per unit, comprised 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 as well as estimated expenses related to the offering. 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 the three months ended September 30, 2018, there were 100,000 warrants exercised. The fair value of the 100,000 exercised warrants decreased $0.2 million from June 30, 2018, to the dates of exercise which has been recognized in the accompanying consolidated statements of comprehensive loss. The $1.8 million fair value of the warrants as of the exercise dates was reclassified to capital contributed in excess of par. As of September 30, 2018, there were 350,000 warrants outstanding.

During October 2018, the remaining warrants were exercised. No warrants remain outstanding.

Treasury Stock

During the three months ended September 30, 2018, there were 29,428 shares received in connection with a non-cash equity transaction related to the Company's Plan.

8. Accumulated Other Comprehensive Loss

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

	Currency Translation Adjustments	Net Unrealized Gains (Losses) on Available-for-Sale Securities	Accumulated Other Comprehensive Loss
Balance, July 1, 2018	$ (339)	$ (14)	$ (353)
Other comprehensive income before reclassifications	4	15	19
Net current-period other comprehensive income	4	15	19
Balance, September 30, 2018	$ (335)	$ 1	$ (334)
Balance, July 1, 2017	$ (234)	$ (69)	$ (303)
Other comprehensive (loss) income before reclassifications	(73)	32	(41)
Net current-period other comprehensive (loss) income	(73)	32	(41)
Balance, September 30, 2017	$ (307)	$ (37)	$ (344)

There were no amounts reclassified from accumulated other comprehensive income (loss). All components of accumulated other comprehensive loss are net of tax, except currency translation adjustments, which exclude income taxes related to indefinite investments in foreign subsidiaries.

9. 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 $555 thousand 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 July 1, 2018 through September 30, 2018, the Company paid M Rosenberg BioPharma $347 thousand 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, and 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, 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.

10. Collaboration Agreement

AstraZeneca/MedImmune

In June 2018, the Company 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 PD-L1, with sacituzumab govitecan as a treatment of patients with triple-negative breast cancer ("TNBC") and UC.

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.

The collaboration terminates thirty days following the expiration of the study periods end-date. Either party may early terminate the collaboration by providing thirty days written notice.

11. Commitments and Contingencies

Commitments and Contingencies

a. Legal Matters
Patent litigation:
Immunomedics filed a first amended complaint on October 22, 2015 and a second amended complaint on January 14, 2016 in the United States District Court for the District of New Jersey, against Roger Williams Medical Center ("RWMC"), Richard P. Junghans, M.D., Ph.D. and Steven C. Katz, M.D. seeking lost profits, unjust enrichment damages and compensatory damages resulting from the infringement of its patents. The second amended complaint alleges that RWMC and Dr. Junghans breached a Material Transfer Agreement ("MTA") through which it provided to them a monoclonal antibody known as MN-14 and related materials. Defendants are alleged to have breached the MTA and to have been negligent by, among other things, using the materials beyond the agreed-upon Research Project, sharing confidential information, failing to provide Immunomedics with a right of first refusal, failing to notify Immunomedics of intended publications prior to publishing, and refusing to return the materials upon request. Immunomedics also asserts defendants: claims of conversion, tortious interference, unjust enrichment, and infringement of three patents owned by Immunomedics. On January 28, 2016, defendants filed an Answer to the Second Amended Complaint. On October 12, 2016, Immunomedics filed a Third Amended Complaint, and further added as defendants Sorrento Therapeutics, Inc. and its subsidiaries TNK Therapeutics, Inc., BDL Products, Inc., and CARgenix Holdings, LLC. Defendants Junghans, Katz, and RWMC subsequently moved to dismiss for failure to state a claim on November 14, 2016, but this motion was denied on January 4, 2017. On December 2, 2016, Sorrento, TNK, BDL, and CARgenix moved to dismiss for lack of personal jurisdiction over them in New Jersey. The court granted this motion on January 25, 2017. On January 20, 2017, the court held a Markman hearing to construe the claims in the patents in suit. On February 28, 2017, the court issued an opinion and order finding, inter alia, that the term "effective amount" in the patents in suit is not indefinite and should be given its plain and order meaning, as proposed by Immunomedics, of "an amount capable of producing the claim result." On May 11, 2017, the court entered an order referring the matter to mediation and designating Garrett E. Brown, Jr. (ret.) as the mediator. The mediation did not result in a settlement. On October 25, 2018, the Company entered into a Settlement Agreement with the defendants in this action, agreeing to dismiss all claims with prejudice in exchange for a settlement payment of $2.4 million.

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., No. 2:16-cv-03335, filed June 9, 2016; and Becker v. Immunomedics, Inc., et al., No. 2:16-cv-03374, 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 SEC filings 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. 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 and the motion was fully briefed as of April 4, 2018. Oral arguments have not yet been scheduled.

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. No. 2017-0108-VCL (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 Defendents 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 mediation was unsuccessful. Geoff Cox, Robert Forrester, Bob Oliver, and Jason Aryeh have submitted motions to dismiss the claims against them in the venBio Action, which remain pending in the Court of Chancery.

b. Other matters:

Immunomedics is also a party to various claims and litigation arising in the normal course of business, which includes some or all of certain of its patents. While it is not possible to determine the outcome of these matters, the Company believes that the resolution of all such matters will not have a material adverse effect on its consolidated financial position or liquidity, but could possibly be material to its consolidated results of operations in any one accounting period.

c. Purchase Obligations:

On September 11, 2018, we entered into a Master Services Agreement (the "MSA") with Samsung BioLogics Co., Ltd. ("Samsung"), pursuant to which Samsung will provide 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 (the "PSA") for the production of hRS7, the antibody used in the Company's lead antibody drug conjugate candidate, sacituzumab govitecan. As a result of entering into the PSA with Samsung, our purchase commitments increased during the quarter. Our total commitments and purchase obligations for manufacturing and consulting services now total $40.0 million in 2019, $31.6 million in 2020 and $10.4 million in 2021.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Cautionary Note Regarding Forward-Looking Statements

The Securities and Exchange Commission (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 Quarterly Report on Form 10-Q 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 Quarterly Report, and they may also be made a part of this Quarterly 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 sir 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: the risk that we may be unable to obtain additional capital through strategic collaborations, licensing, issuance of equity financing in order to continue our research and development activities and secure regulatory approval of and market our drug candidates; 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 secure regulatory approval of and market our drug candidates; our dependence upon pharmaceutical and biotechnology collaborations; 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 other stockholder litigation; and risks of new, changing and competitive technologies and regulations in the United States and internationally. Refer to Item 1A "Risk Factors" in this Quarterly Report on Form 10-Q for more information.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this Quarterly Report or in any document incorporated by reference might not occur. Stockholders are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this Quarterly Report or the date of the document incorporated by reference in this Quarterly Report. 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 authorized to act on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

Overview

We are a clinical-stage biopharmaceutical company that develops 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 antibody-drug conjugates ("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. Our most advanced ADCs are sacituzumab govitecan (“IMMU-132”) and labetuzumab govitecan (“IMMU-130”), which are in advanced trials for a number of solid tumors. Sacituzumab govitecan is our lead product candidate and has received Breakthrough Therapy Designation from the United States Food and Drug Administration ("FDA") for the treatment of patients with metastatic triple-negative breast cancer ("mTNBC") who have received at least two prior therapies for metastatic disease.

Our corporate strategy is to commercialize sacituzumab govitecan on our own in the United States for the benefit of patients with mTNBC and the creation of value for our stockholders. 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 granted Priority Review with a PDUFA target action date of January 18, 2019. If approved, sacituzumab govitecan would be the first and only ADC approved for the treatment of mTNBC.

As of September 30, 2018, we had $585.5 million in cash, cash equivalents and marketable securities. We believe our projected financial resources are adequate to (i) support our next phase of growth as we focus on commercializing and developing sacituzumab govitecan in mTNBC, advanced urothelial cancer ("UC"), advanced HR+ BC, advanced NSCLC and other indications of high medical need, (ii) further build our clinical, medical affairs, commercial and manufacturing infrastructure, (iii) begin to commercialize sacituzumab govitecan globally. In doing so and on the basis of our cash position, we believe we will be able to fund operations assuming we meet our regulatory and commercial objectives. However, in case of regulatory delays, alterations to our commercial forecast, 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 capital markets financing.

On September 11, 2018, we entered into a Master Services Agreement (the "MSA") with Samsung BioLogics Co., Ltd. ("Samsung"), pursuant to which Samsung will provide 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.

To accelerate the clinical and preclinical development of sacituzumab govitecan, we have entered into clinical collaborations with AstraZeneca and Clovis to investigate the ADC in earlier lines of therapy for mTNBC and advanced UC in combination with checkpoint and PARP inhibitors, respectively. We are also working with the University of Wisconsin on a clinical study in prostate cancer, and Yale University Cancer Center on a clinical study in endometrial and cervical cancers.

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:

- we may be unable to obtain additional capital through strategic collaborations, licensing, issuance of convertible debt securities or equity financing in order to continue our research and secure regulatory approval of and market our drug;
- 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 time 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, if at all;
- 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.

See Risk Factors in Item 1A of this Quarterly Report.

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.

For a description of our significant accounting policies, refer to "Part II, Item 8. Financial Statements and Supplementary Data, Note 2 - Summary of Significant Accounting Policies" in our 2018 Annual Report on Form 10-K, as amended. Of these policies, the following are considered critical to an understanding of our Condensed Consolidated Financial Statements as they require the application of the most difficult, subjective and complex judgments; (i) Common stock warrants (ii) Interest expense on liability related to sale of future royalties, and (iii) Stock-based compensation.

Our critical accounting estimates and assumptions impacting the consolidated financial statements relate to revenue, stock compensation expenses, interest expense on liability related to sale of future royalties, and determination of fair value of warrants. Refer to "Note 2 - Revenue", "Note 4 - Debt", and "Note 6 - Estimated Fair Value of Financial Instruments", respectively, for more information.

Recent Accounting Pronouncements

Refer to "Note 1 - Business Overview, Basis of Presentation and Recent Accounting Pronouncements" in the Notes to Unaudited Condensed Consolidated Financial Statements for a discussion of recently adopted accounting pronouncements and accounting pronouncements not yet adopted, and their expected impact on our financial position and results of operations.

Results of Operations

Our results for any interim period, such as those described in the following analysis, are not necessarily indicative of the results for the entire fiscal year or any other future period.

Three-Month Period Ended September 30, 2018 Compared to 2017

Revenues

			($ in thousands)	
			(Decrease)/Increase	
Three Months Ended September 30,	2018	2017	2018 vs 2017	
Product sales	$ —	$ 526	$ (526)	nm
License fee and other revenues	—	1	(1)	nm
Research and development	—	163	(163)	nm
Total revenues	$ —	$ 690	$ (690)	nm

nm - not meaningful

Total revenue for the three months ended September 30, 2018 decreased compared to the three months ended September 30, 2017, primarily due to the discontinued sale of LeukoScan® during third quarter of fiscal 2018 to focus on our ADC business.

Costs and Expenses

			($ in thousands) (Decrease)/Increase	
Three Months Ended September 30,	2018	2017	2018 vs 2017	
Costs of goods sold	$—	$70	$ (70)	nm
Research and development	38,239	17,342	20,897	nm
Sales and marketing	5,799	226	5,573	nm
General and administrative	13,131	4,650	8,481	nm
Total costs and expenses	$57,169	$22,288	$ 34,881	nm

nm - not meaningful

Total costs and expenses for the three months ended September 30, 2018 increased compared to the three months ended September 30, 2017, primarily due to an increase in research and development expenses of $20.9 million, an increase in general and administrative expenses of $8.5 million, and an increase in sales and marketing expenses of $5.6 million attributed primarily to preparations to launch sacituzumab govitecan for commercial sales in the United States for patients with at least two prior lines of treatment for metastatic TNBC, and to expand clinical development of sacituzumab govitecan into earlier lines of therapy and other indications.

Cost of Goods Sold

The cost of goods sold for the three months ended September 30, 2018 decreased compared to the three months ended September 30, 2017, primarily due to the discontinued sale of LeukoScan® during the third quarter of fiscal 2018 to focus on the ADC business.

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.

Research and development costs increased for the three months ended September 30, 2018, approximately $20.9 million to $38.2 million compared to the three months ended September 30, 2017. The increase in research and development costs for the three months ended September 30, 2018 compared to the three months ended September 30, 2017, relate primarily to increases in outside manufacturers' organizations services costs related to preparations to launch sacituzumab govitecan for commercial sales in the United States for patients with at least two prior lines of treatment for metastatic TNBC, an increase in outside consulting services to improve our manufacturing and regulatory functions associated with fulfilling the FDA requirements, an increase in clinical trial costs, and an increase in personnel costs in connection with preparations for the approval and launch of sacituzumab govitecan in the United States for patients with mTNBC.

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

Sales and marketing expenses increased during the three months ended September 30, 2018 compared to the three months ended September 30, 2017, primarily due to commercial launch preparation activities.

General and Administrative Expenses

			($ in thousands) (Decrease)/Increase	
Three Months Ended September 30,	2018	2017	2018 vs 2017	
Labor costs	$5,069	$1,155	$ 3,914	nm
Legal and advisory fees	3,550	2,104	1,446	nm
Consulting services	1,662	520	1,142	nm
Other	2,850	871	1,979	nm
Total General and administrative	$13,131	$4,650	$ 8,481	nm

nm- not meaningful

General and administrative expenses for the three months ended September 30, 2018 increased compared to the three months ended September 30, 2017 primarily due to increased labor costs and consulting services associated with the anticipated launch of sacituzumab govitecan in the United States for patients with mTNBC as well as an increase in legal and advisory fees.

Changes in fair market value of warrant liabilities

We recognized $1.2 million in non-cash income for the three months ending September 30, 2018, as a result of the net appreciation in the fair value of the outstanding warrants throughout the year compared to non-cash expense of $86.4 million for the three months ended September 30, 2017. During the three months ended September 30, 2018, there were 100,000 warrants exercised. The fair value of the 100,000 exercised warrants decreased $0.2 million from June 30, 2018 to the dates of exercise which has been recognized in the accompanying consolidated statements of comprehensive loss. Refer to "Note 7 - Stockholders' Equity" for more information.

Other financing expenses

On September 21, 2017, we entered into separate, privately negotiated Exchange Agreements with certain holders of the Convertible Senior Notes. As a result of the Agreements, we recognized a non-cash loss on induced exchanges of debt of approximately $13.0 million, representing the fair value of the incremental consideration (1.1 million common shares) paid to induce the holders to exchange their Convertible Senior Notes for equity, based on the closing market price of our Common Stock on the date of the Exchange Agreements.

Interest expense

Interest expense for the three months ended September 30, 2018, was $10.1 million, compared to $2.6 million for the three months ended September 30, 2017. The $7.5 million increase was due primarily to increased debt balances as a result of the RPI agreement. Refer to "Note 4 - Debt" for more information.

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Insurance reimbursement

For the three months ended September 30, 2018 we received $0.2 million in insurance reimbursements related to legal costs incurred during our proxy contest during fiscal 2017, compared to $4.4 million for the three months ending September 30, 2017.

Income tax (expense) benefit

There was no income tax expense for the three months ended September 30, 2018.

The Tax Cuts and Jobs Act of 2017 (the "2017 Tax Act") was enacted on December 22, 2017, and, among other changes, reduced the federal statutory tax rate from 35.0% to 21.0%. In accordance with U.S. GAAP for income taxes, as well as SEC Staff Accounting Bulletin No. 118 ("SAB 118"), the company made a reasonable estimate of the impacts of the 2017 Tax Act in its results for the year ended June 30, 2018. SAB 118 allows for a measurement period of up to one year to complete the company's accounting for the impacts of the 2017 Tax Act from the date of enactment. As of September 30, 2018, no additional adjustments have been made to the provisional amounts recorded as of June 30, 2018. The company will continue to evaluate the impacts as additional clarification and implementation guidance related to the 2017 Tax Act is released.

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 September 30, 2018, we had $585.5 million in cash, cash equivalents and marketable securities. We believe our projected financial resources are adequate to (i) support our next phase of growth as we focus on commercializing and developing sacituzumab govitecan in mTNBC, advanced UC, advanced HR+ BC, advanced NSCLC and other indications of high medical need, (ii) further build our clinical, medical affairs, commercial and manufacturing infrastructure, (iii) begin to commercialize sacituzumab govitecan globally, and (iv) fund operations into 2021 or beyond assuming we meet our regulatory and commercial objectives. However, in case of regulatory delays, alterations to our commercial forecast, or other unforeseen events, we may require additional funding in 2021. 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 capital markets financing.

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 Quarterly Report on Form 10-Q. 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.

	($ in thousands)	
	Three Months Ended September 30,	
	2018	2017
Net cash used in operating activities	$(49,652)	$(20,570)
Net cash provided by investing activities	18,634	14,090
Net cash provided by financing activities	339	6,048

Net cash used in operating activities. Net cash used in operating activities during the three months ended September 30, 2018 was approximately $49.7 million, compared to $20.6 million during the three months ended September 30, 2017, an increase in cash used in operating activities of $29.1 million. The increase in cash used in operating activities for the period was primarily due to changes in the fair value of warrant liabilities offset by a decrease in the net loss.

Net cash provided by investing activities. Net cash provided by investing activities during the three months ended September 30, 2018 was $18.6 million, compared to cash provided by investing activities of $14.1 million during the three months ended

September 30, 2017; an increase of approximately $4.5 million, due primarily to an increase of $6.7 million in proceeds from sales or maturities of marketable securities offset by a $2.4 million increase in purchases of property and equipment.

Net cash provided by financing activities. Net cash provided by financing activities during the three months ended September 30, 2018 was $0.3 million, compared to $6.0 million of cash provided by financing activities during the three months ended September 30, 2017. The decrease of $5.7 million was due primarily to our sale of common stock and warrants, net of related expenses in the prior year.

Working Capital and Cash Requirements

Working capital was $549.8 million as of September 30, 2018, compared to $604.6 million as of June 30, 2018, a $54.8 million decrease. The decrease in cash was primarily due to our preparations for the approval and launch of sacituzumab govitecan in the United States for patients with mTNBC.

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 Quarterly Report on Form 10-Q. 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.

Contractual Commitments

On September 11, 2018, we entered into a MSA with Samsung, pursuant to which Samsung will provide 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 (the "PSA") for the production of hRS7, the antibody used in the Company’s lead antibody drug conjugate candidate, sacituzumab govitecan. As a result of entering into the PSA with Samsung, our purchase commitments increased during the quarter. Our total commitments and purchase obligations for manufacturing and consulting services now total $40.0 million in 2019, $31.6 million in 2020 and $10.4 million in 2021.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk has not changed materially since our disclosure in Item 7A, "Quantitative and Qualitative Disclosures About Market Risk" in our Annual Report on Form 10-K for the year ended June 30, 2018, as amended.

ITEM 4. CONTROLS AND PROCEDURES

(a)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 Executive Officer and Principal Financial Officer are responsible for establishing and maintaining these disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) and, as required by the rules of the SEC, evaluating their effectiveness. Based on their evaluation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q, our Chief Executive Officer and Principal Financial Officer believe that these procedures are effective to ensure that we are able to collect, process and disclose the information we are required to disclose in the reports we file with the SEC within the required time periods.

(b)Changes in Internal Controls over Financial Reporting: There were no significant 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.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The information called for by this item is incorporated by reference to "Note 11 - Commitments and Contingencies" of Notes to Unaudited Condensed Consolidated Financial Statements contained in Part I Item 1 of the Quarterly Report on Form 10-Q.

Item 1A. RISK FACTORS

Factors That May Affect Our Business and Results of Operations

Our business is subject to certain risks and uncertainties, each of which could materially adversely affect our business, financial condition, cash flows and results of 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. Our only significant sources of revenue in recent years have been derived from collaboration agreements and sales of our LeukoScan® product in certain European countries. There can be no assurance that we will be profitable in future quarters or other periods. Additionally, the only product sales we have earned to date have come from the limited sales of our LeukoScan® diagnostic imaging product for which our (i) patent protection has expired and (ii) future sales were discontinued during the third quarter of fiscal year 2018. In addition, 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. 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 Royalty Agreement may also erode profitability of this product. 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 financial resources are adequate to support the Company's next phase of growth as it focuses on developing sacituzumab govitecan in mTNBC, advanced UC and other indications of high medical need and on further building its clinical, medical affairs, commercial and manufacturing infrastructure, as well as provide sufficient cash to fund operations well into the future.

We will 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.

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.

Our most advanced therapeutic product candidates are still only in the clinical development stage, and will 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 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.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, the Company may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between the company and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

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 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.

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, CMC (chemistry, manufacturing, and control), 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. For example, 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 will never 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

- limited product sales of LeukoScan® (which were discontinued during February 2018), licenses, grants 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, CRPC, SCLC, 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 in the United States (pending FDA approval), we expect to continue to fund our operations with our current financial resources. We believe our projected financial resources are adequate to (i) support our next phase of growth as we focus on commercializing and developing sacituzumab govitecan in mTNBC, advanced UC, advanced HR+ BC, advanced NSCLC and other indications of high medical need, (ii) further build our clinical, medical affairs, commercial and manufacturing infrastructure, (iii) begin to commercialize sacituzumab govitecan globally, and (iv) fund operations into 2021 or beyond assuming we meet our regulatory and commercial objectives. If, however, we cannot obtain sufficient funding 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) through the sales and marketing of sacituzumab govitecan as a third-line therapy for mTNBC in the United States (pending FDA approval), 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. 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 at this site, whether by natural acts 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 Good Manufacturing Practice regulations or cGMPs, 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 cGMPs 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 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. 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. 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 2019. 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 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 diagnostic and 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 Amgen, AstraZeneca, Bayer Healthcare Pharmaceuticals, Biogen Idec, Bristol-Myers Squibb, Celgene, Eli Lilly, Genmab, GlaxoSmithKline, Immunogen, Johnson & Johnson, Merck, Merck Serono, Novartis, Pfizer, Roche, and Seattle Genetics, are engaged in the development of therapeutic 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 thirteen years. As of September 30, 2018, 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.

As a result of these and other relationships, the potential for both real and perceived conflicts of interest exists 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 excess of $12,500 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. 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.

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. 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. Recent 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% (and 70% commencing 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;
- a new 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
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the ACA established the Center for Medicare and Medicaid Innovation within the Centers for Medicare & Medicaid Center, or Innovation Center, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. The Innovation Center has been 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, or the 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 addition, other legislative changes have been proposed and adopted since the ACA was enacted. 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, or the ATRA, which, among others, 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 overpayments to providers from three to five years. 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. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, 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, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of product candidates paid by consumers. HHS has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. Although most of these, and other, proposals will require authorization through additional legislation to become effective, the United States Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs, including by addressing the role of pharmacy benefit managers in the supply chain. On October 15, 2018, the Department of Health and Human Services Secretary, Alex Azar, unveiled a proposed rule that could require drug companies to disclose the price of

their products in pharmaceutical advertisements. 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.

More recently, 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 such other governments and quasi-official regulatory bodies 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, the 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 are 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;
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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 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;
- 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 government may assert 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.
- 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 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, federal Anti-Kickback Statute violations and 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, or 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, or 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, or the 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, or 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.
- 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”), extends the reporting and transparency requirements for physicians in the Physician Payments Sunshine Act, to physician assistants, nurse practitioners, and other mid-level practitioners. This law will go into effect in 2021, requiring reporting of payments and transfers made in that same calendar year

According to the United States Federal Trade Commission, or the 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.

Analogous state laws and regulations, such as state anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report pricing and marketing information, including, among other things, information related to payments to physicians and other healthcare providers or marketing expenditures, 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.

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.

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

European Union 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 European Union, which was formerly governed by the provisions of the European Union Data Protection Directive, was replaced with the European Union General Data Protection Regulation, or the 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 European Union 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 noncompliant 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 European Union 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 or (d) 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.

Risks Related to Our Securities

Conversion of the Convertible Senior Notes will dilute the ownership interest of existing stockholders and could adversely affect the market price of our common stock.

The conversion of some or all of the Convertible Senior Notes will dilute the ownership interests of existing stockholders. Any sales in the public market of the common stock issuable upon such conversion and exercise could adversely affect prevailing market prices of our common stock. In addition, the existence of the Convertible Senior Notes may encourage short selling by market participants.

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.

We may not have the ability to raise funds necessary to purchase the Convertible Senior Notes upon a fundamental change and our future debt may contain limitations on our ability to repurchase the Convertible Senior Notes.

Following a fundamental change (which includes matters such as a change in control of the Company, approval by the Company’s stockholders of a plan of dissolution or liquidation of the Company, and the cessation of listing of the Company’s common stock on Nasdaq or The New York Stock Exchange, among others as further described in the indenture), holders of Convertible Senior Notes will have the right to require the Company to purchase their Convertible Senior Notes for cash. A fundamental change may also constitute an event of default or require prepayment under, and result in the acceleration of the maturity of, our other then-existing indebtedness. We cannot assure you that we will have sufficient financial resources, or will be able to arrange financing, to pay the fundamental

change purchase price in cash with respect to any Convertible Senior Notes surrendered by holders for purchase upon a fundamental change. In addition, restrictions in the agreements governing our then-outstanding indebtedness, if any, may not allow us to purchase the Convertible Senior Notes upon a fundamental change. Our failure to purchase the Convertible Senior Notes upon a fundamental change when required would result in an event of default with respect to the Convertible Senior Notes which could, in turn, constitute a default under the terms of our other indebtedness, if any. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may

not have sufficient funds to repay the indebtedness and purchase the Convertible Senior Notes, which could have a material and adverse impact on our financial condition and results of operations.

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 September 30, 2018 we had 187,143,011 shares of common stock issued, plus (1) options to purchase 4,585,853 shares of common stock with a weighted-average exercise price of $11.98 per share, (2) 1,520,939 restricted stock units to certain executive officers of the Company, (3) 537,501 performance stock options to certain executive officers of the Company, (4) 6,454,601 shares of common stock reserved for potential future grant under the Plan, (5) warrants to purchase 350,000 shares of common stock with an exercise price of $3.75 and (6) $20.0 million of principal amount of Convertible Senior Notes convertible into approximately 3,916,672 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 45,491,423 shares of common stock that remain available for future issuance.

Our outstanding Convertible Senior Notes, options and warrants 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 Convertible Senior Notes, options and warrants, 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 and warrants or conversion of the outstanding Convertible Senior Notes.

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 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 June 30, 2018 venBio Select Advisor LLC, ("venBio") is the beneficial owner of approximately 9.5% of our outstanding common stock. venBio is our largest stockholder, and Dr. Behzad Aghazadeh, the Managing Partner and portfolio manager of the venBio Select Fund, serves as Chairman of our Board of Directors.

As a result of this voting power, venBio 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 6. EXHIBITS

The exhibits required by Item 601 of Regulation S-K are included with this Form 10-Q and are listed on the “Exhibit Index” immediately following the Signatures.

EXHIBIT INDEX

Exhibit Number	Description of Document
31.1*	Certification of Chief Executive Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002.
32.1*	Certifications of Chief Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
10.57*	Form of Exchange Agreement, dated October 2, 2018, between the Company and certain of the Company's noteholders.
10.58*	Transition Agreement, dated as of August 23, 2018, between the Company and Michael Garone.
10.59*+	Master Services Agreement, dated as of September 11, 2018, between the Company and Samsung BioLogics Co., Ltd.
10.60*+	Product Specific Agreement, dated as of September 11, 2018, between the Company and Samsung BioLogics Co., Ltd.
10.61*	Executive Employment Agreement, dated as of September 24, 2018, between the Company and Jared Freedberg.
10.62*	Nonqualified Stock Option Grant, dated as of September 24, 2018, between the Company and Jared Freedberg.
10.63*	Executive Employment Agreement, dated as of September 26, 2018, between the Company and Kurt Andrews.
10.64*	Nonqualified Stock Option Grant, dated as of July 11, 2018, between the Company and Kurt Andrews.
10.65*	Immunomedics, Inc. Annual Cash Bonus Plan.
101*	The following financial information from this Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2018, formatted in XBRL (eXtensible Business Reporting Language) filed electronically herewith: (i) the Condensed Consolidated Balance Sheets; (ii) the Condensed Consolidated Statements of Comprehensive Loss; (iii) the Condensed Consolidated Statements of Cash Flows; and, (iv) the Notes to Unaudited Condensed Consolidated Financial Statements.

* Filed herewith.

+ Confidential treatment has been requested for certain portions of this exhibit. The confidential portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission.

SIGNATURES

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

IMMUNOMEDICS, INC.

November 7, 2018 /s/ Michael Pehl
Michael Pehl
Chief Executive Officer

November 7, 2018 /s/ Usama Malik
Usama Malik
Principal Financial Officer