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The Level 1 assets include money market funds, which are actively traded daily.

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Note 4. Investments

The Company's available-for-sale investments at fair value consisted of the following at March 31, 2019:

	March 31, 2019			
(In thousands)	Cost	Gross Unrealized (Losses)	Gross Unrealized Gains	Estimated Fair Value
Short-term investments – commercial paper	$ 17,772	$ —	$ —	$ 17,772
Short-term investments – U.S. treasury bills	17,892	—	2	17,894
Total short-term investments	$ 35,664	$ —	$ 2	$ 35,666
Total investments	$ 35,664	$ —	$ 2	$ 35,666

The Company had no realized gains or losses from the sale of investments in available-for-sale securities in each of the three months ended March 31, 2019 and 2018. There were no losses or other-than-temporary declines in value included in "Interest income" on the Company's condensed statements of operations and comprehensive loss for any securities for each of the three months ended March 31, 2019 and 2018.

Note 5. Property and Equipment

At March 31, 2019 and December 31, 2018, property and equipment, net, consisted of the following:

(In thousands)	March 31, 2019	December 31, 2018
Leasehold improvements	$ 107	$ 104
Laboratory equipment and other	762	767
Total property and equipment, at cost	869	871
Less: Accumulated depreciation and amortization	693	664
Property and equipment, net	$ 176	$ 207

Depreciation and amortization expense on property and equipment was less than $0.1 million during the three months ended March 31, 2019 and approximately $0.2 million during the three months ended March 31, 2018. There were no non-cash property additions during each of the three months ended March 31, 2019 and 2018.

Note 6. Accrued Expenses

At March 31, 2019 and December 31, 2018, accrued expenses consisted of the following:

(In thousands)	March 31, 2019	December 31, 2018
Payroll and related costs	$ 982	$ 1,962
Clinical and nonclinical trial expenses	2,908	3,958
Professional and consulting fees	329	605
Restructuring expenses	823	1,147
Other	137	212
Total accrued expenses	$ 5,179	$ 7,884

Included in accrued Payroll and related costs as of March 31, 2019 and December 31, 2018 is $0.4 million and $0.7 million, respectively, of salary continuation severance benefits to be paid in equal installments through October 31, 2019 to former executives.

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Note 7. Stockholders' Equity

Equity Financings

Common Stock Purchase Agreement

On March 4, 2019, the Company entered into a Purchase Agreement with Lincoln Park Capital Fund, LLC ("Investor"), pursuant to which, upon the terms and subject to the conditions and limitations set forth therein, Investor has committed to purchase an aggregate of $35.0 million of shares of Company common stock from time to time at the Company's sole discretion (the "Purchase Agreement"). As consideration for entering into the Purchase Agreement, the Company issued 269,749 shares of Company common stock to Investor as a commitment fee (the "Commitment Shares"). The closing price of the Company's common stock on March 4, 2019 was $2.84 and the Company did not receive any cash proceeds from the issuance of the Commitment Shares. Accordingly, there was no net impact to total stockholders' equity as a result of the issuance. Additionally, no shares were sold to Investor under the Purchase Agreement through March 31, 2019.

"At-The-Market" Equity Program

In November 2018, the Company entered into an Equity Distribution Agreement (the "ATM Agreement") with JMP Securities LLC ("JMP") pursuant to which the Company may issue and sell shares of its common stock having an aggregate offering price of up to $50.0 million (the "Shares") through JMP as its agent. Subject to the terms and conditions of the Agreement, JMP will use its commercially reasonable efforts to sell the Shares from time to time, based upon the Company's instructions, by methods deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, or if specified by the Company, by any other method permitted by law, including but not limited to in negotiated transactions. The Company has no obligation to sell any of the Shares, and the Company or JMP may at any time suspend sales under the ATM Agreement or terminate the ATM Agreement. JMP is entitled to a fixed commission of 3.0% of the gross proceeds from Shares sold. During the three months ended March 31, 2019, the Company sold 532,700 Shares pursuant to the ATM Agreement resulting in net proceeds, after deduction of commissions and other offering expenses, of $1.6 million.

Common Stock Warrants

In connection with various financing transactions, the Company has issued warrants to purchase shares of the Company’s common stock. The Company accounts for common stock warrants as equity instruments, derivative liabilities or liabilities, depending on the specific terms of the warrant agreement. As of March 31, 2019 and December 31, 2018, all of the Company’s outstanding common stock warrants were equity-classified.

The following table summarizes outstanding warrants to purchase shares of the Company’s common stock as of March 31, 2019 and December 31, 2018:

	Number of Shares			
Description	March 31, 2019	December 31, 2018	Weighted-Average Exercise Price	Expiration Date
Issued in May 2013 financing (pre-funded)	1,977,041	1,977,041	$ 0.08	May 2020
Issued in September 2013 financing (pre-funded)	521,997	521,997	$ 0.08	Sep 2020
Issued in February 2014 financing (pre-funded)	269,844	269,844	$ 0.08	Feb 2021
Total	2,768,882	2,768,882		

The table below is a summary of the Company's warrant activity for the three months ended March 31, 2019:

	Number of Warrants	Weighted-Average Exercise Price
Outstanding at December 31, 2018	2,768,882	$ 0.08
Issued	—	—
Exercised	—	—
Expired	—	—
Outstanding at March 31, 2019	2,768,882	$ 0.08

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Note 8. Collaboration and License Agreements

Collaboration with Vivelix

In November 2016, the Company entered into an exclusive license and collaboration agreement with Vivelix pursuant to which the Company granted Vivelix worldwide rights to develop and market IMO-9200, an antagonist of TLR7, TLR8, and TLR9, for non-malignant gastrointestinal disorders, and certain back-up compounds to IMO-9200 (the "Vivelix Agreement"). The Company was previously developing IMO-9200 for potential use in selected autoimmune disease indications. However, the Company determined not to proceed with internal development of IMO-9200 because the large autoimmune disease indications for which IMO-9200 had been developed did not fit within the strategic focus of the Company. Under the terms of the Vivelix Agreement, Vivelix was solely responsible for the development and commercialization of IMO-9200 and any designated back-up compounds. In connection with the Vivelix Agreement, Idera also transferred certain drug material to Vivelix for Vivelix's use in its development activities.

Under the terms of the Vivelix Agreement, the Company received an upfront, non-refundable fee of $15 million and was eligible for future IMO-9200 related development, regulatory and sales milestone payments and sales-based royalties. However, on March 4, 2019, the Company and Vivelix mutually agreed to terminate the Vivelix Agreement. Accordingly, the Company is no longer eligible to receive any future milestone or royalty-based payments and all rights previously granted to Vivelix with respect to IMO-9200 and certain back-up compounds to IMO-9200 reverted back to the Company.

For the three months ended March 31, 2018, the Company recognized Alliance revenues of less than $0.1 million related to certain research activities performed by the Company at Vivelix's request, pursuant to the Vivelix Agreement. No such services were performed during the three months ended March 31, 2019.

Collaboration with GSK

In November 2015, the Company entered into a collaboration and license agreement with GSK to license, research, develop and commercialize pharmaceutical compounds from the Company's nucleic acid chemistry technology for the treatment of selected targets in renal disease (the "GSK Agreement"). In connection with the GSK Agreement, GSK identified an initial target for the Company to attempt to identify a potential population of development candidates to address such target under a mutually agreed upon research plan. From the population of identified development candidates, GSK may designate one development candidate in its sole discretion to move forward into clinical development. Once GSK designates a development candidate, GSK would be solely responsible for the development and commercialization activities for that designated development candidate.

The GSK Agreement also provided GSK with the option to select up to two additional targets at any time during the first two years of the GSK Agreement for further research under mutually agreed upon research plans. Upon selecting additional targets, GSK then had the option to designate one development candidate for each additional target, at which time GSK would have sole responsibility to develop and commercialize each such designated development candidate. GSK did not select any additional targets for research through expiry of the option period.

Under the terms of the GSK Agreement, the Company received a $2.5 million upfront, non-refundable, non-creditable cash payment upon the execution of the GSK Agreement. Additionally, as of March 31, 2019, the Company is eligible to receive an additional $18 million in license, research, clinical development and commercialization milestone payments, of which $1 million would be payable by GSK upon the designation of a development candidate from the initial target and $17 million would be payable by GSK upon the achievement of clinical milestones and commercial milestones. In addition, the Company is eligible to receive royalty payments on sales of licensed products following commercialization at varying rates of up to 5% on annual net sales, as defined in the GSK Agreement.

For the three months ended March 31, 2018, the Company recognized Alliance revenues of less than $0.1 million related to the amortization of the deferred up-front payment received at inception of the GSK Agreement, over the 36-month anticipated performance period, which concluded in the fourth quarter of 2018. Accordingly, no such revenues were recognized during the three months ended March 31, 2019.

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Note 9. Restructuring Costs

In July 2018, the Company determined to wind-down its discovery operations, reduce the workforce in Cambridge, Massachusetts that supports such operations, and close its Cambridge facility. In connection with the reduction-in-workforce, 18 positions are being eliminated, primarily in the area of discovery, representing approximately 40% of the Company's employees. Of the 18 positions being eliminated, 15 were effective July 31, 2018 with the remaining expected to be eliminated by the end of the second quarter of 2019.

Restructuring-related charges to date are comprised of (i) one-time termination costs in connection with the reduction in workforce, including severance, benefits and related costs, of approximately $3.2 million; (ii) contract termination costs of approximately $0.2 million in connection with the early lease termination for the Cambridge facility; and (iii) non-cash asset impairments of approximately $0.7 million, which includes $0.5 million of fixed asset impairments and $0.2 million in write-offs of facility-related prepaid expenses; offset by (iv) a non-cash gain of approximately $0.4 million related to the write-off of the remaining deferred rent liability associated with the Cambridge facility lease.

The following summarizes restructuring-related activity for the three months ended March 31, 2019:

(in thousands)	Employee Severance and Benefits	Contract Termination Costs	Asset Impairments	Total
Accrued restructuring balance as of December 31, 2018	$ 1,147	$ —	$ —	$ 1,147
Charges incurred	131	—	—	131
Cash payments	(437)	—	—	(437)
Accrued restructuring balance as of March 31, 2019	$ 841	$ —	$ —	$ 841

As of March 31, 2019, the short-term portion of the accrued restructuring balance, or $0.8 million, is included in "Accrued expenses" in the accompanying condensed balance sheets. See Note 6. The long-term portion of less than $0.1 million is included within "Other liabilities" in the accompanying condensed balance sheets.

Note 10. Stock-Based Compensation

As of March 31, 2019, the only equity compensation plans from which the Company may currently issue new awards are the Company's 2013 Stock Incentive Plan (as amended to date, the "2013 Plan") and 2017 Employee Stock Purchase Plan (the "2017 ESPP"), each as more fully described below.

Equity Incentive and Employee Stock Purchase Plans

2013 Stock Incentive Plan

The Company's board of directors adopted the 2013 Plan, which was approved by the Company’s stockholders effective July 26, 2013. The 2013 Plan is intended to further align the interests of the Company and its stockholders with its employees, including its officers, non-employee directors, consultants and advisers by providing equity-based incentives. The 2013 Plan allows for the issuance of up to such number of shares of the Company’s common stock as equal to (i) 3,153,057 shares of common stock; plus (ii) such additional number of shares of common stock (up to 868,372 shares) as is equal to the sum of the number of shares of common stock subject to awards granted under the Company’s 2005 Stock Incentive Plan (the “2005 Plan”) or the Company’s 2008 Stock Incentive Plan (the “2008 Plan” and, together with the 2005 Plan, the “Existing Plans”) which awards expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right (subject, however, in the case of incentive stock options to any limitations of the Internal Revenue Code).

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Note 10. Stock-Based Compensation (Continued)

As of March 31, 2019, options to purchase a total of 2,880,400 shares of common stock and 193,625 restricted stock units were outstanding and up to 323,418 shares of common stock remained available for grant under the 2013 Plan. The Company has not made any awards pursuant to other equity incentive plans, including the Existing Plans, since the Company's stockholders approved the 2013 Plan. As of March 31, 2019, options to purchase a total of 464,247 shares of common stock were outstanding under the 2008 Plan.

In addition, as of March 31, 2019, non-statutory stock options to purchase an aggregate of 393,750 shares of common stock were outstanding that were issued outside of the 2013 Plan to certain employees in 2017, 2015 and 2014 pursuant to the Nasdaq inducement grant exception as a material component of new hires' employment compensation.

2017 Employee Stock Purchase Plan

The Company's board of directors adopted the 2017 ESPP, which was approved by the Company's stockholders and became effective on June 7, 2017. The 2017 ESPP provides for the issuance of up to 62,500 shares of common stock to participating employees of the Company or its subsidiaries. Participation is limited to employees that would not own 5% or more of the total combined voting power or value of the stock of the Company after the grant. As of March 31, 2019, 21,198 shares remained available for issuance under the 2017 ESPP.

For the three months ended March 31, 2019 and 2018, the Company issued 11,096 and 6,702 shares of common stock, respectively, under the 2017 ESPP and received proceeds of less than $0.1 million during each period, as a result of employee stock purchases.

Accounting for Stock-based Compensation

The Company recognizes non-cash compensation expense for stock-based awards under the Company's equity incentive plans over an award's requisite service period, or vesting period, using the straight-line attribution method, based on their grant date fair value determined using the Black-Scholes option-pricing model. The Company also recognizes non-cash compensation for stock purchases made under the 2017 ESPP. The fair value of the discounted purchases made under the Company's 2017 ESPP is calculated using the Black-Scholes option-pricing model. The fair value of the look-back provision plus the 15% discount is recognized as compensation expense over each plan period.

Total stock-based compensation expense attributable to stock-based payments made to employees and directors and employee stock purchases included in operating expenses in the Company's statements of operations for the three months March 31, 2019 and 2018 was as follows:

	Three Months Ended March 31,	
(in thousands)	2019	2018
Stock-based compensation:		
Research and development		
Employee Stock Purchase Plans	$ 6	$ 22
Equity Incentive Plans	330	556
	$ 336	$ 578
General and administrative		
Employee Stock Purchase Plans	$ 6	$ 14
Equity Incentive Plans	674	997
	$ 680	$ 1,011
Total stock-based compensation expense	$ 1,016	$ 1,589

During the three months ended March 31, 2019 and 2018, the weighted average fair market value of stock options granted was $1.83 and $9.92, respectively.

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Note 10. Stock-Based Compensation (Continued)

The following weighted average assumptions apply to the options to purchase 480,502 and 514,600 shares of common stock granted to employees and directors during the three months ended March 31, 2019 and 2018, respectively:

	Three Months Ended March 31,	
	2019	2018
Average risk-free interest rate	2.4%	2.1%
Expected dividend yield	—	—
Expected lives (years)	3.6	3.8
Expected volatility	82.0%	74.9%
Weighted average exercise price (per share)	$ 3.14	$ 17.92

All options granted during three months ended March 31, 2019 and 2018 were granted at exercise prices equal to the fair market value of the common stock on the dates of grant.

Stock Option Activity

The following table summarizes stock option activity for the three months ended March 31, 2019:

($ in thousands, except per share data)	Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2018	3,304,531	$ 18.41	6.6	$ —
Granted	480,502	3.14		
Exercised	—	—		
Forfeited	(46,636)	13.52		
Expired	—	—		
Outstanding at March 31, 2019 (1)	3,738,397	$ 16.51	6.7	$ —
Exercisable at March 31, 2019	2,136,642	$ 21.64	4.9	$ —

(1) Includes both vested stock options as well as unvested stock options for which the requisite service period has not been rendered but that are expected to vest based on achievement of a service condition.

The fair value of options that vested during the three months ended March 31, 2019 was $1.6 million. As of March 31, 2019, there was $6.8 million of unrecognized compensation cost related to unvested options, which the Company

expects to recognize over a weighted average period of 2.6 years.

Restricted Stock Activity

The following table summarizes restricted stock activity for the three months ended March 31, 2019:

($ in thousands, except per share data)	Number of Shares	Weighted-Average Grant Date Fair Value
Nonvested shares at December 31, 2018	—	$ —
Granted	194,550	3.14
Cancelled	(925)	3.14
Vested	—	—
Nonvested shares at March 31, 2019	193,625	$ 3.14

As of March 31, 2019, there was $0.6 million of unrecognized compensation expense related to the restricted stock units, which is expected to be recognized over a weighted-average period of 3.8 years.

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Note 11. Related Party Transactions

Overview of Related Parties

Julian C. Baker, a member of the Company’s board of directors until his resignation in September 2018, is a principal of Baker Bros. Advisors LP. Baker Bros. Advisors LP, and certain of its affiliated funds (collectively, “Baker Brothers”) owned approximately 17% of the Company's common stock as of March 31, 2019. Additionally, one of the Company’s directors, Kelvin M. Neu, is an employee of Baker Bros. Advisors, LP as of March 31, 2019. Mr. Neu will resign from the Company’s board of directors effective June 4, 2019.

During the three months ended March 31, 2018, Baker Brothers exercised warrants to purchase 2,539,541 shares of the Company’s common stock at an exercise price of $3.76 per share for a total exercise price of approximately $9.5 million.

As of March 31, 2019, Baker Brothers held pre-funded warrants to purchase up to 2,768,882 shares of the Company’s common stock at an exercise price of $0.08 per share.

Board Fees Paid in Stock

Pursuant to the Company’s director compensation program, in lieu of director board and committee fees incurred of less than $0.1 million during both the three months ended March 31, 2019 and 2018, the Company issued 13,719 and 1,668 shares of common stock, respectively, to certain of its directors. Director board and committee fees are paid in arrears (including fees paid in stock) and the number of shares issued was calculated based on the market closing price of the Company’s common stock on the issuance date.

Note 12. Net Loss per Common Share

Basic and diluted net loss per common share applicable to common stockholders is calculated by dividing net loss applicable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration of common stock equivalents. The Company’s potentially dilutive shares, which include outstanding stock option awards, common stock warrants and convertible preferred stock, are considered to be

common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive. For the three months ended March 31, 2019 and 2018, diluted net loss per common share applicable to common stockholders was the same as basic net loss per common share applicable to common stockholders as the effects of the Company's potential common stock equivalents are antidilutive.

Total antidilutive securities that were excluded from the calculation of diluted net loss per share, due to their anti-dilutive effect, were 6,702,830 and 5,946,315 as of March 31, 2019 and 2018, respectively, and consisted of stock options, preferred stock and warrants.

Note 13. Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure.

Subsequent to March 31, 2019, the Company out-licensed certain non-core technology to a third-party under which the Company will receive, among other things, approximately $1.4 million in cash during the second quarter of 2019.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with:

- our unaudited condensed financial statements and accompanying notes included in Part I, Item 1 of this Quarterly Report on Form 10-Q; and
- our audited financial statements and accompanying notes included in our Annual Report on Form 10-K for 2018, or our 2018 Form 10-K, as well as the information contained under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our 2018 Form 10-K.

Overview

We are a clinical-stage biopharmaceutical company with a business strategy focused on the clinical development, and ultimately the commercialization, of drug candidates for both oncology and rare disease indications characterized by small, well-defined patient populations with serious unmet medical needs. Our current focus is on our Toll-like receptor, or TLR, agonist, tilsotolimod (IMO-2125), for oncology. We believe we can develop and commercialize targeted therapies on our own. To the extent we seek to develop drug candidates for broader disease indications, we have entered into and may explore additional collaborative alliances to support development and commercialization.

TLRs are key receptors of the immune system and play a role in innate and adaptive immunity. As a result, we believe TLRs are potential therapeutic targets for the treatment of a broad range of diseases. Using our chemistry-based platform, we have designed both TLR agonists and antagonists to act by modulating the activity of targeted TLRs. A TLR agonist is a compound that stimulates an immune response through the targeted TLR. A TLR antagonist is a compound that inhibits an immune response by blocking the targeted TLR.

Our current TLR-targeted clinical-stage drug candidate, tilsotolimod, is an agonist of TLR9. We are currently developing tilsotolimod, via intratumoral injection, for the treatment of anti-PD1 refractory metastatic melanoma in combination with ipilimumab, an anti-CTLA4 antibody marketed as Yervoy® by Bristol-Myers Squibb Company, or BMS, in a Phase 3 trial. We are also evaluating intratumoral tilsotolimod in combination with nivolumab, an anti-PD1 antibody marketed as Opdivo® by BMS, and ipilimumab for the treatment of multiple solid tumors in a Phase 2 trial.

Clinical Development

Tilsotolimod (IMO-2125)

Tilsotolimod (IMO-2125) is a synthetic phosphorothioate oligonucleotide that acts as a direct agonist of TLR9 to stimulate the innate and adaptive immune systems. We are developing tilsotolimod for administration via intratumoral injection in combination with systemically administered checkpoint inhibitors for the treatment of various solid tumors, including (i) anti-PD1 refractory metastatic melanoma in combination with ipilimumab, (ii) squamous cell carcinoma of the head and neck in combination with nivolumab and ipilimumab, and (iii) microsatellite stable colorectal cancer in combination with nivolumab and ipilimumab. We refer to our tilsotolimod development program as the ILLUMINATE development program.

Advancements in cancer immunotherapy have included the approval and late-stage development of multiple checkpoint inhibitors, which are therapies that target mechanisms by which tumor cells evade detection by the immune system. Despite these advancements, many patients fail to respond to these therapies. For instance, approximately 50% of patients with melanoma fail to respond to therapy with approved checkpoint inhibitors. Current published data suggests that the lack of response to checkpoint inhibition is related to a non-immunogenic tumor micro environment. We also believe TLR9 agonists may be useful in other solid tumor types that are refractory to anti-PD1 treatment due, in part, to low mutation load and low dendritic cell infiltration. Because TLR9 agonists, such as tilsotolimod, stimulate the immune system, we believe there is a scientific rationale to evaluate the combination of intratumoral injection of tilsotolimod with checkpoint inhibitors. Specifically, we believe

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intratumoral injection of tilsotolimod activates a local immune response in the injected tumor, which may complement the effect of the systemically administered checkpoint inhibitors. Currently, there is minimal immunotherapy benefit, post chemotherapy, for patients with squamous cell carcinoma of the head and neck and no approved immunotherapy options for patients with microsatellite stable colorectal cancer.

In studies in preclinical cancer models conducted in our laboratories, intratumoral injection of TLR9 agonists, such as tilsotolimod, has potentiated the anti-tumor activity of multiple checkpoint inhibitors in multiple tumor models. We believe these data support evaluation of combination regimens including the combination of a TLR9 agonist, such as tilsotolimod, with one or more checkpoint inhibitors for the treatment of cancer.

Melanoma

Melanoma is a type of skin cancer that begins in a type of skin cell called melanocytes. Although melanoma is a rare form of skin cancer, it causes the majority of skin cancer deaths. As is the case in many forms of cancer, melanoma becomes more difficult to treat once the disease has spread beyond the skin to other parts of the body such as the lymphatic system (metastatic disease). We believe, based on internally conducted commercial research, that in the United States, by 2025, approximately 25,000 people will have advanced melanoma appropriate for systemic treatment. Recent advances in therapy, such as immune checkpoint inhibitors, given as single agents or in combination, have improved long-term survival outcomes. However, advanced metastatic melanoma continues to present significant morbidity and mortality as not all patients respond to treatment with checkpoint inhibitors. Some patients who initially respond develop progressive disease requiring further treatment which means that about half of the patients who receive anti-PD1 therapy will require further treatment.

We are currently developing tilsotolimod for use in combination with checkpoint inhibitors for the treatment of patients with anti-PD1 refractory metastatic melanoma. Tilsotolimod has received Orphan Drug Designation for the treatment of melanoma Stages IIb to IV and Fast Track designation for the treatment of anti-PD1 refractory metastatic melanoma in combination with ipilimumab therapy from the U.S. Food and Drug Administration, or FDA.

ILLUMINATE-301 - Phase 3 Trial of Tilsotolimod (IMO-2125) in Combination with Ipilimumab in Patients with Anti-PD1 Refractory Metastatic Melanoma

In the first quarter of 2018, we initiated a Phase 3 trial of the tilsotolimod–ipilimumab combination in patients with anti-PD1 refractory metastatic melanoma, which we refer to as ILLUMINATE-301. This trial will compare the

results of the tilsotolimod–ipilimumab combination to those of ipilimumab alone in a 1:1 randomization, will have a sample size of approximately 300 patients and will be conducted at up to 110 sites worldwide. The primary endpoints of the trial are overall response rate (ORR) by RECIST v1.1 and median overall survival (OS). Key secondary endpoints include ORR by irRECIST, durable response rate, median time to response, median progression free survival (PFS) and patient reported outcomes using a validated scale. Enrollment is ongoing and expected to be completed by the end of 2019.

We have held discussions with and plan to continue to engage with regulatory authorities regarding the paths to registration for tilsotolimod in combination with ipilimumab in anti-PD1 refractory metastatic melanoma patients, including potentially through an accelerated approval process based on the analysis of the ORR in the Phase 3 trial with the final analysis of OS providing the confirmatory data for full approval. We believe that positive results in either of the primary endpoints could lead to approval in the United States.

As discussed below under the heading “Collaborative Alliances,” in May 2018, we entered into a clinical trial collaboration and supply agreement with BMS under which BMS has agreed to manufacture and supply YERVOY® (ipilimumab), at its cost and for no charge to us, for use in ILLUMINATE-301.

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ILLUMINATE-204 - Phase 1/2 Trial of Tilsotolimod (IMO-2125) in Combination with Ipilimumab or Pembrolizumab in Patients with Anti-PD1 Refractory Metastatic Melanoma

In December 2015, we initiated a Phase 1/2 clinical trial to assess the safety and efficacy of tilsotolimod, administered intratumorally, in combination with ipilimumab, in patients with metastatic melanoma (refractory to treatment with a PD1 inhibitor, also referred to as anti-PD1 refractory), which we refer to as ILLUMINATE-204. We subsequently amended the trial protocol to enable an additional arm to study the combination of tilsotolimod with pembrolizumab, an anti-PD1 antibody marketed as Keytruda® by Merck & Co., Inc., in the same patient population. The Phase 2 expansion of our ILLUMINATE-204 trial closed for enrollment in February 2019 with a total of 52 patients dosed at 8 mg tilsotolimod in combination with ipilimumab. Final ORR data is expected during the fourth quarter of 2019.

In this clinical trial, tilsotolimod is administered intratumorally into a selected tumor lesion at weeks 1, 2, 3, 5, 8, 11, 17, 23 and 29 (total of 9 doses) together with the standard dosing regimen of ipilimumab or pembrolizumab, administered intravenously. For patients who lack superficially accessible disease for injection, tilsotolimod is administered via injection into deep lesions, such as liver metastases, using interventional radiology guidance.

The trial was initiated at The University of Texas, MD Anderson Cancer Center, or MD Anderson, under the strategic research alliance we entered into with MD Anderson in June 2015, and additional sites have been added through the fourth quarter of 2018. The primary objectives of the Phase 1 portion of the trial include characterizing the safety of the combinations and determining the recommended Phase 2 dose. A secondary objective of the Phase 1 portion of the trial is describing the anti-tumor activity of tilsotolimod when administered intratumorally in combination with ipilimumab or pembrolizumab. The primary objective of the Phase 2 portion of the trial is to determine the objective response rate to the combinations using immune-related response criteria (irRC) and RECIST v1.1 criteria. The secondary objectives of the Phase 2 portion of the trial include the assessment of treatment response utilizing irRC, determination of median progression free survival (PFS) and median overall survival (OS), and to continue to characterize the safety of the combinations. In the Phase 1 portion of the trial, serial biopsies are being taken of selected injected and non-injected tumor lesions pre- and post-24 hours of the first dose of tilsotolimod, as well as at 8 and 13 weeks, to assess immune changes and response assessments. In the Phase 2 portion of the trial, biopsies are optional.

Ipilimumab Arm

In the Phase 1 portion of the ipilimumab arm of our Phase 1/2 clinical trial of tilsotolimod, escalating doses of tilsotolimod ranging from 4 mg through 32 mg were evaluated in a total of 18 patients, each of which but one had progressed on nivolumab or pembrolizumab prior to enrollment in the trial. The combination of tilsotolimod and ipilimumab had been well tolerated at all dose levels studied. In April 2017, we completed tilsotolimod dose

escalation and based on the safety and efficacy data and data from translational immune parameters, selected the 8 mg dose level as the recommended dose level for the Phase 2 portion of the ipilimumab arm of the trial.

In April 2017, we initiated enrollment in the Phase 2 portion of the ipilimumab arm of our Phase 1/2 clinical trial of tilsotolimod with the 8 mg dose of intratumoral tilsotolimod. The Phase 2 portion of the trial utilizes a Simon two-stage design to evaluate the objective response rate of tilsotolimod in combination with ipilimumab, compared to historical data for ipilimumab alone in the anti-PD1 refractory metastatic melanoma population. Based on the responses observed, the trial met the pre-specified futility assessment and advanced into the second stage of the Phase 2 portion.

At the 37th Annual J.P. Morgan Healthcare Conference in January 2019, we provided an update on our Phase 1/2 trial evaluating tilsotolimod in combination with ipilimumab at the recommended 8 mg dose level, noting that as of our December 2018 data-cut, a total of 37 patients had been dosed at the 8 mg dose level and 34 patients treated at the 8 mg dose level had at least one post-baseline disease assessment. Of these 34 patients, three had a complete response and eight had a partial response, representing an overall response rate of 32.4%. One of the three patients who had a complete response has been continuing off active treatment for more than two years and

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has remained disease free. Additionally, fifteen other patients who were treated at the 8 mg dose level experienced stable disease. In the aggregate, 26 of the 34 patients achieved stable disease or better, representing a disease control rate of 76.5%. Additionally, as of the response data cutoff date, one patient who was treated at the 4 mg dose had an ongoing partial response and had been off active treatment for more than two years. The combination of tilsotolimod and ipilimumab continues to be well-tolerated.

In addition, other key findings include data demonstrating a clear systemic antitumor effect on distant uninjected tumors from the treatment of tilsotolimod in combination with ipilimumab. Also, data was presented showing that clinical responses were observed in patients whose tumors had low HLA-ABC expression at baseline, before treatment was started. Given that HLA-ABC expression is required for ipilimumab anti-tumor activity (Rodig, 2018), this demonstrates the contribution of tilsotolimod to overcome resistance to ipilimumab in tumors with low HLA-ABC expression, thereby enhancing the overall response rate compared to that expected with ipilimumab alone.

Pembrolizumab Arm

In the Phase 1 portion of the pembrolizumab arm of our Phase 1/2 clinical trial of tilsotolimod, we are evaluating escalating doses of tilsotolimod ranging from 8 mg through 32 mg.

We completed enrollment with a total of nine patients dosed in the 8 mg, 16 mg and 32 mg dosing cohorts in the Phase 1 dose escalation portion of the pembrolizumab arm of the trial. One patient who was treated at the 16 mg dose has experienced an ongoing complete response by RECIST v1.1 criteria.

Refractory Solid Tumors

ILLUMINATE-101 - Phase 1b Trial of Intra-tumoral Tilsotolimod (IMO-2125) Monotherapy in Patients with Refractory Solid Tumors

In March 2017, we initiated a Phase 1b dose escalation trial of tilsotolimod administered intratumorally as a single agent in multiple tumor types, which we refer to as ILLUMINATE-101. In this trial, tilsotolimod is administered intratumorally on days 1, 8 and 15 of cycle 1 and on day 1 of each subsequent 21-day cycle, up to 17 cycles (19 total doses). We completed enrollment of a total of 38 patients in four dose-escalation cohorts at doses of 8mg (cohort 1, n=11), 16mg (cohort 2, n=8), 23mg (cohort 3, n=10) and 32mg (cohort 4, n=9). There were no dose-limiting

toxicities observed and tilsotolimod appeared to be well tolerated at each of the dose levels tested. We are also enrolling a melanoma expansion cohort to assess whether tilsotolimod as a single agent (8mg dose) has any clinical activity, as demonstrated for objective response according to RECIST v1.1 criteria, in patients with metastatic melanoma who have progressed on or after treatment with a PD-(L)1 inhibitor. We believe this is unlikely and are therefore utilizing a Simon's optimal two-stage design to test for clinically and statistically relevant clinical activity. With this method, eight patients were to be treated and monitored for a RECIST v1.1 response in Stage 1. If two or more patients have a response, then the cohort will continue to Stage 2, in which 14 more patients will be treated, for a total of 22 patients. To date, 16 patients have been enrolled, however, no objective responses were reported in the first eight patients, therefore, further enrollment has been stopped.

At the American Association for Cancer Research (AACR) 2019 Annual Meeting in April 2019, we provided an update on ILLUMINATE-101, noting that as of February 28, 2019, a total of 54 patients had been dosed, including 38 patients in the dose-evaluation portion of the trial and 16 patients in the melanoma does-expansion cohort. Of the 29 evaluable patients, 13 had a RECIST v1.1 disease assessment of stable disease, with a disease control rate of 45%. Of the 13 patients with stable disease, five had maximum tumor shrinkage greater than 10% below baseline and duration of stable disease ranged from 1.3 to 9.7+ months from start of treatment, with three patients ongoing. There were no correlations between dose and efficacy observed.

An additional purpose of this study was to obtain tumor biopsies to assess the effect of tilsotolimod on the tumor microenvironment in multiple types of solid tumors and inform the expansion of the development program beyond melanoma. Initial translational data confirms robust Type I IFN pathway activation 24 hours following a

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single intratumoral dose of tilsotolimod, which is similar to that observed and previously reported in the tumor biopsies from the ILLUMINATE-204 melanoma subjects. This observation provided additional rationale to expand the tilsotolimod program to additional solid tumors.

Other Solid Tumors

Advancements in cancer immunotherapy have included the approval and late-stage development of multiple checkpoint inhibitors, as single agents or in combination, for other solid tumors including, among others, squamous cell carcinoma of the head and neck (SCCHN) and dMMR/MSI-H colorectal cancer (CRC).

Squamous cell carcinoma is the most frequent malignant tumor of the head and neck region and develops from the mucosal linings of the upper aerodigestive tract. Although the majority of patients present with loco-regional disease, more than 50% will succumb to recurrent or metastatic disease despite aggressive therapy with surgery, radiation, and/or chemotherapy. Relapsed or metastatic SCCHN (RM SCCHN) is currently an incurable disease with a poor prognosis and the mortality rate of patients presenting with advanced disease remains high. Recently, the results from prospectively conducted trials employing the immune-modulating antibodies nivolumab and pembrolizumab following chemotherapy heralded a new era of treatment for RM SCCHN. Patients responding to these agents have seen durable responses and in controlled studies an overall survival benefit has been demonstrated for the anti PD-1 antibodies versus standard of care chemotherapy. The challenge remains to increase the percentage of patients responding to these treatments, which currently ranges from 13% to 23% depending on the line of therapy.

Nivolumab administered as monotherapy or in combination with ipilimumab, has demonstrated benefit and is approved for the treatment of dMMR/MSI-H mCRC. However, in a previously treated microsatellite stable (MSS) CRC patient population, nivolumab + ipilimumab combination therapy did not produce objective responses. MSS CRC has been shown to be highly immunosuppressive. Moreover, the tumor microenvironment in MSS CRC has been shown to keep dendritic cells in an immature state. Given tilsotolimod’s mechanism of action of activating dendritic cells, it may serve a complementary function to nivolumab and ipilimumab, within the immunosuppressive TME of MSS CRC patients.

We believe, based on internally conducted research, that annually in the United States, approximately 140,000 people are diagnosed with CRC, of which 85% are MSS, and there are approximately 50,000 deaths attributed to CRC. Additionally, we believe that annually in the United States, approximately 64,000 people are diagnosed with SCCHN and there are approximately 14,000 deaths attributed to SCCHN.

ILLUMINATE-206 - Phase 2 Trial of Tilsotolimod (IMO-2125) in Combination with Nivolumab and Ipilimumab for the treatment of Solid Tumors

In December 2018, we submitted an IND application to the FDA to evaluate tilsotolimod administered intratumorally, in combination with nivolumab and ipilimumab in a Phase 2, multi-cohort study that anticipates the study of multiple solid tumors. We received notification from the FDA in January 2019 that the study may proceed and expect to initiate the Phase 2, multicohort study for the treatment of specific solid tumors in the second quarter of 2019. We refer to this study as ILLUMINATE-206.

Each cohort in this study is designed to be conducted in two parts. The purpose of the first part (Part 1) is for signal finding and utilizes a Simon's minimax two-stage design in a single-arm. The primary objective of Part 1 is to evaluate the efficacy (measured by ORR based on RECIST v1.1) of intratumoral tilsotolimod in combination with nivolumab and ipilimumab. The secondary objectives of Part 1 are to assess tilsotolimod in combination with nivolumab and ipilimumab by evaluating safety, tolerability, plasma concentrations and immunogenicity. Based on the data from Part 1 of each cohort, expansion of a cohort may be conducted as Part 2. Part 2 objectives will be determined after the decision is made to initiate Part 2 of a given cohort. The start and end of the study will be independent for each cohort.

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The initial ILLUMINATE-206 cohorts are as follows:

- Cohort 1: RM SCCHN in immunotherapy-naïve patients treated with tilsotolimod in combination with nivolumab and ipilimumab;
- Cohort 2: RM SCCHN in immunotherapy-refractory patients treated with tilsotolimod in combination with nivolumab and ipilimumab; and
- Cohort 3: Relapsed/refractory MSS CRC in immunotherapy-naïve patients treated with tilsotolimod in combination with nivolumab and ipilimumab.

Within Cohort 1, 41 patients are planned to be enrolled (22 patients in Stage 1 and 19 patients in Stage 2). Within Cohorts 2 and 3, 36 patients each are planned for enrollment (20 patients in Stage 1 and 16 patients in Stage 2). Each cohort is planned to be recruited for the first stage of Part 1.

We expect to initiate enrollment for cohorts 1 and 3 (immunotherapy-naïve patients) at approximately 12 total sites within the United States and Spain in the second quarter of 2019. We intend to initiate cohort 2 (immunotherapy-refractory patients) at the appropriate time.

As discussed below under the heading “Collaborative Alliances,” in March 2019, we entered into a clinical trial collaboration and supply agreement with BMS under which BMS has agreed to manufacture and supply YERVOY® (ipilimumab) and OPDIVO® (nivolumab), at its cost and for no charge to us, for use in ILLUMINATE-206.

Collaborative Alliances

In addition to our current alliances, we may explore potential collaborative alliances to support development and commercialization of our TLR agonists and antagonists. Our current alliances include collaborations with BMS, as described below, GlaxoSmithKline Intellectual Property Development Limited, or GSK, and Abbott Molecular as described in Note 8 of the notes to our condensed financial statements in this Quarterly Report on Form 10-Q and/or in our Annual Report on Form 10-K for the year ended December 31, 2018.

Collaboration with Bristol-Myers Squibb

Effective May 18, 2018, we entered into a clinical trial collaboration and supply agreement with BMS to clinically evaluate the combination of tilsotolimod with BMS’s therapy YERVOY® (ipilimumab), which agreement we refer to as the May 2018 BMS Agreement. Under the May 2018 BMS Agreement, we will sponsor, fund and conduct our ongoing global, open-label, multi-center Phase 3 clinical trial of tilsotolimod in combination with YERVOY® entitled “A Randomized Phase 3 Comparison of IMO-2125 with Ipilimumab versus Ipilimumab Alone in Patients with

Anti-PD-1 Refractory Melanoma" in accordance with an agreed-upon protocol, which we refer to as ILLUMINATE-301. Under the May 2018 BMS Agreement, BMS has granted us a non-exclusive, non-transferrable, royalty-free license (with a right to sublicense) under its intellectual property to use YERVOY® in ILLUMINATE-301 and has agreed to manufacture and supply YERVOY®, at its cost and for no charge to us, for use in ILLUMINATE-301.

Effective March 11, 2019, we entered into a second clinical trial collaboration and supply agreement with BMS to clinically evaluate the combination of tilsotolimod with BMS's therapy YERVOY® (ipilimumab) and OPDIVO® (nivolumab), which agreement we refer to as the March 2019 BMS Agreement. Under the March 2019 BMS Agreement, we will sponsor, fund and conduct a Phase 2, open-label, global, multi-center, multi-cohort study of intratumoral tilsotolimod in combination with YERVOY® and OPDIVO® entitled "Study of Tilsotolimod in Combination with Nivolumab and Ipilimumab For the Treatment of Solid Tumors" in accordance with an agreed-upon protocol, which we refer to as ILLUMINATE-206. Under the March 2019 BMS Agreement, BMS has granted us a non-exclusive, non-transferrable, royalty-free license (with a right to sublicense) under its intellectual property to use YERVOY® and OPDIVO® in ILLUMINATE-206 and has agreed to manufacture and supply YERVOY® and OPDIVO®, at its cost and for no charge to us, for use in ILLUMINATE-206.

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Critical Accounting Policies and Estimates

This management's discussion and analysis of financial condition and results of operations is based on our condensed financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities. On an ongoing basis, management evaluates its estimates and judgments, which are affected by the application of our accounting policies. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be appropriate under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

We regard an accounting estimate or assumption underlying our financial statements as a "critical accounting estimate" where:

(i) the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and

(ii) the impact of the estimates and assumptions on financial condition or operating performance is material.

Our significant accounting policies are described in Note 2 of the notes to our financial statements included in our 2018 Form 10-K. However, please refer to Note 2 in the accompanying notes to the condensed financial statements contained in this Quarterly Report on Form 10-Q for updated policies and estimates, if applicable, that could impact our results of operations, financial position, and cash flows. Not all of these significant policies, however, fit the definition of critical accounting policies and estimates. We believe that our accounting policies relating to revenue recognition, stock-based compensation and research and development prepayments, accruals and related expenses, as described under the caption "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Estimates" in our 2018 Form 10-K, fit the description of critical accounting estimates and judgments.

New Accounting Pronouncements

New accounting pronouncements are discussed in Note 2 in the notes to the condensed financial statements in this Quarterly Report on Form 10-Q.

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Financial Condition, Liquidity and Capital Resources

Financial Condition

We have incurred operating losses in all fiscal years since our inception except 2002, 2008 and 2009. As of March 31, 2019, we had an accumulated deficit of $675.3 million. To date, substantially all of our revenues have been from collaboration and license agreements and we have received no revenues from the sale of commercial products. We have devoted substantially all of our efforts to research and development, including clinical trials, and we have not completed development of any commercial products. Our research and development activities, together with our selling, general and administrative expenses, are expected to continue to result in substantial operating losses for the foreseeable future. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity, total assets and working capital. Because of the numerous risks and uncertainties associated with developing drug candidates, and if approved, commercial products, we are unable to predict the extent of any future losses, whether or when any of our drug candidates will become commercially available or when we will become profitable, if at all.

Liquidity and Capital Resources

Overview

We require cash to fund our operating expenses and to make capital expenditures. Historically, we have funded our cash requirements primarily through the following:

(i) sale of common stock, preferred stock and warrants;
(ii) exercise of warrants;
(iii) debt financing, including capital leases;
(iv) license fees, research funding and milestone payments under collaborative and license agreements; and
(v) interest income.

We filed a shelf registration statement on Form S-3 on August 10, 2017, which was declared effective on September 8, 2017. Under this registration statement, we may sell, in one or more transactions, up to $250.0 million of common stock, preferred stock, depository shares and warrants. As of April 30, 2019, we may sell up to an additional $190.7 million of securities under this registration statement, such amount which includes $35.0 million shares which may be issued pursuant to our common stock purchase agreement with Lincoln Park, as described below, and additional shares which may be issued under our "At-the-market" equity program.

See Note 7 to the condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for additional information regarding our recent equity financings.

Funding Requirements

We had cash, cash equivalents and investments of approximately $59.9 million at March 31, 2019. We believe that, based on our current operating plan, our existing cash, cash equivalents and investments will enable us to fund our operations through the one-year period subsequent to the filing date of this Quarterly Report on Form 10-Q. Specifically, we believe that our available funds will be sufficient to enable perform the following:

(i) complete enrollment, where applicable, and continue to execute on:
   a) the Phase 1 portion of our ongoing Phase 1/2 clinical trial of tilsotolimod in combination with pembrolizumab in anti-PD1 refractory melanoma (ILLUMINATE-204);
b) the Phase 2 portion of our ongoing Phase 1/2 clinical trial of tilsotolimod in combination with ipilimumab in anti-PD1 refractory melanoma (ILLUMINATE-204);

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c) the Phase 3 clinical trial of tilsotolimod in combination with ipilimumab for the treatment of anti-PD1 refractory metastatic melanoma (ILLUMINATE-301); and

d) the Phase 1b monotherapy clinical trial of tilsotolimod in multiple refractory tumor types (ILLUMINATE-101);

(ii) initiate our Phase 2 study of tilsotolimod in combination with nivolumab and ipilimumab for the treatment of certain solid tumors (ILLUMINATE-206);

(iii) fund certain investigator initiated clinical trials of tilsotolimod; and

(iv) maintain our current level of general and administrative expenses in order to support the business.

We expect that we will need to raise additional funds in order to complete our ongoing clinical trials of tilsotolimod and to continue to fund our operations. We are seeking and expect to continue to seek additional funding through collaborations, the sale or license of assets or financings of equity or debt securities. We believe that the key factors that will affect our ability to obtain funding are:

(i) the results of our clinical development activities in our tilsotolimod program or any other drug candidates we develop on the timelines anticipated;

(ii) the cost, timing, and outcome of regulatory reviews;

(iii) competitive and potentially competitive products and technologies and investors' receptivity to tilsotolimod or any other drug candidates we develop and the technology underlying them in light of competitive products and technologies;

(iv) the receptivity of the capital markets to financings by biotechnology companies generally and companies with drug candidates and technologies similar to ours specifically;

(v) the receptivity of the capital markets to any in-licensing, product acquisition or other transaction we may enter into; and

(vi) our ability to enter into additional collaborations with biotechnology and pharmaceutical companies and the success of such collaborations.

In addition, increases in expenses or delays in clinical development may adversely impact our cash position and require additional funds or cost reductions.

Financing may not be available to us when we need it or may not be available to us on favorable or acceptable terms or at all. We could be required to seek funds through collaborative alliances or through other means that may require us to relinquish rights to some of our technologies, drug candidates or drugs that we would otherwise pursue on our own. In addition, if we raise additional funds by issuing equity securities, our then existing stockholders may experience dilution. The terms of any financing may adversely affect the holdings or the rights of existing stockholders. An equity financing that involves existing stockholders may cause a concentration of ownership. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and are likely to include rights that are senior to the holders of our common stock. Any additional debt or equity financing may contain terms which are not favorable to us or to our stockholders, such as liquidation and other preferences, or liens or other restrictions on our assets. As discussed in Note 13 to the financial statements included in our 2018 Form 10-K, additional equity financings may also result in cumulative changes in ownership over a three-year period in excess of 50% which would limit the amount of net operating loss and tax credit carryforwards that we may utilize in any one year.

If we are unable to obtain adequate funding on a timely basis or at all, we will be required to terminate, modify or delay our clinical trials of tilsotolimod, or relinquish rights to portions of our technology, drug candidates and/or products.

Common Stock Purchase Agreement

On March 4, 2019, the Company entered into a purchase agreement with Lincoln Park Capital Fund, LLC, or Lincoln Park, pursuant to which, upon the terms and subject to the conditions and limitations set forth therein,

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Lincoln Park has committed to purchase an aggregate of $35.0 million of shares of Company common stock from time to time at the Company's sole discretion, which we refer to as the Purchase Agreement. As consideration for entering into the Purchase Agreement, the Company issued 269,749 shares of Company common stock to Lincoln Park as a commitment fee, or the Commitment Shares. The Company did not receive any cash proceeds from the issuance of the Commitment Shares. See Item 9B, Other Information, in our 2018 Form 10-K for additional information.

Cash Flows

The following table presents a summary of the primary sources and uses of cash for the three months ended March 31, 2019 and 2018:

	Three months ended March 31,	
(in thousands)	2019	2018
Net cash provided by (used in):		
Operating activities	$ (13,357)	$ (14,747)
Investing activities	(35,481)	(14)
Financing activities	1,605	9,591
Decrease in cash and cash equivalents	$ (47,233)	$ (5,170)

Operating Activities. Net cash used in operating activities in both periods presented resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. The decrease in cash used in operating activities for the three months ended March 31, 2019, as compared to the 2018 period, was primarily due to decreases in cash outflows related to our prior discovery and development programs, including payments to contract research organizations, and merger-related costs.

Investing Activities. Net cash used in investing activities primarily reflect the transfer of cash and cash equivalents into short-term investments and purchases of property and equipment as follows:

- for the three months ended March 31, 2019, purchases of $35.5 million in available-for-sale securities; and
- for the three months ended March 31, 2018, purchases of less than $0.1 million of property and equipment.

Financing Activities. Net cash provided by financing activities primarily consisted of the following amounts received in connection with the issuances of common stock and payments on our note under our loan and security agreement with Oxford Finance LLC, or our note payable:

- for the three months ended March 31, 2019, $1.6 million in net proceeds from the issuance of common stock under our “At-the-market” equity program and employee stock purchases under our 2017 Employee Stock Purchase Plan, or 2017 ESPP; and
- for the three months ended March 31, 2018, $9.7 million in aggregate proceeds from the exercise of common stock warrants and employee stock purchases under our 2017 ESPP, partially offset by $0.1 million in payments made on our note payable.

Contractual Obligations

During the three months ended March 31, 2019, there were no material changes outside the ordinary course of our business to our contractual obligations as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018.

Off-Balance Sheet Arrangements

As of March 31, 2019, we had no off-balance sheet arrangements.

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Results of Operations

Three Months Ended March 31, 2019 and 2018

Alliance Revenue

Alliance revenues consist of revenue generated through collaborative research, development and/or commercialization agreements. The terms of these agreements may include payment to us of one or more of the following: nonrefundable, up-front license fees; research, development and commercial milestone payments; and other contingent payments due based on the activities of the counterparty or the reimbursement by licensees of costs associated with patent maintenance.

Alliance revenue for the three months ended March 31, 2018 totaled $0.3 million and primarily related to the recognition of the $2.5 million upfront payment received in connection with the execution of the GSK Agreement in November 2015, which has been recognized on a straight-line basis through the fourth quarter of 2018, the end of the anticipated performance period of the agreement. Accordingly, no such revenues were recognized during the three months ended March 31, 2019. See Note 8 to the condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for additional information on our collaboration with GSK. Other amounts recognized during the 2018 period relate to amounts earned in connection with collaborations which are not material to our current operations nor expected to be material in the future, including reimbursements by licensees of costs associated with patent maintenance.

Research and Development Expenses

For each of our research and development programs, we incur both direct and indirect expenses. We track direct research and development expenses by program, which include third party costs such as contract research, consulting and clinical trial and manufacturing costs. We do not allocate indirect research and development expenses, which may include regulatory, laboratory (equipment and supplies), personnel, facility and other overhead costs (including depreciation and amortization), to specific programs.

In the table below, research and development expenses are set forth in the following categories which are discussed beneath the table:

($ in thousands)	Three months ended March 31, 2019	2018	% Change	
IMO-2125 external development expense	$ 5,414	$ 6,518	(17%)	(1)
IMO-8400 external development expense	38	1,216	(97%)	(2)
Other drug development expense	2,650	3,755	(29%)	(3)
Basic discovery expense	—	2,067	(100%)	(4)
Total research and development expenses	$ 8,102	$ 13,556	(40%)	

(1) IMO-2125 External Development Expenses. These expenses include external expenses that we have incurred in connection with the development of tilsotolimod (IMO-2125) as part of our immuno-oncology program. These external expenses include payments to independent contractors and vendors for drug development activities conducted after the initiation of tilsotolimod clinical development in immuno-oncology, but exclude internal costs such as payroll and overhead expenses. We commenced clinical development of tilsotolimod as part of our immuno-oncology program in July 2015 and from July 2015 through March 31, 2019 we incurred approximately $45.1 million in IMO-2125 external development expenses as part of our immuno-oncology program, including costs associated with the preparation for and conduct of the ongoing Phase 1/2 clinical trial to assess the safety and efficacy of tilsotolimod in combination with ipilimumab and with pembrolizumab in patients with metastatic melanoma (ILLUMINATE-204), the preparation and conduct of our ongoing Phase 1b clinical trial of tilsotolimod monotherapy in patients with refractory solid tumors (ILLUMINATE-101), the preparation for, initiation and conduct of our ongoing Phase 3 clinical trial of tilsotolimod in combination with ipilimumab in patients with metastatic melanoma (ILLUMINATE-301), the preparation for our Phase 2 clinical trial of

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tilsotolimod in combination with nivolumab and ipilimumab for the treatment of solid tumor (ILLUMINATE-206), and the manufacture of additional drug substance for use in our clinical trials and additional nonclinical studies.

The decrease in our IMO-2125 external development expenses during the three months ended March 31, 2019, as compared to the 2018 period, was primarily due to decreases in manufacturing-related costs associated due to the timing of manufacture and receipt of bulk drug product.

Going forward, we expect ongoing IMO-2125 external development expenses to be significant as our focus in 2019 continues to be on the clinical development of tilsotolimod (IMO-2125). See additional information under the heading “Financial Condition, Liquidity and Capital Resources” regarding our future funding requirements.

(2) IMO-8400 External Development Expenses. These expenses include external expenses that we have incurred in connection with IMO-8400 since October 2012, when we commenced clinical development of IMO-8400. These external expenses include payments to independent contractors and vendors for drug development activities conducted after the initiation of IMO-8400 clinical development but exclude internal costs such as payroll and overhead expenses. Since October 2012, we have incurred approximately $45.4 million in IMO-8400 external development expenses through March 31, 2019, including costs associated with our Phase 1 clinical trial in healthy subjects; our Phase 2 clinical trial in patients with psoriasis, our Phase 1/2 clinical trial in patients with Waldenström’s macroglobulinemia and our Phase 1/2 clinical trial in patients with diffuse large B-cell lymphoma, or DLBCL, harboring the MYD88 L265P oncogenic mutation, which we discontinued in September 2016; our Phase 2 clinical trial in patients with dermatomyositis, which we determined in July 2018 to discontinue upon completion of final close-out activities; the manufacture of additional drug substance for use in our clinical trials; and expenses associated with our collaboration with Abbott Molecular for the development of a companion diagnostic for identification of patients with DLBCL harboring the MYD88 L265P oncogenic mutation. In July 2018, we terminated further development of IMO-8400. As a result, we expect IMO-8400 external development expenses to be insignificant in future periods.

The decrease in our IMO-8400 external development expenses during the three months ended March 31, 2019, as compared to the 2018 period, was primarily due to our decision to discontinue all development of IMO-8400.

(3) Other Drug Development Expenses. These expenses include external expenses associated with preclinical development of identified compounds in anticipation of advancing these compounds into clinical development, including IDRA-008. In addition, these expenses include internal costs, such as payroll and overhead expenses, associated with preclinical development and products in clinical development. The external expenses associated with preclinical compounds include payments to contract vendors for manufacturing and the related stability studies, preclinical studies, including animal toxicology and pharmacology studies, and professional fees. Other drug development expenses also include costs associated with compounds that were previously being developed but are not currently being developed. In July 2018, we suspended further preclinical research. As a result, we expect other drug development expenses to be lower in future periods.

The decrease in other drug development expenses during the three months ended March 31, 2019, as compared to the 2018 period, was primarily due to a decrease in internal employee and facility overhead related costs and external costs of preclinical programs, including related toxicology studies, bulk drug manufacturing and awareness and education programs, as we suspended preclinical research activities in July 2018 and focused on the development of our clinical drug candidates.

(4) Basic Discovery Expenses. These expenses include our internal and external expenses relating to our discovery efforts with respect to our TLR-targeted programs, including agonists and antagonists of TLR3, TLR7, TLR8 and TLR9, and our nucleic acid chemistry research programs. These expenses reflect charges for laboratory supplies, external research, and professional fees, as well as payroll and overhead expenses. In July 2018, we suspended all internal discovery programs. As a result, we expect basic discovery expenses to be insignificant in future periods.

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We do not know if we will be successful in developing and commercializing any drug candidate. At this time, and without knowing the results from our ongoing clinical trial of tilsotolimod, we cannot reasonably estimate or know the nature, timing, and costs of the efforts that will be necessary to complete the remainder of the development of, or the period, if any, in which material net cash inflows may commence from, any drug candidate. Moreover, the clinical development of tilsotolimod is subject to numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of unanticipated events arising during clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of payroll, stock-based compensation expense, consulting fees and professional legal fees associated with our patent applications and maintenance, our corporate regulatory filing requirements, our corporate legal matters, and our business development initiatives. For the three months ended March 31, 2019 and 2018, general and administrative expenses totaled $3.1 million and $3.5 million, respectively.

The decrease in general and administrative expenses during the three months ended March 31, 2019, as compared to the 2018 period, was primarily due to lower employee-related costs and facility-related costs as a result of cost savings realized in connection with our restructuring activities and the closing of our Cambridge, Massachusetts facility post-restructuring in July 2018.

Merger-related Costs, net

Merger-related costs, net consists of charges and, where applicable, credits for transaction and integration-related professional fees, employee retention, and other incremental costs directly related to these activities, which are offset by merger termination fees. See our 2018 Form 10-K for additional information on our previously contemplated merger transaction.

Merger-related costs, net for the three months ended March 31, 2018 amounted to a net charge of $3.5 million. No such costs were incurred during the three months ended March 31, 2019.

Restructuring Costs

Restructuring costs consist primarily of severance and related benefit costs related to workforce reductions, contract termination and wind-down costs and asset impairments.

Restructuring costs for the three months ended March 31, 2019 totaled approximately $0.1 million and relate to our decision in July 2018 to wind-down our discovery operations, reduce the workforce in Cambridge, Massachusetts that supported such operations, and close our Cambridge facility. No such costs were incurred during the three months ended March 31, 2018.

Interest Income

Interest income for each of the three months ended March 31, 2019 and 2018 totaled approximately $0.4 million and $0.2 million, respectively. Amounts may fluctuate from period to period due to changes in average investment balances, including commercial paper and money market funds classified as cash equivalents, and composition of investments. Interest income increased by approximately $0.2 million, or 92%, in the 2019 period, as compared to 2018, primarily due to an increase in average investment balances, including certain investments classified as cash equivalents, during the three months ended March 31, 2019 as a result of our decision to invest more cash in income-generating investments.

Interest Expense

Interest expense for the three months ended March 31, 2018 totaled less than $0.1 million and related to interest incurred on the outstanding principal balance of our note payable, which was paid off in June 2018. No such expenses were incurred during the three months ended March 31, 2019.

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Net Loss Applicable to Common Stockholders

As a result of the factors discussed above, our net loss applicable to common stockholders was $11.0 million and $20.1 million for the three months ended March 31, 2019 and 2018, respectively.

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Item 3. Quantitative and Qualitative Disclosures about Market Risk.

As of March 31, 2019, all of our material assets and liabilities are in U.S. dollars, which is our functional currency.

We maintain investments in accordance with our investment policy. The primary objectives of our investment activities are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. We regularly review our investment holdings in light of the then current economic environment. At March 31, 2019, our invested funds were invested in money market funds and commercial paper, classified in cash and cash equivalents on the accompanying balance sheet, and commercial paper and U.S. treasury bills classified in investments on the accompanying balance sheet.

Based on a hypothetical 10% adverse movement in interest rates, the potential losses in future earnings, fair value of risk sensitive financial instruments, and cash flows are immaterial, although the actual effects may differ materially from the hypothetical analysis.

Item 4. Controls and Procedures.

(a) Evaluation of Disclosure Controls and Procedures. Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of March 31, 2019. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and principal financial officer concluded that as of March 31, 2019, our disclosure controls and procedures were (1) designed to ensure that material information relating to us is made known to our principal executive officer and principal financial officer by others, particularly during the period in which this report was prepared, and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms.

(b) Changes in Internal Controls. There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended March 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II — OTHER INFORMATION

Item 1A. Risk Factors.

Investing in our securities involves a high degree of risk. In addition to the other information contained elsewhere in this report, you should carefully consider the factors discussed in “Part I, Item 1A. Risk Factors” in our most recent Annual Report on Form 10-K for the year ended December 31, 2018, which could be materially and adversely affect our business, financial condition or future results.

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Item 6.Exhibits.

Exhibit No.	Description
10.1*	Clinical Trial Collaboration and Supply Agreement, by and between Idera Pharmaceuticals, Inc. and Bristol-Myers Squibb Company, dated March 11, 2019
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* In accordance with Item 601(b)(10) of Regulation S-K, portions of this exhibit have been omitted in order for them to remain confidential.

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SIGNATURES

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

IDERA PHARMACEUTICALS, INC.

Date: May 2, 2019 /s/ Vincent J. Milano
Vincent J. Milano
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 2, 2019 /s/ John J. Kirby
John J. Kirby
Vice President of Finance
(Principal Financial and Accounting Officer)