

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

FORM 10-Q

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

For the quarterly period ended June 30, 2020

OR

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

For transition period from _____ to _____.

Commission File Number: 001-31918



IDERA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

04-3072298

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

505 Eagleview Blvd., Suite 212

Exton, Pennsylvania

(Address of principal executive offices)

19341

(Zip code)

(484) 348-1600

(Registrant's telephone number, including area code)

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

Title of each class
Common Stock, par value \$0.001 per share

Trading Symbol(s)
IDRA

Name of each exchange on which registered
Nasdaq Capital Market

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

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

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

Large accelerated filer
Non-accelerated filer

Accelerated filer
Smaller reporting company
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

Common Stock, par value \$.001 per share
Class

35,199,246
Outstanding as of July 31, 2020

**IDERA PHARMACEUTICALS, INC.
FORM 10-Q**

TABLE OF CONTENTS

	<u>Page</u>
<u>PART I — FINANCIAL INFORMATION</u>	
Item 1. <u>Financial Statements</u>	1
<u>Condensed Balance Sheets as of June 30, 2020 and December 31, 2019</u>	1
<u>Condensed Statements of Operations and Comprehensive Income (Loss) for the Three and Six Months Ended June 30, 2020 and 2019</u>	2
<u>Condensed Statements of Cash Flows for the Six Months Ended June 30, 2020 and 2019</u>	3
<u>Condensed Statements of Redeemable Preferred Stock and Stockholders' Equity (Deficit) for the Three and Six Months Ended June 30, 2020 and 2019</u>	4
<u>Notes to Condensed Financial Statements</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	23
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	35
Item 4. <u>Controls and Procedures</u>	35
<u>PART II — OTHER INFORMATION</u>	
Item 1A. <u>Risk Factors</u>	36
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	36
Item 6. <u>Exhibits</u>	37
<u>Signatures</u>	38

Unless the context otherwise indicates, references in this Quarterly Report on Form 10-Q to “Idera,” the “Company,” “we,” “us,” and “our” refer to Idera Pharmaceuticals, Inc.

IMO® and Idera® are our trademarks. All other trademarks and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (“Form 10-Q”) contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). All statements, other than statements of historical fact, included or incorporated in this report regarding our strategy, future operations, clinical trials, collaborations, intellectual property, cash resources, financial position, future revenues, projected costs, prospects, plans, and objectives of management are forward-looking statements. The words “believes,” “anticipates,” “estimates,” “plans,” “expects,” “intends,” “may,” “could,” “should,” “potential,” “likely,” “projects,” “continue,” “will,” “schedule,” “would,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. These forward-looking statements involve known and unknown risks, uncertainties, and other factors, which may be beyond Idera’s control, and which may cause the actual results, performance, or achievements of the Company to be materially different from future results, performance, or achievements expressed or implied by such forward-looking statements.

There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by forward-looking statements. These important factors include those set forth under Part I, Item 1A “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, which was filed with the Securities and Exchange Commission (“SEC”) on March 12, 2020 (the “2019 Form 10-K”), and in our other disclosures and filings with the SEC. These factors and the other cautionary statements made in this Quarterly Report on Form 10-Q should be read as being applicable to all related forward-looking statements whenever they appear in this Quarterly Report on Form 10-Q.

In addition, any forward-looking statements represent our estimates only as of the date that this Quarterly Report on Form 10-Q is filed with the SEC and should not be relied upon as representing our estimates as of any subsequent date. All forward-looking statements included in this Quarterly Report on Form 10-Q are made as of the date hereof, and are expressly qualified in their entirety by this cautionary notice. We do not assume any obligation to update any forward-looking statements. We disclaim any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as may be required by law.

PART I — FINANCIAL INFORMATION**Item 1. Financial Statements.****IDERA PHARMACEUTICALS, INC.****CONDENSED BALANCE SHEETS
(UNAUDITED)**

(In thousands)	June 30, 2020	December 31, 2019*
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 27,810	\$ 40,019
Short-term investments	3,196	2,774
Prepaid expenses and other current assets	<u>2,681</u>	<u>3,475</u>
Total current assets	33,687	46,268
Property and equipment, net	63	97
Operating lease right-of-use asset	965	1,054
Other assets	70	70
Total assets	<u>\$ 34,785</u>	<u>\$ 47,489</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 345	\$ 457
Accrued expenses	7,023	7,461
Operating lease liability	166	163
Future tranche right liability	<u>—</u>	<u>46,436</u>
Total current liabilities	7,534	54,517
Warrant liability, long-term	3,053	3,241
Future tranche right liability, long-term	41,074	—
Operating lease liability, net of current portion	<u>815</u>	<u>899</u>
Total liabilities	52,476	58,657
Commitments and contingencies		
Preferred stock, \$0.01 par value, Authorized — 5,000 shares:		
Series B1 redeemable convertible preferred stock (Note 7); Designated — 278 shares, Issued and outstanding — 24 shares at June 30, 2020 and December 31, 2019	<u>—</u>	<u>—</u>
Stockholders' equity (deficit)		
Preferred stock, \$0.01 par value, Authorized — 5,000 shares:		
Series A convertible preferred stock; Designated — 1,500 shares, Issued and outstanding — 1 share	<u>—</u>	<u>—</u>
Common stock, \$0.001 par value, Authorized — 140,000 shares; Issued and outstanding — 34,291 and 29,672 at June 30, 2020 and December 31, 2019, respectively	34	30
Additional paid-in capital	718,574	709,692
Accumulated deficit	<u>(736,299)</u>	<u>(720,890)</u>
Total stockholders' deficit	<u>(17,691)</u>	<u>(11,168)</u>
Total liabilities and stockholders' deficit	<u>\$ 34,785</u>	<u>\$ 47,489</u>

* The condensed balance sheet at December 31, 2019 has been derived from the audited financial statements at that date.

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

IDERA PHARMACEUTICALS, INC.

**CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)**

(In thousands, except per share amounts)	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Alliance revenue	\$ —	\$ 1,448	\$ —	\$ 1,448
Operating expenses:				
Research and development	5,379	10,024	\$ 14,889	\$ 18,126
General and administrative	2,632	2,895	6,274	6,038
Restructuring costs	—	45	—	176
Total operating expenses	<u>8,011</u>	<u>12,964</u>	<u>21,163</u>	<u>24,340</u>
Loss from operations	(8,011)	(11,516)	(21,163)	(22,892)
Other income (expense):				
Interest income	27	339	152	743
Warrant revaluation (loss) gain	(913)	—	188	—
Future tranche right revaluation (loss) gain	(15,349)	—	5,362	—
Foreign currency exchange gain (loss)	20	1	52	(1)
Net loss	<u>\$ (24,226)</u>	<u>\$ (11,176)</u>	<u>\$ (15,409)</u>	<u>\$ (22,150)</u>
Net loss per share applicable to common stockholders (Note 12)				
— Basic	<u>\$ (0.72)</u>	<u>\$ (0.39)</u>	<u>\$ (0.48)</u>	<u>\$ (0.79)</u>
— Diluted	<u>\$ (0.72)</u>	<u>\$ (0.39)</u>	<u>\$ (0.52)</u>	<u>\$ (0.79)</u>
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders				
— Basic	<u>33,583</u>	<u>28,461</u>	<u>31,941</u>	<u>28,070</u>
— Diluted	<u>33,583</u>	<u>28,461</u>	<u>34,123</u>	<u>28,070</u>
Comprehensive loss:				
Net loss	\$ (24,226)	\$ (11,176)	\$ (15,409)	\$ (22,150)
Other comprehensive income (loss):				
Unrealized gain on available-for-sale securities	—	—	—	2
Total other comprehensive income	—	—	—	2
Comprehensive loss	<u>\$ (24,226)</u>	<u>\$ (11,176)</u>	<u>\$ (15,409)</u>	<u>\$ (22,148)</u>

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

IDERA PHARMACEUTICALS, INC.

**CONDENSED STATEMENTS OF CASH FLOWS
(UNAUDITED)**

(In thousands)	Six Months Ended June 30,	
	2020	2019
Cash Flows from Operating Activities:		
Net loss	\$ (15,409)	\$ (22,150)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,504	1,905
Warrant liability revaluation gain	(188)	—
Future tranche right liability revaluation gain	(5,362)	—
Issuance of common stock for services rendered	98	59
Accretion of discounts on short-term investments	(36)	(353)
Unrealized gain on available-for-sale securities	—	2
Depreciation and amortization expense	41	67
Gain on disposal of property and equipment	—	(11)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	819	(423)
Accounts payable, accrued expenses, and other liabilities	(575)	(2,426)
Other	8	—
Net cash used in operating activities	(19,100)	(23,330)
Cash Flows from Investing Activities:		
Purchases of available-for-sale securities	(5,535)	(35,486)
Proceeds from maturity of available-for-sale securities	5,149	23,350
Proceeds from the sale of property and equipment	—	11
Purchases of property and equipment	(7)	(11)
Net cash used in investing activities	(393)	(12,136)
Cash Flows from Financing Activities:		
Proceeds from common stock financings, net	7,230	3,857
Proceeds from employee stock purchases	54	68
Other	—	(6)
Net cash provided by financing activities	7,284	3,919
Net decrease in cash and cash equivalents	(12,209)	(31,547)
Cash and cash equivalent, beginning of period	40,019	71,431
Cash and cash equivalents, end of period	\$ 27,810	\$ 39,884
Supplemental disclosure of cash flow information:		
Increase to right-of-use asset upon adoption of ASC 842	\$ —	\$ 261
Increase to lease liability upon adoption of ASC 842	\$ —	\$ 261
Supplemental disclosure of non-cash financing and investing activities:		
Capitalized offering costs in accounts payable and accrued expenses	\$ 25	\$ —

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

IDERA PHARMACEUTICALS, INC.

**CONDENSED STATEMENTS OF REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY
(DEFICIT)
(UNAUDITED)**

(In thousands)	For the Six Months Ended June 30, 2019								
	Series B1 Preferred		Common Stock		Additional		Accumulated		
	Number of Shares	\$0.01 Par Value	Number of Shares	\$0.001 Par Value	Paid-In Capital	Accumulated Deficit	Other Comprehensive Income	Stockholders' Equity	
Balance, December 31, 2018	<u>—</u>	<u>\$ —</u>	27,188	\$ 27	\$ 728,342	\$ (664,375)	\$ —	\$ 63,994	
Sale of common stock, net of issuance costs	—	—	533	1	1,584	—	—	1,585	
Issuance of commitment shares (Note 8)	—	—	270	—	—	—	—	—	
Issuance of common stock under employee stock purchase plan	—	—	11	—	26	—	—	26	
Issuance of common stock for services rendered	—	—	6	—	23	—	—	23	
Stock-based compensation	—	—	—	—	1,016	—	—	1,016	
Unrealized gain on marketable securities	—	—	—	—	—	—	2	2	
Net loss	—	—	—	—	—	(10,974)	—	—	(10,974)
Balance, March 31, 2019	<u>—</u>	<u>\$ —</u>	28,008	\$ 28	\$ 730,991	\$ (675,349)	\$ 2	\$ 55,672	
Sale of common stock, net of issuance costs	—	—	786	1	2,271	—	—	2,272	
Issuance of common stock under employee stock purchase plan	—	—	19	—	42	—	—	42	
Issuance of common stock for services rendered	—	—	14	—	36	—	—	36	
Stock-based compensation	—	—	—	—	889	—	—	889	
Net loss	—	—	—	—	—	(11,176)	—	—	(11,176)
Balance, June 30, 2019	<u>—</u>	<u>\$ —</u>	<u>28,827</u>	<u>\$ 29</u>	<u>\$ 734,229</u>	<u>\$ (686,525)</u>	<u>\$ 2</u>	<u>\$ 47,735</u>	

IDERA PHARMACEUTICALS, INC.

**CONDENSED STATEMENTS OF REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY
(DEFICIT) (CONTINUED)
(UNAUDITED)**

	For the Six Months Ended June 30, 2020									
	Series B1 Preferred		Common Stock		Additional		Other		Accumulated Stockholders' Deficit	
	Number of Shares	\$0.01 Par Value	Number of Shares	\$0.001 Par Value	Paid-In Capital	Accumulated Deficit	Comprehensive Income	Total		
(In thousands)										
Balance, December 31, 2019	24	\$ —	29,672	\$ 30	\$ 709,692	\$ (720,890)	—	—	\$ (11,168)	
Sale of common stock, net of issuance costs	—	—	854	1	1,405	—	—	—	1,406	
Issuance of common stock under employee stock purchase plan	—	—	19	—	25	—	—	—	25	
Issuance of common stock under equity incentive plan (vesting of restricted stock units)	—	—	48	—	—	—	—	—	—	
Issuance of common stock for services rendered	—	—	14	—	26	—	—	—	26	
Stock-based compensation	—	—	—	—	750	—	—	—	750	
Net income	—	—	—	—	—	8,817	—	—	8,817	
Balance, March 31, 2020	24	\$ —	30,607	\$ 31	\$ 711,898	\$ (712,073)	\$ —	\$ —	\$ (144)	
Sale of common stock, net of issuance costs	—	—	3,607	3	5,821	—	—	—	5,824	
Issuance of common stock under employee stock purchase plan	—	—	21	—	29	—	—	—	29	
Issuance of common stock under equity incentive plan (vesting of restricted stock units)	—	—	—	—	—	—	—	—	—	
Issuance of common stock for services rendered	—	—	56	—	72	—	—	—	72	
Stock-based compensation	—	—	—	—	754	—	—	—	754	
Net loss	—	—	—	—	—	(24,226)	—	—	(24,226)	
Balance, June 30, 2020	24	\$ —	34,291	\$ 34	\$ 718,574	\$ (736,299)	\$ —	\$ (17,691)		

The accompanying notes are an integral part of these financial statements

IDERA PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS (UNAUDITED)
June 30, 2020

Note 1. Business and Organization

Business Overview

Idera Pharmaceuticals, Inc. (“Idera” or the “Company”), a Delaware corporation, is 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. The Company’s current focus is on its Toll-like receptor (“TLR”) agonist, tilsotolimod (IMO-2125), for oncology. The Company believes it can develop and commercialize targeted therapies on its own. To the extent the Company seeks to develop drug candidates for broader disease indications, it has entered into and may explore additional collaborative alliances to support development and commercialization.

Liquidity and Financial Condition

As of June 30, 2020, the Company had an accumulated deficit of \$736.3 million and a cash, cash equivalents, and short-term investments balance of \$31.0 million. The Company expects to incur substantial operating losses in future periods and will require additional capital as it seeks to advance tilsotolimod and any future drug candidates through development to commercialization. The Company does not expect to generate product revenue, sales-based milestones or royalties until the Company successfully completes development of and obtains marketing approval for tilsotolimod or other future drug candidates, either alone or in collaboration with third parties, which the Company expects will take a number of years. In order to commercialize tilsotolimod and any future drug candidates, the Company needs to complete clinical development and comply with comprehensive regulatory requirements. The Company is subject to a number of risks and uncertainties similar to those of other companies of the same size within the biotechnology industry, such as uncertainty of clinical trial outcomes, uncertainty of additional funding, and history of operating losses.

The Company follows the provisions of Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Topic 205-40, *Presentation of Financial Statements—Going Concern*, which requires management to assess the Company’s ability to continue as a going concern within one year after the date the financial statements are issued. Management currently believes that the Company’s balance of cash, cash equivalents, and short-term investments on hand as of June 30, 2020, plus \$5.1 million gross proceeds received in July 2020 pursuant to the July 2020 Securities Purchase Agreement (Note 13), is sufficient to fund operations into the second quarter of 2021. As a result, there is substantial doubt about the Company’s ability to continue as a going concern through the one-year period from the date these financial statements are issued. Management’s plans that are intended to mitigate the risk of going concern include raising additional capital through the Company’s December 2019 Securities Purchase Agreement (Note 7), Common Stock Purchase Agreement (Note 8), “At-The-Market” Equity Program (Note 8), April 2020 Securities Purchase Agreement (Note 8), July 2020 Securities Purchase Agreement (Note 13), or additional financing or strategic transactions. Management’s plans may also include the possible deferral of certain operating expenses unless additional capital is received. The Company has and will continue to evaluate available alternatives to extend its operations beyond the one-year period after the date the financial statements are issued. Management’s operating plan, which underlies the analysis of the Company’s ability to continue as a going concern, involves the estimation of the amount and timing of future cash inflows and outflows. Actual results could vary from the operating plan.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited financial statements included herein have been prepared by the Company in accordance with U.S. generally accepted accounting principles (“GAAP”) for interim financial information and pursuant to the rules and regulations of the SEC. Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, all adjustments, consisting of normal recurring adjustments, and disclosures considered necessary for a fair presentation of interim period results have been included. Interim results for the three and six months ended June 30, 2020 are not necessarily indicative of results that may be expected for the year ending December 31, 2020. For further information, refer to the financial statements and footnotes thereto included in the Company’s 2019 Form 10-K.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of 90 days or less when purchased to be “cash equivalents.” Cash and cash equivalents at June 30, 2020 and December 31, 2019 consisted of cash and money market funds.

Financial Instruments

The fair value of the Company’s financial instruments is determined and disclosed in accordance with the three-tier fair value hierarchy specified in Note 3. The Company is required to disclose the estimated fair values of its financial instruments. As of June 30, 2020 and December 31, 2019, the Company’s financial instruments consisted of cash, cash equivalents, short-term investments, receivables and warrant and future tranche right liabilities. The estimated fair values of these financial instruments approximate their carrying values. As of June 30, 2020, the Company did not have any other derivatives, or any hedging or other similar financial instruments.

Concentration of Credit Risk

Financial instruments that subject the Company to credit risk primarily consist of cash, cash equivalents, and short-term investments. The Company’s credit risk is managed by investing in highly rated money market instruments, corporate bonds, commercial paper and/or other debt securities. Due to these factors, no significant credit risk is believed by management to be inherent in the Company’s assets. As of June 30, 2020, all of the Company’s cash, cash equivalents and short-term investments were held at two financial institutions.

Operating Lease Right-of-use Asset and Lease Liability

The Company accounts for leases under ASC Topic 842, *Leases*. The Company determines if an arrangement is a lease at inception. Operating leases are included in long-term right-of-use assets and current and long-term lease liabilities within the Company’s condensed balance sheets. Right-of-use (“ROU”) assets represent the Company’s right to use an underlying asset for the lease term and lease liabilities represent the Company’s obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As most of the Company’s leases do not provide an implicit rate, the Company uses its incremental borrowing rates, which are the rates incurred to borrow on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment. Lease expense for lease payments is recognized on a straight-line basis over the lease term. The right-of-use assets are tested for impairment according to ASC Topic 360, *Property, Plant, and Equipment*. Leases with an initial term of 12 months or less are not recorded on the balance sheet and are recognized as lease expense on a straight-line basis over the lease term.

As of June 30, 2020 and December 31, 2019, the Company’s operating lease ROU asset and corresponding short-term and long-term lease liabilities relate to its existing Exton, PA facility operating lease which expires on May 31, 2025 as a result of the Company’s election to exercise its five-year renewal option in January 2020.

Note 2. Summary of Significant Accounting Policies (Continued)

Warrant Liability

The Company accounts for stock warrants as either equity instruments, liabilities or derivative liabilities in accordance with ASC Topic 480, *Distinguishing Liabilities from Equity* (ASC 480) and/or ASC Topic 815, *Derivatives and Hedging* (ASC 815), depending on the specific terms of the warrant agreement. Freestanding warrants for shares that are potentially redeemable, whereby the Company may be required to transfer assets (e.g. cash or other assets) outside of its control, are classified as liabilities. Liability-classified warrants are recorded at their estimated fair values at each reporting period until they are exercised, terminated, reclassified or otherwise settled. Changes in the estimated fair value of liability-classified warrants are recorded in Warrant Revaluation (Loss) Gain in the Company's condensed statements of operations and comprehensive loss. Equity-classified warrants are recorded within additional paid-in capital at the time of issuance and not subject to remeasurement. For additional discussion on warrants, see Note 7.

Future Tranche Right Liability

On December 23, 2019, the Company entered into a Securities Purchase Agreement (the "December 2019 Securities Purchase Agreement") with institutional investors affiliated with Baker Brothers (the "Purchasers"), an existing stockholder and related party (see Note 11). As more fully described in Note 7, the December 2019 Securities Purchase Agreement contains call options on redeemable preferred shares with warrants (conditionally exercisable for shares that are puttable). The Company determined that these call options represent freestanding financial instruments and accounts for the options as liabilities ("Future Tranche Right Liability") under ASC 480, which requires the measurement and recognition of the fair value of the liability at the time of issuance and at each reporting period. Any change in fair value is recognized in Future Tranche Right Liability Revaluation (Loss) Gain in the Company's condensed statements of operations and comprehensive loss.

As of June 30, 2020, the Future Tranche Right Liability is classified as a long-term liability in the Company's condensed balance sheet as settlement is in the form of the applicable Series B convertible preferred stock and warrants exercisable for shares of either Series B1 Preferred Stock or the Company's common stock. As of December 31, 2019, the Future Tranche Right Liability was classified as a current liability as the Future Tranche Rights and related Option Fee, each defined in Note 7, were subject to the Company obtaining required shareholder approval and filing the Charter Amendment, as defined in Note 3.

Preferred Stock

The Company applies ASC 480 when determining the classification and measurement of its preferred stock. Preferred shares subject to mandatory redemption are classified as liability instruments and are measured at fair value. Conditionally redeemable preferred shares (including preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control) are classified as temporary equity. At all other times, preferred shares are classified as stockholders' equity.

Accretion of redeemable convertible preferred stock includes the accretion of the Company's Series B redeemable convertible preferred stock to its stated value. The carrying value of the Series B redeemable convertible preferred stock is being accreted to redemption value using the effective interest method, from the date of issuance to the earliest date the holders can demand redemption.

Income Taxes

In accordance with ASC Topic 270, *Interim Reporting*, and ASC Topic 740, *Income Taxes*, the Company is required at the end of each interim period to determine the best estimate of its annual effective tax rate and then apply that rate in providing for income taxes on a current year-to-date (interim period) basis. For the three and six months ended June 30, 2020 and 2019, the Company recorded no tax expense or benefit due to the expected current year loss and its historical losses. The Company has not recorded its net deferred tax asset as of either June 30, 2020 or December 31, 2019 because it maintained a full valuation allowance against all deferred tax assets as of these dates as management has determined that it is not more likely than not that the Company will realize these future tax benefits. As of June 30, 2020 and December 31, 2019, the Company had no uncertain tax positions.

Note 2. Summary of Significant Accounting Policies (Continued)

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB and rules are issued by the SEC that the Company has or will adopt as of a specified date. Unless otherwise noted, management does not believe that any other recently issued accounting pronouncements issued by the FASB or guidance issued by the SEC had, or is expected to have, a material impact on the Company's present or future financial statements.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued Accounting Standard Update ("ASU") No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). This standard requires that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, this standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. The Company adopted ASU 2016-13 in the first quarter of 2020. The adoption of this ASU did not have a material effect on the Company's financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"), which amends ASC 820, *Fair Value Measurement*. ASU 2018-13 modifies the disclosure requirements for fair value measurements by removing, modifying, or adding certain disclosures. The Company adopted ASU 2018-13 in the first quarter of 2020. The adoption of this ASU did not have a material effect on the Company's financial statements.

COVID-19

The full extent to which the novel coronavirus disease ("COVID-19") pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, including expenses and manufacturing, clinical trials and research and development costs, will depend on future developments that are highly uncertain at this time.

Note 3. Fair Value Measurements

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company applies the guidance in ASC Topic 820, *Fair Value Measurement*, to account for financial assets and liabilities measured on a recurring basis. Fair value is measured at the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that is determined based on assumptions that market participants would use in pricing an asset or liability.

The Company uses a fair value hierarchy, which distinguishes between assumptions based on market data (observable inputs) and an entity's own assumptions (unobservable inputs). The guidance requires that fair value measurements be classified and disclosed in one of the following three categories:

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
- Level 2: Quoted prices in markets that are not active or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability
- Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

Note 3. Fair Value Measurements (Continued)

Determining which category an asset or liability falls within the hierarchy requires significant judgment. The Company evaluates its hierarchy disclosures each reporting period. There were no transfers between Level 1, 2 and 3 during the six months ended June 30, 2020.

The table below presents the assets and liabilities measured and recorded in the financial statements at fair value on a recurring basis at June 30, 2020 and December 31, 2019 categorized by the level of inputs used in the valuation of each asset and liability.

(In thousands)	June 30, 2020			
	Total	Level 1	Level 2	Level 3
Assets				
Cash	\$ 250	\$ 250	\$ —	\$ —
Cash equivalents – money market funds	27,560	27,560	—	—
Short-term investments – commercial paper	3,196	—	3,196	—
Total assets	<u>\$ 31,006</u>	<u>\$ 27,810</u>	<u>\$ 3,196</u>	<u>\$ —</u>
Liabilities				
Warrant liability	\$ 3,053	\$ —	\$ —	\$ 3,053
Future tranche right liability	41,074	—	—	41,074
Total liabilities	<u>\$ 44,127</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 44,127</u>

(In thousands)	December 31, 2019			
	Total	Level 1	Level 2	Level 3
Assets				
Cash	\$ 250	\$ 250	\$ —	\$ —
Cash equivalents – money market funds	39,769	39,769	—	—
Short-term investments – commercial paper	2,774	—	2,774	—
Total assets	<u>\$ 42,793</u>	<u>\$ 40,019</u>	<u>\$ 2,774</u>	<u>\$ —</u>
Liabilities				
Warrant liability	\$ 3,241	\$ —	\$ —	\$ 3,241
Future tranche right liability	46,436	—	—	46,436
Total liabilities	<u>\$ 49,677</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 49,677</u>

The Level 1 assets consist of money market funds, which are actively traded daily. The Level 2 assets consist of commercial paper whose fair value may not represent actual transactions of identical securities. The fair value of commercial paper is generally determined based on the relationship between the investment's discount rate and the discount rates of the same issuer's commercial paper available in the market which may not be actively traded daily. Since these fair values may not be based upon actual transactions of identical securities, they are classified as Level 2.

Changes in Level 3 Liabilities Measured at Fair Value on a Recurring Basis

Warrant Liability and Future Tranche Right Liability

The reconciliation of the Company's warrant and future tranche right liability measured at fair value on a recurring basis using unobservable inputs (Level 3) is as follows:

(In thousands)	Warrant Liability	Future	
		Tranche Right	Liability
Balance, December 31, 2019	\$ 3,241	\$ 46,436	
Change in the fair value of liability	(188)	(5,362)	
Balance, June 30, 2020	<u>\$ 3,053</u>	<u>\$ 41,074</u>	

Note 3. Fair Value Measurements (Continued)***Assumptions Used in Determining Fair Value of Liability-Classified Warrants***

The Company utilizes an option pricing model to value its liability-classified warrants. Inherent in the valuation model are assumptions related to volatility, risk-free interest rate, expected term, dividend rate, and other scenarios (i.e. probability of complex features of the warrants being triggered).

The fair value of the warrants has been estimated with the following weighted-average assumptions:

	June 30, 2020	December 31, 2019
Risk-free interest rate	0.42%	1.79%
Expected dividend yield	—	—
Expected term (years)	6.48	6.98
Expected volatility	80%	80%
Exercise price (per share)	\$ 1.52	\$ 1.52

Assumptions Used in Determining Fair Value of Future Tranche Rights

The Company utilizes a binomial lattice model to value the Series B2 (tranche 2) and B3 (tranche 3) tranches and a Monte Carlo simulation to value the Series B4 (tranche 4) future tranche rights. The Company selected these models as it believes they are reflective of all significant assumptions that market participants would likely consider in negotiating the transfer of the Future Tranche Rights (as defined in Note 7). Such assumptions include, among other inputs, stock price volatility, risk-free rates, redemption and early exercise assumptions, cancellation and conversion assumptions, and the potential for future adjustment of the conversion price due to a future dilutive financing.

The estimated fair value of the Future Tranche Rights is determined using Level 2 and Level 3 inputs. Significant inputs and assumptions used in the valuation models are as follows:

	June 30, 2020	December 31, 2019
Risk-free interest rate	0.49% - 0.55%	1.84% - 1.88%
Expected dividend yield	—	—
Expected term (years) of call option on preferred stock	0.66 - 1.62	1.16 - 2.16
Expected term (years) of warrants	7.66 - 8.62	8.16 - 9.16
Expected volatility	80%	80%
Exercise price (per share) for common stock equivalent for preferred stock and warrant	\$ 1.52 - 1.82	\$ 1.52 - 1.82

Note 4. Investments

The Company's available-for-sale investments at fair value consisted of the following as of June 30, 2020 and December 31, 2019:

	June 30, 2020			
	Cost	Gross Unrealized (Losses)	Gross Unrealized Gains	Estimated Fair Value
(In thousands)				
Short-term investments – commercial paper	\$ 3,196	\$ —	\$ —	\$ 3,196
Total short-term investments	<u>\$ 3,196</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 3,196</u>
December 31, 2019				
	Cost	Gross Unrealized (Losses)	Gross Unrealized Gains	Estimated Fair Value
	\$ 2,774	\$ —	\$ —	\$ 2,774
(In thousands)				
Short-term investments – commercial paper	\$ 2,774	\$ —	\$ —	\$ 2,774
Total short-term investments	<u>\$ 2,774</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2,774</u>

The Company had no realized gains or losses from the sale of investments in available-for-sale securities during each of the six months ended June 30, 2020 and December 31, 2019. In accordance with ASU 2016-13, if the fair value of the Company's investments in available-for-sale debt securities is less than the amortized cost, the Company records (i) an allowance for credit losses with a corresponding charge to net income (loss) for any credit-related impairment, with subsequent improvements in expected credit losses recognized as a reversal of the allowance, and/or (ii) any non-credit impairment loss to other comprehensive income (loss).

As of June 30, 2020 and December 31, 2019, the Company had no allowance for credit losses pertaining to the Company's investments in available-for-sale debt securities. Additionally, there were no impairment charges or recoveries recorded during each of the periods ended June 30, 2020 and December 31, 2019.

Note 5. Property and Equipment

At June 30, 2020 and December 31, 2019, property and equipment, net, consisted of the following:

	June 30, 2020	December 31, 2019
(In thousands)		
Leasehold improvements	\$ 107	\$ 107
Equipment and other	770	764
Total property and equipment, at cost	\$ 877	\$ 871
Less: Accumulated depreciation and amortization	814	774
Property and equipment, net	<u>\$ 63</u>	<u>\$ 97</u>

Depreciation and amortization expense on property and equipment was less than \$0.1 million for each of the three and six months ended June 30, 2020 and 2019. Additionally, there were no non-cash property additions or impairment-related charges recognized during each of the respective time periods.

Note 6. Accrued Expenses

At June 30, 2020 and December 31, 2019, accrued expenses consisted of the following:

	June 30, 2020	December 31, 2019
(In thousands)		
Payroll and related costs	\$ 1,796	\$ 2,179
Clinical and nonclinical trial expenses	4,405	4,199
Professional and consulting fees	692	859
Restructuring expenses	16	113
Other	114	111
Total accrued expenses	<u>\$ 7,023</u>	<u>\$ 7,461</u>

Note 7. Redeemable Convertible Preferred Stock

December 2019 Private Placement

On December 23, 2019, the Company entered into the December 2019 Securities Purchase Agreement, under which the Company sold 23,684 shares of Series B1 convertible preferred stock (“Series B1 Preferred Stock”) and warrants to purchase 2,368,400 shares of the Company’s common stock at an exercise price of \$1.52 per share (or, if the holder elects to exercise the warrants for shares of Series B1 Preferred Stock, 23,684 shares of Series B1 Preferred Stock at an exercise price of \$152 per share) for aggregate gross proceeds of \$3.9 million (the “Initial Closing”).

In addition, the Company has agreed to sell to the Purchasers, at their option and subject to certain conditions, shares of Series B2 convertible preferred stock (“Series B2 Preferred Stock”), Series B3 convertible preferred stock (“Series B3 Preferred Stock”) and Series B4 convertible preferred stock (“Series B4 Preferred Stock”) and accompanying warrants to purchase common stock (or preferred stock at the election of the holder) over a 21-month period following stockholder approval for the Charter Amendment (the “Future Tranche Rights”). As of June 30, 2020, the Company’s outstanding Future Tranche Rights are as follows:

Future Tranche Rights	Preferred Shares	Price Per Share	Aggregate Purchase Price
Tranche 2 (Series B2) (1)	98,685	\$ 152	\$ 15,000,120
Tranche 3 (Series B3) (2)	82,418	\$ 182	15,000,076
Tranche 4 (Series B4) (2)	82,418	\$ 182	15,000,076
Total	263,521		\$ 45,000,272

- (1) Accompanied by related warrants to purchase up to 9,868,500 shares of the Company’s common stock (or, if the holder elects to exercise the warrants for shares of Series B1 Preferred Stock, 98,685 shares of Series B1 Preferred Stock), at an exercise price of \$1.52 per share (or, if the holder elects to exercise the warrants for Series B1 Preferred Stock, \$152 per share of Series B1 Preferred Stock).
- (2) Accompanied by related warrants to purchase up to 6,593,440 shares of the Company’s common stock (or, if the holder elects to exercise the warrants for shares of Series B1 Preferred Stock, 65,934 shares of Series B1 Preferred Stock), at an exercise price of \$1.82 per share (or, if the holder elects to exercise the warrants for Series B1 Preferred Stock, \$182 per share of Series B1 Preferred Stock).

As consideration for the Future Tranche Rights, the Company received aggregate gross proceeds of \$6.2 million (the “Option Fee”) in December 2019. In the event the Company did not receive the required shareholder approval to increase the Company’s authorized shares of common stock in an amount sufficient to cover the conversion of all potential convertible securities issuable under the December 2019 Securities Purchase Agreement on or prior to December 31, 2020, the Option Fee was refundable to the Purchasers. At the Company’s 2020 Annual Meeting of Stockholders held on May 12, 2020, stockholders of the Company voted to approve an amendment to the Company’s Restated Certificate of Incorporation to increase the authorized number of shares of common stock, par value \$0.001 per share, to 140,000,000 (the “Charter Amendment”), representing an amount sufficient to cover the conversion of all potential future convertible securities. As a result of stockholder approval of the Charter Amendment, the Company is not required to return the Option Fee.

Note 7. Redeemable Convertible Preferred Stock (Continued)

The purchase and sale of the securities issuable under tranches 2, 3 and 4 may occur in up to three separate closings, each to be conducted at the Purchasers' discretion. The right of the Purchasers to purchase Series B2, Series B3 and Series B4 Preferred Stock will expire on February 12, 2021 (or on the 10th business day following the Company's ORR Data Announcement, as defined in the December 2019 Securities Purchase Agreement, for its ILLUMINATE-301 study, if later), August 12, 2021, and February 12, 2022, respectively. However, the Purchasers' right to purchase securities under tranches 3 and 4 is contingent on the purchase of all of the securities in each preceding tranche right. In the event the Purchaser's do not purchase all of the securities in a given tranche, their right to purchase shares in future tranches terminates and any outstanding warrants issued under the December 2019 Securities Purchase Agreement would terminate. Additionally, the Company has the right to decline the Series B4 Preferred Stock investment if its common stock trades at \$7.60 for 20 days out of 30 days subsequent to the closing of the Series B3 Preferred Stock investment.

In addition to the aggregate gross proceeds received from the Initial Closing and the Option Fee, the Company is eligible, at the discretion of the Purchasers, to receive aggregate gross proceeds of up to an additional \$87.6 million under the December 2019 Securities Purchase Agreement.

Accounting Considerations

The Company determined that the Series B1 Preferred Stock, the accompanying Series B1 warrants, and each of the Future Tranche Rights represented a freestanding financial instrument. The warrants and the Future Tranche Rights are liability classified as the underlying shares are potentially redeemable and such redemption is deemed to be outside of the Company's control.

Due to the redeemable nature of the Series B1 Preferred Stock, the Series B1 Preferred Stock is currently classified as temporary equity. While the Series B1 Preferred Stock is not currently redeemable, it will become redeemable either on (i) the fifth anniversary of the initial issue date, or December 23, 2024, provided that certain events (the "Redemption Loss Events") do not occur first or (ii) upon a liquidation or deemed liquidation event, provided that certain events (the "Liquidation Loss Events") do not occur first. The Company cannot assess the probability of whether the Redemption Loss Events will occur prior to the fifth anniversary of the initial issue date, if ever, as certain factors triggering such events are outside the control of the Company. Accordingly, the carrying value of the Series B1 Preferred Stock is being accreted to its redemption value as of June 30, 2020. In the event the holders of the Series B1 Preferred Stock lose their right to request redemption, the Series B Preferred Stock will no longer be accreted to its redemption value until redemption upon a liquidation event is deemed probable. For the three and six months ended June 30, 2020, accretion was de minimis.

Note 8. Stockholders' Equity

Common Stock – Authorized Shares

On May 12, 2020, the Company's stockholders approved the Charter Amendment. Also on May 12, 2020, following stockholder approval, the Company filed the Charter Amendment with the Secretary of State of the State of Delaware.

Equity Financings

April 2020 Private Placement

On April 7, 2020, the Company entered into a Securities Purchase Agreement (the "April 2020 Securities Purchase Agreement") with Pillar Partners, an existing stockholder and related party as more fully described in Note 11, under which the Company sold 3,039,514 shares of common stock and accompanying warrants to purchase 3,039,514 shares of the Company's common stock with an exercise price of \$2.28 per share, for aggregate gross proceeds of \$5.0 million. Each share and the accompanying common warrant had a combined purchase price of \$1.645, which included \$0.125 for each share of common stock underlying each warrant.

Note 8. Stockholders' Equity (Continued)

Through June 30, 2020, net proceeds received pursuant to the April 2020 Securities Purchase Agreement, after deduction of offering expenses, was \$4.7 million. All proceeds have been recorded within the Company's condensed statements of stockholders' equity (deficit) as all securities issued in connection with the April 2020 Securities Purchase Agreement, including the option provided to Pillar Partners' to participate in the April 2020 Private Placement Second Closing as further described below, were determined to be freestanding equity-classified instruments.

In addition, the Company has agreed to sell to Pillar Partners, at its option, 2,747,252 shares of the Company's common stock (or pre-funded warrants to purchase shares of the Company's common stock in lieu of certain shares to the extent that purchasing such shares will cause Pillar Investment Entities to beneficially own in excess of 19.99% of the total number of shares of common stock outstanding post transaction) and warrants to purchase up to 1,373,626 shares of the Company's common stock (with an exercise price of \$2.71), for aggregate gross proceeds of \$5.0 million (the "April 2020 Private Placement Second Closing"). Each share and the accompanying 0.5 common warrant will have a combined purchase price of \$1.82 and each pre-funded warrant and the accompanying 0.5 common warrant will have a combined purchase price of \$1.81. The pre-funded warrants issued in the April 2020 Private Placement Second Closing will have an exercise price of \$0.01 per share of common stock. The April 2020 Private Placement Second Closing can occur on or before December 30, 2020 (at the option of Pillar Partners) and will be held on or before the fifth day following delivery of written notice by Pillar Partners to the Company; provided that, if at any time after June 30, 2020, the Company's common stock has achieved a closing price on the Nasdaq Capital Market of at least \$3.01 per share for twenty (20) consecutive trading days, the Company may elect, in its sole discretion, to cancel the April 2020 Private Placement Second Closing.

Common Stock Purchase Agreement

On March 4, 2019, the Company entered into a Purchase Agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which, upon the terms and subject to the conditions and limitations set forth therein, 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 (the "LPC Purchase Agreement"). As consideration for entering into the LPC Purchase Agreement, the Company issued 269,749 shares of Company common stock to Lincoln Park 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. During the six months ended June 30, 2020 and 2019, the Company sold 600,000 and 785,848 shares pursuant to the LPC Purchase Agreement, resulting in net proceeds of \$1.1 million and \$2.3 million, respectively. As of June 30, 2020, the Company may sell up to an additional \$30.2 million of shares under the LPC Agreement, subject to certain limitations.

"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 ATM 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 six months ended June 30, 2020 and 2019, the Company sold 821,018 and 532,700 Shares, respectively, pursuant to the ATM Agreement, resulting in net proceeds, after deduction of commissions and other offering expenses, of \$1.4 million and \$1.6 million, respectively. As of June 30, 2020, the Company may sell up to an additional \$46.8 million of shares under the ATM Agreement.

Note 8. Stockholders' Equity (Continued)***Common Stock Warrants***

In connection with various financing transactions, the Company has issued warrants to purchase shares of the Company's common and preferred stock. The Company accounts for common and preferred stock warrants as equity instruments or liabilities, depending on the specific terms of the warrant agreement.

The following table summarizes outstanding warrants to purchase shares of the Company's common and preferred stock as of June 30, 2020 and December 31, 2019:

<u>Description</u>	<u>Number of Shares</u>		<u>Weighted-Average Exercise Price</u>	<u>Expiration Date</u>
	<u>June 30, 2020</u>	<u>December 31, 2019</u>		
Liability-classified Warrants				
December 2019 Series B1 warrants (1)	2,368,400	2,368,400	\$ 1.52	Dec 2026
	<u>2,368,400</u>	<u>2,368,400</u>		
Equity-classified Warrants				
May 2013 warrants	1,949,754	1,949,754	\$ 0.08	None
September 2013 warrants	514,756	514,756	\$ 0.08	None
February 2014 warrants	266,006	266,006	\$ 0.08	None
April 2020 warrants	3,039,514	—	\$ 2.28	Apr 2023
	<u>5,770,030</u>	<u>2,730,516</u>		
Total outstanding	<u><u>8,138,430</u></u>	<u><u>5,098,916</u></u>		

- (1) The Series B1 warrants are exercisable for either common stock (exercise price of \$1.52) or Series B1 Convertible Preferred Stock (exercise price of \$152) at the discretion of the warrant holder.

Note 9. Collaboration and License Agreements***Option and License Agreement with Licensee***

In April 2019, the Company entered into an amended and restated option and license agreement with a privately-held biopharmaceutical company ("Licensee"), pursuant to which the Company granted Licensee (i) exclusive worldwide rights to develop and market IMO-8400 for the treatment, palliation and diagnosis of all diseases, conditions or indications in humans (the "IMO-8400 License"), (ii) an exclusive right and license to develop IMO-9200 in accordance with certain IMO-9200 pre-option exercise protocols (the "IMO-9200 Option Period License"), and (iii) an exclusive option, exercisable at Licensee's discretion, to obtain the exclusive worldwide rights to develop and market IMO-9200 for the treatment, palliation and diagnosis of all diseases, conditions or indications in humans (the "IMO-9200 Option") (collectively, the "Licensee Agreement"). In connection with the Licensee Agreement, the Company transferred certain drug material to Licensee for Licensee's use in development activities. Licensee is solely responsible for the development and commercialization of IMO-8400 and, if Licensee exercises the IMO-9200 Option, Licensee would be solely responsible for the development and commercialization of IMO-9200.

Under the terms of the Licensee Agreement, the Company received upfront, non-refundable fees totaling approximately \$1.4 million and ownership of 10% of Licensee's outstanding common stock, subject to future adjustment, for granting Licensee the IMO-8400 License, the IMO-9200 Option Period License and transfer of related drug materials. In addition, the Company is eligible to receive a \$1 million non-refundable fee upon Licensee exercising the IMO-9200 Option ("Option Fee") and is entitled to certain sub-licensing payments on sublicense revenue received by Licensee, if any. The Company may also be eligible for certain development and sales-based milestone payments and royalties on global net sales for any future products. The Company does not anticipate the receipt of any of the future milestones or royalties in the short term, if ever.

Note 9. Collaboration and License Agreements (Continued)

The Company accounts for the Licensee Agreement in accordance with ASC Topic 606. As of June 30, 2020, the Option Fee and all potential future development/sales milestone payments were fully constrained, and there were no remaining performance obligations under the Licensee Agreement. The Company re-evaluates its performance obligations and the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

As disclosed above, in connection with the Licensee Agreement, the Company owns 10% of Licensee's outstanding common stock, subject to future adjustment. The Company accounts for the investment using the measurement alternative provided for in ASC Topic 321, *Investments-Equity Securities*, as the equity securities are without a readily determinable fair value, and the arrangement does not result in Idera having control or significant influence over Licensee. Accordingly, the securities are measured at cost, less any impairment, plus or minus changes resulting from observable price changes and are recorded in Other assets at a value of less than \$0.1 million in the accompanying balance sheets. As of June 30, 2020, the Company considered the cost of the investment to not exceed the fair value of the investment and did not identify any observable price changes.

Note 10. Stock-Based Compensation

As of June 30, 2020, 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 (as amended to date, the "2017 ESPP"), each as more fully described below.

Equity Incentive and Employee Stock Purchase Plans

2013 Stock Incentive Plan

The 2013 Plan allows for the issuance of incentive stock options intended to qualify under Section 422 of the Internal Revenue Code, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units, other stock-based awards and performance awards. The total number of shares of common stock authorized for issuance under the 2013 Plan is 5,653,057 shares of the Company's common stock, plus such additional number of shares of common stock (up to 868,372 shares) as is equal to the number of shares of common stock subject to awards granted under the Company's 2005 Stock Incentive Plan or 2008 Stock Incentive Plan (the "2008 Plan"), to the extent such 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.

As of June 30, 2020, options to purchase a total of 4,035,439 shares of common stock and 376,210 restricted stock units were outstanding and up to 1,464,378 shares of common stock remained available for grant under the 2013 Plan.

Other Awards and Inducement Grants

The Company has not made any awards pursuant to other equity incentive plans, including the 2008 Plan, since the Company's stockholders approved the 2013 Plan. As of June 30, 2020, options to purchase a total of 327,262 shares of common stock were outstanding under the 2008 Plan. In addition, as of June 30, 2020, non-statutory stock options to purchase an aggregate of 393,750 shares of common stock were outstanding. These options were issued outside of the 2013 Plan to certain newly-hired employees in 2017, 2015 and 2014 pursuant to the Nasdaq inducement grant exception as a material component of such new hires' employment compensation.

Note 10. Stock-Based Compensation (Continued)**2017 Employee Stock Purchase Plan**

The 2017 ESPP is intended to qualify as an "employee stock purchase plan" as defined in Section 423 of the Internal Revenue Code. The total number of shares of common stock authorized for issuance under the 2017 ESPP is 412,500 shares of common stock, subject to adjustment as described in the 2017 ESPP. As of June 30, 2020, 281,317 shares remained available for issuance under the 2017 ESPP.

For the six months ended June 30, 2020 and 2019, the Company issued 40,024 and 30,570 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 condensed statements of operations for the three and six months ended June 30, 2020 and 2019 were as follows:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Stock-based compensation:				
Research and development				
Employee Stock Purchase Plans	\$ 15	\$ 12	\$ 26	\$ 18
Equity Incentive Plans	192	320	385	650
	\$ 207	\$ 332	\$ 411	\$ 668
General and administrative				
Employee Stock Purchase Plans	\$ 1	\$ 8	\$ 2	\$ 14
Equity Incentive Plans	546	549	1,091	1,223
	\$ 547	\$ 557	\$ 1,093	\$ 1,237
Total stock-based compensation expense	\$ 754	\$ 889	\$ 1,504	\$ 1,905

During the six months ended June 30, 2020 and 2019, the weighted average fair market value of stock options granted was \$1.09 and \$1.83, respectively.

Note 10. Stock-Based Compensation (Continued)

The following weighted average assumptions apply to the options to purchase 727,129 and 610,002 shares of common stock granted to employees and directors during the six months ended June 30, 2020 and 2019, respectively:

	Six Months Ended June 30,	
	2020	2019
Average risk-free interest rate	1.5%	2.3%
Expected dividend yield	—	—
Expected lives (years)	3.9	4.0
Expected volatility	82.5%	82.8%
Weighted average exercise price (per share)	\$ 1.82	\$ 3.02

All options granted during the six months ended June 30, 2020 and 2019 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 six months ended June 30, 2020:

(\$ 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, 2019	4,220,417	\$ 13.08	6.6	\$ —
Granted	727,129	1.82		
Exercised	—	—		
Forfeited	(38,874)	5.67		
Expired	(152,221)	19.83		
Outstanding at June 30, 2020 (1)	4,756,451	\$ 11.20	6.8	\$ —
Exercisable at June 30, 2020	2,541,439	\$ 17.18	5.0	\$ —

(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 six months ended June 30, 2020 was \$1.5 million. As of June 30, 2020, there was \$4.5 million of unrecognized compensation cost related to unvested options, which the Company expects to recognize over a weighted average period of 2.3 years.

Restricted Stock Activity

The following table summarizes restricted stock activity for the six months ended June 30, 2020:

(\$ in thousands, except per share data)	Number of Shares	Weighted-Average Grant Date Fair Value
Nonvested shares at December 31, 2019	193,625	\$ 3.14
Granted	237,675	1.79
Cancelled	(6,688)	2.34
Vested	(48,402)	3.14
Nonvested shares at June 30, 2020	376,210	\$ 2.30

As of June 30, 2020, there was \$0.7 million of unrecognized compensation expense related to the restricted stock units, which is expected to be recognized over a weighted-average period of 3.0 years.

Note 11. Related Party Transactions

Baker Brothers

Julian C. Baker, a member of the Company's Board until his resignation in September 2018, is a principal of Baker Bros. Advisors, LP. Additionally, Kelvin M. Neu, a member of Company's Board until his resignation in June 2019, is an employee of Baker Bros. Advisors, LP. As of June 30, 2020, Baker Bros. Advisors, LP and certain of its affiliated funds (collectively, "Baker Brothers") held sole voting power with respect to an aggregate of 4,608,786 shares of the Company's common stock, representing approximately 13% of the Company's outstanding common stock.

As of June 30, 2020, Baker Brothers held warrants to purchase up to 2,708,812 shares of the Company's common stock at an exercise price of \$0.08 per share, and warrants to purchase up to 2,368,400 shares of the Company's common stock (or, if Baker Brothers elects to exercise the warrants for shares of Series B1 Preferred Stock, 23,684 shares of Series B1 Preferred Stock), at an exercise price of \$1.52 per share (or, if Baker Brothers elects to exercise the warrants for shares of Series B1 Preferred Stock, \$152 per Series B1 Preferred Warrant Share).

Pillar Investment Entities

Youssef El Zein, a member of the Company's board of directors until his resignation in October 2017, is a director and controlling stockholder of Pillar Invest Corporation, which is the general partner of Pillar Pharmaceuticals I, L.P. ("Pillar I"), Pillar Pharmaceuticals II, L.P. ("Pillar II"), Pillar Pharmaceuticals III, L.P. ("Pillar III"), Pillar Pharmaceuticals IV, L.P. ("Pillar IV"), Pillar Pharmaceuticals V, L.P. ("Pillar V"), Pillar Pharmaceuticals 6 L.P. ("Pillar 6"), and Pillar Partners Foundation, L.P. ("Pillar Partners") (collectively, "Pillar"). As of June 30, 2020, Pillar owned approximately 18% of the Company's common stock.

In April 2020, the Company sold shares of common stock and common stock warrants to Pillar Partners in a private placement transaction as more fully described in Note 8. As of June 30, 2020, Pillar held warrants to purchase up to 3,039,514 shares of the Company's common stock at an exercise price of \$2.28 and an option to purchase Company securities in the April 2020 Private Placement Second Closing, provided for in the April 2020 Securities Purchase Agreement, as more fully described in Note 8.

Subsequent to June 30, 2020, in July 2020, the Company sold shares of its common stock, pre-funded warrants and warrants to purchase shares of the Company's common stock to Pillar Partners in a private placement transaction, as more fully described in Note 13. Immediately following the private placement transaction, Pillar owned approximately 19.99% of the Company's common stock.

Board Fees Paid in Stock

Pursuant to the Company's director compensation program, in lieu of director board and committee fees of \$0.1 million during each of the six months ended June 30, 2020 and 2019, the Company issued 96,551 and 26,331 shares of common stock, respectively, to certain of its directors. Director board and committee fees are paid in arrears 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

The Company uses the two-class method to compute net income (loss) per common share during periods the Company realizes net income and has securities outstanding (redeemable convertible preferred stock) that entitle the holder to participate in dividends and earnings of the Company. In addition, the Company analyzes the potential dilutive effect of outstanding redeemable convertible preferred stock under the "if-converted" method when calculating diluted earnings per share and reports the more dilutive of the approaches (two class or "if-converted"). The two-class method is not applicable during periods with a net loss, as the holders of the redeemable convertible preferred stock have no obligation to fund losses. For all periods presented, the two-class method was not applicable.

The Company also analyzes the potential dilutive effect of stock options, restricted stock units, warrants and shares underlying future tranche rights under the treasury stock method (as applicable), during periods of income, or during periods in which income is recognized related to changes in fair value of its liability-classified securities.

Details in the computation of basic and diluted net loss per common share were as follows:

(\$ in thousands except per share data)	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net loss per share — Basic:				
Net loss	\$ (24,226)	\$ (11,176)	\$ (15,409)	\$ (22,150)
Denominator for basic net loss per share	33,583	28,461	31,941	28,070
Basic net loss per common share	<u>\$ (0.72)</u>	<u>\$ (0.39)</u>	<u>\$ (0.48)</u>	<u>\$ (0.79)</u>
Net loss per share — Diluted:				
Net loss	\$ (24,226)	\$ (11,176)	\$ (15,409)	\$ (22,150)
Less: Future tranche right revaluation gain applicable to dilutive liability-classified future tranche rights	—	—	(2,284)	—
Numerator for diluted net loss per share	<u>\$ (24,226)</u>	<u>\$ (11,176)</u>	<u>\$ (17,693)</u>	<u>\$ (22,150)</u>
Denominator for basic net loss per share	33,583	28,461	31,941	28,070
Plus: Incremental shares underlying "in the money" liability-classified future tranche rights outstanding	—	—	2,182	—
Denominator for diluted net loss per share	33,583	28,461	34,123	28,070
Diluted net loss per common share	<u>\$ (0.72)</u>	<u>\$ (0.39)</u>	<u>\$ (0.52)</u>	<u>\$ (0.79)</u>

Potentially dilutive securities, whose effect would have been antidilutive, were excluded from the computation of diluted earnings per share for each of the three and six months ended June 30, 2020 and 2019. Total antidilutive securities excluded from the calculation of diluted net loss per share for the respected periods were as follows:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Stock options	4,756	3,844	4,756	3,844
Restricted stock units	376	194	376	194
Common stock warrants	8,138	2,769	8,138	2,769
Convertible preferred stock	2,369	—	2,369	—
Future tranche rights	53,528	—	33,791	—
Total	<u>69,167</u>	<u>6,807</u>	<u>49,430</u>	<u>6,807</u>

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.

July 2020 Private Placement

On July 13, 2020, the Company entered into a Securities Purchase Agreement (the “July 2020 Securities Purchase Agreement”) with Pillar Partners, an existing stockholder and related party as more fully described in Note 11, under which the Company sold in a private placement transaction (i) 749,993 shares of common stock, (ii) pre-funded warrants to purchase up to 2,014,234 shares of common stock, at an exercise price of \$0.01 per share, in lieu of certain shares of common stock to the extent that purchasing such shares would have caused Pillar Partners to beneficially own in excess of 19.99% of the total number of shares of the Company’s common stock outstanding post transaction, and (iii) warrants to purchase 2,764,227 shares of the Company’s common stock with an exercise price of \$2.58 per share, for aggregate gross proceeds of \$5.1 million. Each share (or pre-funded warrant) and the accompanying common warrant had a combined purchase price of \$1.845, which included \$0.125 for each share of common stock underlying each accompanying warrant.

In addition, the Company has agreed to sell to Pillar Partners, at its option, pre-funded warrants to purchase up to 784,615 shares of the Company’s common stock, at an exercise price of \$0.01 per share, and warrants to purchase up to 274,615 shares of the Company’s common stock, at an exercise price of \$9.75, for aggregate gross proceeds of \$5.1 million (the “July 2020 Private Placement Second Closing”). Each pre-funded warrant and the 0.35 associated common warrant will have a combined purchase price of \$6.50 (\$6.45625 per pre-funded warrant plus \$0.04375 per 0.35 associated common warrant). The July 2020 Private Placement Second Closing will occur on or before the tenth Business Day following the ORR Data Announcement (as defined in the Securities Purchase Agreement) and will be held on or before the fifth day following delivery of written notice by Pillar Partners to the Company.

Subject to certain beneficial ownership limitation, the pre-funded warrants will be immediately exercisable upon issuance and do not have an expiration date.

The common warrants are exercisable at any time or times upon issuance, provided that Pillar Partners will be prohibited, subject to certain exceptions, from exercising to the extent that immediately prior to or after giving effect to such exercise, Pillar Partners, together with their affiliates and other attribution parties, would own more than 19.99% of the total number of shares of the Company’s common stock then issued and outstanding, which percentage may be changed at the holder’s election to a lower percentage at any time or to a higher percentage not to exceed 19.99% upon 61 days’ notice to the Company. The common warrants will expire three years from the date of issuance.

Concurrent with the execution of the July 2020 Securities Purchase Agreement, the Company entered into a registration rights agreement (the “July 2020 Registration Rights Agreement”) with Pillar Partners, pursuant to which the Company agreed, following demand by Pillar Partners, to file a registration statement on Form S-3 covering the resale of all of the registrable securities as promptly as reasonably practicable following such demand, and in any event within 60 days of such demand.

The foregoing descriptions of the July 2020 Securities Purchase Agreement, July 2020 Registration Rights Agreement, and the warrants are qualified in their entirety by reference to Exhibits 4.1, 4.2, 4.4, and 10.1 of this Form 10-Q, which exhibits are incorporated herein by reference.

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

This Management's Discussion and Analysis of 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 the 2019 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 2019 Form 10-K.*

In addition to historical information, this discussion and analysis contains forward-looking statements. These forward-looking statements are subject to risks and uncertainties, including those discussed in the section titled "Risk Factors," set forth in Item 1A of our 2019 Form 10-K, that could cause actual results to differ materially from historical results or anticipated results. In particular, we encourage you to review the risk factor related to the impact of the coronavirus pandemic titled "We face risks related to health epidemics and other outbreaks of communicable diseases, which could significantly disrupt our operations and may materially and adversely affect our business and financial condition."

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 ("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 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 ("BMS") in a Phase 3 registration 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 multicohort Phase 2 trial.

Recent Developments

In April 2020 and July 2020, we entered into two private placement financing transactions, each with Pillar Partners, an existing stockholder and related party, collectively providing for up to an aggregate of \$40.7 million in gross proceeds, in which \$5.0 million was received in connection with the April 2020 private placement and \$5.1 million was received in connection with the July 2020 private placement. Please refer to Note 8 and Note 13 of the notes to the condensed financial statements in this Quarterly Report on Form 10-Q for more information about these private placements.

Clinical Development

Tilsotolimod (IMO-2125)

Tilsotolimod is a synthetic phosphorothioate oligonucleotide that acts as a direct agonist of TLR9 to stimulate the innate and adaptive immune systems. Tilsotolimod is being developed for administration via intratumoral injection in combination with systemically administered checkpoint inhibitors and costimulation therapies for the treatment of various solid tumors, including (i) anti-PD1 refractory metastatic melanoma in combination with ipilimumab, (ii) microsatellite stable (“MSS”) colorectal cancer (“CRC”) in combination with nivolumab and ipilimumab, and (iii) squamous cell carcinoma of the head and neck (“SCCHN”) in combination with ABBV-368 and other combinations. We refer to our tilsotolimod development program as the ILLUMINATE development program. See additional information under the heading “Collaborative Alliances” for information on the development of tilsotolimod in collaboration with AbbVie Inc. (“AbbVie”) for patients with SCCHN.

Melanoma

Melanoma is a cancer that begins in a type of skin cell called melanocytes. While melanoma is one of the least common types of skin cancer, it has a poor prognosis when not detected and treated early. As is the case in many forms of cancer, melanoma becomes more difficult to treat once the disease has spread, or metastasized, beyond the skin to other parts of the body. Checkpoint inhibitors have changed the treatment of advanced melanoma and have become the standard of care, with anti-PD-1 agents being the most commonly used immunotherapy in the first-line setting. However, due to primary or acquired resistance mechanisms that exclude or inhibit anti-tumor immune cells, as many as 60% of patients do not benefit from this type of therapy, and up to one-third of initial responders develop resistance to the therapy and ultimately experience disease progression. Today, these refractory patients are left with few options for further treatment, paving the way for novel investigational therapies such as tilsotolimod.

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 (“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-PD-1 refractory metastatic melanoma, which we refer to as ILLUMINATE-301. This trial, which completed target enrollment in March 2020, will compare the results of the tilsotolimod-ipilimumab combination to those of ipilimumab alone in a 1:1 randomization. The family of primary endpoints of the trial consists of overall response rate (“ORR”) by blinded independent central review using Response Evaluation Criteria in Solid Tumors (“RECIST v1.1”) and median overall survival (“OS”). We believe positive results in either of the primary endpoints could lead to approval in the United States. Key secondary endpoints include durable response rate, duration of response, median time to response, median progression free survival (“PFS”) and patient-reported outcomes using a validated scale. ILLUMINATE-301 is being monitored by an Independent Data Monitoring Committee.

As further discussed under the caption “Item 1. Business — Collaborative Alliances” in our 2019 Form 10-K, in May 2018, we entered into a clinical trial collaboration and supply agreement with BMS under which BMS granted us a non-exclusive, non-transferable, 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.



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 intratumoral tilsotolimod in combination with ipilimumab in patients with anti-PD-1 refractory metastatic melanoma, which we refer to as ILLUMINATE-204. We subsequently amended the trial protocol to include an additional treatment 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 primary objectives of the Phase 1 portion of the trial included characterizing the safety of the combinations and determining the recommended Phase 2 dose. A secondary objective of the Phase 1 portion of the trial was to describe the antitumor activity of tilsotolimod when administered intratumorally in combination with ipilimumab or pembrolizumab. Objectives of the Phase 2 portion of the trial included evaluation of the ORR of the tilsotolimod-ipilimumab combination using RECIST v1.1 criteria and immune-related response criteria (“irRC”), median OS, other efficacy measures, and to continue to characterize the safety of the combination.

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 as the recommended dose level based on the safety and efficacy data from the Phase 1 portion of the trial and data from translational immune parameters. The Phase 2 portion of the trial utilized a two-stage design to evaluate the ORR 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 advanced with the expansion of the tilsotolimod-ipilimumab combination arm of ILLUMINATE-204 at the recommended Phase 2 dose of 8 mg tilsotolimod.

Final topline data from the trial was reported in April 2020. A total of 52 subjects were treated with the tilsotolimod-ipilimumab combination at the recommended Phase 2 dose of 8 mg tilsotolimod. Of the 49 subjects evaluable for efficacy, 11 had a confirmed response per RECIST v1.1, representing an ORR of 22.4%. Additionally, 35 of the 49 patients achieved stable disease or better, representing a disease control rate of 71.4%. Durable responses (>6 months) were observed in 7 of 11 confirmed responses per RECIST v1.1. Median OS was 21.0 months. The combination regimen was generally well-tolerated among the 62 ILLUMINATE-204 patients receiving tilsotolimod at any dose in combination with ipilimumab.

Refractory Solid Tumors



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

In March 2017, we initiated a Phase 1b dose escalation trial of intratumoral tilsotolimod as a single agent in multiple tumor types, which we refer to as ILLUMINATE-101. 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 generally well-tolerated at each of the dose levels tested. We also completed enrollment of 16 patients in a melanoma expansion cohort, which utilized a Simon's optimal two-stage design, to assess whether tilsotolimod as a single agent (8mg dose) has any statistically relevant 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. The study was completed in October 2019.

At the American Association for Cancer Research Annual Meeting in April 2020, we provided final results of ILLUMINATE-101, noting that 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 dose-expansion cohort. Of the 51 evaluable patients, 29% (n=15) had a best response of stable disease. Duration of stable disease ranged from 1.5 to 12+ months from the start of treatment, with stable disease ongoing beyond 12 months for one patient as of the close of the study. 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. Translational research in ILLUMINATE-101 demonstrated that tilsotolimod increased dendritic cell activation and upregulated MHC class II and IFN- α signaling, which suggests improved antigen presentation, and 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 clinical development 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, microsatellite instability high/deficient mismatch repair (“MSI-H/dMMR”) colorectal cancer (“CRC”) and squamous cell carcinoma of the head and neck (“SCCHN”).

In patients with CRC, nivolumab administered as monotherapy or in combination with ipilimumab has demonstrated benefit and is approved for the treatment of MSI-H/dMMR 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 tumor microenvironment (“TME”) of MSS-CRC patients.

In patients with relapsed or metastatic SCCHN (“RM-SCCHN”), results from prospectively conducted trials employing the immune-modulating antibodies nivolumab and pembrolizumab following chemotherapy heralded a new era of treatment for patients with 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.

See information on our clinical trial and supply agreement with AbbVie under the heading “Collaborative Alliances” which discusses the development of tilsotolimod in combination with ABBV-368 and other combinations for the treatment of SCCHN.



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

In September 2019, we initiated a Phase 2, open-label, global, multicohort study to evaluate tilsotolimod administered intratumorally in combination with nivolumab and ipilimumab for the treatment of solid tumors. The basis for this study is supported by data generated from our ILLUMINATE-101 and ILLUMINATE-204 trials, which suggest the mechanism of action for tilsotolimod may be tumor-type agnostic and potentially beneficial in combination with checkpoint modulation in a variety of tumor types. We refer to this study as ILLUMINATE-206.

The objectives of ILLUMINATE-206 are to test the safety and effectiveness of intratumoral tilsotolimod in combination with nivolumab and ipilimumab for the treatment of solid tumors. During the second quarter of 2020,

we changed the study design and eliminated the statistical methodology to allow for flexibility in cohort-specific study designs and optimize the signal finding objective of the study.

Currently, we are evaluating relapsed/refractory MSS-CRC in immunotherapy-naïve patients treated with tilsotolimod in combination with nivolumab and ipilimumab (the “MSS-CRC Cohort”). An initial group of ten patients was enrolled to evaluate the safety of administering the combination of tilsotolimod, nivolumab and ipilimumab. To investigate the safety profile of this triplet combination, ILLUMINATE-206 was designed with a stepwise approach to Yervoy® dosage. Patients in this initial safety cohort of the study, many of whom were heavily pre-treated and rapidly progressing, received 8 mg of intratumoral tilsotolimod and 3 mg/kg of intravenous (IV) Opdivo® every 2 weeks, along with 1 mg/kg of IV Yervoy® every 8 weeks. This regimen was generally well tolerated; no patients discontinued treatment due to adverse events (AEs) and none experienced Grade 4 or 5 AEs. One patient experienced stable disease per RECIST v1.1 criteria and 9 patients progressed as defined by RECIST v1.1. Investigators reported that 6 of the progressing patients had stability or reduction in size of injected lesions and 6 had stability or reduction in overall size of uninjected lesions.

Based on these results, we plan to enroll additional patients in the MSS-CRC cohort of ILLUMINATE-206. Planned changes in the study design intended to improve potential outcomes in this patient population include increasing the frequency of Yervoy® dosing to every 3 weeks and limiting the number of allowed prior lines of treatment to two. Enrollment of the next 10 patients is targeted to begin in the fourth quarter of 2020. Pending data from those patients, the trial may be expanded further.

As further discussed under the caption “Item 1. Business — Collaborative Alliances” in our 2019 Form 10-K, in May 2018, we entered into a clinical trial collaboration and supply agreement with BMS under which BMS granted us a non-exclusive, non-transferable, 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.

Collaborative Alliances

Our current alliances include collaborations with AbbVie, described below, and BMS, as described under the caption “Item 1. Business — Collaborative Alliances” in our 2019 Form 10-K. In addition to our current alliances, we may seek to enter into additional collaborative alliances to support development and commercialization of our TLR agonists and antagonists.

Collaboration with AbbVie

Effective August 27, 2019, we entered into a clinical trial collaboration and supply agreement with AbbVie, a global, research-based biopharmaceutical company, to conduct a clinical study to evaluate the efficacy and safety of combinations of an OX40 agonist (ABBV-368), tilsotolimod, nab-paclitaxel and/or an anti-programmed cell death 1 (PD-1) antagonist (ABBV-181), which we refer to as the AbbVie Agreement. Under the AbbVie Agreement, we will provide a clinical trial supply of tilsotolimod to AbbVie and AbbVie will sponsor, fund and conduct the study entitled “A Phase 1b, Multicenter, Open-Label Study to Determine the Safety, Tolerability, Pharmacokinetics, and Preliminary Efficacy of ABBV-368 plus Tilsotolimod and Other Therapy Combinations in Subjects with Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma” (the “AbbVie Study”). We have agreed to manufacture and supply tilsotolimod at its cost and for no charge to AbbVie, for use in the AbbVie Study.

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 and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. 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 2019 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 (i) research and development prepayments, accruals and related expenses, (ii) stock-based compensation, and (iii) warrant and future tranche right liabilities and related revaluation gain (loss), 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 2019 Form 10-K, fit the description of critical accounting estimates and judgments.

The full extent to which the novel coronavirus disease ("COVID-19") pandemic will directly or indirectly impact our business, results of operations and financial condition, including expenses and manufacturing, clinical trials and research and development costs, will depend on future developments that are highly uncertain at this time.

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.

Financial Condition, Liquidity and Capital Resources

Financial Condition

As of June 30, 2020, we had an accumulated deficit of \$736.3 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 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 (deficit), 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, future tranche rights and warrants (including pre-funded 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, relating to the sale, from time to time, in one or more transactions, up to \$250.0 million of common stock, preferred stock, depository shares and warrants. As of July 31, 2020, approximately \$107.5 million remained available for issuance under this registration statement, taking into account the full contractual amounts provided for under our Common Stock Purchase Agreement with Lincoln Park Capital Fund LLC (the "LPC Purchase Agreement") and our "At-The-Market" Equity Program pursuant to a Equity Distribution Agreement with JMP Securities LLC (the "ATM Agreement"), which are more fully described in Note 8 of the notes to our condensed financial statements included elsewhere in this Quarterly Report on Form 10-Q. As described in Note 8, during the six months ended June 30, 2020, we sold 600,000 shares of common stock pursuant to the LPC Purchase Agreement resulting in \$1.1 million in net proceeds, 821,018 shares of common stock pursuant to the ATM Agreement resulting in \$1.4 million in net proceeds and 3,039,514 shares of common stock with accompanying warrants resulting in net proceeds of \$4.7 million.

In addition to the potential funding under the LPC Purchase Agreement and the ATM Agreement, the December 2019 Securities Purchase Agreement (more fully described in Note 7 to the condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q), under which we received \$10.1 million in gross proceeds in December 2019, provides for up to \$87.6 million additional aggregate gross proceeds at the sole discretion of Baker Brothers in connection with additional sales of securities and warrant exercises. Additionally, the April 2020 Securities Purchase Agreement (more fully described in Note 8 to the condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q), under which we received \$5.0 million gross proceeds in April 2020, provides for up to \$15.7 million additional aggregate gross proceeds at the sole discretion of Pillar Partners in connection with sales of additional securities and warrant exercises. Further, the July 2020 Securities Purchase Agreement (more fully described in Note 13 to the condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q), under which we received \$5.1 million gross proceeds in July 2020, provides for up to \$14.9 million additional aggregate gross proceeds at the sole

discretion of Pillar Partners in connection with sales of additional securities and warrant exercises. Assuming Baker Brothers and Pillar Partners exercise their rights under their respective securities purchase agreement and no other forms of external funding, we expect the proceeds could fund operations beyond an NDA filing for tilsotolimod.

See Notes 7, 8, and 13 to the condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for additional information regarding our recent equity financing activities.

Funding Requirements

We had cash, cash equivalents, and short-term investments of approximately \$31.0 million at June 30, 2020. We believe that, based on our current operating plan, our existing cash, cash equivalents, and short-term investments on hand as of June 30, 2020 will enable us to fund our operations into the second quarter of 2021 allowing us to:

- (i) continue to execute on our ongoing Phase 3 clinical trial of tilsotolimod in combination with ipilimumab for the treatment of anti-PD1 refractory metastatic melanoma (ILLUMINATE-301), including announcing key topline data and beginning the filing of a New Drug Application with the FDA;
- (ii) initiate and continue enrollment in the signal-finding stage of our Phase 2 study of tilsotolimod in combination with nivolumab and ipilimumab for the treatment of MSS-CRC (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;
- (vi) our ability to enter into additional collaborations with biotechnology and pharmaceutical companies and the success of such collaborations; and
- (vii) the impact of the novel coronavirus disease, COVID-19, to global economy and capital markets, and to our business and our financial results.

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. Additionally, Baker Brothers may not exercise their right to purchase shares of convertible preferred stock and common warrants or exercise warrants in connection with the December 2019 Securities Purchase Agreement and Pillar Partners may not exercise their right to purchase shares of common stock (or pre-funded warrants) and common warrants, or exercise common warrants in connection with the April 2020 Securities Purchase Agreement or the July 2020 Securities Purchase Agreement. 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 14 to the financial statements included in our 2019 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.

Cash Flows

The following table presents a summary of the primary sources and uses of cash for the six months ended June 30, 2020 and 2019:

(in thousands)	Six Months Ended June 30,	
	2020	2019
Net cash provided by (used in):		
Operating activities	\$ (19,100)	\$ (23,330)
Investing activities	(393)	(12,136)
Financing activities	7,284	3,919
Decrease in cash and cash equivalents	\$ (12,209)	\$ (31,547)

Operating Activities. The net cash used in operating activities for all periods presented consists primarily of net loss adjusted for non-cash charges and changes in components of working capital. The decrease in cash used in operating activities for the six months ended June 30, 2020, as compared to 2019, was primarily due to timing of cash outflows related to our current IMO-2125 development program, including payments to contract research organizations, and lower severance payments related to the reduction in workforce associated with the closure of our prior Cambridge, Massachusetts facility.

Investing Activities. Cash used in investing activities primarily consisted of the following amounts relating to our investments in available-for-sale securities and purchases and disposals of property and equipment:

- for the six months ended June 30, 2020, purchases of \$5.5 million in available-for-sale securities, partially offset by \$5.1 million in proceeds received from the maturity of available-for-sale securities; and
- for the six months ended June 30, 2019, purchases of \$35.5 million in available-for-sale securities, partially offset by \$23.4 million of proceeds from available-for-sale securities.

Financing Activities. Net cash provided by financing activities primarily consisted of the following amounts received in connection with the following transactions:

- for the six months ended June 30, 2020, \$7.2 million in aggregate net proceeds from financing arrangements consisting of \$4.7 million in net proceeds received pursuant to the April 2020 Securities Purchase Agreement, \$1.4 million received pursuant to the ATM Agreement and \$1.1 million in net proceeds received pursuant to the LPC Purchase Agreement, and \$0.1 million in aggregate proceeds from employee stock purchases under our 2017 ESPP; and
- for the six months ended June 30, 2019, \$3.9 million in aggregate net proceeds from financing arrangements consisting of \$1.6 million in net proceeds received pursuant to the ATM Agreement and \$2.3 million in net proceeds received pursuant to the LPC Purchase Agreement, and \$0.1 million in aggregate proceeds from employee stock purchases under our 2017 ESPP.

Contractual Obligations

During the six months ended June 30, 2020, there were no material changes outside the ordinary course of our business to our contractual obligations as disclosed in our 2019 Form 10-K.

Off-Balance Sheet Arrangements

As of June 30, 2020, we had no off-balance sheet arrangements.

Results of Operations

Three and Six Months Ended June 30, 2020 and 2019

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 June 30,		% Change	Six months ended June 30,		% Change
	2020	2019		2020	2019	
IMO-2125 external development expense	\$ 3,491	\$ 7,686	(55%)	\$ 10,562	\$ 13,100	(19%)(1)
IMO-8400 external development expense	—	7	(100%)	—	45	(100%)
Other drug development expense	1,888	2,331	(19%)	4,327	4,981	(13%)(2)
Total research and development expenses	<u>\$ 5,379</u>	<u>\$ 10,024</u>	<u>(46%)</u>	<u>\$ 14,889</u>	<u>\$ 18,126</u>	<u>(18%)</u>

- (1) *IMO-2125 External Development Expenses.* These expenses include external expenses incurred in connection with the development of tilsotolimod 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 June 30, 2020 we incurred approximately \$75.8 million in tilsotolimod external development expenses as part of our immuno-oncology program, including costs associated with the preparation for and conduct of ILLUMINATE-204, ILLUMINATE-101, ILLUMINATE-301, ILLUMINATE-206, and the manufacture of additional drug substance for use in our clinical trials and additional nonclinical studies.

The decreases in our IMO-2125 external development expenses during both the three and six months ended June 30, 2020, as compared to corresponding 2019 period, was primarily due to decreases in costs incurred with contract research and manufacturing organizations and outside consultants related to our ILLUMINATE development program, including costs to support our ongoing ILLUMINATE-301 trial, which we initiated in the first quarter of 2018, and ongoing ILLUMINATE-206 trial, which we initiated in the second quarter of 2019, as well as costs to support our ILLUMINATE-101 and ILLUMINATE-204 trials.

Going forward, we expect ongoing IMO-2125 external development expenses to continue to be significant as our focus in 2020 is on the clinical development of tilsotolimod (IMO-2125), including preparing for an NDA submission with the FDA. See additional information under the heading “Financial Condition, Liquidity and Capital Resources” regarding our future funding requirements.

- (2) *Other Drug Development Expenses.* These expenses include external expenses, such as payments to contract vendors, associated with compounds that were previously being developed but are not currently being developed. In addition, these expenses include internal costs, such as payroll and overhead expenses, associated with our clinical development programs.

The decreases in other drug development expenses for each of the three and six months ended June 30, 2020, compared to the corresponding prior period, were primarily due to lower internal payroll costs.

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 June 30, 2020 and 2019, general and administrative expenses totaled \$2.6 million and \$2.9 million, respectively. For the six months ended June 30, 2020 and 2019, general and administrative expenses totaled \$6.3 million and \$6.0 million, respectively.

The decrease in general and administrative expenses during the three months ended June 30, 2020, as compared to the 2019 period, was primarily due to lower employee expense related to former executives and lower legal costs. The increase in general and administrative expenses during the six months ended June 30, 2020, as compared to the 2019 period, was primarily due to severance expense for former executives and increased commercial costs, offset by lower stock compensation expense, legal fees and consulting costs.

Restructuring Costs

Restructuring costs for the three and six months ended June 30, 2019 totaled less than \$0.1 million and approximately \$0.2 million, respectively, and are comprised primarily of severance and related benefit costs related 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 or six months ended June 30, 2020.

Interest Income

Interest income for the three months ended June 30, 2020 and 2019 totaled less than \$0.1 million and approximately \$0.3 million, respectively. Interest income for the six months ended June 30, 2020 and 2019 totaled approximately \$0.2 million and \$0.7 million, respectively. The period-over-period decreases were primarily due to a decrease in average short-term investment balances. 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.

Warrant Revaluation (Loss) Gain

During the three months ended June 30, 2020, we recorded a non-cash warrant revaluation loss of approximately \$0.9 million. During the six months ended June 30, 2020, we recorded a non-cash warrant revaluation gain of approximately \$0.2 million. The non-cash charges for all periods relate to the change in fair value during the respective period of our liability-classified warrants, which were issued in connection with the December 2019 Private Placement. Due to the nature of and inputs in the model used to assess the fair value of our outstanding warrants, it is not abnormal to experience significant fluctuations during each remeasurement period. These fluctuations may be due to a variety of factors, including changes in our stock price and changes in estimated stock price volatility over the remaining life of the warrants. Changes in the fair value of our liability-classified warrants for all periods presented was driven primarily by changes in our stock price. No such non-cash revaluation gain (loss) was recognized during the corresponding 2019 periods.

Future Tranche Right Revaluation (Loss) Gain

During the three months ended June 30, 2020, we recorded a non-cash future tranche right revaluation loss of approximately \$15.3 million. During the six months ended June 30, 2020, we recorded a non-cash future tranche right revaluation gain of approximately \$5.4 million. The non-cash charges for all periods relate to the change in fair value during the respective period of the future tranche right liability (right to purchase preferred stock and warrants to an investor at future dates), associated with the Future Tranche Rights issued in connection with the December 2019 Securities Purchase Agreement. Due to the nature of and inputs in the model used to assess the fair value of the future tranche rights, it is not abnormal to experience significant fluctuations during each remeasurement period. These fluctuations may be due to a variety of factors, including changes in our stock price and changes in estimated stock price volatility over the remaining estimated lives of the future tranche rights. Changes in the fair value of the future tranche right liability during all periods presented was driven primarily by changes in our stock price. No such non-cash revaluation gain (loss) was recognized during the corresponding 2019 periods.

Net Loss Applicable to Common Stockholders

As a result of the factors discussed above, our net loss applicable to common stockholders for the three and six months ended June 30, 2020 was \$24.2 million and \$15.4 million, respectively, compared to a net loss applicable to common stockholders of \$11.2 million and \$22.2 million for the three and six months ended June 30, 2019, respectively. Excluding the non-cash warrant revaluation loss of \$0.9 million and future tranche right revaluation loss of \$15.3 million for the three months ended June 30, 2020, net loss applicable to common stockholders was \$8.0 million. Excluding the non-cash warrant revaluation gain of \$0.2 million and future tranche right revaluation gain of \$5.4 million for the six months ended June 30, 2020, net loss applicable to common stockholders was \$21.0 million.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

There were no material changes in our exposure to market risk from December 31, 2019. Our market risk profile as of December 31, 2019 is disclosed in Item 7A, *Quantitative and Qualitative Disclosures About Market Risk*, of our 2019 Form 10-K.

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 June 30, 2020. 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 June 30, 2020, 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 June 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1A. Risk Factors.

Risk factors that may affect our business and financial results are discussed within Item 1A “Risk Factors” of our annual report on Form 10-K filed with the SEC on March 12, 2020 (“2019 Form 10-K”). There have been no material changes to the disclosures relating to this item from those set forth in our 2019 Form 10-K.

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

There were no unregistered sales of equity securities during the three months ended June 30, 2020, other than as reported in our Current Report on Form 8-K filed with the SEC on April 7, 2020 in connection with our offering of shares of the Company’s common stock and warrants to purchase shares of common stock pursuant to the April 2020 Securities Purchase Agreement. These securities were issued in a private placement in reliance on Section 4(a)(2) of the Securities Act. Please refer to Note 8 of the Notes to the Condensed Financial Statements in this Quarterly Report on Form 10-Q for additional details.

Item 6. Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
3.1	<u>Certificate of Amendment to the Restated Certificate of Incorporation of Idera Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on May 18, 2020)</u>
4.1	<u>Form of Pre-funded Warrant issuable pursuant to the July 2020 Securities Purchase Agreement (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on July 15, 2020)</u>
4.2	<u>Form of Common Warrant issuable pursuant to the July 2020 Securities Purchase Agreement (Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on July 15, 2020)</u>
4.3	<u>Registration Rights Agreement, dated July 13, 2020, by and among Idera Pharmaceuticals, Inc. and Pillar Partners Foundation, L.P. (Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on July 15, 2020)</u>
10.1	<u>Securities Purchase Agreement, dated July 13, 2020, by and among Idera Pharmaceuticals, Inc. and Pillar Partners Foundation, L.P. (Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on July 15, 2020)</u>
31.1	<u>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</u>
31.2	<u>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</u>
32.1	<u>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</u>
32.2	<u>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</u>
101.INS	XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, formatted in Inline XBRL

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: August 4, 2020

/s/ Vincent J. Milano

Vincent J. Milano
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 4, 2020

/s/ John J. Kirby

John J. Kirby
Chief Financial Officer
(Principal Financial and Accounting Officer)

**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**

I, Vincent J. Milano, certify that:

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

Dated: August 4, 2020

/s/ VINCENT J. MILANO

Vincent J. Milano
Chief Executive Officer

**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**

I, John J. Kirby, certify that:

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

Dated: August 4, 2020

/s/ JOHN J. KIRBY

John J. Kirby
Chief Financial Officer

**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**

In connection with the Quarterly Report on Form 10-Q of Idera Pharmaceuticals, Inc. (the “Company”) for the period ended June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned, Vincent J. Milano, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement has been provided to Idera Pharmaceuticals, Inc. and will be retained by Idera Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Dated: August 4, 2020

/s/ VINCENT J. MILANO

Vincent J. Milano
Chief Executive Officer

**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**

In connection with the Quarterly Report on Form 10-Q of Idera Pharmaceuticals, Inc. (the "Company") for the period ended June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, John J. Kirby, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement has been provided to Idera Pharmaceuticals, Inc. and will be retained by Idera Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Dated: August 4, 2020

/s/ JOHN J. KIRBY

John J. Kirby
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)
