
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 September 30, 2021

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)

505 Eagleview Blvd., Suite 212
Exton, Pennsylvania

(Address of principal executive offices)

04-3072298

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

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	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	IDRA	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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

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

Common Stock, par value \$.001 per share

Class

52,798,295

Outstanding as of November 8, 2021

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

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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 will actually 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 our 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, 2020, which was filed with the Securities and Exchange Commission (“SEC”) on March 1, 2021 (the “2020 Form 10-K”), in this Quarterly Report on Form 10-Q, 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 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)	September 30, 2021	December 31, 2020*
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 36,602	\$ 33,229
Short-term investments	—	4,499
Prepaid expenses and other current assets	1,697	3,627
Total current assets	38,299	41,355
Property and equipment, net	27	44
Operating lease right-of-use assets	784	930
Other assets	70	70
Total assets	\$ 39,180	\$ 42,399
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 276	\$ 329
Accrued expenses	5,085	6,072
Operating lease liability	205	191
Other current liability	—	435
Total current liabilities	5,566	7,027
Warrant liability, long-term	—	6,983
Future tranche right liability, long-term	—	118,803
Operating lease liability, net of current portion	603	758
Total liabilities	6,169	133,571
Commitments and contingencies (Note 13)		
Preferred stock, \$0.01 par value, Authorized — 5,000 shares:		
Series B1 redeemable convertible preferred stock (Note 7); Designated — 278 shares, Issued and outstanding — 0 and 24 shares at September 30, 2021 and December 31, 2020, respectively	—	—
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	—	—
Common stock, \$0.001 par value, Authorized — 140,000 shares; Issued and outstanding — 52,777 and 38,291 at September 30, 2021 and December 31, 2020, respectively	53	38
Additional paid-in capital	764,300	742,342
Accumulated deficit	(731,342)	(833,552)
Total stockholders' equity (deficit)	33,011	(91,172)
Total liabilities and stockholders' equity (deficit)	\$ 39,180	\$ 42,399

* The condensed balance sheet at December 31, 2020 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
(UNAUDITED)

(In thousands, except per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 3,507	\$ 4,766	\$ 14,271	\$ 19,655
General and administrative	2,331	2,718	7,959	8,992
Restructuring costs	130	—	1,322	—
Total operating expenses	5,968	7,484	23,552	28,647
Loss from operations	(5,968)	(7,484)	(23,552)	(28,647)
Other income (expense):				
Interest income	2	9	7	161
Interest expense	—	—	(7)	—
Warrant revaluation gain (loss)	—	(683)	6,983	(495)
Future tranche right revaluation gain (loss)	—	(12,350)	118,803	(6,988)
Foreign currency exchange (loss) gain	1	(44)	(24)	8
Net income / (loss)	\$ (5,965)	\$ (20,552)	\$ 102,210	\$ (35,961)
Net income (loss) applicable to common stockholders (Note 12)				
— Basic	\$ (5,965)	\$ (20,552)	\$ 100,574	\$ (35,961)
— Diluted	\$ (5,965)	\$ (20,552)	\$ (23,576)	\$ (35,961)
Net income (loss) per share applicable to common stockholders (Note 12)				
— Basic	\$ (0.11)	\$ (0.59)	\$ 2.10	\$ (1.09)
— Diluted	\$ (0.11)	\$ (0.59)	\$ (0.46)	\$ (1.09)
Weighted-average number of common shares used in computing net income (loss) per share applicable to common stockholders				
— Basic	52,740	35,091	47,990	32,999
— Diluted	52,740	35,091	51,613	32,999

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

IDERA PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(UNAUDITED)

(In thousands)	Nine Months Ended September 30,	
	2021	2020
Cash Flows from Operating Activities:		
Net income (loss)	\$ 102,210	\$ (35,961)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Stock-based compensation	1,990	2,273
Warrant liability revaluation gain	(6,983)	495
Future tranche right liability revaluation gain	(118,803)	6,988
Issuance of common stock for services rendered	130	170
Accretion of discounts on short-term investments	(1)	(43)
Depreciation and amortization expense	17	52
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	1,930	1,215
Accounts payable, accrued expenses, and other liabilities	(1,040)	(1,391)
Other	5	10
Net cash used in operating activities	(20,545)	(26,192)
Cash Flows from Investing Activities:		
Purchases of available-for-sale securities	—	(12,180)
Proceeds from maturity of available-for-sale securities	4,500	8,350
Purchases of property and equipment	—	(7)
Net cash provided by (used in) investing activities	4,500	(3,837)
Cash Flows from Financing Activities:		
Proceeds from common stock financings, net	19,534	12,258
Proceeds from employee stock purchases	48	84
Proceeds from exercise of common stock options and warrants	271	—
Payments on seller-financed purchases	(435)	—
Net cash provided by financing activities	19,418	12,342
Net increase (decrease) in cash and cash equivalents	3,373	(17,687)
Cash and cash equivalent, beginning of period	33,229	40,019
Cash and cash equivalents, end of period	\$ 36,602	\$ 22,332
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 5	\$ —
Supplemental disclosure of non-cash financing and investing activities:		
Offering costs in accounts payable and accrued expenses	\$ —	\$ 91

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)

For the Nine Months Ended September 30, 2020

(In thousands)	Series B1 Preferred		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Number of Shares	\$0.01 Par Value	Number of Shares	\$0.001 Par Value			
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 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)
Sale of common stock and prefunded warrants, net of issuance costs	—	—	868	1	4,936	—	4,937
Issuance of common stock under employee stock purchase plan	—	—	19	—	30	—	30
Issuance of common stock for services rendered	—	—	41	—	72	—	72
Stock-based compensation	—	—	—	—	769	—	769
Net loss	—	—	—	—	—	(20,552)	(20,552)
Balance, September 30, 2020	24	\$ —	35,219	\$ 35	\$ 724,381	\$ (756,851)	\$ (32,435)

IDERA PHARMACEUTICALS, INC.

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

For the Nine Months Ended September 30, 2021

(In thousands)	Series B1 Preferred		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Number of Shares	\$0.01 Par Value	Number of Shares	\$0.001 Par Value			
Balance, December 31, 2020	24	\$ —	38,291	\$ 38	\$ 742,342	\$ (833,552)	\$ (91,172)
Sale of common stock, net of issuance costs	—	—	3,195	3	16,258	—	16,261
Conversion of Series B1 preferred stock	(14)	—	1,415	1	(1)	—	—
Issuance of common stock under employee stock purchase plan	—	—	8	—	28	—	28
Issuance of common stock under equity incentive plan (vesting of restricted stock units)	—	—	237	—	—	—	—
Issuance of common stock upon exercise of common stock options and warrants	—	—	3,375	4	267	—	271
Issuance of common stock for services rendered	—	—	16	—	67	—	67
Stock-based compensation	—	—	—	—	1,111	—	1,111
Net income	—	—	—	—	—	115,738	115,738
Balance, March 31, 2021	<u>10</u>	<u>\$ —</u>	<u>46,537</u>	<u>\$ 46</u>	<u>\$ 760,072</u>	<u>\$ (717,814)</u>	<u>\$ 42,304</u>
Sale of common stock, net of issuance costs	—	—	2,076	2	2,510	—	2,512
Conversion of Series B1 preferred stock	(10)	—	953	1	(1)	—	—
Issuance of common stock under employee stock purchase plan	—	—	6	—	6	—	6
Issuance of common stock upon exercise of common stock options and warrants	—	—	2,496	3	(3)	—	—
Issuance of common stock for services rendered	—	—	47	—	63	—	63
Stock-based compensation	—	—	—	—	404	—	404
Net loss	—	—	—	—	—	(7,563)	(7,563)
Balance, June 30, 2021	<u>—</u>	<u>\$ —</u>	<u>52,115</u>	<u>\$ 52</u>	<u>\$ 763,051</u>	<u>\$ (725,377)</u>	<u>\$ 37,726</u>
Sale of common stock, net of issuance costs	—	—	647	1	760	—	761
Issuance of common stock under employee stock purchase plan	—	—	15	—	14	—	14
Stock-based compensation	—	—	—	—	475	—	475
Net loss	—	—	—	—	—	(5,965)	(5,965)
Balance, September 30, 2021	<u>—</u>	<u>\$ —</u>	<u>52,777</u>	<u>\$ 53</u>	<u>\$ 764,300</u>	<u>\$ (731,342)</u>	<u>\$ 33,011</u>

The accompanying notes are an integral part of these financial statements

IDERA PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS (UNAUDITED)

September 30, 2021

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 rare disease indications characterized by small, well-defined patient populations with serious unmet medical needs. The Company’s current focus is to identify and potentially acquire rights to novel development or commercial stage rare disease programs, as well as 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. The Company has in the past and may in the future explore collaborative alliances to support development and commercialization of any of its drug candidates.

Reduction-in-Force

In April 2021, following the announcement that the Company’s ILLUMINATE-301 trial did not meet its primary endpoint of objective response rate (“ORR”), the Company implemented a reduction-in-force which affected approximately 50% of its workforce through September 30, 2021. 17 positions were eliminated, primarily in the area of research and development. The decision was made in order to align the Company’s workforce with its needs in light of the outcome of ILLUMINATE-301’s ORR endpoint, its ongoing ILLUMINATE development program and other business development activities focused on identifying new portfolio opportunities.

In connection with these actions, the Company incurred and paid termination costs for the reduction in workforce, which includes severance, benefits and related costs, of approximately \$1.2 million and \$0.1 million during the second and third quarter of 2021, respectively.

Liquidity and Financial Condition

As of September 30, 2021, the Company had an accumulated deficit of \$731.3 million and a cash and cash equivalents balance of \$36.6 million. The Company expects to incur substantial operating losses in future periods and will require additional capital as it seeks to advance tilsotolimod and/or acquire and advance any new 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 any other future drug candidates, either alone or in collaboration with third parties, which the Company expects will take a number of years, if at all. To commercialize tilsotolimod and any other 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”) 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 anticipates that the Company’s balance of cash and cash equivalents on hand as of September 30, 2021 is sufficient to enable the Company to continue as a going concern through the one-year period subsequent to the filing date of this Quarterly Report on Form 10-Q. The Company has and will continue to evaluate available alternatives to extend its operations beyond this date, which include raising additional capital through the LPC Agreement (Note 8) and ATM Agreement (Note 8) or additional financing or strategic transactions. Additionally, management’s plans may include the possible deferral of certain operating expenses unless additional capital is received. 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 nine months ended September 30, 2021 are not necessarily indicative of results that may be expected for the year ending December 31, 2021. For further information, refer to the financial statements and footnotes thereto included in the Company’s 2020 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 September 30, 2021 consisted of cash and money market funds. Cash and cash equivalents at December 31, 2020 consisted of cash and cash equivalents and short-term investments.

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 September 30, 2021, the Company’s financial instruments consisted of cash and cash equivalents. As of December 31, 2020, 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 September 30, 2021, the Company did not have any derivatives, hedging instruments 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, U.S. treasury bills, corporate bonds, commercial paper and/or other debt securities. Due to these factors, no significant additional credit risk is believed by management to be inherent in the Company’s assets. As of September 30, 2021, all the Company’s cash and cash equivalents were held at two financial institutions.

Operating Lease Right-of-use Assets and Lease Liability

The Company accounts for leases under ASC Topic 842, *Leases*. Operating leases are included in “Operating lease right-of-use assets” within the Company’s condensed balance sheets and represent the Company’s right to use an underlying asset for the lease term. The Company’s related obligation to make lease payments are included in “Operating lease liability” and “Operating lease liability, net of current portion” within the Company’s condensed balance sheets. Operating lease right-of-use (“ROU”) 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 ROU 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 September 30, 2021 and December 31, 2020, the Company’s operating lease ROU assets and corresponding short-term and long-term lease liabilities primarily relate to its existing Exton, PA facility operating lease which expires on May 31, 2025.

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. Equity-classified warrants are recorded within additional paid-in capital at the time of issuance and not subject to remeasurement. During the three months ended March 31, 2021, all the Company's liability-classified warrants terminated and, accordingly, the liability balance was derecognized. For additional discussion on warrants, see Note 8.

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 (as defined below), an existing stockholder (see Note 11). As more fully described in Note 7, the December 2019 Securities Purchase Agreement contained call options on redeemable preferred shares with warrants (conditionally exercisable for shares that are puttable). The Company determined that these call options represented freestanding financial instruments and accounted 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 Gain (Loss) in the Company's condensed statements of operations. During the three months ended March 31, 2021, the liability-classified call options provided for under the December 2019 Securities Purchase Agreement terminated and, accordingly, the liability balance was derecognized. For additional discussion on the Future Tranche Right Liability, see Note 7.

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 accreted to redemption value using the effective interest method, from the date of issuance to the earliest date the holders can demand redemption or until the redeemable convertible preferred stock cease to be outstanding.

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 nine months ended September 30, 2021 and 2020, 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 September 30, 2021 or December 31, 2020 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 September 30, 2021 and December 31, 2020, 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, as of September 30, 2021, 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 August 2020, the FASB issued ASU No. 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU 2020-06"), which simplifies the guidance on an issuer's accounting for convertible instruments and contracts in its own equity. The Company adopted ASU 2020-06 in the first quarter of 2021. The adoption of this ASU did not have a material effect on the Company's financial statements.

COVID-19

While the Company is not aware of a material impact from the continuation of the coronavirus ("COVID-19") pandemic through September 30, 2021, the full extent to which the 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, depends 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, or
- 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).

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 nine months ended September 30, 2021.

Note 3. Fair Value Measurements (Continued)

The table below presents the assets and liabilities measured and recorded in the financial statements at fair value on a recurring basis at September 30, 2021 and December 31, 2020 categorized by the level of inputs used in the valuation of each asset and liability.

(In thousands)	September 30, 2021			
	Total	Level 1	Level 2	Level 3
Assets				
Cash	\$ 250	\$ 250	\$ —	\$ —
Cash equivalents – money market funds	36,352	36,352	—	—
Total assets	<u>\$ 36,602</u>	<u>\$ 36,602</u>	<u>\$ —</u>	<u>\$ —</u>

(In thousands)	December 31, 2020			
	Total	Level 1	Level 2	Level 3
Assets				
Cash	\$ 250	\$ 250	\$ —	\$ —
Cash equivalents – money market funds	32,979	32,979	—	—
Short-term investments – commercial paper	3,499	—	3,499	—
Short-term investments – US treasury bills	1,000	—	1,000	—
Total assets	<u>\$ 37,728</u>	<u>\$ 33,229</u>	<u>\$ 4,499</u>	<u>\$ —</u>
Liabilities				
Warrant liability	\$ 6,983	\$ —	\$ —	\$ 6,983
Future tranche right liability	118,803	—	—	118,803
Total liabilities	<u>\$ 125,786</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 125,786</u>

The Level 1 assets consist of money market funds, which are actively traded daily. The Level 2 assets consist of commercial paper and U.S. treasury bills 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, 2020	\$ 6,983	\$ 118,803
Change in the fair value of liability (1)	(6,983)	(118,803)
Balance, September 30, 2021	<u>\$ —</u>	<u>\$ —</u>

(1) During the nine months ended September 30, 2021, the Company's liability-classified warrants and future tranche rights terminated, and accordingly, the liabilities were derecognized.

Note 4. Investments

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

(In thousands)	December 31, 2020			
	Cost	Gross Unrealized (Losses)	Gross Unrealized Gains	Estimated Fair Value
Short-term investments – commercial paper	\$ 3,499	\$ —	\$ —	\$ 3,499
Short-term investments – US treasury bills	1,000	—	—	1,000
Total short-term investments	<u>\$ 4,499</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 4,499</u>

The Company had no realized gains or losses from the sale of investments in available-for-sale securities during each of the nine months ended September 30, 2021 and 2020. 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 December 31, 2020, 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 nine months ended September 30, 2021 and 2020.

Note 5. Property and Equipment

At September 30, 2021 and December 31, 2020, property and equipment, net, consisted of the following:

(In thousands)	September 30, 2021	December 31, 2020
Leasehold improvements	\$ 107	\$ 107
Equipment and other	712	770
Total property and equipment, at cost	\$ 819	\$ 877
Less: Accumulated depreciation and amortization	792	833
Property and equipment, net	<u>\$ 27</u>	<u>\$ 44</u>

Depreciation and amortization expense on property and equipment was less than \$0.1 million for each of the three and nine months ended September 30, 2021 and 2020. Additionally, there were no non-cash property additions or impairment-related charges recognized during each of the three and nine months ended September 30, 2021 and 2020.

Note 6. Accrued Expenses

At September 30, 2021 and December 31, 2020, accrued expenses consisted of the following:

(In thousands)	September 30, 2021	December 31, 2020
Payroll and related costs	\$ 816	\$ 2,133
Clinical and nonclinical trial expenses	3,594	3,229
Professional and consulting fees	550	584
Other	125	126
Total accrued expenses	<u>\$ 5,085</u>	<u>\$ 6,072</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 elected 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 agreed to sell to the purchasers, at their option and subject to certain conditions, (i) 98,685 shares of Series B2 convertible preferred stock (“Series B2 Preferred Stock”) and 9,868,500 warrants to purchase common stock at an exercise price of \$1.52 per share (or, at the election of the holder, 98,685 shares of Series B2 Preferred Stock at a price of \$152 per share), for aggregate gross proceeds of \$15 million (the “Series B2 Tranche”), (ii) 82,418 shares of Series B3 convertible preferred stock (“Series B3 Preferred Stock”) and 6,593,440 warrants to purchase common stock at an exercise price of \$1.82 per share (or, at the election of the holder, 65,934 shares of Series B3 Preferred Stock at a price of \$182 per share), for aggregate gross proceeds of \$15 million (the “Series B3 Tranche”), and (iii) 82,418 shares of Series B4 convertible preferred stock (“Series B4 Preferred Stock”) and 6,593,440 warrants to purchase common stock at an exercise price of \$1.82 per share (or, at the election of the holder, 65,934 shares of Series B3 Preferred Stock at a price of \$182 per share), for aggregate gross proceeds of \$15 million (the “Series B4 Tranche”) over a period of up to 21 months following the Company’s 2020 Annual Meeting of Stockholders held on May 12, 2020, where 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 the Company’s common stock to 140,000,000. As consideration for the future tranche rights, the Company received aggregate gross proceeds of \$6.2 million in December 2019.

The purchase and sale of the securities issuable under the Series B2, B3, and B4 tranches described above were subject 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 was set to expire 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. As a result of the purchasers not exercising the Series B2 Tranche prior to expiration, all future tranche rights and outstanding warrants previously issued pursuant to the December 2019 Securities Purchase Agreement were terminated during the three months ended March 31, 2021. Accordingly, the Company is no longer eligible to receive additional proceeds pursuant to the December 2019 Securities Purchase Agreement and the related warrant liability and future tranche right liability were derecognized during the three months ended March 31, 2021.

Accounting Considerations

The Company determined that the Series B1 Preferred Stock, the accompanying Series B1 warrants, and each of the future tranche rights represent freestanding financial instruments. The Series B1 warrants and the future tranche rights were classified as liabilities until their termination in March 2021 as the underlying shares were potentially redeemable and such redemption was 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 was classified as temporary equity and the carrying value was being accreted to its redemption value as of December 31, 2020 and while the Series B1 Preferred Stock was outstanding during 2021. During the nine months ended September 30, 2021, all the Company’s 23,684 shares of Series B1 Preferred Stock outstanding were converted into shares of the Company’s common stock. See Note 11 for details. For the three and nine months ended September 30, 2021 and 2020, accretion was de minimis.

Note 8. Stockholders' Equity

Equity Financings

Common Stock Purchase Agreement

On March 4, 2019, the Company entered into a Purchase Agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park"), which was amended on September 2, 2020 (as amended to date, the "LPC Purchase Agreement"), 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 over a 36-month period. As consideration for entering into the LPC Purchase Agreement, the Company issued 269,749 shares of its 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 nine months ended September 30, 2021 and 2020, the Company sold 800,000 and 600,000 shares, respectively, pursuant to the LPC Purchase Agreement, resulting in net proceeds of \$4.2 million and \$1.0 million, respectively. As of September 30, 2021, the Company may sell up to an additional \$25.3 million of shares under the LPC Purchase 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 "ATM 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 ATM 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, or if specified by the Company, by any other method permitted by law, including but not limited to through negotiated transactions. The Company has no obligation to sell any of the ATM 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 ATM Shares sold.

During the nine months ended September 30, 2021 and 2020, the Company sold 5,117,357 and 938,669 shares, respectively, pursuant to the ATM Agreement, resulting in net proceeds, after deduction of commissions and other offering expenses, of \$15.3 million and \$1.6 million, respectively. The Company may sell up to an additional \$19.5 million of shares under the ATM Agreement.

April 2020 Private Placement

On April 7, 2020, the Company entered into a Securities Purchase Agreement with Pillar Partners Foundation, L.P. ("Pillar Partners"), a related party as more fully described in Note 11, which was amended on December 11, 2020 (as amended to date, the "April 2020 Securities Purchase Agreement"), 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. The April 2020 Securities Purchase Agreement also provided for the option for Pillar Partners to purchase 2,747,252 shares of the Company's common stock (or pre-funded warrants to purchase shares of the Company's common stock at an exercise price of \$0.01 in lieu of certain shares to the extent that purchasing such shares will cause Pillar Investment Entities (as defined below) 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"). Subsequently, in December 2020, the April 2020 Private Placement Second Closing was consummated. Total net proceeds received pursuant to the April 2020 Securities Purchase Agreement, after deduction of offering expenses, was \$9.8 million.

Note 8. Stockholders' Equity (Continued)

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, Pillar Pharmaceuticals 6 L.P. ("Pillar 6"), and Pillar Pharmaceuticals 7 L.P. ("Pillar 7" and, together with Pillar Partners and Pillar 6, the "July 2020 Purchasers"), each a related party as more fully described in Note 11, pursuant to which, among other things, provided the July 2020 Purchasers the option to purchase, at their sole discretion, 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"). During the three months ended March 31, 2021, the option to purchase securities in the July 2020 Private Placement Second Closing terminated. As a result, the Company is no longer eligible to receive additional proceeds from the sale of additional securities pursuant to the July 2020 Securities Purchase Agreement. However, the July 2020 Purchasers still hold outstanding warrants previously issued under the July 2020 Securities Purchase Agreement, as detailed below under the heading "Common Stock Warrants".

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 September 30, 2021 and December 31, 2020:

Description	Number of Shares		Weighted-Average Exercise Price	Expiration Date
	September 30, 2021	December 31, 2020		
Liability-classified Warrants				
December 2019 Series B1 warrants (1)	—	2,368,400	\$ 1.52	Dec 2026
	—	2,368,400		
Equity-classified Warrants				
May 2013 warrants	15,437	1,949,754	\$ 0.08	None
September 2013 warrants	4,096	514,756	\$ 0.08	None
February 2014 warrants	2,171	266,006	\$ 0.08	None
April 2020 Private Placement first closing warrants	3,039,514	3,039,514	\$ 2.28	Apr 2023
April 2020 Private Placement second closing warrants	1,373,626	1,373,626	\$ 2.71	Dec 2023
April 2020 Private Placement second closing warrants	1,143,428	2,677,311	\$ 0.01	None
July 2020 Private Placement first closing warrants	389,731	2,014,234	\$ 0.01	None
July 2020 Private Placement first closing warrants	2,764,227	2,764,227	\$ 2.58	Jul 2023
	<u>8,732,230</u>	<u>14,599,428</u>		
Total outstanding	<u>8,732,230</u>	<u>16,967,828</u>		

- (1) The Series B1 warrants were exercisable for either common stock (exercise price of \$1.52) or Series B1 Convertible Preferred Stock (exercise price of \$1.52) at the discretion of the warrant holder. However, as more fully disclosed in Note 7, the December 2019 Series B1 warrants were terminated during the three months ended March 31, 2021 contemporaneously with the termination of the future tranche rights.

Note 8. Stockholders' Equity (Continued)

The table below is a summary of the Company's warrant activity for the nine months ended September 30, 2021.

	Number of Warrants	Weighted-Average Exercise Price
Outstanding at December 31, 2020	16,967,828	\$ 1.28
Issued	—	—
Exercised (1)	(5,867,198)	0.04
Expired	(2,368,400)	1.52
Outstanding at September 30, 2021	8,732,230	\$ 2.04

(1) During the nine months ended September 30, 2021, certain related parties exercised warrants as more fully described in Note 11.

Note 9. Collaboration and License Agreements***Scriptr Collaboration and Option Agreement***

In February 2021, the Company entered into a collaboration and option agreement with Scriptr Global, Inc. ("Scriptr"), pursuant to which (i) the Company and Scriptr will conduct a research collaboration utilizing Scriptr Platform Technology ("SPT") to identify, research and develop gene therapy candidates (each, a "Collaboration Candidate") for the treatment, palliation, diagnosis or prevention of (a) myotonic dystrophy type 1 ("DM1 Field") and (b) Friedreich's Ataxia ("FA Field") on a Research Program-by-Research Program basis, as applicable, and (ii) the Company was granted an exclusive option, in its sole discretion, to make effective the Scriptr License Agreement, as defined below, for a given Research Program, as defined below, to make use of Collaboration Candidates and related intellectual property (collectively, the "Scriptr Agreement").

Pursuant to the Scriptr Agreement, Scriptr will use commercially reasonable efforts to carry out research activities set forth in accordance with the applicable DM1 Field and FA Field research plans, including certain pre-clinical proof of concept studies, to identify research Collaboration Candidates utilizing SPT (each, a "Research Program"). Following the completion of activities under a given Research Program, Scriptr will prepare and submit to Idera a comprehensive data package (each, a "Data Package") that summarizes, on a Research Program-by-Research Program basis, any Collaboration Candidates researched under the Research Program, including any data and results. Upon receipt of a Data Package, the Company has, in its sole discretion, up to two-hundred seventy (270) calendar days to make effective the exclusive license agreement entered into by and between the Company and Scriptr, pursuant to which, among other things, grants Idera exclusive rights and licenses with respect to the development, manufacture and commercialization of licensed candidates and products, subject to certain conditions and limitations (the "Scriptr License Agreement"), for a given Research Program (each licensed Research Program, a "Licensed Program"). The Scriptr License Agreement provides for customary development milestones on candidates developed under a Licensed Program and royalties on licensed products, if any.

In partial consideration of the rights granted by Scriptr to the Company under the Scriptr Agreement, the Company made a one-time, non-creditable and non-refundable payment to Scriptr during the first quarter of 2021. In order to fund the Research Programs, the Company shall reimburse Scriptr for costs incurred by or on behalf of Scriptr in connection with the conduct of each Research Program during the research term in accordance with the applicable Research Program budget and payment schedule. The Company incurred approximately \$0.4 million and \$1.7 million in research and development expenses under the Scriptr Agreement during the three and nine months ended September 30, 2021, respectively.

Note 10. Stock-Based Compensation

As of September 30, 2021, 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 of 1986, as amended (the "Code"), non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units ("RSUs"), 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 September 30, 2021, options to purchase a total of 4,796,063 shares of common stock and 576,371 RSUs were outstanding and up to 93,469 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 September 30, 2021, options to purchase a total of 207,908 shares of common stock were outstanding under the 2008 Plan. In addition, as of September 30, 2021, non-statutory stock options to purchase an aggregate of 325,000 shares of common stock were outstanding. These options were issued outside of the 2013 Plan to certain newly-hired employees in 2015 and 2014 pursuant to the Nasdaq inducement grant exception as a material component of such new hires' employment compensation.

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 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 September 30, 2021, 216,326 shares remained available for issuance under the 2017 ESPP.

For the nine months ended September 30, 2021 and 2020, the Company issued 29,016 and 59,319 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.

Note 10. Stock-Based Compensation (Continued)

Accounting for Stock-based Compensation

The Company recognizes non-cash compensation expense for stock-based awards under the Company's equity incentive plans and employee stock purchases under the Company's 2017 ESPP as follows:

- **Stock Options:** Compensation cost is recognized over an award's requisite service period, or vesting period, using the straight-line attribution method, based on the grant date fair value determined using the Black-Scholes option-pricing model.
- **RSUs:** Compensation cost for time-based RSUs, which vest over time based only on continued service, is recognized on a straight-line basis over the requisite service period based on the fair value of the Company's common stock on the date of grant. Compensation cost for awards that are subject to market considerations is recognized on a straight-line basis over the implied requisite service period, based on the grant date fair value estimated using a Monte Carlo simulation. Compensation cost for awards that are subject to performance conditions is recognized over the period of time commencing when the performance condition is deemed probable of achievement based on the fair value of the Company's common stock on the date of grant.
- **Employee Stock Purchases:** Compensation cost is recognized over each plan period based on the fair value of the look-back provision, calculated using the Black-Scholes option-pricing model, taking into account the 15% discount on shares purchased.

Total stock-based compensation expense attributable to stock-based awards 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 nine months ended September 30, 2021 and 2020 were as follows:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Stock-based compensation:				
Research and development				
Employee Stock Purchase Plan	\$ 7	\$ 17	\$ 22	\$ 43
Equity Incentive Plan	51	141	469	526
	<u>\$ 58</u>	<u>\$ 158</u>	<u>\$ 491</u>	<u>\$ 569</u>
General and administrative				
Employee Stock Purchase Plan	\$ —	\$ 2	\$ 3	\$ 4
Equity Incentive Plan	417	609	1,496	1,700
	<u>\$ 417</u>	<u>\$ 611</u>	<u>\$ 1,499</u>	<u>\$ 1,704</u>
Total stock-based compensation expense	<u>\$ 475</u>	<u>\$ 769</u>	<u>\$ 1,990</u>	<u>\$ 2,273</u>

During the nine months ended September 30, 2021 and 2020, the weighted average fair market value of stock options granted was \$1.54 and \$1.25, respectively.

The following weighted average assumptions apply to the options to purchase 1,356,700 and 1,215,382 shares of common stock granted to employees and directors during the three and nine months ended September 30, 2021 and 2020, respectively:

	2021	2020
Average risk-free interest rate	0.4%	1.0%
Expected dividend yield	—	—
Expected lives (years)	3.6	3.9
Expected volatility	94%	84%
Weighted average exercise price (per share)	\$ 2.68	\$ 2.08

All options granted during the nine months ended September 30, 2021 and 2020 were granted at exercise prices equal to the fair market value of the common stock on the dates of grant. As further described below, the vesting of certain options granted to employees were accelerated during the nine months ended September 30, 2021.

Note 10. Stock-Based Compensation (Continued)

Stock Option Activity

The following table summarizes stock option activity for the nine months ended September 30, 2021:

(\$ 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, 2020	4,614,323	\$ 9.78	6.8	\$ 2,949
Granted	1,356,700	2.68		
Exercised	(22,500)	2.11		
Forfeited	(260,053)	4.42		
Expired	(359,499)	12.38		
Outstanding at September 30, 2021 (1)	<u>5,328,971</u>	<u>\$ 8.09</u>	<u>6.6</u>	<u>\$ —</u>
Exercisable at September 30, 2021	<u>4,152,055</u>	<u>\$ 9.66</u>	<u>5.9</u>	<u>\$ —</u>

- (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.

During the three months ended March 31, 2021, the Company accelerated the vesting of 1,535,578 options, which were previously granted from 2019 through 2021. As of September 30, 2021, there was \$1.6 million of unrecognized compensation cost related to unvested options, which the Company expects to recognize over a weighted average period of 2.1 years.

Restricted Stock Activity

The following table summarizes restricted stock activity for the nine months ended September 30, 2021:

(\$ in thousands, except per share data)	Time-based Awards		Market/Performance-based Awards	
	Number of Shares	Weighted-Average Grant Date Fair Value	Number of Shares	Weighted-Average Grant Date Fair Value
Nonvested shares at December 31, 2020	354,003	\$ 2.27	549,318	\$ 1.54
Granted	—	—	—	—
Forfeited	(48,563)	2.31	(41,622)	1.54
Vested	(236,765)	2.25	—	—
Nonvested shares at September 30, 2021	<u>68,675</u>	<u>\$ 2.30</u>	<u>507,696</u>	<u>\$ 1.54</u>

Time-Based Restricted Stock Units

During the three months ended March 31, 2021, the Company accelerated the vesting of 137,872 unvested time-based restricted stock units which were previously granted in 2019 and 2020. During the nine months ended September 30, 2021, the Company recognized \$0.1 million of compensation expense related to these awards. As of September 30, 2021, there was \$0.1 million of unrecognized compensation cost for the time-based component of these awards, which is expected to be recognized over a weighted-average period of 1.8 years.

Market/Performance-Based Restricted Stock Units

In July 2020, the Company granted RSUs to certain employees, including executive officers, under the 2013 Plan, with vesting that may occur upon a combination of specific performance and/or market conditions. Accordingly, the Company views these RSUs as two separate awards: (i) an award that vests if the market condition is achieved, and (ii) an award that vests whether or not the market condition is achieved, so long as the performance condition is achieved.

The Company is currently recognizing compensation expense for these awards over the estimated requisite service period of 2.36 years based on the estimated fair value when considering the market condition of the award, which was determined using a Monte Carlo simulation. During the nine months ended September 30, 2021, the Company recognized \$0.1 million of compensation expense related to these awards. As of September

30, 2021, the remaining unrecognized compensation cost for the market-based component of these awards, which is expected to be recognized over a weighted-average period of 1.2 years, is \$0.5 million. In addition, should the performance condition be achieved, the Company would recognize an additional \$0.3 million of compensation expense.

Note 11. Related Party Transactions

Baker Brothers

Julian C. Baker, previously a member of the Company's Board of Directors (the "Board") until his resignation in September 2018, is a principal of Baker Bros. Advisors, LP. Additionally, Kelvin M. Neu, previously a member of Company's Board until his resignation in June 2019, was an employee of Baker Bros. Advisors, LP. At December 31, 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 12% of the Company's outstanding common stock.

During the nine months ended September 30, 2021, Baker Brothers exercised warrants to purchase 2,708,812 shares of the Company's common stock at an exercise price of \$0.08 per share for a total exercise price of approximately \$0.2 million. Additionally, during the nine months ended September 30, 2021, Baker Brothers converted 23,684 shares Series B1 Preferred Stock into 2,368,400 shares of the Company's common stock. As of September 30, 2021, Baker Brokers held approximately 4% of the Company's outstanding stock.

Pillar Investment Entities

Youssef El Zein, previously a member of the Company's Board 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 6, Pillar 7, and Pillar Partners (collectively, the "Pillar Investment Entities"). As of September 30, 2021, the Pillar Investment Entities owned approximately 19.9% of the Company's common stock.

During the nine months ended September 30, 2021, certain of the Pillar Investment Entities exercised warrants to purchase 3,158,386 shares of the Company's common stock at an exercise price of \$0.01 per share for a total exercise price of less than \$0.1 million. 19,052 shares were used as cashless shares for the exercise costs.

As of September 30, 2021, the Pillar Investment Entities held (i) prefunded warrants to purchase up to 1,533,159 shares of the Company's common stock at an exercise price of \$0.01 per share, (ii) warrants to purchase up to 3,039,514 shares of the Company's common stock at an exercise price of \$2.28 per share, (iii) warrants to purchase up to 2,764,227 shares of the Company's common stock at an exercise price of \$2.58 per share, and (iv) warrants to purchase up to 1,373,626 shares of the Company's common stock at an exercise price of \$2.71 per share.

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 and \$0.2 million during each of the nine months ended September 30, 2021 and 2020, the Company issued 68,699 and 128,799 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 Income (Loss) per Common Share

The Company uses the two-class method to compute net income 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.

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.

For the nine months ended September 30, 2021 and 2020, the Company used the two-class method to compute net income per common share. Under this method, net income is reduced by the amount of any dividends earned and the accretion of redeemable convertible preferred stock to its redemption value, if any, during the period. The remaining earnings (undistributed earnings) are allocated to common stock and each series of redeemable convertible preferred stock to the extent that each preferred security may share in earnings as if all the earnings for the period had been distributed. The total earnings allocated to common stock is then divided by the number of outstanding shares to which the earnings are allocated to determine the earnings per share.

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

(\$ in thousands except per share data)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2021	2020	2021	2020
Net (loss) income per share — Basic:				
Net (loss) income	\$ (5,965)	\$ (20,552)	\$ 102,210	\$ (35,961)
Less: Undistributed earnings to preferred stockholders	—	—	(1,636)	—
Net (loss) income attributable to common stockholders	\$ (5,965)	\$ (20,552)	\$ 100,574	\$ (35,961)
Net (loss) income attributable to common stockholders	\$ (5,965)	\$ (20,552)	\$ 100,574	\$ (35,961)
Denominator for basic net (loss) income per share	52,740	35,091	47,990	32,999
Basic net (loss) income per common share	\$ (0.11)	\$ (0.59)	\$ 2.10	\$ (1.09)
Net (loss) income per share — Diluted:				
Net (loss) income	\$ (5,965)	\$ (20,552)	\$ 102,210	\$ (35,961)
Less: Warrant revaluation gain applicable to dilutive warrants	—	—	(6,983)	—
Less: Future tranche right revaluation gain applicable to dilutive future tranche rights	—	—	(118,803)	—
Less: Undistributed earnings to preferred stockholders	—	—	—	—
Numerator for diluted net (loss) income per share	\$ (5,965)	\$ (20,552)	\$ (23,576)	\$ (35,961)
Denominator for basic net income per share	52,740	35,091	47,990	32,999
Plus: Incremental shares underlying "in the money" warrants outstanding	—	—	223	—
Plus: Incremental shares underlying "in the money" future tranche rights outstanding	—	—	3,400	—
Denominator for diluted net (loss) income per share	52,740	35,091	51,613	32,999
Diluted net (loss) income per common share	\$ (0.11)	\$ (0.59)	\$ (0.46)	\$ (1.09)

Note 12. Net Income (Loss) per Common Share (Continued)

Total antidilutive securities excluded from the calculation of diluted net loss per share for the three and nine months ended September 30, 2021 and 2020 were as follows:

(in thousands)	2021	2020	2021	2020
Stock options	5,329	5,111	5,329	5,111
Restricted stock units	576	914	576	914
Common stock warrants	8,732	12,917	8,732	12,917
Convertible preferred stock	—	2,369	—	2,369
Future tranche rights	—	54,588	—	54,588
Total	<u>14,637</u>	<u>75,899</u>	<u>14,637</u>	<u>75,899</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.

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 2020 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 2020 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 2020 Form 10-K, our subsequent filings with the SEC, and this Quarterly Report on Form 10-Q, that could cause actual results to differ materially from historical results or anticipated results.

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 rare disease indications characterized by small, well-defined patient populations with serious unmet medical needs. Our current focus is to identify and potentially acquire rights to novel development and commercial stage rare disease programs through new business development opportunities. Historically, we have focused on our Toll-like receptor (“TLR”) agonist, tilsotolimod (IMO-2125), for oncology. We are currently seeking to broaden our portfolio and develop and commercialize targeted therapies on our own. We have in the past and may in the future explore collaborative alliances to support development and commercialization of any of its drug candidates.

Our current TLR-targeted clinical-stage drug candidate, tilsotolimod, is an agonist of TLR9. Until May 2021, we were 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. During the first quarter of 2021, we announced that ILLUMINATE-301, the Company’s pivotal registration trial of tilsotolimod in combination with ipilimumab versus ipilimumab alone in patients with anti-PD-1 refractory advanced melanoma, did not meet its primary endpoint of objective response rate (“ORR”). Based on subsequent evaluation of the full data set in May 2021, we announced that we would not continue the trial to its Overall Survival (OS) primary endpoint.

We are continuing to evaluate 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 2021, following the announcement that ILLUMINATE-301 did not meet its primary endpoint of ORR, we decided to implement a reduction-in-force, which affected approximately 50% of our workforce as of September 30, 2021. The decision was made to align our workforce to our needs in light of the topline data results from ILLUMINATE-301’s ORR endpoint and subsequent decision not to continue to the study’s OS endpoint. In connection with these actions, we incurred termination costs during the second and third quarters of 2021, which included severance, benefits, and related costs, of approximately \$1.2 million and \$0.1 million, respectively.

We are actively evaluating other novel therapeutic assets, including developmental and potentially commercial-stage assets, which may represent an opportunity to expand our pipeline.

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) microsatellite stable (“MSS”) colorectal cancer (“CRC”) in combination with nivolumab and ipilimumab, and (ii) squamous cell carcinoma of the head and neck (“HNSCC”) 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 HNSCC.

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 solid tumors including, among others, microsatellite instability high/deficient mismatch repair (“MSI-H/dMMR”) CRC and HNSCC.

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 CRC. 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 HNSCC (“RM-HNSCC”), 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-HNSCC. 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.



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 the safety and effectiveness of tilsotolimod administered intratumorally in combination with nivolumab and ipilimumab for the treatment of solid tumors. We refer to this study as ILLUMINATE-206.

Currently, we are evaluating relapsed/refractory MSS-CRC in immunotherapy-naïve patients treated with tilsotolimod in combination with nivolumab and ipilimumab (the “MSS-CRC Study”). 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 MSS-CRC 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 two weeks, along with 1 mg/kg of IV Yervoy® every eight weeks (the “Low-Dose, Low-Frequency Cohort”). This regimen was generally well tolerated; no patients discontinued treatment due to adverse events (“AEs”) and none experienced Grade 4 or 5 AEs. As of the response data cutoff date, one patient experienced stable disease per RECIST v1.1 (as defined below) criteria and nine patients progressed as defined by RECIST v1.1. Investigators reported that six of the progressing patients had stability or reduction in size of injected lesions and six had stability or reduction in overall size of uninjected lesions.

Based on these results, we have fully enrolled patients in a second MSS-CRC Study cohort. Changes in the study design intended to improve potential outcomes in the targeted patient population included increasing the frequency of Yervoy® dosing to every three weeks and limiting the number of allowed prior lines of treatment to two. Accordingly, the 10 patients in the second group enrolled in the MSS-CRC Study will receive 8 mg of intratumoral tilsotolimod (total of 9 doses over approximately 28 weeks) and 3 mg/kg of intravenous (IV) Opdivo® every three weeks followed by 480 mg of IV Opdivo® every four weeks, along with 1 mg/kg of IV Yervoy® every three weeks for four doses (the “Low-Dose, High-Frequency Cohort”). Based on data from these patients, the MSS-CRC Study may be expanded further and/or provide rationale to explore additional tumor types.

As further discussed, under the caption “Item 1. Business - Collaborative Alliances” in our 2020 Form 10K, in March 2019, we entered into a clinical trial collaboration and supply agreement with BMS, under which BMS has agreed to manufacture and supply YERVOY® (ipilimumab) and OPDIVO® (nivolumab), at its cost and for no charge to us, for use in ILLUMINATE-206.



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 of 454 patients in March 2020, compared 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 ORR by blinded independent central review using Response Evaluation Criteria in Solid Tumors (“RECIST v1.1”) and median OS.

In March 2021, we reported that ILLUMINATE-301 did not meet its primary endpoint of ORR. In May 2021, following evaluation of the full data set, we announced that we would not continue ILLUMINATE-301 to its OS primary endpoint.

Collaborative Alliances

Our current alliances include collaborations with Scriptr, described below, and AbbVie and BMS, each described under the caption “Item 1. Business — Collaborative Alliances” in our 2020 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 and/or research additional drug candidates.

Collaboration with Scriptr

In February 2021, we entered into a collaboration and option agreement with Scriptr Global, Inc. (“Scriptr”), pursuant to which (i) Scriptr and us will conduct a research collaboration utilizing Scriptr Platform Technology (“SPT”) to identify, research and develop gene therapy candidates (each, a “Collaboration Candidate”) for the treatment, palliation, diagnosis or prevention of (a) myotonic dystrophy type 1 (“DM1 Field”) and (b) Friedreich’s Ataxia (“FA Field”) on a Research Program-by-Research Program basis, as applicable, and (ii) we were granted an exclusive option, in our sole discretion, to make effective the Scriptr License Agreement, as defined below, for a given Research Program, as defined below, to make use of Collaboration Candidates and related intellectual property (collectively, the “Scriptr Agreement”).

Pursuant to the Scriptr Agreement, Scriptr will use commercially reasonable efforts to carry out research activities set forth in accordance with the applicable DM1 Field and FA Field research plans, including certain pre-clinical proof of concept studies, to identify research Collaboration Candidates utilizing SPT (each, a “Research Program”). Following the completion of activities under a given Research Program, Scriptr will prepare and submit to us a comprehensive data package (each, a “Data Package”) that summarizes, on a Research Program-by-Research Program basis, any Collaboration Candidates researched under the Research Program, including any data and results. Upon receipt of a Data Package, we have, in our sole discretion, up to two-hundred seventy (270) calendar days to make effective the exclusive license agreement entered into by and between Scriptr and us,

pursuant to which, among other things, grants us exclusive rights and licenses with respect to the development, manufacture and commercialization of licensed candidates and products, subject to certain conditions and limitations (the “Scriptr License Agreement”), for a given Research Program (each licensed Research Program, a “Licensed Program”). The Scriptr License Agreement provides for customary development milestones on candidates developed under a Licensed Program and royalties on licensed products, if any.

In partial consideration of the rights granted by Scriptr to us under the Scriptr Agreement, we made a one-time, non-creditable and non-refundable payment to Scriptr during the first quarter of 2021. In order to fund the Research Programs, we shall reimburse Scriptr for costs incurred by or on behalf of Scriptr in connection with the conduct of each Research Program during the research term in accordance with the applicable Research Program budget and payment schedule, provided that, any such cost reimbursement payments shall initially be deducted from the initial Research Program payment. We incurred approximately \$1.7 million in research and development expenses under the Scriptr Agreement during the nine months ended September 30, 2021.

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 2020 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 significant policies, however, fit the definition of critical accounting policies and estimates. We believe that our accounting policies relating to (i) warrant and future tranche right liabilities and related revaluation gain (loss), (ii) research and development prepayments, accruals and related expenses, and (iii) stock-based compensation, 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 2020 Form 10-K, fit the description of critical accounting estimates and judgments.

New Accounting Pronouncements

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

Financial Condition, Liquidity and Capital Resources

Financial Condition

As of September 30, 2021, we had an accumulated deficit of \$731.3 million. To date, substantially all 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 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 4, 2020, which was declared effective on September 2, 2020, relating to the sale, from time to time, in one or more transactions, of up to \$150.0 million of common stock, preferred stock, depository shares and warrants. As of November 8, 2021, approximately \$73.2 million remained available for issuance under this registration statement, assuming the full contractual amounts provided for under the LPC Purchase Agreement and the ATM Agreement (each as defined below) were to be sold.

LPC 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").

During the nine months ended September 30, 2021 and 2020, the Company sold 800,000 and 600,000 shares, respectively, pursuant to the LPC Purchase Agreement, resulting in net proceeds of \$4.2 million and \$1.0 million, respectively. As of September 30, 2021, the Company may sell up to an additional \$25.3 million of shares under the LPC Purchase Agreement, subject to certain limitations.

ATM Agreement

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 through JMP as its agent.

During the nine months ended September 30, 2021 and 2020, the Company sold 5,117,357 and 938,669 shares of common stock, respectively, pursuant to the ATM Agreement, resulting in net proceeds, after deduction of commissions and other offering expenses, of \$15.3 million and \$1.6 million, respectively. The Company may sell up to an additional \$19.5 million of shares under the ATM Agreement.

The LPC Purchase Agreement and ATM Agreement are more fully described in Note 8 of the Notes to Condensed Financial Statements included elsewhere in this Quarterly Report on Form 10-Q.

Private Placements

As previously disclosed in our 2020 Form 10-K, between December 2019 and July 2020, the Company entered into three private placement financings with certain investors which, collectively, provided for up to \$138.4 million in total funding, of which \$25.2 million had been received through December 31, 2020. However, as of September 30, 2021, as a result of Baker Brothers not exercising their right to purchase convertible preferred stock or exercise warrants in connection with the December 2019 Securities Purchase Agreement and the Pillar Investment Entities not exercising their right to purchase shares of common stock (or pre-funded warrants) and common warrants in connection with the July 2020 Securities Purchase Agreement prior to expiration, the potential additional funding related to our private placement transactions is limited to approximately \$17.8 million upon the exercise, at the sole discretion of the Pillar Investment Entities, of outstanding warrants issued in connection with the April 2020 Securities Purchase Agreement and July 2020 Securities Purchase Agreement. See Note 8 of the Notes to Condensed Financial Statements included elsewhere in this Quarterly Report on Form 10-Q for details related to the Company's outstanding warrants.

During the nine months ended September 30, 2021, certain of the Pillar Investment Entities exercised warrants to purchase 3,158,386 shares of the Company's common stock at an exercise price of \$0.01 per share for a total exercise price of less than \$0.1 million. 19,052 shares were used as cashless shares for the exercise costs.

Funding Requirements

We had cash, cash equivalents and investments of approximately \$36.6 million at September 30, 2021. We believe, based on our current operating plan, our existing cash and cash equivalents on hand as of September 30, 2021 will enable us to fund our operations through the one-year period subsequent to the filing date of this Quarterly Report on Form 10-Q. Specifically, we believe our available funds will be sufficient to enable us to perform the following:

- (i) continue to execute on the current Low-Dose, High-Frequency Cohort of our Phase 2 study of tilsotolimod in combination with nivolumab and ipilimumab for the treatment of MSS-CRC (ILLUMINATE-206);
- (ii) fund business development related activities, such as identifying and potentially acquiring rights to novel development and commercial stage rare disease programs;
- (iii) conclude our Phase 3 clinical trial of tilsotolimod in combination with ipilimumab for the treatment of anti-PD1 refractory metastatic melanoma (ILLUMINATE-301);
- (iv) fund certain research including investigator initiated clinical trials of tilsotolimod and the Scriptr Agreement; and
- (v) maintain a level of general and administrative expenses in order to support the business.

In addition, 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 receptivity of the capital markets to any in-licensing, product acquisition or other transaction we may enter into;

- (ii) the receptivity of the capital markets to financings by biotechnology companies generally and companies with drug candidates and technologies similar to ours specifically;
- (iii) the results of our clinical development activities in our tilsotolimod program or any other drug candidates we develop on the timelines anticipated;
- (iv) 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;
- (v) the cost, timing, and outcome of regulatory reviews;
- (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 coronavirus ("COVID-19") pandemic 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. 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 2020 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 operations.

Cash Flows

The following table presents a summary of the primary sources and uses of cash for the nine months ended September 30, 2021 and 2020:

<i>(in thousands)</i>	Nine Months Ended September 30,	
	2021	2020
Net cash provided by (used in):		
Operating activities	\$ (20,545)	\$ (26,192)
Investing activities	4,500	(3,837)
Financing activities	19,418	12,342
Increase (decrease) in cash and cash equivalents	\$ 3,373	\$ (17,687)

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 nine months ended September 30, 2021, as compared to the same period in 2020, was primarily due to timing of cash outflows related to our current IMO-2125 development program, including payments to contract research organizations, offset by severance payments related to the reduction in workforce associated with the outcome of ILLUMINATE-301's ORR endpoint.

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 nine months ended September 30, 2021, \$4.5 million in proceeds received from the maturity of available-for-sale securities; and
- for the nine months ended September 30, 2020, purchases of \$12.2 million in available-for-sale securities, partially offset by \$8.4 million in proceeds received from the maturity of 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 nine months ended September 30, 2021, \$19.4 million in aggregate net proceeds from financing arrangements consisting of \$15.3 million received pursuant to the ATM Agreement and \$4.2 million received under the LPC Purchase Agreement and \$0.3 million received from the exercise of stock options and warrants, partially offset by \$0.4 million in payments related to our short-term insurance premium financing arrangement; and
- for the nine months ended September 30, 2020, \$12.3 million in aggregate net proceeds from financing arrangements consisting of \$9.7 million in net proceeds received pursuant to the April 2020 Securities Purchase Agreement and July 2020 Securities Purchase Agreement, \$1.6 million received pursuant to the ATM Agreement and \$1.0 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 Employee Stock Purchase Plan.

Contractual Obligations

During the nine months ended September 30, 2021, there were no material changes outside the ordinary course of our business to our contractual obligations as disclosed in our 2020 Form 10-K.

Off-Balance Sheet Arrangements

As of September 30, 2021, we had no off-balance sheet arrangements.

Results of Operations

Three and Nine Months Ended September 30, 2021 and 2020

Overview

During the three months ended September 30, 2021, our loss from operations totaled \$6.0 million, a 20% decrease compared to a loss from operations of \$7.5 million for the three months ended September 30, 2020. During the nine months ended September 30, 2021, our loss from operations totaled \$23.6 million, a 18% decrease compared to a loss from operations of \$28.6 million for the nine months ended September 30, 2020. Research and development expenses comprise the majority of our total operating expenses, as shown in the table below.

(\$ in thousands)	Three months ended September 30,		% Change	Nine months ended September 30,		% Change
	2021	2020		2021	2020	
Operating expenses:						
Research and development	\$ 3,507	\$ 4,766	(26)%	\$ 14,271	\$ 19,655	(27)%
General and administrative	2,331	2,718	(14)%	7,959	8,992	(11)%
Restructuring costs	130	—	—	1,322	—	—
Total operating expenses	\$ 5,968	\$ 7,484	(20)%	\$ 23,552	\$ 28,647	(18)%
Loss from operations	\$ (5,968)	\$ (7,484)	(20)%	\$ (23,552)	\$ (28,647)	(18)%

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.

During the three and nine months ended September 30, 2021, our overall research and development expenses declined by 26% and 27%, respectively, as compared to the same period in 2020, primarily due to decreases in external development costs associated with tilsotolimod (IMO-2125). This decrease is primarily related to: (i) costs incurred with contract research organizations during the three and nine months ended September 30, 2021 to support our ILLUMINATE-301 trial, which was discontinued by the Company in the second quarter of 2021; and (ii) lower costs incurred with drug manufacturing activities. The decrease of the research and development expenses is offset by the costs associated with the continuing preparation and conduct of ILLUMINATE-206 and the Scriptr Agreement.

Tilsotolimod (IMO-2125) external development expenses as well as expenses related to the Scriptr Agreement (as more fully described under the heading “Collaborative Alliances” above) will continue to be a significant portion of our total research and development spending.

In the table below, research and development expenses are set forth in the following categories: Tilsotolimod (IMO-2125) and other drug development expenses.

(\$ in thousands)	Three months ended September 30,		% Change	Nine months ended September 30,		% Change
	2021	2020		2021	2020	
Tilsotolimod (IMO-2125) external development expense	\$ 2,336	\$ 2,818	(17)%	\$ 8,277	\$ 13,380	(38)%
Other drug development expense	1,171	1,948	(40)%	5,994	6,275	(4)%
Total research and development expenses	\$ 3,507	\$ 4,766	(26)%	\$ 14,271	\$ 19,655	(27)%

Tilsotolimod (IMO-2125) External Development Expenses

These expenses include external expenses that we have 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 September 30, 2021, we incurred approximately \$90.1 million in tilsotolimod external development expenses, 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.

Other Drug Development Expenses

These expenses include internal costs, such as payroll and overhead expenses, associated with all our clinical development programs. In addition, 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. Included in the three and nine months ended September 30, 2021 are \$0.4 million and \$1.7 million, respectively, of expenses related to the Scriptr collaboration program.

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 September 30, 2021 and 2020, general and administrative expenses totaled \$2.3 million and \$2.7 million, respectively. For the nine months ended September 30, 2021 and 2020, general and administrative expenses totaled \$8.0 million and \$9.0 million, respectively.

The decrease in general and administrative expenses during the three months ended September 30, 2021, as compared to the 2020 period, was primarily due to lower salary, bonus, and stock compensation expense and other employee-related expenses associated with our reduction-in-force and offset by increased consulting costs. The decrease in general and administrative expenses during the nine months ended September 30, 2021, as compared to the 2020 period, was due to lower salary, bonus, and stock compensation expense and employee-related expense related to terminated employees as part of our reduction-in-force, partially offset by increased consulting expenses.

Restructuring Costs

Restructuring costs for the three and nine months ended September 30, 2021 totaled approximately \$0.1 million and \$1.3 million, respectively, and are comprised primarily of the termination costs including severance, benefits and related costs associated with our decision in April 2021 to implement a reduction-in-force. No such costs were incurred during the three and nine months ended September 30, 2020.

Interest Income

We recognized nominal interest income for the three and nine months ended September 30, 2021. Interest income for the three and nine months ended September 30, 2020 totaled less than \$0.1 million and approximately \$0.2 million, respectively. The period-over-period decrease was primarily due to lower interest rates and decrease in average short-term investment balances and yields. 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 Gain or Loss

During the three months ended September 30, 2021, we recorded no non-cash warrant revaluation gain or loss. During the nine months ended September 30, 2021, we recorded a non-cash warrant revaluation gain of approximately \$7.0 million. During the three months ended September 30, 2020, we recorded a non-cash warrant revaluation loss of approximately \$0.7 million. During the nine months ended September 30, 2020, we recorded a non-cash warrant revaluation gain of approximately \$0.5 million.

The non-cash gain for the nine months ended September 30, 2021 relates to the derecognition of the warrant liability during the first quarter of 2021 associated with our liability-classified warrants issued in connection with the December 2019 Private Placement, as more fully described in Note 7 of the Notes to Condensed Financial Statements appearing elsewhere in this Quarterly Report on Form 10-Q, due to the termination of such liability-classified warrants during the quarter.

The non-cash gain (loss) for the 2020 period relates to the change in fair value of our liability-classified warrants. 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 the warrant liability and resulting warrant revaluation gain (loss) for 2020 was driven primarily by the changes in our stock price during the period.

Future Tranche Right Revaluation Gain or Loss

During the three months ended September 30, 2021, we recorded no non-cash future tranche right revaluation gain or loss. During the nine months ended September 30, 2021, we recorded a non-cash future tranche right revaluation gain of approximately \$118.8 million. During the three months ended September 30, 2020, we recorded a non-cash future tranche right loss of \$12.4 million. During the nine months ended September 30, 2020, we recorded a non-cash future tranche right revaluation loss of \$7.0 million.

The non-cash gain for the nine months ended September 30, 2021 relates to the derecognition of the future tranche right liability during the first quarter of 2021 associated with the future tranche rights issued in connection with the December 2019 Private Placement, as more fully described in Note 7 of the Notes to Condensed Financial Statements appearing elsewhere in this Quarterly Report on Form 10-Q, due to the termination of the future tranche rights during the quarter.

The non-cash loss for the 2020 period relates to the change in fair value of the future tranche rights. 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 estimated lives of the future tranche rights. Changes in the fair value of the future tranche right liability and resulting future tranche right revaluation loss for 2020 was driven primarily by changes in our stock price during the period.

Net Income or Loss Applicable to Common Stockholders

As a result of the factors discussed above, our net loss for the three months ended September 30, 2021 was \$6.0 million and our net income for the nine months ended September 30, 2021 was \$102.2 million compared to net loss of \$20.6 million and \$36.0 million for the three and nine months ended September 30, 2020, respectively.

Basic net loss applicable to common stockholders for the three months ended September 30, 2021 was \$6.0 million and basic net income applicable to common stockholders for the nine months ended September 30, 2021 was \$100.6 million. Basic net loss applicable to common stockholders for the three and nine months ended September 30, 2020 was \$20.6 million and \$36.0 million, respectively.

Excluding the non-cash warrant revaluation gain of \$7.0 million and future tranche right revaluation gain of \$118.8 million, for the nine months ended September 30, 2021, diluted net loss applicable to common stockholders was \$23.6 million. Excluding the non-cash warrant revaluation loss of \$0.7 million and future tranche right revaluation loss of \$12.4 million for the three months ended September 30, 2020, net loss applicable to common stockholders was \$7.5 million. Excluding the non-cash warrant revaluation loss in of \$0.5 million and future tranche right revaluation loss of \$7.0 million for the nine months ended September 30, 2020, net loss applicable to common stockholders was \$28.5 million.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

There were no material changes in our exposure to market risk from December 31, 2020. Our market risk profile as of December 31, 2020 is disclosed in Item 7A, *Quantitative and Qualitative Disclosures About Market Risk*, of our 2020 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 September 30, 2021. 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 September 30, 2021, 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 September 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 5. Other Information.

On October 12, 2021, the Company terminated the consulting arrangement provided for in Section 6(h) (the “Consulting Arrangement”) of the Severance and Change of Control Agreement, by and between the Company and Elizabeth Tarka, M.D., dated as of June 26, 2019, and as amended by the Amendment to the Severance and Change of Control Agreement, dated as of May 18, 2021. As previously announced, Dr. Tarka ceased to serve as Senior Vice President, Chief Medical Officer of the Company, effective May 28, 2021. Thereafter, in accordance with the terms of the Consulting Arrangement, Dr. Tarka provided certain consulting services to the Company. Accordingly, Dr. Tarka is no longer providing any services to the Company.

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 2020 Form 10-K and below. Except as set forth below, there have been no material changes to the disclosures relating to this item from those set forth in our 2020 Form 10-K.

We expect that we will continue to incur substantial and increasing net losses in the foreseeable future.

As of September 30, 2021, we had an accumulated deficit of \$731.3 million and a cash and cash equivalents balance of \$36.6 million. We expect to incur substantial operating losses in future periods and will require additional capital as we seek to advance tilsotolimod and/or any other future drug candidates through development to commercialization. We do not expect to generate product revenue, sales-based milestones or royalties until we successfully complete development of and obtain marketing approval for tilsotolimod or any other future drug candidates, either alone or in collaboration with third parties, which may not occur or may take a number of years. To commercialize tilsotolimod and any other future drug candidates, we need to complete clinical development and comply with comprehensive regulatory requirements. We are subject to numerous 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.

Even if we succeed in receiving marketing approval for and commercializing tilsotolimod or any other product candidate, we will continue to incur substantial research and development and other expenditures to develop and market additional potential indications or products. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders’ equity and working capital.

Our stock price has been and may continue to be volatile, and the value of an investment in our common stock may decline.

We historically have experienced significant volatility in our stock price. Since December 31, 2020, our common stock has traded as low as \$0.85 per share. The realization of any of the risks described in these risk factors or other unforeseen risks could have an adverse effect on the market price of our common stock. The trading price of our common stock is likely to continue to be highly volatile and could be subject to declines in response to numerous factors, including disappointing results in a clinical program, as was the case following the announcement of topline results for ILLUMINATE-301. Other risk factors include results from ongoing clinical trials; our ability to successfully commercialize tilsotolimod; FDA regulatory actions; announcements by us or our competitors of acquisitions, regulatory approvals, clinical milestones, new products, significant contracts, commercial relationships or capital commitments; additions or departures of key personnel; commencement of, or our involvement in, litigation; and any major change in our Board of Directors or management.

From time to time, we estimate the timing of the potential accomplishment of clinical and other development goals or milestones. These estimated milestones may include the commencement or completion of clinical trials. Also, from time to time, we expect that we will publicly announce the anticipated timing of some of these milestones. All these estimated milestones are based on numerous assumptions. These milestones may change and the actual timing of meeting these milestones may vary dramatically from our estimates, in some cases for reasons beyond our control. If we do not meet these estimated milestones, or the anticipated timing thereof, as publicly announced, our stock price may decline.

We may not be able to comply with Nasdaq’s continued listing standards.

Our common stock trades on The Nasdaq Capital Market (“Nasdaq”) under the symbol “IDRA.” There is also no guarantee that we will be able to perpetually satisfy Nasdaq’s continued listing requirements to maintain our listing on Nasdaq for any periods of time. Our failure to continue to meet these requirements may result in our securities being delisted from Nasdaq.

Among the conditions required for continued listing on Nasdaq, we are required to maintain a stock price over \$1.00 per share pursuant to Rule 5550(a)(2) of the Nasdaq Listing Rules. As noted above, since December 31, 2020, our common stock has traded as low as \$0.85 per share. Accordingly, we may not be able to maintain a stock price over \$1.00 per share and could face the risk of our common stock being delisted if the closing bid price for our common stock falls below \$1.00 per share for 30 consecutive business days and we are unable to regain compliance.

If we fail to comply with Nasdaq rules and requirements, our stock may be delisted. In addition, even if we demonstrate compliance with the requirement above, we will have to continue to meet other objective and subjective listing requirements to continue to be listed on Nasdaq. Delisting from Nasdaq could make trading our common stock more difficult for investors, potentially leading to declines in our share price and liquidity. Without a Nasdaq listing, stockholders may have a difficult time getting a quote for the sale or purchase of our common stock, the sale or purchase of our common stock would likely be made more difficult, and the trading volume and liquidity of our common stock could decline. Delisting from Nasdaq could also result in negative publicity and could also make it more difficult for us to raise additional capital. The absence of such a listing may adversely affect the acceptance of our common stock as currency or the value accorded by other parties. Further, if we are delisted, we would also incur additional costs under state blue sky laws in connection with any sales of our securities. These requirements could severely limit the market liquidity of our common stock and the ability of our stockholders to sell our common stock in the secondary market. If our common stock is delisted by Nasdaq, our common stock may be eligible to trade on an over-the-counter quotation system, such as the OTCQB Market, where an investor may find it more difficult to sell our stock or obtain accurate quotations as to the market value of our common stock. In the event our common stock is delisted from Nasdaq, we may not be able to list our common stock on another national securities exchange or obtain quotation on an over-the counter quotation system.

Our recent organizational changes, focus on new business development opportunities, and cost cutting measures may not be successful.

In April 2021, following the announcement that ILLUMINATE-301 did not meet its primary endpoint of ORR, we decided to implement a reduction-in-force affecting approximately 50% of our workforce starting at the second quarter of 2021. The objective of this workforce reduction was to realign our workforce to meet our needs in light of the outcome of ILLUMINATE-301's ORR endpoint. In May 2021, we announced that we would not continue ILLUMINATE-301 toward its OS endpoint. In connection with these actions, we have incurred the termination costs, which include severance, benefits, and related costs, of approximately \$1.2 million and \$0.1 million in the second and third quarters of 2021, respectively.

We believe these changes are needed to streamline our organization and reallocate our resources to better align with our current strategic goals, including our current focus on new portfolio opportunities. However, these restructuring and cost cutting activities may yield unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond our intended reduction-in-force, a reduction in morale among our remaining employees, and the risk that we may not achieve the anticipated benefits, all of which may have an adverse effect on our results of operations or financial condition. In addition, while positions have been eliminated certain functions necessary to our reduced operations remain, and we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees. We may also discover that the reductions in workforce and cost cutting measures will make it difficult for us to pursue new opportunities and initiatives, requiring us to hire qualified replacement personnel, which may require us to incur additional and unanticipated costs and expenses. Moreover, there is no assurance that we will be successful in our pursuit of any new business development opportunities. Our failure to successfully accomplish any of the above activities and goals may have a material adverse impact on our business, financial condition, and results of operations.

Item 6. Exhibits.

Exhibit No.	Description
31.1*	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document – 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 September 30, 2021, formatted in Inline XBRL

† Management contract or compensatory plan or arrangement

* Filed herewith

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: November 8, 2021

/s/ Vincent J. Milano

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

Date: November 8, 2021

/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: November 8, 2021

/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: November 8, 2021

/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 September 30, 2021 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: November 8, 2021

/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 September 30, 2021 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: November 8, 2021

/s/ JOHN J. KIRBY

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