Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2022

OR

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

For the transition period from _____ to _____

Commission File Number: 000-50484

MEI Pharma, Inc.

(Exact name of registrant as specified in its charter)

DELAWARE	**51-0407811**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

11455 El Camino Real, San Diego, CA 92130
(Address of principal executive offices) (Zip Code)

(858) 369-7100
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.00000002 par value	**MEIP**	**The Nasdaq Stock Market LLC**

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, 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 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 ☒

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes ☒ No ☐

As of November 10, 2022, the number of shares outstanding of the issuer's common stock, $0.00000002 par value, was 133,260,865.

MEI PHARMA, INC.

Table of Contents

PART I FINANCIAL INFORMATION

Item 1. Condensed Financial Statements

MEI PHARMA, INC.
CONDENSED BALANCE SHEETS
(In thousands, except par value data)

	September 30, 2022 (Unaudited)	June 30, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 14,653	$ 15,740
Short-term investments	123,714	137,512
Total cash, cash equivalents and short-term investments	138,367	153,252
Unbilled receivables	7,758	10,044
Prepaid expenses and other current assets	2,782	3,830
Total current assets	148,907	167,126
Operating lease right-of-use asset	13,052	9,054
Property and equipment, net	1,624	1,660
Total assets	$ 163,583	$ 177,840
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 8,418	$ 7,918
Accrued liabilities	9,216	10,820
Deferred revenue	4,500	4,834
Operating lease liability	1,301	871
Total current liabilities	23,435	24,443
Deferred revenue, long-term	89,973	90,610
Operating lease liability, long-term	12,381	8,771
Warrant liability	486	1,603
Total liabilities	126,275	125,427
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.01 par value; 100 shares authorized; none outstanding	—	—
Common stock, $0.00000002 par value; 226,000 shares authorized; 133,261 and 133,152 shares issued and outstanding at September 30, 2022 and June 30, 2022, respectively	—	—
Additional paid-in capital	428,091	426,572
Accumulated deficit	(390,783)	(374,159)
Total stockholders' equity	37,308	52,413
Total liabilities and stockholders' equity	$ 163,583	$ 177,840

See accompanying notes to condensed financial statements.

MEI PHARMA, INC.
CONDENSED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended September 30,	
	2022	2021
Revenue	$ 8,730	$ 7,757
Operating expenses:		
Research and development	19,463	19,953
General and administrative	7,486	7,909
Total operating expenses	26,949	27,862
Loss from operations	(18,219)	(20,105)
Other income (expense):		
Change in fair value of warrant liability	1,117	2,587
Interest and dividend income	480	8
Other expense, net	(2)	—
Net loss	$ (16,624)	$ (17,510)
Net loss:		
Basic	$ (16,624)	$ (17,510)
Diluted	$ (16,624)	$ (20,097)
Net loss per share:		
Basic	$ (0.12)	$ (0.16)
Diluted	$ (0.12)	$ (0.18)
Shares used in computing net loss per share:		
Basic	133,255	112,677
Diluted	133,255	113,917

See accompanying notes to condensed financial statements.

MEI PHARMA, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands)
(Unaudited)

	Common Shares	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at June 30, 2022	133,152	$ 426,572	$ (374,159)	$ 52,413
Net loss	—	—	(16,624)	(16,624)
Issuance of common stock for vested restricted stock units	109	(40)	—	(40)
Share-based compensation expense	—	1,559	—	1,559
Balance at September 30, 2022	133,261	$ 428,091	$ (390,783)	$ 37,308

	Common Shares	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at June 30, 2021	112,615	$ 369,171	$ (319,705)	$ 49,466
Net loss	—	—	(17,510)	(17,510)
Issuance of common stock for vested restricted stock units	63	(194)	—	(194)
Share-based compensation expense	—	2,539	—	2,539
Balance at September 30, 2021	112,678	$ 371,516	$ (337,215)	$ 34,301

See accompanying notes to condensed financial statements.

MEI PHARMA, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Three Months Ended September 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (16,624)	$ (17,510)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of warrant liability	(1,117)	(2,587)
Share-based compensation	1,559	2,539
Depreciation and amortization	99	77
Non-cash lease expense	349	—
Changes in operating assets and liabilities:		
Accounts receivable	—	(10,000)
Unbilled receivables	2,286	(538)
Prepaid expenses and other current assets	1,048	70
Accounts payable	500	2,117
Accrued liabilities	(1,604)	(2,303)
Deferred revenue	(971)	20,417
Operating lease liability	(307)	(3)
Net cash used in operating activities	(14,782)	(7,721)
Cash flows from investing activities:		
Purchases of short-term investments	(34,052)	(59,992)
Proceeds from maturity of short-term investments	47,850	74,993
Purchases of property and equipment	(63)	(8)
Net cash provided by investing activities	13,735	14,993
Cash flows from financing activities:		
Payment of RSU tax withholdings in exchange for common shares surrendered by RSU holders	(40)	(194)
Net cash used in financing activities	(40)	(194)
Net (decrease) increase in cash and cash equivalents	(1,087)	7,078
Cash and cash equivalents at beginning of the period	15,740	8,543
Cash and cash equivalents at end of the period	$ 14,653	$ 15,621
Supplemental disclosures:		
Operating lease right-of-use assets obtained in exchange for operating lease liabilities	$ 4,347	$ —

See accompanying notes to condensed financial statements.

MEI PHARMA, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)

Note 1. The Company and Summary of Significant Accounting Policies

The Company

MEI Pharma, Inc. is a late-stage pharmaceutical company committed to the development and commercialization of novel cancer therapies intended to improve outcomes for patients. Our portfolio of drug candidates includes three clinical-stage assets, including zandelisib (f/k/a ME-401), currently in multiple ongoing clinical studies intended to support marketing applications with the United States ("U.S.") Food and Drug Administration ("FDA") and other regulatory authorities globally. Our approach to building our pipeline is to license or acquire promising cancer agents and build value in programs through development, commercialization and strategic partnerships, as appropriate. Our common stock is listed on the Nasdaq Capital Market under the symbol "MEIP."

Clinical Development Programs

We build our pipeline by licensing or acquiring promising cancer agents and creating value in programs through development, commercialization and strategic partnerships, as appropriate. Our objective is to leverage the mechanisms and properties of our pipeline drug candidates to optimize the balance between efficacy and tolerability to meet the needs of patients with cancer. Our drug candidate pipeline includes:

- Zandelisib, an oral phosphatidylinositol 3-kinase delta ("PI3Kδ") inhibitor;
- Voruciclib, an oral cyclin-dependent kinase ("CDK") inhibitor; and
- ME-344, a mitochondrial inhibitor targeting the oxidative phosphorylation ("OXPHOS") complex.

The results of pre-clinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates may not have favorable results in later studies or trials. The commercial opportunity will be reduced or eliminated if competitors develop and market products that are more effective, have fewer side effects or are less expensive than our drug candidates. We will need substantial additional funds to progress the clinical trial programs for the drug candidates zandelisib, voruciclib, and ME-344, and to develop new compounds. The actual amount of funds that will be needed are determined by a number of factors, some of which are beyond our control. Negative U.S. and global economic conditions may pose challenges to our business strategy, which relies on funding from the financial markets or collaborators.

Liquidity

We have accumulated losses of $390.8 million since inception and expect to incur operating losses and generate negative cash flows from operations for the foreseeable future. As of September 30, 2022, we had $138.4 million in cash and cash equivalents and short-term investments. We believe that these resources will be sufficient to meet our obligations and fund our liquidity and capital expenditure requirements for at least the next 12 months from the issuance of these financial statements. Our current business operations are focused on continuing the clinical development of our drug candidates. Changes to our research and development plans or other changes affecting our operating expenses may affect actual future use of existing cash resources. Our research and development expenses are expected to increase in the foreseeable future. We cannot determine with certainty costs associated with ongoing and future clinical trials or the regulatory approval process. The duration, costs and timing associated with the development of our product candidates will depend on a variety of factors, including uncertainties associated with the results of our clinical trials.

To date, we have obtained cash and funded our operations primarily through equity financings and license agreements. In order to continue the development of our drug candidates, at some point in the future we expect to pursue one or more capital transactions, whether through the sale of equity securities, debt financing, license agreements or entry into strategic partnerships. There can be no assurance that we will be able to continue to raise additional capital in the future.

Basis of Presentation

The accompanying unaudited financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. ("U.S. GAAP") for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, the accompanying financial statements do not include all of the information and notes required by U.S. GAAP for complete financial statements. In the opinion of management, the accompanying financial statements reflect all adjustments (consisting of normal recurring adjustments) that are necessary for a fair statement of the financial position, results of operations and cash flows for the periods presented.

The accompanying unaudited financial statements should be read in conjunction with the audited financial statements and notes thereto as of and for the fiscal year ended June 30, 2022, included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on September 8, 2022 ("2022 Annual Report"). Interim results are not necessarily indicative of results for a full year.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and disclosures made in the accompanying notes to the financial statements. We use estimates that affect the reported amounts (including assets, liabilities, revenues and expenses) and related disclosures. Actual results could materially differ from those estimates.

Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value is as follows:

- Level 1 – Observable inputs such as quoted prices in active markets for identical assets or liabilities.
- Level 2 – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Revenue Recognition

Revenues from Customers

In accordance with Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("Topic 606"), we recognize revenue when control of the promised goods or services is transferred to our customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. For enforceable contracts with our customers, we first identify the distinct performance obligations – or accounting units – within the contract. Performance obligations are commitments in a contract to transfer a distinct good or service to the customer.

Payments received under commercial arrangements, such as licensing technology rights, may include non-refundable fees at the inception of the arrangements, milestone payments for specific achievements designated in the agreements, and royalties on the sale of products. At the inception of arrangements that include milestone payments, we use judgment to evaluate whether the milestones are probable of being achieved and we estimate the amount to include in the transaction price using the most likely method. If it is probable that a significant revenue reversal will not occur, the estimated amount is included in the transaction price. Milestone payments that are not within our or the licensee’s control, such as regulatory approvals, are not included in the transaction price until those approvals are received. At the end of each reporting period, we re-evaluate the probability of achievement of development milestones and any related constraint and, as necessary, we adjust our estimate of the overall transaction price.

We may enter into arrangements that consist of multiple performance obligations. Such arrangements may include any combination of our deliverables. To the extent a contract includes multiple promised deliverables, we apply judgment to determine whether promised deliverables are capable of being distinct and are distinct in the context of the contract. If these criteria are not met, the promised deliverables are accounted for as a combined performance obligation. For arrangements with multiple distinct performance obligations, we allocate variable consideration related to our 50-50 cost share for development services directly to the associated performance obligation and then allocate the remaining consideration among the performance obligations based on their relative stand-alone selling price.

Stand-alone selling price is the price at which we would sell a promised good or service separately to the customer. When not directly observable, we typically estimate the stand-alone selling price for each distinct performance obligation. Variable consideration that relates specifically to our efforts to satisfy specific performance obligations is allocated entirely to those performance obligations. Other components of the transaction price are allocated based on the relative stand-alone selling price, over which management has applied significant judgment. We develop assumptions that require judgment to determine the stand-alone selling price for license-related performance obligations, which may include forecasted revenues, development timelines,

reimbursement rates for personnel costs, discount rates and probabilities of technical, regulatory and commercial success. We estimate stand-alone selling price for research and development performance obligations by forecasting the expected costs of satisfying a performance obligation plus an appropriate margin.

In the case of a license that is a distinct performance obligation, we recognize revenue allocated to the license from non-refundable, up-front fees at the point in time when the license is transferred to the licensee and the licensee can use and benefit from the license. For licenses that are bundled with other distinct or combined obligations, we use judgment to assess the nature of the performance obligation to determine whether the performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. If the performance obligation is satisfied over time, we evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

The selection of the method to measure progress towards completion requires judgment and is based on the nature of the products or services to be provided. Revenue is recorded proportionally as costs are incurred. We generally use the cost-to-cost measure of progress because it best depicts the transfer of control to the customer which occurs as we incur costs. Under the cost-to-cost measure of progress, the extent of progress towards completion is measured based on the ratio of costs incurred to date to the total estimated costs at completion of the performance obligation (an “input method” under Topic 606). We use judgment to estimate the total cost expected to complete the research and development performance obligations, which include subcontractors’ costs, labor, materials, other direct costs and an allocation of indirect costs. We evaluate these cost estimates and the progress each reporting period and, as necessary, we adjust the measure of progress and related revenue recognition.

For arrangements that include sales-based or usage-based royalties, we recognize revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, we have not recognized any sales-based or usage-based royalty revenue from license agreements.

In connection with our License, Development and Commercialization Agreement (the "KKC Commercialization Agreement") with Kyowa Kirin Co., Ltd. ("KKC"), we perform development services related to our 50-50 cost sharing arrangement for which revenue is recognized over time. Additionally, we perform services for KKC at their request, the costs of which are fully reimbursed to us. We record the reimbursement for such pass through services as revenue at 100% of reimbursed costs, as control of the additional services for KKC is transferred at the time we incur such costs. The costs of these services are recognized in the Condensed Statements of Operations as research and development expense.

We recognized revenue associated with the KKC Commercialization Agreement for the periods presented (in thousands):

	Three Months Ended September 30,	
	2022	2021
Revenue	$ 8,730	$ 7,757
Timing of Revenue Recognition:		
Services performed over time	$ 8,359	$ 7,185
Pass through services at a point in time	371	572
	$ 8,730	$ 7,757

Contract Balances

Accounts receivable are included in “Prepaid expenses and other current assets”, and contract liabilities are included in “Deferred revenue" and "Deferred revenue, long-term” on our Condensed Balance Sheets. The following table presents changes in

accounts receivable, unbilled receivables and contract liabilities accounted for under Topic 606 for the periods presented (in thousands):

	Three Months Ended September 30,	
	2022	2021
Accounts receivable		
Accounts receivable, beginning of period	$ —	$ —
Amounts billed	10,044	27,638
Payments received	(10,044)	(17,638)
Accounts receivable, end of period	$ —	$ 10,000
Unbilled receivables		
Unbilled receivables, beginning of period	$ 10,044	$ 7,582
Billable amounts	7,758	28,176
Amounts billed	(10,044)	(27,638)
Unbilled receivables, end of period	$ 7,758	$ 8,120
Contract liabilities		
Contract liabilities, beginning of period	$ 30,900	$ 14,677
Payments received	—	20,000
Revenue recognized	(971)	417
Contract liabilities, end of period	$ 29,929	$ 35,094

The timing of revenue recognition, invoicing and cash collections results in billed accounts receivable and unbilled receivables and deferred revenue (contract liabilities). We invoice our customers in accordance with agreed-upon contractual terms, typically at periodic intervals or upon achievement of contractual milestones. Invoicing may occur subsequent to revenue recognition, resulting in unbilled receivables. We may receive advance payments from our customers before revenue is recognized, resulting in contract liabilities. The unbilled receivables and deferred revenue reported on the Condensed Balance Sheets relate to the KKC Commercialization Agreement.

As of September 30, 2022 and June 30, 2022, we had $94.5 million and $95.4 million, respectively, of deferred revenue associated with the KKC Commercialization Agreement, of which $64.5 million relates to the U.S. license which is a unit of account under the scope of ASC Topic 808, *Collaborative Arrangements* ("Topic 808") and is not a performance obligation under Topic 606. The remaining balance of deferred revenue as of September 30, 2022 and June 30, 2022 of $29.9 million and $30.9 million, respectively, relates to the development services performance obligations which are under the scope of Topic 606.

Our contract liabilities accounted for under Topic 606 relate to the amount of initial upfront consideration that was allocated to the development services performance obligations. Contract liabilities are recognized over the duration of the performance obligations based on the costs incurred relative to total expected costs.

Revenues from Collaborators

At contract inception, we assess whether the collaboration arrangements are within the scope of Topic 808 to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed based on the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of Topic 808 that contain multiple units of account, we first determine which units of account within the arrangement are within the scope of Topic 808 and which elements are within the scope of Topic 606. For units of account within collaboration arrangements that are accounted for pursuant to Topic 808, an appropriate recognition method is determined and applied consistently, by analogy to authoritative accounting literature. For elements of collaboration arrangements that are accounted for pursuant to Topic 606, we recognize revenue as discussed above. Consideration received that does not meet the requirements to satisfy Topic 606 revenue recognition criteria is recorded as deferred revenue in the accompanying Condensed Balance Sheets, classified as either short-term or long-term deferred revenue based on our best estimate of when such amounts will be recognized.

Research and Development Costs

Research and development costs are expensed as incurred and include costs paid to third-party contractors to perform research, conduct clinical trials and develop and manufacture drug materials. Clinical trial costs, including costs associated with third-party contractors, are a significant component of research and development expenses. We expense research and development costs based on work performed. In determining the amount to expense, management relies on estimates of total costs based on contract components

completed, the enrollment of subjects, the completion of trials, and other events. Costs incurred related to the purchase or licensing of in-process research and development for early-stage products or products that are not commercially viable and ready for use, or have no alternative future use, are charged to expense in the period incurred.

Leases

We account for our leases under ASC Topic 842, *Leases* (“Topic 842”). Leases which are identified within the scope of Topic 842 and which have a term greater than one year are recognized on our Condensed Balance Sheets as right-of-use ("ROU") assets and lease liabilities. Operating lease liabilities and their corresponding ROU assets are recorded based on the present value of lease payments over the expected remaining lease term. The lease term includes any renewal options and termination options that we are reasonably certain to exercise. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, we use our incremental borrowing rate. The incremental borrowing rate is determined based on the rate of interest that we would pay to borrow on a collateralized basis an amount equal to the lease payments for a similar term and in a similar economic environment. The interest rate implicit in lease contracts to calculate the present value is typically not readily determinable. As such, significant management judgment is required to estimate the incremental borrowing rate.

Rent expense for operating leases is recognized on a straight-line basis over the lease term based on the total lease payments. We have elected the practical expedient to not separate lease and non-lease components for our real estate leases. Our non-lease components are primarily related to property maintenance, which varies based on future outcomes, and thus is recognized in rent expense when incurred.

Share-Based Compensation

Share-based compensation expense stock options and restricted stock units ("RSUs") granted to employees and directors is recognized in the Condensed Statements of Operations based on estimated amounts. The cost of stock options is measured at the grant date, based on the estimated fair value of the stock option using the Black-Scholes valuation model, which incorporates various assumptions, including expected volatility, risk-free interest rate, the expected term of the award and the dividend yield on the underlying stock. Expected volatility is calculated based on the historical volatility of our stock over the expected option life and other appropriate factors. The expected option term is computed using the "simplified" method as permitted under the provisions of ASC Topic 718, *Compensation - Stock Compensation*. We use the simplified method to calculate the expected term of stock options and similar instruments, as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. Risk-free interest rates are calculated based on continuously compounded risk-free rates for the appropriate term. The dividend yield is assumed to be zero as we have never paid or declared any cash dividends and do not intend to do so in the foreseeable future. For RSUs, we estimate the grant date fair value using our closing stock price on the date of grant. The estimated fair value of stock options and RSUs is amortized on a straight-line basis over the requisite service period, adjusted for actual forfeitures at the time they occur. The requisite service period is generally the time over which our share-based awards vest.

Income Taxes

Our income tax expense consists of current and deferred income tax expense or benefit. Current income tax expense or benefit is the amount of income taxes expected to be payable or refundable for the current year. A deferred income tax asset or liability is recognized for the future tax consequences attributable to tax credits and loss carryforwards and to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. As of September 30, 2022, we have established a valuation allowance to fully reserve our net deferred tax assets. Tax rate changes are reflected in income during the period such changes are enacted. Changes in our ownership may limit the amount of net operating loss carryforwards that can be utilized in the future to offset taxable income.

There have been no material changes in our unrecognized tax benefits since June 30, 2022, and, as such, the disclosures included in our 2022 Annual Report continue to be relevant for the three months ended September 30, 2022.

Recent Accounting Pronouncement

In June 2016, the Financial Accounting Standards Board issued Accounting Standards Update 2016-13, *Financial Instruments–Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), as amended. The amendments in ASU 2016-13 require, among other things, financial assets measured at amortized cost basis to be presented at the net amount expected to be collected as compared to previous U.S. GAAP which delayed recognition until it was probable a loss had been incurred. The amendments in ASU 2016-13 are effective for fiscal years beginning after December 15, 2022, including interim

periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact that adoption of ASU 2016-13 will have on our financial statements and related disclosures.

Note 2. Fair Value Measurements

The carrying amounts of financial instruments such as cash equivalents, short-term investments and accounts payable approximate the related fair values due to the short-term maturities of these instruments. We invest our excess cash in financial instruments which are readily convertible into cash, such as money market funds and U.S. government securities. Cash equivalents and short-term investments are measured at fair value on a recurring basis and are classified as Level 1 as defined by the fair value hierarchy.

In May 2018, we issued warrants in connection with our private placement of shares of common stock. Pursuant to the terms of the warrants, we could be required to settle the warrants in cash in the event of an acquisition of the Company and, as a result, the warrants are required to be measured at fair value and reported as a liability in the Condensed Balance Sheet. We recorded the fair value of the warrants upon issuance using the Black-Scholes valuation model and are required to revalue the warrants at each reporting date with any changes in fair value recorded on our Condensed Statement of Operations. The valuation of the warrants is considered under Level 3 of the fair value hierarchy due to the need to use assumptions in the valuation that are both significant to the fair value measurement and unobservable. Inputs used to determine estimated fair value of the warrant liabilities include the estimated fair value of the underlying stock at the valuation date, the estimated term of the warrants, risk-free interest rates, expected dividends and the expected volatility of the underlying stock. The significant unobservable inputs used in the fair value measurement of the warrant liabilities were the volatility rate and the estimated term of the warrants. Generally, increases (decreases) in the fair value of the underlying stock and estimated term would result in a directionally similar impact to the fair value measurement. The change in the fair value of the Level 3 warrant liability is reflected in the Condensed Statements of Operations for the three months ended September 30, 2022 and 2021, respectively.

To calculate the fair value of the warrant liability, the following assumptions were used for the periods presented:

	September 30, 2022	June 30, 2022
Risk-free interest rate	4.0%	2.8%
Expected life (years)	0.6	0.9
Expected volatility	155.7%	139.4%
Dividend yield	0.0%	0.0%
Black-Scholes Fair Value	$ 0.03	$ 0.10

The following table sets forth a summary of changes in the estimated fair value of our Level 3 warrant liability for the three months ended September 30, 2022 and 2021 (in thousands):

	Fair Value of Warrants Using Significant Unobservable Inputs (Level 3)	
	2022	2021
Balance at July 1,	$ 1,603	$ 22,355
Change in estimated fair value of liability classified warrants	(1,117)	(2,587)
Balance at September 30,	$ 486	$ 19,768

Note 3. Short-Term Investments

As of September 30, 2022, and June 30, 2022, our short-term investments consisted of $123.7 million and $137.5 million, respectively, in U.S. government securities. The short-term investments held as of September 30, 2022 and June 30, 2022 had maturity dates of less than one year, are considered to be “held to maturity” and are carried at amortized cost. As of September 30, 2022, and June 30, 2022, the gross holding gains and losses were immaterial.

Note 4. License Agreements

KKC License, Development and Commercialization Agreement

In April 2020, we entered into the KKC Commercialization Agreement under which we granted to KKC a co-exclusive, sublicensable, payment-bearing license under certain patents and know-how controlled by us to develop and commercialize zandelisib and any pharmaceutical product containing zandelisib for all human indications in the U.S. (the "U.S. License"), and an exclusive (subject to certain retained rights to perform obligations under the KKC Commercialization Agreement), sublicensable,

payment-bearing, license under certain patents and know-how controlled by us to develop and commercialize zandelisib and any pharmaceutical product containing zandelisib for all human indications in countries outside of the U.S. (the “Ex-U.S." and the “Ex-U.S. License”). KKC granted to us a co-exclusive, sublicensable, license under certain patents and know-how controlled by KKC to develop and commercialize zandelisib for all human indications in the U.S., and a co-exclusive, sublicensable, royalty-free, fully paid license under certain patents and know-how controlled by KKC to perform our obligations in the Ex-U.S. under the KKC Commercialization Agreement. KKC paid us an initial payment of $100.0 million. Additionally, we may earn up to approximately $582.5 million in potential development, regulatory and commercialization milestone payments, plus royalties on net sales of zandelisib in the Ex-U.S., which are tiered beginning in the teens.

KKC will be responsible for the development and commercialization of zandelisib in the Ex-U.S. and, subject to certain exceptions, will be solely responsible for all costs related thereto. We will co-develop and co-promote zandelisib with KKC in the U.S., with the Company recording all revenue from U.S. sales. We will share U.S. profits and costs (including development costs) on a 50-50 basis with KKC. We will also provide to KKC certain drug supplies necessary for the development and commercialization of zandelisib in the Ex-U.S., with the understanding that KKC will assume responsibility for manufacturing for the Ex-U.S. as soon as practicable.

We assessed the KKC Commercialization Agreement in accordance with Topic 808 and Topic 606 and determined that our obligations comprise the U.S. License, the Ex-U.S. License, and development services (the “Development Services”). We determined that the KKC Commercialization Agreement is a collaborative arrangement in accordance with Topic 808 that contains multiple units of account, as we and KKC are both active participants in the development and commercialization activities and are exposed to significant risks and rewards that are dependent on commercial success of the activities of the arrangement. The U.S. License is a unit of account under the scope of Topic 808 and is not a deliverable under Topic 606, while the Ex-U.S. License and Development Services performance obligations are under the scope of Topic 606.

As of September 30, 2022, we updated our assessment of the total transaction price from the KKC Commercialization Agreement to be $364.5 million, comprised of the upfront payment of $100.0 million, milestone payments of $20.0 million, estimated development cost-sharing of $239.3 million, and deferred revenue of $5.2 million. As of September 30, 2022, the updated assessment reflects an increase in estimated variable consideration related to development cost sharing of $4.4 million from June 30, 2022. We increased our estimate primarily as a result of further visibility into total expected costs for these development estimates. Any variable consideration related to sales-based royalties and commercial milestones related to licenses of intellectual property will be determined when the sale or usage occurs, and is therefore excluded from the transaction price. In addition, we are eligible to receive future development and regulatory milestones upon the achievement of certain criteria; however, these amounts are excluded from variable consideration as the risk of significant revenue reversal will only be resolved depending on future research and development and/or regulatory approval outcomes. We re-evaluate the estimated variable consideration included in the transaction price and any related constraints at the end of each reporting period.

We allocated the transaction price of the Ex-U.S. License and Development Services performance obligations to each unit of account. Variable consideration that relates specifically to our efforts to satisfy specific performance obligations are allocated entirely to those performance obligations. Other components of the transaction price are allocated based on the relative stand-alone selling price, over which management has applied significant judgment. We developed the estimated stand-alone selling price for the licenses using the risk-adjusted net present values of estimated cash flows, and the estimated stand-alone selling price of the development services performance obligations by estimating costs to be incurred, and an appropriate margin, using an income approach.

We determined that control of the U.S. License and Ex-U.S. License were transferred to KKC during the year ended June 30, 2020, and recognized revenue of $21.0 million related to the Ex-U.S. License. The $64.5 million transaction price allocated to the U.S. License obligation accounted for under Topic 808 is included as non-current deferred revenue and will begin to be recognized upon future commercialization as non-ASC 606 revenue. As of September 30, 2022 and June 30, 2022, we have deferred revenue of $29.9 million and $30.9 million, respectively, related to the transaction price allocated to the Development Services performance obligations and are recognizing this revenue based on the proportional performance of these development activities, which we expect to recognize through fiscal year 2030.

Presage License Agreement

In September 2017, we entered into a license agreement with Presage Biosciences, Inc. (“Presage”). Under the terms of such license agreement (the “Presage License Agreement”), Presage granted to us exclusive worldwide rights to develop, manufacture and commercialize voruciclib, a clinical-stage, oral and selective CDK inhibitor, and related compounds. In exchange, we paid $2.9 million. With respect to the first indication, an incremental $2.0 million payment, due upon dosing of the first subject in the first registration trial, will be owed to Presage, for total payments of $4.9 million prior to receipt of marketing approval of the first indication in the U.S., E.U. or Japan. Additional potential payments of up to $179 million will be due upon the achievement of certain development, regulatory and commercial milestones. We will also pay mid-single-digit tiered royalties on the net sales of any product successfully developed. As an alternative to milestone and royalty payments related to countries in which we sublicense product

rights, we will pay to Presage a tiered percent (which decreases as product development progresses) of amounts received from such sublicensees.

Note 5. BeiGene Collaboration

In October 2018, we entered into a clinical collaboration with BeiGene, Ltd. ("BeiGene") to evaluate the safety and efficacy of zandelisib in combination with BeiGene's zanubrutinib (marketed as Brukinsa®), an inhibitor of Bruton's tyrosine kinase, for the treatment of patients with B-cell malignancies. Under the terms of the clinical collaboration agreement, we amended our ongoing Phase 1b trial to include evaluation of zandelisib in combination with zanubrutinib in patients with B-cell malignancies. Study costs are being shared equally by the parties, and we agreed to supply zandelisib and BeiGene agreed to supply zanubrutinib. We record the costs reimbursed by BeiGene as a reduction of our research and development expenses. We retained full commercial rights for zandelisib and BeiGene retained full commercial rights for zanubrutinib.

Note 6. Net Loss Per Share

Basic and diluted net loss per share are computed using the weighted average number of shares of common stock outstanding during the period, less any shares subject to repurchase or forfeiture. There were no shares of common stock subject to repurchase or forfeiture for the three months ended September 30, 2022 and 2021. Diluted net loss per share is computed based on the sum of the weighted average number of common shares and potentially dilutive common shares outstanding during the period.

The following table presents the calculation of net loss used to calculate basic loss and diluted loss per share (in thousands):

	Three Months Ended September 30,	
	2022	2021
Net loss – basic	$ (16,624)	$ (17,510)
Change in fair value of warrant liability	—	(2,587)
Net loss – diluted	$ (16,624)	$ (20,097)

Share used in calculating net loss per share was determined as follows (in thousands):

	Three Months Ended September 30,	
	2022	2021
Weighted average shares used in calculating basic net loss per share	133,255	112,677
Effect of potentially dilutive common shares from equity awards and liability-classified warrants	—	1,240
Weighted average shares used in calculating diluted net loss per share	133,255	113,917

Our potentially dilutive shares, which include outstanding stock options, restricted stock units and warrants, are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The following table presents weighted average potentially dilutive shares that have been excluded from the calculation of net loss per share because of their anti-dilutive effect (in thousands):

	Three Months Ended September 30,	
	2022	2021
Stock options	27,760	20,882
Warrants	16,059	—
Restricted stock units	10	259
Total anti-dilutive shares	43,829	21,141

Note 7. Commitments and Contingencies

We have contracted with various consultants and third parties to assist us in pre-clinical research and development and clinical trials work for our leading drug compounds. The contracts are terminable at any time, but obligate us to reimburse the providers for any time or costs incurred through the date of termination. We also have employment agreements with certain of our current

employees that provide for severance payments and accelerated vesting for share-based awards if their employment is terminated under specified circumstances.

Presage License Agreement

As discussed in Note 4, we are party to a license agreement with Presage under which we may be required to make future payments upon the achievement of certain development, regulatory and commercial milestones, as well as potential future royalties based upon net sales. As of September 30, 2022, we had not accrued any amounts for potential future payments as achievement of the milestones had not been met.

COVID-19

As a result of the ongoing COVID-19 pandemic, various public health orders and guidance measures have been implemented across much of the U.S., and across the globe, including in the locations of our office, clinical trial sites, key vendors and partners. Despite the relaxation of many governmental orders earlier this year, COVID-19 still impacts the normal conduct of business. While we continue to enroll and dose patients in our clinical trials, our clinical development program timelines may continue to be subject to potential negative impacts from the ongoing pandemic in the U.S. and globally.

We have experienced enrollment delays and suspensions, patient withdrawals, postponement of planned clinical or preclinical studies, redirection of site resources from studies, and study deviations or noncompliance. We may also need to maintain or implement study modifications, suspensions, or terminations, the introduction of additional remote study procedures and modified informed consent procedures, study site changes, direct delivery of investigational products to patient homes or alternative sites, which may require state licensing, and changes or delays in site monitoring. The foregoing may require that we consult with relevant review and ethics committees, Institutional Review Boards and the FDA. The foregoing may also impact the integrity of our study data. The ongoing COVID-19 pandemic may further increase the need for clinical trial patient monitoring and regulatory reporting of adverse effects, and may delay regulatory authority meetings, inspections, or the regulatory review of marketing or investigational applications or submissions.

Not only might the ongoing COVID-19 pandemic impact the conduct of our clinical trials, but it may also impact our ability to procure the necessary supply of our investigational drug products, as well as any ancillary supplies necessary for the conduct of our studies. Third party manufacturers may also need to implement measures and changes, or deviate from typical manufacturing requirements that may otherwise adversely impact our product candidates.

Nasdaq Bid Price Letter

On May 9, 2022, we received a letter from Nasdaq indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued listing on the Nasdaq Capital Market.

In accordance with Nasdaq listing rules, we were provided an initial period of 180 calendar days, or until November 7, 2022, to regain compliance. On November 10, 2022, we received a letter from Nasdaq that we have been granted an additional 180 calendar day compliance period and that our compliance period now ends on May 8, 2023. The letter states that Nasdaq will provide written notification that we have achieved compliance with its rules if, at any time before May 8, 2023, the bid price of our common stock closes at $1.00 per share or more for a minimum of ten consecutive business days. The Nasdaq letter had no immediate effect on the listing or trading of our common stock and our common stock continued to trade on the Nasdaq Capital Market.

We have not regained compliance with Nasdaq listing rules as of the date these financial statements were issued.

Note 8. Leases

In July 2020, we entered into a lease agreement (the "Initial Lease Agreement") for approximately 32,800 square feet of office space in San Diego, California. The Initial Lease Agreement was extended to November 30, 2029, in accordance with the amended lease agreement that we entered into in January 2022 (the "Amended Lease Agreement"). The Amended Lease Agreement, which began on July 1, 2022 and expires on November 30, 2029, provides for an additional 12,300 square feet of office space adjacent to our current office in San Diego, for a total of approximately 45,100 square feet of office space. The Initial Lease Agreement and Amended Lease Agreement are collectively referred to as the "Lease Agreements" and have been accounted for as operating leases.

The following is a schedule of the future minimum lease payments under the Lease Agreements, reconciled to the operating lease liability, as of September 30, 2022 (in thousands):

	September 30, 2022
Remainder of fiscal year ending June 30, 2023	$ 1,699
Years ending June 30,	
2024	2,335
2025	1,913
2026	2,477
2027	2,551
2028	2,715
Thereafter	4,386
Total lease payments	18,076
Less: Present value discount	(4,394)
Total operating lease liability	$ 13,682
Balance Sheet Classification – Operating Leases	
Operating lease liability	$ 1,301
Operating lease liability, long-term	12,381
Total operating lease liability	$ 13,682
Other Balance Sheet Information – Operating Leases	
Weighted average remaining lease term (in years)	7.4
Weighted average discount rate	7.50%

The Lease Agreements include rent escalations over the lease terms. In addition, the Lease Agreements include renewal options which were not included in the determination of the ROU assets or lease liabilities as the renewals were not reasonably certain at the inception of the Lease Agreements. Under the terms of the Lease Agreements, we are subject to charges for variable non-lease components (e.g., common area maintenance, maintenance, etc.) that are not included in the ROU assets and operating lease liabilities and are recorded as an expense in the period incurred.

Upon taking control of the additional 12,300 square feet of office space adjacent to our current office in San Diego on July 1, 2022, we recognized operating lease ROU assets obtained in exchange for operating lease liabilities of $4.3 million. As of September 30, 2022 and June 30, 2022, total operating lease ROU assets were $13.1 million and $9.1 million, respectively.

Total operating lease expense and cash paid under the Lease Agreements was approximately $0.6 million and $0.4 million for the three months ended September 30, 2022 and 2021, respectively.

Note 9. Stockholders' Equity

Equity Transactions

Shelf Registration Statement

We have a shelf registration statement that permits us to sell, from time to time, up to $200.0 million of common stock, preferred stock and warrants. The shelf registration was filed and declared effective in May 2020, and carried forward approximately $107.5 million of unsold securities registered under the prior shelf registration statement. As of September 30, 2022, there was $123.4 million aggregate value of securities available under the shelf registration statement, including $60.0 million remaining available under the 2020 ATM Sales Agreement described below.

At-The-Market Equity Offering

On November 10, 2020, we entered into an At-The-Market Equity Offering Sales Agreement (the "2020 ATM Sales Agreement"), pursuant to which we may sell an aggregate of up to $60.0 million of our common stock pursuant to the shelf registration statement. As of September 30, 2022, there was $60.0 million remaining available under the 2020 ATM Sales Agreement.

Warrants

As of September 30, 2022, we have outstanding warrants to purchase 16,058,985 shares of our common stock. The warrants are fully vested, exercisable at a price of $2.54 per share and expire in May 2023. Pursuant to the terms of the warrants, we could be required to settle the warrants in cash in the event of an acquisition of the Company and, as a result, the warrants are required to be measured at fair value and reported as a liability in the Condensed Balance Sheets. The warrants were revalued as of September 30,

2022 and June 30, 2022 at $0.5 million and $1.6 million, respectively. The change in fair value of $1.1 million was recorded on the Condensed Statement of Operations for the three months ended September 30, 2022.

Note 10. Share-based Compensation

We use equity-based compensation programs to provide long-term performance incentives for our employees. These incentives consist primarily of stock options and RSUs. In December 2008, we adopted the MEI Pharma, Inc. 2008 Stock Omnibus Equity Compensation Plan (“Omnibus Plan”), as amended and restated from time-to-time, under which 29,014,794 shares of common stock are authorized for issuance. The Omnibus Plan provides for the grant of options and/or other stock-based or stock-denominated awards to our non-employee directors, officers, and employees. As of September 30, 2022, there were 1,832,393 shares available for future grant under the Omnibus Plan.

In May 2021, we adopted the 2021 Inducement Plan ("Inducement Plan"), under which 2,500,000 shares of common stock are authorized for issuance. The Inducement Plan is intended to assist us in attracting and retaining selected individuals to serve as employees who are expected to contribute to our success, by providing an inducement for such individuals to enter into employment with us, and to achieve long-term objectives that will benefit stockholders of the Company. As of September 30, 2022, there were 17,000 shares available for future grant under the Inducement Plan.

Total share-based compensation expense for all stock awards consisted of the following for the periods presented (in thousands):

	Three Months Ended September 30,	
	2022	2021
Research and development	$ 649	$ 622
General and administrative	910	1,917
Total share-based compensation	$ 1,559	$ 2,539

Stock Options

Stock options granted to employees vest 25% one year from the date of grant and ratably each month thereafter for a period of 36 months and expire ten years from the date of grant. Stock options granted to directors vest ratably each month for a period of 12 months from the date of grant and expire ten years from the date of grant. Of the total options outstanding of 27,382,279 as of September 30, 2022, 24,899,279 were granted under the Omnibus Plan and 2,483,000 were granted under the Inducement Plan.

A summary of our stock option activity and related data follows:

	Number of Options	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at June 30, 2022	19,934,007	$ 2.85		
Granted	9,028,410	0.54		
Forfeited/Cancelled	(1,580,138)	2.28		
Outstanding at September 30, 2022	27,382,279	2.12	8.0	$ —
Vested and exercisable at September 30, 2022	11,829,885	2.93	6.3	$ —

As of September 30, 2022, the aggregate intrinsic value of outstanding options was calculated as the difference between the exercise price of the underlying options and the closing price of our common stock of $0.39 on that date.

Unrecognized compensation expense related to non-vested stock options totaled $7.6 million as of September 30, 2022. Such compensation expense is expected to be recognized over a weighted average period of 1.7 years. As of September 30, 2022, we expect all options to vest.

We use the Black-Scholes valuation model to estimate the grant date fair value of stock options. To calculate these fair values, the following weighted average assumptions were used for the periods presented:

	Three Months Ended September 30,	
	2022	2021
Risk-free interest rate	2.8%	1.1%
Expected life (years)	6.0	6.1
Expected volatility	84.1%	67.8%
Dividend yield	0.0%	0.0%
Weighted average grant date fair value	$ 0.39	$ 1.78

Restricted Stock Units

A summary of our RSU activity and related data for the three months ended September 30, 2022 was as follows:

	Number of RSUs	Weighted Average Grant Date Fair Value
Non-vested at June 30, 2022	184,400	$ 3.49
Vested	(184,400)	$ 3.49
Non-vested at September 30, 2022	—	$ —

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

This Quarterly Report on Form 10-Q ("Quarterly Report") includes 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 facts contained in this Quarterly Report, including statements regarding the future financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," and similar expressions, as they relate to us, are intended to identify forward-looking statements. We have based these forward-looking statements largely on current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, without limitation, those described in "Risk Factors" in our 2022 Annual Report on Form 10-K ("2022 Annual Report"), as filed with the Securities and Exchange Commission on September 8, 2022. Set forth below is a summary of the principal risks we face:

- We have identified a material weakness in our internal control over financial reporting and determined that our disclosure controls and procedures were ineffective as of June 30, 2021, as a result of the restatement of our financial statements as of and for the years ended June 30, 2021 and 2020. Relevant unaudited interim financial information for each of the quarterly periods ended September 30, 2020 through December 31, 2021 have also been restated. In the future, we may identify additional material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting or adequate disclosure controls and procedures, which may result in material errors of our financial statements or cause us to fail to meet our periodic reporting obligations;
- We will need substantial additional funds to progress the clinical trial programs for our drug candidates, to commercialize our drug candidates, and to develop new compounds. The actual amount of funds we will need will be determined by a number of factors, some of which are beyond our control;
- We are a late-stage clinical research and development stage company and are likely to incur operating losses for the foreseeable future;
- The results of pre-clinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates may not have favorable results in later studies or trials;
- The ongoing novel coronavirus disease, or COVID-19, pandemic or other pandemic, epidemic or outbreak of an infectious disease may materially and adversely impact our business, including our preclinical studies and clinical trials;
- There is substantial uncertainty regarding the impact of rising inflation and the increase in interest rates as a result, the ongoing COVID-19 pandemic, and the ongoing conflict in the Ukraine on our business, industry, global economic conditions and government policy;
- Changes in drug candidate manufacturing or formulation may result in additional costs or delay;
- If KKC or other parties with whom we collaborate on the development and commercialization of our drug candidates do not satisfy their obligations, do not otherwise pursue development or commercialization of our drug candidates or if they terminate their agreements with us, we may not be able to develop or commercialize our drug candidates;
- We are subject to significant obligations to Presage in connection with our license of voruciclib, and we may become subject to significant obligations in connection with future licenses we obtain, which could adversely affect the overall profitability of any products we may seek to commercialize, and such licenses of drug candidates, the development and commercialization for which we are solely responsible, may never become profitable;
- Our business strategy may include entry into additional collaborative or license agreements. We may not be able to enter into collaborative or license agreements or may not be able to negotiate commercially acceptable terms for these agreements;
- Final approval by regulatory authorities of our drug candidates for commercial use may be delayed, limited or prevented, any of which would adversely affect our ability to generate operating revenues;
- The FDA may determine that our drug candidates have undesirable side effects that could delay or prevent their regulatory approval or commercialization;
- The FDA has specifically expressed concerns related to the risk benefit analysis regarding the use of approved PI3Kδ inhibitors to treat indolent lymphomas which may adversely affect the approval and commercial viability of zandelisib;
- If we experience delays or difficulties in the enrollment of patients in clinical trials, our completion of clinical trials and receipt of necessary regulatory approvals could be delayed or prevented;
- Changes in funding for the FDA and other government agencies or future government shutdowns could cause delays in the submission and regulatory review of marketing applications, which could negatively impact our business or prospects;
- Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing our products internationally;

- Any designation granted by the FDA for any of our product candidates may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval. We may also not be able to obtain or maintain any such designation;
- Any orphan drug designations we receive may not confer marketing exclusivity or other benefits;
- Even if we or our licensees receive regulatory approval to commercialize our drug candidates, our ability to generate revenues from any resulting products will be subject to a variety of risks, many of which are out of our control;
- If any products we develop become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, our ability to successfully commercialize our products will be impaired;
- Our drug candidates are subject to ongoing government regulation both before and after regulatory approval;
- We may not be able to establish the contractual arrangements necessary to develop, market and distribute our drug candidates;
- Our commercial opportunity will be reduced or eliminated if competitors develop and market products that are more effective, have fewer side effects or are less expensive than our drug candidates;
- Our product candidates may face competition sooner than anticipated;
- We rely on third parties to conduct our clinical trials and pre-clinical studies. If those parties do not successfully carry out their contractual duties or meet expected deadlines, our drug candidates may not advance in a timely manner or at all;
- We will depend on third party suppliers and contract manufacturers for the manufacturing of our drug candidates and have no direct control over the cost of manufacturing our drug candidates. Increases in the cost of manufacturing our drug candidates would increase our costs of conducting clinical trials and could adversely affect our future profitability;
- We rely on acquisitions or licenses from third parties to expand our pipeline of drug candidates;
- Our commercial success is dependent, in part, on obtaining and maintaining patent protection and preserving trade secrets, which cannot be guaranteed;
- Claims by other companies that we infringe on their proprietary technology may result in liability for damages or stop our development and commercialization efforts;
- We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property;
- We may be subject to substantial costs stemming from our defense against third-party intellectual property infringement claims;
- We face a risk of product liability claims and claims may exceed our insurance limits;
- Our employees, independent contractors, consultants, commercial partners, principal investigators, or CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business;
- Our business and operations would suffer in the event of system failures;
- Our efforts will be seriously jeopardized if we are unable to retain and attract key employees;
- Negative U.S. and global economic conditions may pose challenges to our business strategy, which relies on funding from the financial markets or collaborators;
- Laws, rules and regulations relating to public companies may be costly and impact our ability to attract and retain directors and executive officers;
- We are not in compliance with the Nasdaq continued listing requirements. If we are unable to comply with the continued listing requirements of the Nasdaq Capital Market, our common stock could be delisted, which could affect our common stock's market price and liquidity and reduce our ability to raise capital;
- Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer;
- If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business;
- We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster;
- Limitations on the deductibility of net operating losses could adversely affect our business and financial condition;
- The trading price of the shares of our common stock has been and may continue to be highly volatile and could decline in value and we may incur significant costs from class action litigation;
- Future sales of our common stock, including common stock issued upon exercise of outstanding warrants or options, may depress the market price of our common stock and cause stockholders to experience dilution;
- Because we do not intend to pay, and have not paid, any cash dividends on our shares of common stock, our stockholders will not be able to receive a return on their shares unless the value of our common stock appreciates and they sell their shares;
- We will have broad discretion over the use of the net proceeds from any exercise of outstanding warrants and options;

- We are authorized to issue blank check preferred stock, which could adversely affect the holders of our common stock;
- Anti-takeover provisions contained in our amended and restated certificate of incorporation and third amended and restated bylaws, as well as provisions of Delaware law, could impair a takeover attempt;
- Our third amended and restated bylaws require, to the fullest extent permitted by law, that derivative actions brought in our name, actions against our directors, officers, other employees or stockholders for breach of fiduciary duty and other similar actions may be brought only in the Court of Chancery in the State of Delaware and, if brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder's counsel, which may have the effect of discouraging lawsuits against our directors, officers, other employees or stockholders; and
- Our executive officers and directors may sell shares of their stock, and these sales could adversely affect our stock price.

These risks are not exhaustive. Other sections of this report and our other filings with the Securities and Exchange Commission ("SEC") include additional factors which could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. There is substantial uncertainty regarding the impact of the ongoing COVID-19 pandemic on our business, industry, global economic conditions and government policy. New risk factors emerge from time to time and it is not possible for us to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Past performance may not be an indicator of future results. The following discussion is qualified in its entirety by, and should be read in conjunction with, the more detailed information set forth in the financial statements and the notes thereto appearing elsewhere in this Quarterly Report and the audited financial statements and notes thereto included in our 2022 Annual Report, as filed with the SEC. Operating results are not necessarily indicative of results that may occur in future periods.

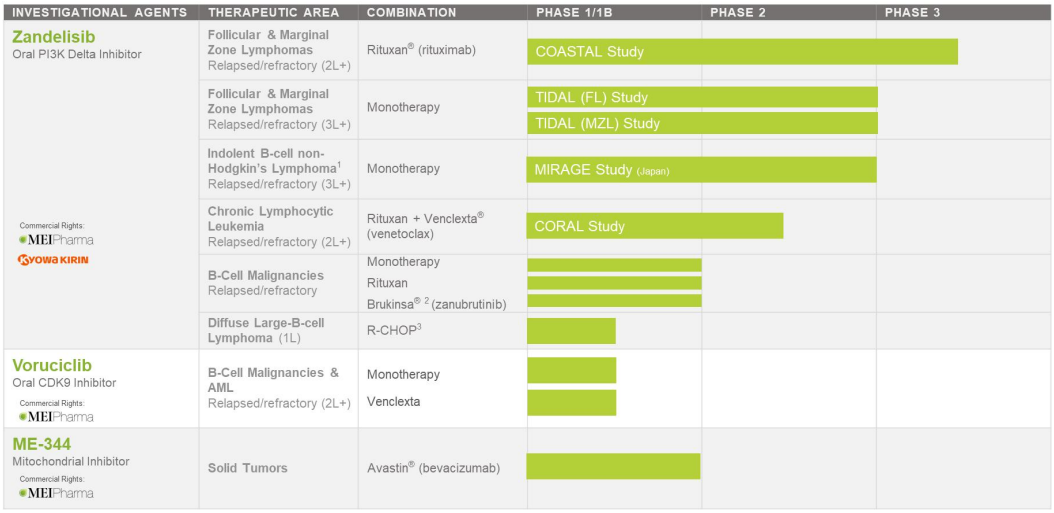
Overview

We are a late-stage pharmaceutical company committed to the development and commercialization of novel cancer therapies intended to improve outcomes for patients. Our portfolio of drug candidates includes three clinical-stage assets, including zandelisib (f/k/a ME-401), currently in multiple ongoing clinical studies intended to support marketing applications with the U.S. Food and Drug Administration ("FDA") and other regulatory authorities globally. Our approach to building our pipeline is to license or acquire promising cancer agents and build value in programs through development, commercialization and strategic partnerships, as appropriate. Our common stock is listed on the Nasdaq Capital Market under the symbol "MEIP."

Clinical Development Programs

We build our pipeline by licensing or acquiring promising cancer agents and creating value in programs through development, commercialization and strategic partnerships, as appropriate. Our objective is to leverage the mechanisms and properties of our pipeline drug candidates to optimize the balance between efficacy and tolerability to meet the needs of patients with cancer. Our drug candidate pipeline includes:

- Zandelisib, an oral phosphatidylinositol 3-kinase delta ("PI3Kδ") inhibitor;
- Voruciclib, an oral cyclin-dependent kinase 9 ("CDK9") inhibitor; and
- ME-344, a mitochondrial inhibitor targeting the oxidative phosphorylation ("OXPHOS") complex.



1. Study evaluating patients with Indolent B-cell non-Hodgkin's lymphoma (iB-NHL) without small lymphocytic lymphoma (SLL), lymphoplasmacytic lymphoma (LPL), and Waldenström's macroglobulinemia (WM) conducted by Kyowa Kirin.
2. Study arm initiated under clinical collaboration with BeiGene, Ltd.
3. Investigator-initiated trial.

Zandelisib: PI3Kδ Inhibitor in Multiple Trials Intended to Support Marketing Approvals in Relapsed or Refractory Follicular and Marginal Zone Lymphomas

Zandelisib is an oral, once-daily, selective PI3Kδ inhibitor in clinical development for the treatment of B-cell malignancies. Registrational and combination clinical studies are focused on the time-limited, intermittent dosing ("ID"), of zandelisib in patients with relapsed or refractory (“r/r”) indolent non-Hodgkin lymphomas and chronic lymphocytic leukemia ("CLL"). “Time-limited” therapy is treatment which is to be administered for a fixed period of time and not based on an event like disease progression or tolerability to study drug.

In March 2020, the FDA granted zandelisib Fast Track designation for the treatment of adult patients with r/r follicular lymphoma (“FL”) who have received at least two prior systemic therapies. In November 2021, the FDA granted orphan-drug designation to zandelisib for the treatment of follicular lymphoma. In April 2020, we entered into a global license, development and commercialization agreement to further develop and commercialize zandelisib with Kyowa Kirin Co., Ltd. (“KKC”). MEI Pharma and KKC will co-develop and co-promote zandelisib in the U.S., with MEI Pharma recording all revenue from U.S. sales. KKC has exclusive commercialization rights outside of the U.S.

We are conducting multiple ongoing studies evaluating zandelisib. Our studies include TIDAL, a global Phase 2 study evaluating zandelisib as a monotherapy in patients with r/r FL and marginal zone lymphoma (“MZL”) patients who have received at least two prior lines of treatment.

Enrollment in the FL cohort of TIDAL is complete. Data from the TIDAL study as reported at the American Society of Clinical Oncology Annual Meeting 2022 and the European Hematology Association 2022 Hybrid Congress in the cohort of patients with FL, demonstrated an overall response rate of 70.3% in the primary efficacy population of 91 patients as determined by Independent Review Committee assessment; the complete response rate was 35.2%. It was also reported that zandelisib was generally well tolerated in the TIDAL study; with 9.4 months (range: 0.8-24) median duration of follow-up in the total study population of 121 patients with FL, interim data demonstrated a discontinuation rate due to any drug related adverse event of 9.9%. Patients enrolled in the study continue to be followed for safety as well as duration of response.

On March 24, 2022, we reported on the outcome of an end of Phase 2 meeting with the FDA to discuss the TIDAL study. Specifically, the FDA stated that a randomized trial is needed to adequately assess drug efficacy and safety of PI3Kδ inhibitor drug candidates, including zandelisib. Based on this view, the agency discouraged a planned filing based on the single arm Phase 2 TIDAL study data and emphasized that the Company continue efforts with the ongoing, randomized Phase 3 COASTAL study as planned. In addition, while the FDA stated that safety on the 60 mg ID schedule appears reasonable, it recommended continued dose exploration. We will continue to evaluate our existing data, forthcoming dose-response data and any other additional efforts, as appropriate, to ensure we address questions from the FDA concerning the selection of our current zandelisib dose and schedule.

On April 21, 2022, the FDA's Oncology Drugs Advisory Committee ("ODAC") concluded that, to better assess potential safety concerns, companies developing PI3Kδ inhibitors for hematologic malignancies should conduct randomized trials, not single arm studies, to support approval. At a subsequent ODAC meeting on September 23, 2022, the FDA heard an update on the new drug application, for COPIKTRA® (duvelisib), a PI3K inhibitor approved for adult patients with relapsed or refractory CLL or small lymphocytic lymphoma ("SLL") after at least two prior therapies. The committee voted that given the potential detriment to overall survival, as well as concerns related to dose and safety issues with approved PI3Kδ inhibitors, duvelisib did not demonstrate a favorable benefit/risk ratio for patients with r/r CLL.

The FDA has been contemporaneously communicating a broader initiative called Project FrontRunner, replacing its long-standing approach to accelerated approvals generally. In brief, under Project FrontRunner, the FDA communicated its intent to consider support for accelerated approval of cancer drugs based on data from randomized studies, rendering data generated by single arm studies, such as TIDAL, generally insufficient by the FDA to adequately assess risk and benefit, and thus support an accelerated approval marketing authorization. Accordingly, in line with the FDA's recommendation, and Project FrontRunner, and associated regulatory activity relevant approved PI3Kδ inhibitors, we no longer plan to submit an FDA marketing application based on the single arm Phase 2 TIDAL study.

COASTAL, the ongoing Phase 3, randomized study, is evaluating the ID and time-limited therapy of zandelisib in combination with rituximab in patients with r/r FL and MZL who have received at least one prior line of treatment. COASTAL is intended to support marketing applications in the U.S. and globally in r/r FL and MZL patients receiving at least one prior line of treatment.

We are also conducting a multi-arm, open-label, Phase 1b dose finding and expansion trial evaluating zandelisib as a monotherapy and in combination with other therapies in patients with relapsed or refractory B-cell malignancies. Other initiated studies include Phase 1 and Phase 2 studies ("MIRAGE") being conducted by KKC evaluating zandelisib as a monotherapy in patients in Japan with indolent B-cell malignancies, pursuant to our agreement with KKC.

Zandelisib: Potentially Highly Differentiated Pharmaceutical Properties within a Clinically Validated Class of Treatments

The approved PI3Kδ inhibitors have been developed for the treatment of B-cell malignancies. Previous entrants to the class have been challenged by toxicities, modest efficacy and/or inconvenience of administration route. We believe this provides an opportunity for the development of a next-generation candidate with pharmaceutical properties that may realize the therapeutic potential of PI3Kδ inhibition by limiting toxicities and improving upon modest efficacy, which together hinder clinical utility.

The molecular structure and pharmacodynamic characteristics of zandelisib are distinct from the FDA approved PI3Kδ inhibitors. Clinical and preclinical data demonstrate that zandelisib's distinct characteristics include prolonged target binding, preferential cellular accumulation, high volume of distribution throughout the body tissues, and an approximately 28-hour half-life suitable for once daily oral administration. The properties of zandelisib support the evaluation of an ID regimen. The ID regimen consists of daily dosing only in the first seven days of each 28-day dosing cycle. The unique zandelisib ID regimen is hypothesized to allow for the recovery of regulatory T cells, which in turn may lead to fewer and/or less severe immune-related adverse events. This may provide long-term disease control through maintenance therapy, without the need for dose reductions or premature discontinuations. Clinical evaluation of the ID regimen to date has demonstrated the potential to maintain clinical benefit while minimizing immune-related toxicities common to approved PI3Kδ agents, either as a monotherapy or in combination with other therapies.

KKC License, Development and Commercialization Agreement

In April 2020, we entered into a License, Development and Commercialization Agreement (the "KKC Commercialization Agreement") with KKC under which we granted to KKC a co-exclusive, sublicensable, payment-bearing license under certain patents and know-how controlled by us to develop and commercialize zandelisib and any pharmaceutical product containing zandelisib for all human indications in the U.S. (the "U.S. License"), and an exclusive (subject to certain retained rights to perform obligations under the agreement), sublicensable, payment-bearing, license under certain patents and know-how controlled by us to develop and commercialize zandelisib and any pharmaceutical product containing zandelisib for all human indications in countries outside of the U.S. (the "Ex-U.S." and the "Ex-U.S. License"). KKC granted to us a co-exclusive, sublicensable, license under certain patents and know-how controlled by KKC to develop and commercialize zandelisib for all human indications in the U.S., and a co-exclusive, sublicensable, royalty-free, fully paid license under certain patents and know-how controlled by KKC to perform our obligations in the Ex-U.S. under the KKC Commercialization Agreement. The KKC Commercialization Agreement substantially retains and consolidates the terms of the 2018 license agreement with KKC to develop and commercialize zandelisib in Japan.

KKC will be responsible for the development and commercialization of zandelisib in the Ex-U.S. and, subject to certain exceptions, will be solely responsible for all costs related thereto. We will co-develop and co-promote zandelisib with KKC in the U.S., with the Company recording all revenue from U.S. sales. We will share U.S. profits and costs (including development costs) on a 50-50 basis with KKC. We will also provide to KKC certain drug supplies necessary for the development and commercialization of zandelisib in the Ex-U.S. pursuant to supply agreements to be entered into on customary terms, with the understanding that KKC will assume responsibility for manufacturing for the Ex-U.S. as soon as practicable.

Under the terms of the KKC Commercialization Agreement, KKC paid us an initial payment of $100.0 million. Additionally, during the fiscal year ended June 30, 2022, two $10.0 million milestones were received in connection with the initiation of the Phase 3 COASTAL study. We may also earn up to approximately $582.5 million in potential development, regulatory and commercialization milestone payments, plus royalties on net sales of zandelisib in the Ex-U.S., which are tiered beginning in the teens.

Zandelisib Scientific Overview: at the Crossroads of B-cell Signaling Pathways

The PI3K/AKT/mTOR pathway is an important signaling pathway for many cellular functions such as cell survival, cell cycle progression and cellular growth. PI3Ks are a family of enzymes within this pathway that have been shown to play a critical role in the proliferation and survival of certain cancer cells.

There are several isoforms of PI3K that are expressed in different types of cells. The PI3Kδ isoform is at the crossroads of B-cell receptor signaling pathways that are major drivers of survival and proliferation of many B-cell malignancies. Because the δ isoform is often overexpressed in cancer cells of the B-lymphocyte lineage, such as B-cell leukemias and lymphomas, it is understood to be important for survival of these cells. Zandelisib displays high selectivity for the PI3K delta isoform and functions to inhibit its activity.

Clinical Program Overview

We are conducting multiple ongoing studies evaluating zandelisib including TIDAL and COASTAL. Clinical evaluation is focused on ID of zandelisib as part of time-limited therapy.

Additionally, we are conducting a multi-arm, open-label, Phase 1b dose escalation and expansion trial as a monotherapy and in combination with rituximab or zanubrutinib in patients with FL and other B-cell malignancies. Zanubrutinib (marketed as BRUKINSA®), is an inhibitor of Bruton’s tyrosine kinase developed by BeiGene, Ltd. (“BeiGene”). This study arm completed the safety evaluation stage in patients with B-cell malignancies and expanded into disease specific FL and mantle cell lymphoma ("MCL") cohorts. The evaluation of zandelisib in combination with zanubrutinib is conducted under a collaboration established with BeiGene in October 2018, pursuant to which the cost of the combination trial is being equally shared, and each company is supplying its own investigational agent. We retain all commercial rights to zandelisib (subject to the KKC Commercialization Agreement), and BeiGene retains all commercial rights to zanubrutinib.

Ongoing clinical trials also include Phase 1 and Phase 2 studies conducted by KKC evaluating zandelisib as a monotherapy in patients in Japan with indolent B-cell malignancies. The Phase 2 study is intended to support marketing authorization in Japan.

In addition to other planned and ongoing clinical studies sponsored by us, such as the Phase 2 CORAL study evaluating zandelisib in combination with venetoclax plus rituximab in patients with CLL, in which we plan to dose the first patient by the end of calendar year 2022, we also are supporting select investigator-initiated studies, including one being conducted at the Cleveland Clinic evaluating zandelisib combined with standard of care in patients with newly diagnosed diffuse large B-cell lymphoma (“DLBCL”).

All ongoing studies, as well as planned studies, utilize zandelisib’s unique ID regimen intended to optimize zandelisib’s therapeutic profile and also support its potential as a backbone for combination approaches with other modalities in the treatment of B-cell malignancies.

Phase 1b Multi-Arm Trial

In July 2022, results from the Phase 1b study evaluating zandelisib with continuous or ID as monotherapy or in combination with rituximab in patients with relapsed or refractory B-cell malignancy were published in The Lancet Oncology. The manuscript reports on a total of 97 patients, including 31 patients in the dose escalation stage that established 60 mg once daily as the recommended Phase 2 dose. The study evaluated zandelisib in 56 patients as a monotherapy and 41 patients in combination with rituximab. Zandelisib was administered either on a continuous schedule of 60 mg once daily (38 patients) or an ID schedule of 60 mg once daily for the initial two 28-day cycles followed by the ID schedule of 60 mg once daily on days 1-7 starting in Cycle 3 (59 patients).

In the initial monotherapy dose-finding part of the study, no dose-limiting toxicities were observed across the evaluated doses of 60 mg, 120 mg and 180 mg given daily continuously, and anti-tumor activity was similar across doses. With a median duration of treatment of 10.4 months and 15.2 months, in the continuous and ID group respectively, Grade 3 or worse adverse events of special interest occurred less frequently in the ID group than in the continuous dosing group. For example, Grade 3 diarrhea or colitis in 8%

vs 24%, and Grade 3 lung infection or pneumonia occurred in 2% *vs* 16%, of patients in the ID group *vs* the continuous dosing group, respectively. Grade 3 or worse aspartate aminotransferase ("AST") or alanine aminotransferase ("ALT") elevation and rash were uncommon (5% each in each dosing schedule). There was a continued increased risk of Grade 3 diarrhea or colitis in the continuous dosing group, compared with a decreased risk over time in the ID group after switching to the ID. At a median follow-up of 24.9 months in the continuous dosing group and 15.7 months (95% CI 6·5-33·9) in the ID group the cumulative incidence of Grade 3 or worse adverse events of special interest was 45% in the continuous dosing group and 20% in the ID group. ID showed comparable efficacy to continuous dosing. Patients with indolent B-cell malignancies (follicular lymphoma, chronic lymphocytic leukemia or small lymphocytic lymphoma, and marginal zone lymphoma) demonstrated an objective overall response rate of 87%.

In June 2022, updated data from the Phase 1b clinical trial was also featured in a poster presentation at the European Hematology Association 2022. The poster included the report of data of 32 patients with FL administered zandelisib 60 mg on ID regimen from Cycle 1 plus zanubrutinib 80 mg twice daily. The overall response rate in patients treated with zandelisib plus zanubrutinib was 82.1% (23 of 28 patients). The median duration of response was not yet mature in this group of patients, with median drug exposure of 7.1 months. The safety and tolerability of zandelisib plus zanubrutinib was generally well tolerated. One patient in this group had reversible Grade 4 drug rash with eosinophilia and systemic symptoms (DRESS) syndrome. The Phase 1b study also enrolled patients with r/r MCL in an expansion cohort evaluating the combination of zandelisib 60 mg administered on days 1-7 starting Cycle 1 and zanubrutinib administered at 80 mg twice daily.

TIDAL: A Phase 2 Trial Evaluating Zandelisib as a Single-Agent in Follicular and Marginal Zone Lymphoma Patients

TIDAL is an ongoing global Phase 2 trial evaluating the intermittent administration of zandelisib as a monotherapy across two study cohorts: the first study cohort for the treatment of adults with r/r FL and the second study cohort for r/r MZL, in both cases after failure of at least two prior systemic therapies including chemotherapy and an anti-CD20 antibody. The study is evaluating zandelisib administered once daily at 60 mg for two 28-day cycles and then on the ID regimen of once daily dosing for the first seven days of each subsequent 28-day cycle. The primary efficacy endpoint is the rate of objective responses to therapy, and other endpoints include duration of response and tolerability of zandelisib. The primary efficacy population ("PEP") sample size for r/r FL is 91 patients. Total study enrollment in the FL cohort is 121 patients administered zandelisib on the ID regimen after two cycles (56 days) of daily dosing, and also 16 FL patients administered zandelisib once daily continuously, to provide additional safety data. Enrollment of the FL cohort of the TIDAL study is complete. To support and focus enrollment on the Phase 3 COASTAL study, we have closed enrollment of the MZL cohort in the TIDAL study and will follow enrolled MZL patients to assess safety and tolerability as well as response and durability of response.

In November 2021, we first reported data from the TIDAL study, which data was also reported at the American Society of Clinical Oncology Annual Meeting 2022 and the European Hematology Association 2022 Hybrid Congress. The primary endpoint of overall response rates ("ORR") of zandelisib as a single agent in the PEP was 70.3% (64 patients) as assessed by Independent Review Committee; the complete response rate was 35.2% (32 patients). Responses across sub-groups (i.e. response to last treatment, number of prior therapies and POD24) were all greater than 63%. Responses were first observed in the first two cycles of therapy in 87.5% of all responses (56 patients) and 75% of all CRs (24 patients) were observed in the first four cycles. As of the data cutoff date, the data are not sufficiently mature to accurately estimate the final duration of response in the PEP.

With a median follow-up of 9.4 months (range 0.8 to 24 months) in the safety population of 121 patients, 9.9% (12 patients) of patients had discontinued therapy due to any drug-related adverse event. Grade 3 adverse events of special interest ("AESI") were diarrhea in 5% (6 patients), colitis in 1.7% (2 patients), cutaneous rash in 3.3% (4 patients), stomatitis in 2.5% (3 patients), and 0.8% (1 patient) each for AST and ALT elevation, and non-infectious pneumonitis. Grade 3 AESIs primarily (83%, 15 of 18 patients) occurred in Cycles 1-3, with only 3 cases reported on ID in Cycles 4 or more. No Grade 4 or Grade 5 AESI were recorded. Treatment-emergent COVID-19 infections were reported in 8.3% of patients (10), and 8.3% of patients (10) reported other Grade 3 infections. Four COVID infections were fatal, as were one case each of pneumonia and Tumor Lysis Syndrome.

We plan to report new data from the FL cohort in the Phase 2 TIDAL study by the end of calendar year 2022.

COASTAL: A Phase 3 Trial Intended to Support Full FDA and Global Marketing Authorizations

COASTAL is a global, randomized, two-arm Phase 3 trial comparing the intermittent and time-limited administration of zandelisib plus rituximab to standard of care chemotherapy plus rituximab, in patients with r/r FL or MZL who received at least one prior line of therapy, which must have included an anti-CD20 antibody in combination with chemotherapy or lenalidomide. COASTAL is expected to enroll 534 patients. Zandelisib will be administered once daily for two 28-day cycles followed by an intermittent schedule of once daily dosing for seven days of each subsequent 28-day cycle for a total of 24 months, in combination with rituximab ("R") in the first six months only. The control arm will consist of six cycles of the standard chemoimmunotherapy regimens R-CHOP or R-bendamustine. The primary efficacy endpoint is progression-free survival; secondary endpoints include overall response rate, overall survival, patient reported outcomes assessments, and safety and tolerability.

COASTAL is intended to support marketing applications in the U.S. and globally in r/r FL and MZL patients who have received at least one prior line of treatment.

Impact of Current Events on the TIDAL and COASTAL Studies

The extent to which the ongoing COVID-19 pandemic will further impact the progress of the zandelisib development program, including the enrollment and completion of the COASTAL and TIDAL studies, is subject to future developments, which are highly uncertain and cannot be anticipated with confidence. Currently, we believe that the integrity of the program and individual studies remains intact; however, the pandemic did have a negative impact on the rate of enrollment in the TIDAL study. Enrollment in the FL cohort of the TIDAL study was completed in August 2021, and data was reported in November 2021; enrollment in the MZL cohort was discontinued in August 2022. The COASTAL study was initiated in 2021, with the first patient enrolled in July 2021. The COVID-19 pandemic and the military conflict between Russia and Ukraine have had a negative impact on the enrollment of the COASTAL study. We will continue to closely monitor for ongoing negative impacts on the development program related to these current events, as well as other factors which may be having a negative impact on the zandelisib development program, such as the FDA's communications regarding the risk benefit analysis of approved PI3Kδ inhibitors to treat indolent lymphomas. We will continue efforts to be proactive in managing the impact from the pandemic, the ongoing military conflict between Russia and Ukraine, and other potential factors, such as various actions to communicate with sites and investigators, and making accommodations to patients consistent with FDA guidance and guidance from other regulatory authorities, as we may deem appropriate.

Impact of Supply Chain Issues on COASTAL and CORAL Clinical Studies

We are currently experiencing what we believe to be a temporary supply chain issue affecting the availability of properly labeled zandelisib blister packs for use in the COASTAL and CORAL clinical studies. The issue relates to a change in the zandelisib packaging material intended to facilitate greater ease of opening without damaging capsules. The zandelisib drug supply using the current packaging material is exhibiting an estimated 42 month shelf life, 13 months shorter than the previous 55 month estimate. We believe there is no safety issue for patients nor a diminution of potency for zandelisib drug product. Patients currently on study continue to receive drug. However, we must pause enrollment of new patients until regulatory review of the new specification is complete and newly labelled blister packs are supplied to depots. We believe that this pause will extend enrollment completion in COASTAL by approximately three months.

Voruciclib: Potent Orally Administered CDK9 Inhibitor in Phase 1 Studies

Voruciclib is a potent orally administered CDK9 inhibitor. Voruciclib is being evaluated in a Phase 1 trial evaluating dose and schedule in patients with acute myeloid leukemia (“AML”) and B-cell malignancies. Voruciclib is also being evaluated in pre-clinical studies to explore the potential synergistic activity in various solid tumor cancers of voruciclib in combination with drug-candidates that targets in the RAS signaling pathway, including KRAS.

Voruciclib Scientific Overview: Cell Cycle Signaling

CDK9 has important functions in cell cycle regulation, including the modulation of two therapeutic targets in cancer:

- CDK9 is a transcriptional regulator of the myeloid leukemia cell differentiation protein ("MCL1"), a member of the family of anti-apoptotic proteins which, when elevated, may prevent the cell from undergoing cell death. Inhibition of CDK9 blocks the production of MCL1, which is an established resistance mechanism to the B-cell lymphoma ("BCL2") inhibitor venetoclax (marketed as Venclexta®).
- CDK9 is a transcriptional regulator of the MYC proto-oncogene protein ("MYC") which regulates cell proliferation and growth. Upregulation of MYC is implicated in many human cancers and is frequently associated with poor prognosis and unfavorable patient survival. CDK9, in addition to being a transcription factor for MYC, also decreases phosphorylation of MYC protein that is implicated in stabilizing MYC in KRAS mutant cancers. Targeting MYC directly has historically been difficult, but CDK9 is a promising approach to target this oncogene.

Voruciclib: Inhibition of MCL1

In pre-clinical studies voruciclib shows dose-dependent suppression of MCL1; in December 2017, a study of voruciclib published in the journal *Nature Scientific Reports* reported that the combination of voruciclib plus the BCL-2 inhibitor venetoclax was capable of inhibiting two master regulators of cell survival, MCL-1 and BCL-2, and achieved synergistic antitumor effect in an aggressive subset of DLBCL pre-clinical models.

In a peer reviewed manuscript published in 2020 by Luedtke et al, it was reported that the inhibition of CDK9 by voruciclib synergistically enhances cell death induced by the Bcl-2 selective inhibitor venetoclax in preclinical models of AML. The data demonstrated that voruciclib synergizes with venetoclax to induce programmed cell death, or apoptosis, in both AML cell lines and primary patient samples. It was also demonstrated that voruciclib downregulates MCL1, which is relevant for the synergy between voruciclib and venetoclax, and further that voruciclib also downregulates MYC, which also contributes to the synergies with venetoclax.

The research presented suggests that voruciclib is an attractive therapeutic target for treating cancers in combination with venetoclax or other BCL-2 inhibitors and is supportive of our ongoing clinical evaluation of voruciclib in B-cell malignancies and AML.

Voruciclib: Inhibition of MYC

Many cancers are associated with overexpression of MYC, a transcription factor regulating cell proliferation and growth. CDK9 is a known regulator of MYC transcription and a modulator of MYC protein phosphorylation. Data reported at the American Association for Cancer Research ("AACR") Annual Meeting 2021 in preclinical models demonstrates that voruciclib:

- Results in a rapid decrease in the phosphorylation of proteins that promote MYC transcription;
- Rapidly decreases phosphorylation of MYC protein on Ser62, a site implicated in stabilizing MYC in KRAS mutant cancers;
- Possesses single agent activity against multiple KRAS mutant cancer cell lines both *in vitro* and *in vivo;* and
- Synergistically inhibits KRAS G12C mutant cancer cell lines in combination with KRAS G12C inhibitors, both *in vitro* and *in vivo.*

The research presented suggests that voruciclib could be an attractive therapeutic agent for cancers, including solid tumors, dependent on the activity of MYC.

Clinical Program

We are evaluating patients with hematological malignancies in a Phase 1 clinical trial evaluating the dose and schedule of voruciclib. The trial started with the evaluation of dose and schedule of voruciclib as a monotherapy in patients with relapsed and refractory B-cell malignancies and AML after failure of prior standard therapies to determine the safety, preliminary efficacy and maximum tolerated dose. We are now also starting to evaluate the dose and schedule of voruciclib in combination with venetoclax, a BCL2 inhibitor, to assess synergies and the opportunity for combination treatments, initially in patients with AML and subsequently across multiple indications.

As reported at the American Society of Hematology 2021 annual meeting in a poster presentation, data to date from the Phase 1 study evaluating voruciclib as a monotherapy on an optimized schedule of 14 consecutive days in a 28-day cycle was well tolerated. No dose limiting toxicities were observed and no significant myelosuppression was seen in patients with B-cell malignancies, suggesting a lower likelihood of additive toxicities in combination with venetoclax. Disease stabilization was observed in heavily pretreated patients and differentiation syndrome was observed in AML patients, which is indicative of biologic activity. We expect to initiate a Phase 1 study to evaluate voruciclib in combination with venetoclax in patients with AML by the end of calendar year 2022.

Voruciclib was also previously evaluated in more than 70 patients with solid tumors in multiple Phase 1 studies. The totality of the clinical data, along with data from pre-clinical studies, suggests voruciclib’s ability to inhibit its molecular target at a projected dose as low as 150 mg daily. In one clinical study, voruciclib was evaluated in combination with vemurafenib (marketed as Zelboraf®) in nine patients with BRAF mutated advanced/inoperable malignant melanoma. All three BRAF/MEK naive patients achieved a response: two partial responses and one complete response. In this study voruciclib was dosed at 150 mg daily plus vemurafenib 720 mg or 960 mg twice daily in 28-day cycles. The most common adverse events were fatigue, constipation, diarrhea, arthralgia and headache. One instance of grade 3 fatigue was dose limiting, and no serious adverse events related to voruciclib were reported. Other clinical studies evaluated voruciclib at doses up to 850 mg in patients with solid tumors, demonstrating additional evidence of potential biologic activity and an adverse event profile generally consistent with other drugs in its class.

Impact of COVID-19 on the Voruciclib Clinical Development Program

While the extent to which the ongoing COVID-19 pandemic will further impact the progress of the voruciclib clinical development program, including the ongoing Phase 1 study, is subject to future developments which are highly uncertain and cannot be predicted with confidence, the Phase 1 study remains ongoing and is continuing to enroll patients; however, the rate of enrollment of patients has been negatively impacted by the pandemic. We will continue efforts to be proactive in managing the impact from the pandemic, including various actions to communicate with sites and investigators, and making accommodations to patients consistent with FDA guidance as we may deem appropriate.

ME-344: Clinical Stage Mitochondrial Inhibitor with Combinatorial Potential

ME-344 is our novel and tumor selective, isoflavone-derived mitochondrial inhibitor drug candidate. It targets the OXPHOS pathway involved in adenosine triphosphate ("ATP") production in the mitochondria. ME-344 was studied in an investigator-initiated, multi-center, randomized clinical trial in combination with the vascular endothelial growth factor (“VEGF”) inhibitor bevacizumab (marketed as Avastin®) that enrolled a total of 42 patients with human epidermal growth factor receptor 2 (“HER2”) negative breast cancer.

ME-344 Scientific Overview: Cancer Metabolism

Tumor cells often display a high metabolic rate to support cell division and growth. This heightened metabolism requires a continual supply of energy in the form of ATP. The two major sources of ATP are the specialized cellular organelles termed mitochondria and through the metabolism of carbohydrates via the glycolysis pathway, which is frequently upregulated in cancer cells in a phenomenon called the Warburg Effect.

ME-344 was identified through a screen of more than 400 new chemical structures originally created based on the central design of naturally occurring plant isoflavones. We believe that some of these synthetic compounds, including our drug candidate ME-344, interact with specific mitochondrial enzyme targets, resulting in the inhibition of ATP generation. When these compounds interact with their target, a rapid reduction in ATP occurs, which leads to a cascade of biochemical events within the cell and ultimately to cell death.

Clinical Program

ME-344 demonstrated evidence of single agent activity against refractory solid tumors in a Phase 1 trial, and in pre-clinical studies tumor cells treated with ME-344 resulted in a rapid loss of ATP and cancer cell death. In addition to single agent activity, ME-344 may also have significant potential in combination with anti-angiogenic therapeutics. In pre-clinical studies, it was shown that one outcome of anti-angiogenics was to reduce the rate of glycolysis in tumors as a mechanism to slow tumor growth. However, tumor metabolism was able to shift to mitochondrial metabolism for energy production to support continued tumor proliferation. In such cases of tumor plasticity in the presence of treatment with anti-angiogenics, targeting the alternative metabolic source with ME-344 may open an important therapeutic opportunity.

Support for this combinatorial use of ME-344 was first published in the June 2016 edition of *Cell Reports*; pre-clinical data from a collaboration with the Spanish National Cancer Research Centre in Madrid demonstrated mitochondria-specific effects of ME-344 in cancer cells, including substantially enhanced anti-tumor activity when combined with agents that inhibit the activity of VEGF. These data demonstrating the potential anti-cancer effects of combining ME-344 with a VEGF inhibitor due to an inhibition of both mitochondrial and glycolytic metabolism provided a basis for commencement of an investigator-initiated trial of ME-344 in combination with bevacizumab in HER2 negative breast cancer patients.

Results published in the November 2019 issue of *Clinical Cancer Research* from a multicenter, investigator-initiated, randomized, open-label, clinical trial that evaluated the combination of ME-344 and bevacizumab in 42 women with early HER2-negative breast cancer further support the combinatorial use of ME-344 with anti-angiogenic therapeutics.

The primary objective of the trial was to show proof of ME-344 biologic activity as measured by Ki67 reductions in the presence of the nuclear protein Ki67 (expression of which is strongly associated with tumor cell proliferation and growth) from days 0 to 28 compared to the control group who received bevacizumab alone. Secondary objectives included determining whether ME-344 biologic activity correlates with vascular normalization. The data demonstrate significant biologic activity in the ME-344 treatment group:

- In ME-344 treated patients, mean absolute Ki67 decreases were 13.3 compared to an increase of 1.1 in the bevacizumab monotherapy group (P=0.01).
- In ME-344 treated patients, mean relative Ki67 decreases were 23% compared to an increase of 186% in the bevacizumab monotherapy group (P < 0.01).

- The mean relative Ki67 reduction in patients experiencing vascular normalization in the ME-344 treated patients was 33%, compared to an increase of 11.8% in normalized patients from the bevacizumab monotherapy group (P=0.09). Approximately one-third of patients in each arm had vascular normalization.

Treatment was generally well tolerated; three grade 3 adverse events of high blood pressure were reported, two in the ME-344 arm and one in the bevacizumab monotherapy arm.

Results from our earlier, first-in-human, single-agent Phase 1 clinical trial of ME-344 in patients with refractory solid tumors were published in the April 1, 2015 edition of *Cancer*. The results indicated that eight of 21 evaluable patients (38%) treated with ME-344 achieved stable disease or better, including five who experienced progression-free survival that was at least twice the duration of their last prior treatment before entry into the trial. In addition, one of these patients, a heavily pre-treated patient with small cell lung cancer, achieved a confirmed partial response and remained on study for two years. ME-344 was generally well tolerated at doses equal to or less than 10 mg/kg delivered on a weekly schedule for extended durations. Treatment-related adverse events included nausea, dizziness and fatigue. Dose-limiting toxicities were observed at both the 15 mg/kg and 20 mg/kg dose levels, consisting primarily of grade 3 peripheral neuropathy. We are planning to advance ME-344 in combination with the anti-angiogenic antibody bevacizumab in a Phase 1b study evaluating patients with relapsed colorectal cancer in the first half of calendar year 2023.

Additionally, ME-344 may also have clinical potential against hematological malignancies. At the AACR Annual Meeting 2022, a poster presentation reported results from preclinical studies exploring the ability of ME-344 to enhance the activity of venetoclax against AML. Data from the in vitro and in vivo preclinical studies evaluating the combination of ME-344 with venetoclax in standard-of-care-resistant AML cell lines and relapsed or refractory AML patient samples suggest that ME-344, both alone and in combination with venetoclax, inhibits purine biosynthesis, suppresses oxidative phosphorylation, induces apoptosis and decreases MCL-1, which together target metabolic vulnerabilities of AML cells. The data demonstrated that ME-344 and venetoclax prolong survival in MV4-11 and MV4-11/AraC-R-derived xenograft AML models. The poster concludes that ME-344 enhances venetoclax activity against AML cells including resistant AML.

Results of Operations

Comparison of three months ended September 30, 2022 and 2021

Revenue: We recognized revenue of $8.7 million for the three months ended September 30, 2022 compared to $7.8 million for the three months ended September 30, 2021. Revenue increased as a result of higher progress towards completion of our performance obligations under our KKC Commercialization Agreement, offset by decreased reimbursement of expenses from KKC due to research and development activity related to zandelisib.

***Research and Development*:** The following is a summary of our research and development expenses to supplement the more detailed discussion below. The dollar values in the following table are in thousands.

	Three Months Ended September 30,	
Research and development expenses	**2022**	**2021**
Zandelisib	$ 11,606	$ 12,392
Voruciclib	733	1,041
ME-344	785	640
Other	6,339	5,880
Total research and development expenses	$ 19,463	$ 19,953

Research and development expenses consist primarily of clinical trial costs (including payments to contract research organizations “CROs”), pre-clinical study costs, and costs to manufacture our drug candidates for non-clinical and clinical studies. Other research and development expenses consist primarily of salaries and personnel costs, share-based compensation, legal costs, and other costs not allocated to specific drug programs. Costs related to zandelisib decreased primarily as a result of lower costs related to the TIDAL study due to enrollment completing prior to the three months ended September 30, 2022. Costs related to voruciclib decreased for the three months ended September 30, 2022 compared with the three months ended September 30, 2021, due to lower costs related to the Phase 1 study. Costs related to ME-344 increased for the three months ended September 30, 2022 compared with the three months ended September 30, 2021, due to increased drug manufacturing costs. The increase in other research and development costs is primarily due to higher personnel costs.

***General and Administrative*:** General and administrative expenses decreased by $0.4 million to $7.5 million for the three months ended September 30, 2022 compared to $7.9 million for the three months ended September 30, 2021. The decrease is primarily due to

decreased share-based compensation ($1.0 million) and external professional services and legal costs ($0.4 million), partially offset by increased personnel costs ($0.4 million), and corporate overhead costs ($0.6 million).

Other income or expense: We recorded a non-cash gain of $1.1 million during the three months ended September 30, 2022 due to a change in the fair value of our warrant liability. The change in the warrant liability is primarily due to changes in our stock price. Additionally, we received interest and dividend income of $0.5 million for the three months ended September 30, 2022 compared to $8,000 for the three months ended September 30, 2021. The increase is primarily due to higher yields during the three months ended September 30, 2022 compared to the three months ended September 30, 2021.

Liquidity and Capital Resources

We have accumulated losses of $390.8 million since inception and expect to incur operating losses and generate negative cash flows from operations for the foreseeable future. As of September 30, 2022, we had $138.4 million in cash and cash equivalents, and short-term investments. We believe that these resources will be sufficient to fund our operations for at least 12 months from the issuance of this Quarterly Report. Our current business operations are focused on continuing the clinical development of our drug candidates. Changes to our research and development plans or other changes affecting our operating expenses may affect actual future use of existing cash resources. Our research and development expenses are expected to increase in the foreseeable future. We cannot determine with certainty costs associated with ongoing and future clinical trials or the regulatory approval process. The duration, costs and timing associated with the development of our product candidates will depend on a variety of factors, including uncertainties associated with the results of our clinical trials.

To date, we have obtained cash and funded our operations primarily through equity financings and license agreements. In order to continue the development of our drug candidates, at some point in the future we expect to pursue one or more capital transactions, whether through the sale of equity securities, debt financing, license agreements or entry into strategic partnerships. There can be no assurance that we will be able to continue to raise additional capital in the future.

Sources and Uses of Our Cash

Net cash used in operating activities for the three months ended September 30, 2022 was $14.8 million as compared to net cash used in operating activities of $7.7 million for the three months ended September 30, 2021. The increase in net cash used in operating activities period over period reflects the receipt of a $10.0 million milestone in September 2021 related to the KKC Commercialization Agreement, with no corresponding receipt for the three months ended September 30, 2022, as well as other changes in working capital.

Net cash provided by investing activities for the three months ended September 30, 2022 was $13.7 million as compared to $15.0 million provided by investing activities for the three months ended September 30, 2021. The change was primarily due to decreased proceeds from maturities of short-term investments in 2022, net of purchases.

Net cash used in financing activities during the three months ended September 30, 2022 was $40,000 compared with $0.2 million used in financing activities during the three months ended September 30, 2021 due to the payment of RSU tax withholdings in exchange for common shares surrendered by RSU holders.

Contractual Obligations

We have contracted with various consultants and third parties to assist us in pre-clinical research and development and clinical trials work for our leading drug compounds. The contracts are terminable at any time but obligate us to reimburse the providers for any time or costs incurred through the date of termination. Additionally, we have employment agreements with certain of our current employees that provide for severance payments and accelerated vesting for share-based awards if their employment is terminated under specified circumstances.

We lease office space in San Diego, California under non-cancelable operating leases. The leases are subject to additional variable non-lease component charges (e.g., common area maintenance, maintenance, etc.). See Note 8 *Leases* of the unaudited condensed financial statements for additional details related to our lease obligations.

Presage License Agreement

In September 2017, we entered into the Presage License Agreement. Under the terms of the Presage License Agreement, Presage granted to us exclusive worldwide rights to develop, manufacture and commercialize voruciclib, a clinical-stage, oral and selective CDK inhibitor, and related compounds. In exchange, we paid Presage $2.9 million. With respect to the first indication, an incremental $2.0 million payment, due upon dosing the first subject in the first registration trial will be owed to Presage, for total payments of $4.9 million prior to receipt of marketing approval of the first indication in the U.S., E.U. or Japan. Additional potential payments of up to $179 million will be due upon the achievement of certain development, regulatory and commercial milestones. We

will also pay mid-single-digit tiered royalties on the net sales of any product successfully developed. As an alternative to milestone and royalty payments related to countries in which we sublicense product rights, we will pay to Presage a tiered percent (which decreases as product development progresses) of amounts received from such sublicensees. As of September 30, 2022, we had not accrued any amounts for potential future payments.

COVID-19

As a result of the ongoing COVID-19 pandemic, various public health orders and guidance measures have been implemented across much of the U.S., and across the globe, including in the locations of our office, clinical trial sites, key vendors and partners. Despite the relaxation of many governmental orders earlier this year, COVID-19 still impacts the normal conduct of business.

While we continue to enroll and dose patients in our clinical trials, our clinical development program timelines may continue to be subject to potential negative impacts from the ongoing pandemic in the U.S. and globally. The extent to which the ongoing pandemic continues to impact our business, including our preclinical studies, CMC studies, manufacturing, and clinical trials, will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

We may experience enrollment delays and suspensions, patient withdrawals, postponement of planned clinical or preclinical studies, redirection of site resources from studies, and study deviations or noncompliance. We may also need to maintain or implement study modifications, suspensions, or terminations, the introduction of additional remote study procedures and modified informed consent procedures, study site changes, direct delivery of investigational products to patient homes or alternative sites, which may require state licensing, and changes or delays in site monitoring. The foregoing may require that we consult with relevant review and ethics committees, Institutional Review Boards (“IRBs”), and the FDA. The foregoing may also impact the integrity of our study data. The ongoing COVID-19 pandemic may further increase the need for clinical trial patient monitoring and regulatory reporting of adverse effects, and may delay regulatory authority meetings, inspections, or the regulatory review of marketing or investigational applications or submissions.

The ongoing COVID-19 pandemic may also impact our ability to procure the necessary supply of our investigational drug products, as well as any ancillary supplies necessary for the conduct of our studies. Third party manufacturers may also need to implement measures and changes or deviate from typical manufacturing requirements that may otherwise adversely impact our product candidates.

In light of the ongoing COVID-19 pandemic, the FDA issued a number of new guidance documents. Specifically, as a result of the potential effect of the ongoing COVID-19 pandemic on many clinical trial programs in the U.S. and globally, the FDA issued guidance concerning potential impacts on clinical trial programs, which guidance FDA has continually updated. In addition, the European Medicines Agency (“EMA”) as well as various country regulatory authorities (EU and UK) have issued similar guidance. We have adapted the FDA and EMA/UK guidance for study procedures, data collection, and oversight resulting from the ongoing COVID-19 pandemic.

Critical Accounting Policies and Management Estimates

We describe our significant accounting policies in *Note 1. The Company and Summary of Significant Accounting Policies*, of the notes to the financial statements included in our 2022 Annual Report. We discuss our critical accounting estimates in *Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations*, in our 2022 Annual Report. There have been no changes in our significant accounting policies or critical accounting estimates since June 30, 2022.

Recent Accounting Pronouncement

See *Note 1. The Company and Summary of Significant Accounting Policies* in the Notes to Condensed Financial Statements in this Quarterly Report.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

Our exposure to market interest rates relates primarily to the investments of cash balances and short-term investments. We have cash reserves held in U.S. dollars and we place funds on deposit with financial institutions, which are readily available. Our short-term investments consist solely of U.S. government securities with a maturity of three to twelve months.

We place our cash deposits with high credit quality financial institutions and by policy limit the amount of credit exposure to any one corporation or bank. These deposits are in excess of the Federal Deposit Insurance Corporation (“FDIC”) insurance limits. We are adverse to principal loss and we ensure the safety and preservation of our invested funds by limiting default risk, market risk and reinvestment risk. We seek to mitigate default risk by depositing funds with high credit quality financial institutions, by limiting the amount of credit exposure to any one corporation or bank, by purchasing short-term investments consisting of U.S. government

securities, and by positioning our portfolio to respond appropriately to a significant reduction in a credit rating of any such financial institution.

We do not consider the effects of interest rate movements to be a material risk to our financial condition.

Item 4. Controls and Procedures

(a) Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports we file or submit pursuant to the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were not effective due to the material weakness in our internal control over financial reporting related to the inadequate design and implementation of controls to evaluate and monitor the accounting for revenue recognition related to license agreements.

After giving full consideration to the material weakness, and the additional analyses and other procedures that we performed to ensure that preparation and fair presentation of our financial statements included in this Quarterly Report, our management and the board of directors has concluded that our financial statements present fairly, in all material respects, our financial position, results of operations and cash flows for the periods disclosed in conformity with U.S. GAAP.

Plan for Remediation of Material Weakness

Management is implementing enhanced internal controls to remediate the material weakness. The remediation plan includes enhancement of our contract review of license agreements to confirm appropriate understanding of the terms, as well as implementation of a control designed to evaluate and monitor, at inception and on a quarterly basis, the estimated consideration to be received under license agreements for purposes of revenue recognition, analysis of deferred revenue balances, and enhanced detailed review of our revenue recognition models.

Changes in Internal Control over Financial Reporting

Other than the ongoing remediation efforts related to the material weakness discussed above, there were no changes in our internal control over financial reporting (as such term is defined by Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the most recent fiscal quarter ended September 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

The elements of our remediation plan can only be accomplished over time, and we can offer no assurance that these initiatives will ultimately have the intended effects.

PART II OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

There have been no material changes in our risk factors from those included in our 2022 Annual Report.

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

None.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Index

Exhibits	
10.1	Letter Agreement between Brian G. Drazba and MEI Pharma, Inc., dated as of July 7, 2022 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on July 7, 2022 (File No. 000-50484)).
31.1	Rule 13a-14(a) or Rule 15d-14(a) Certification of Principal Executive Officer.
31.2	Rule 13a-14(a) or Rule 15d-14(a) Certification of Principal Financial Officer.
32.1	Certification of Principal Executive Officer and Principal Financial Officer required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C 1350).
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

MEI Pharma, Inc.

/s/ Daniel P. Gold
Daniel P. Gold
President and Chief Executive Officer

Date: November 14, 2022

Exhibit 31.1

CERTIFICATION

I, Daniel P. Gold, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of MEI Pharma, Inc.;

2. Based on my knowledge, this Quarterly 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 Quarterly Report;

3. Based on my knowledge, the financial statements, and other financial information included in this Quarterly 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 Quarterly 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 Quarterly 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 the Quarterly Report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Quarterly Report based on such evaluation; and

   (d) disclosed in this Quarterly 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.

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:

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2022

/s/ Daniel P. Gold
Daniel P. Gold
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Brian G. Drazba, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of MEI Pharma, Inc.;

2. Based on my knowledge, this Quarterly 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 Quarterly Report;

3. Based on my knowledge, the financial statements, and other financial information included in this Quarterly 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 Quarterly 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 Quarterly 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 the Quarterly Report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Quarterly Report based on such evaluation; and

   (d) disclosed in this Quarterly 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.

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:

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2022

/s/ Brian G. Drazba
Brian G. Drazba
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), Daniel P. Gold, the Chief Executive Officer of MEI Pharma, Inc. (the "Registrant"), and Brian G. Drazba, the Chief Financial Officer of the Registrant, each hereby certifies that, to his knowledge:

1. The Registrant's Quarterly Report on Form 10-Q for the period ended September 30, 2022, (the "Form 10-Q") to which this Certification is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Form 10-Q fairly presents, in all material respects, the financial condition of the Registrant at the end of the period covered by the Form 10-Q and results of operations of the registrant for the period covered by the Form 10-Q.

These certifications accompanying the Form 10-Q to which they relate, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Dated: November 14, 2022

/s/ Daniel P. Gold
Daniel P. Gold
Chief Executive Officer
(Principal Executive Officer)

/s/ Brian G. Drazba
Brian G. Drazba
Chief Financial Officer
(Principal Financial Officer)