Table of Contents

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

FORM 10-Q

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

For the quarterly period ended September 30, 2020

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	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, a smaller reporting company, or an emerging growth company. See 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 checkmark 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 ☒

As of November 6, 2020, the number of shares outstanding of the issuer’s common stock, $0.00000002 par value, was 112,522,001.

MEI PHARMA, INC.

Table of Contents

PART I FINANCIAL INFORMATION

Item 1: Condensed Financial Statements – Unaudited

MEI PHARMA, INC.
CONDENSED BALANCE SHEETS
(In thousands, except per share amounts)

	September 30, 2020 (unaudited)	June 30, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 10,956	$ 12,331
Short-term investments	165,179	170,299
Total cash, cash equivalents and short-term investments	176,135	182,630
Receivable for foreign tax withholding	20,420	20,420
Prepaid expenses and other current assets	7,375	5,594
Total current assets	203,930	208,644
Operating lease right-of-use asset	8,420	—
Property and equipment, net	1,659	1,084
Total assets	$ 214,009	$ 209,728
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,375	$ 2,437
Accrued liabilities	5,537	6,090
Deferred revenue	18,972	14,777
Operating lease liabilities	602	—
Total current liabilities	31,486	23,304
Deferred revenue, long-term	64,864	67,723
Warrant liability	27,259	40,483
Operating lease liabilities, long-term	8,072	—
Total liabilities	131,681	131,510
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.01 par value; 100 shares authorized; none outstanding	—	—
Common stock, $0.00000002 par value; 226,000 shares authorized; 112,522 and 111,514 shares issued and outstanding at September 30, 2020 and June 30, 2020, respectively	—	—
Additional paid-in capital	361,654	355,452
Accumulated deficit	(279,326)	(277,234)
Total stockholders' equity	82,328	78,218
Total liabilities and stockholders' equity	$ 214,009	$ 209,728

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,	
	2020	2019
Revenue	$ 3,834	$ 1,157
Operating expenses:		
Cost of revenue	509	688
Research and development	12,996	8,962
General and administrative	5,915	4,130
Total operating expenses	19,420	13,780
Loss from operations	(15,586)	(12,623)
Other income (expense):		
Change in fair value of warrant liability	13,224	9,269
Interest and dividend income	275	374
Other expense	(5)	(14)
Net loss	$ (2,092)	$ (2,994)
Net loss:		
Basic	$ (2,092)	$ (2,994)
Diluted	$ (15,316)	$ (2,994)
Net loss per share:		
Basic	$ (0.02)	$ (0.04)
Diluted	$ (0.13)	$ (0.04)
Shares used in computing net loss per share:		
Basic	112,435	73,628
Diluted	114,957	73,628

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, 2020	111,514	$355,452	$ (277,234)	$ 78,218
Net loss	—	—	(2,092)	(2,092)
Issuance of common stock	958	3,136	—	3,136
Exercise of stock options	50	124	—	124
Share-based compensation expense	—	2,942	—	2,942
Balance at September 30, 2020	112,522	$361,654	$ (279,326)	$ 82,328

	Common Shares	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at June 30, 2019	73,545	$279,148	$ (231,218)	$ 47,930
Net loss	—	—	(2,994)	(2,994)
Issuance of common stock	64	159	—	159
Exercise of stock options	46	72	—	72
Share-based compensation expense	—	2,113	—	2,113
Balance at September 30, 2019	73,655	$281,492	$ (234,212)	$ 47,280

See accompanying notes to condensed financial statements.

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

	Three Months Ended September 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (2,092)	$ (2,994)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of warrant liability	(13,224)	(9,269)
Share-based compensation	2,942	2,113
Depreciation and amortization	69	31
Non-cash lease expense	269	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,781)	300
Accounts payable	3,938	(1,689)
Accrued liabilities	(553)	(1,702)
Deferred revenue	1,336	(868)
Operating lease liability	(15)	—
Net cash used in operating activities	(9,111)	(14,078)
Cash flows from investing activities:		
Purchases of property and equipment	(644)	—
Purchases of short-term investments	(54,989)	(19,979)
Proceeds from maturity of short-term investments	60,109	24,946
Net cash provided by investing activities	4,476	4,967
Cash flows from financing activities:		
Proceeds from exercise of stock options	124	72
Proceeds from issuance of common stock, net	3,136	159
Collection of common stock proceeds receivable	—	5,274
Net cash provided by financing activities	3,260	5,505
Net decrease in cash and cash equivalents	(1,375)	(3,606)
Cash and cash equivalents at beginning of the period	12,331	9,590
Cash and cash equivalents at end of the period	$ 10,956	$ 5,984
Supplemental disclosures:		
Income taxes paid	$ (8)	$ (1)
Operating lease right-of-use assets obtained in exchange for operating lease liabilities	$ 8,689	$ —

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

We are a late-stage pharmaceutical company focused on leveraging our extensive development and oncology expertise to identify and advance new therapies intended to meaningfully improve the treatment of cancer. Our portfolio of drug candidates contains four clinical-stage assets, including zandelisib (formerly known as ME-401), currently in an ongoing Phase 2 clinical trial that we intend to submit to the U.S. Food and Drug Administration ("FDA") to support accelerated approval of a marketing application. Our common stock is listed on the NASDAQ Capital Market under the symbol "MEIP".

Clinical Development Programs

Our approach to building our pipeline is to license promising cancer agents and build value in programs through development, commercialization and strategic partnerships, as appropriate. Our drug candidate pipeline includes:

- Zandelisib (formerly known as ME-401), an oral phosphatidylinositol 3-kinase ("PI3K") delta inhibitor;
- Voruciclib, an oral cyclin-dependent kinase ("CDK") inhibitor;
- ME-344, a mitochondrial inhibitor targeting the oxidative phosphorylation ("OXPHOS") complex; and
- Pracinostat, an oral histone deacetylase ("HDAC") inhibitor.

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, ME-344 and pracinostat, 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 $279.3 million since inception and expect to incur operating losses and generate negative cash flows from operations for the foreseeable future. As of September 30, 2020, we had $176.1 million in cash and cash equivalents and short-term investments. Additionally, we had a receivable of $20.4 million from the Japanese taxing authorities that had been withheld from the $100 million upfront payment associated with the License, Development and Commercialization Agreement with Kyowa Kirin Company (formerly "Kyowa Hakko Kirin Co., Ltd.") ("KKC"), a Japanese life sciences company (the "KKC Commercialization Agreement") (Note 3). The receivable was received in October 2020. 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 United States ("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. We have evaluated subsequent events through the date the financial statements were issued.

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, 2020, included in our Annual Report on Form 10-K ("2020 Annual Report") filed with the Securities and Exchange Commission ("SEC") on September 9, 2020. Interim results are not necessarily indicative of results for a full year.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("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.

Revenue Recognition

ASC Topic 606, Revenue from Contracts with Customers ("Topic 606")

Beginning July 1, 2018, 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. Any adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

We develop estimates of 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 royalty revenue from license agreements.

We recognized revenue associated with the following license agreements (in thousands):

	Three Months Ended September 30,	
	2020	2019
KKC License Agreements	$ 3,569	$ 797
Helsinn License Agreement	265	360
	$ 3,834	$ 1,157
Timing of Revenue Recognition:		
Services performed over time	$ 3,834	$ 1,157
	$ 3,834	$ 1,157

The KKC Commercialization Agreement and KKC Japan License Agreement include other distinct performance obligations that will be satisfied over time, and accordingly we recognized $3.6 million and $0.8 million related to our progress toward satisfying those obligations during the three months ended September 30, 2020 and 2019, respectively.

Based on the characteristics of the Helsinn License Agreement (Note 3), control of the remaining deliverables occurs over time and therefore we recognize revenue based on the extent of progress towards completion of the performance obligations. Accordingly, we recognized $0.3 million and $0.4 million related to our progress toward satisfying those obligations during the three months ended September 30, 2020 and 2019, respectively.

Contract Balances

Receivables and contract assets are included in our balance sheet in “Prepaid expenses and other current assets”, and contract liabilities are included in “Deferred revenue” and “Deferred revenue long-term”. The following table presents changes in contract assets and contract liabilities during the three months ended September 30, 2020 and 2019 (in thousands):

	Three Months Ended September 30,	
	2020	2019
Receivables		
Receivables, beginning of period	$ 2,605	$ —
Net change	(2,488)	326
Receivables, end of period	$ 117	$ 326
Contract assets		
Contract assets, beginning of period	$ 604	$ 686
Net change	4,775	(217)
Contract assets, end of period	$ 5,379	$ 469
Contract liabilities		
Contract liabilities, beginning of period	$82,500	$7,774
Net change	1,336	(868)
Contract liabilities, end of period	$83,836	$6,906

The timing of revenue recognition, invoicing and cash collections results in billed accounts receivable and unbilled receivables (contract assets), which are classified as “prepaid expenses and other current assets” on our Condensed Balance Sheet, 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 contract assets. We may receive advance payments from our customers before revenue is recognized, resulting in contract liabilities. The contract assets and liabilities reported on the Condensed Balance Sheet relate to the KKC Agreements and Helsinn License Agreement.

As of September 30, 2020, we had $83.8 million of deferred revenue associated with our remaining performance obligations under the KKC Commercialization Agreement. We expect to recognize approximately $19.0 million of deferred revenue in the next 12 months, and an additional $64.9 million thereafter.

Revenues from Collaborators

We earn revenue in connection with collaboration agreements, which are described in Note 3, License Agreements, and Note 4, BeiGene Collaboration.

At contract inception, we assess whether the collaboration arrangements are within the scope of ASC Topic 808, *Collaborative Arrangements* ("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 consolidated balance sheets, classified as either short-term or long-term deferred revenue based on our best estimate of when such amounts will be recognized.

Cost of Revenue

Cost of revenue primarily includes external costs paid to third-party contractors to perform research, conduct clinical trials and develop and manufacture drug materials, and internal compensation and related personnel expenses to support our research and development performance obligations associated with the Helsinn License Agreement.

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.

Share-based Compensation

Share-based compensation expense for employees and directors is recognized in the Condensed Statement of Operations based on estimated amounts, including the grant date fair value and the expected service period. For stock options, we estimate the grant date fair value using a Black-Scholes valuation model, which requires the use of multiple subjective inputs including estimated future volatility, expected forfeitures and the expected term of the awards. We estimate the expected future volatility based on the stock's historical price volatility. The stock's future volatility may differ from the estimated volatility at the grant date. For restricted stock unit ("RSU") equity awards, we estimate the grant date fair value using our closing stock price on the date of grant. We recognize the effect of forfeitures in compensation expense when the forfeitures occur. The estimated forfeiture rates may differ from actual forfeiture rates which would affect the amount of expense recognized during the period. We recognize the value of the awards over the awards' requisite service or performance periods. 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, 2020 and 2019, 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, 2020, and, as such, the disclosures included in our 2020 Annual Report continue to be relevant for the three months ended September 30, 2020.

Leases

Effective July 1, 2019, we adopted FASB ASC Topic 842, Leases ("ASC 842"), using a modified retrospective basis method under which prior comparative periods are not restated. This standard requires lessees to recognize in the statement of financial position a liability to make lease payments and a right-of-use ("ROU") asset representing our right to use the underlying asset for the lease term. At the inception of an arrangement, we determine whether the arrangement is or contains a lease based on the unique facts and circumstances within the arrangement. A lease is identified where an arrangement conveys the right to control the use of identified property, plant, and equipment for a period of time in exchange for consideration. Leases which are identified within the scope of ASC

842 and which have a term greater than one year are recognized on our Condensed Balance Sheet as 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.

Note 2. 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.

We measure the following financial instruments at fair value on a recurring basis. The fair values of these financial instruments were as follows (in thousands):

	September 30, 2020			June 30, 2020		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Warrant liability	$ —	$ —	$(27,259)	$ —	$ —	$(40,483)
Total	$ —	$ —	$(27,259)	$ —	$ —	$(40,483)

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, where applicable, and short-term investments 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 Statement of Operations for the three months ended September 30, 2020 and 2019, respectively.

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

	September 30, 2020	June 30, 2020
Risk-free interest rate	0.2%	0.2%
Expected life (years)	2.6	2.9
Expected volatility	81.6%	77.4%
Dividend yield	0.0%	0.0%
Black-Scholes Fair Value	$ 1.70	$ 2.52

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, 2020 and 2019 (in thousands):

	Fair Value of Warrants Using Significant Unobservable Inputs (Level 3)	
	2020	2019
Balance at July 1,	$ 40,483	$ 17,613
Change in estimated fair value of liability classified warrants	(13,224)	(9,269)
Balance at September 30,	$ 27,259	$ 8,344

Note 3. License Agreements

KKC License, Development and Commercialization Agreement

In April 2020, we entered into the KKC Commercialization Agreement. Under the agreement, 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 United States (the "Ex-U.S.") (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 million in May 2020. Of the $100 million paid by KKC, $20.4 million was remitted by KKC to the Japanese taxing authorities as a result of the U.S. Internal Revenue Service being closed due to the COVID pandemic, and therefore being unable to provide necessary documentation to support an exemption from the required foreign withholding. We received the amount remitted to the Japanese taxing authorities in October 2020. 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 and KKC will co-develop and co-promote zandelisib in the U.S., with us recording all revenue from U.S. sales. We and KKC will share U.S. profits and costs (including development costs) on a 50-50 basis. 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 also under the scope of Topic 606.

We determined, at the time of our initial assessment, that the total transaction price of $191.5 million is comprised of the upfront payment of $100.0 million, expected milestone payments of $20.0 million, estimated development cost-sharing of $66.3 million, and deferred revenue of $5.2 million from the KKC Japan License Agreement. During the three months ended September 30, 2020, we updated our initial assessment to reflect estimated development cost-sharing of $77.8 million. We included the amount of estimated variable consideration that is not constrained for development cost-sharing in the transaction price, and also determined that any variable consideration related to sales-based royalties and commercial milestones related to licenses of intellectual property as it is 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 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 $64.3 million transaction price allocated to the U.S. License obligation accounted for under Topic 808 is recorded as non-current deferred revenue and will begin to be recognized upon future commercialization as non-ASC 606 revenue. As of September 30, 2020 and June 30, 2020, we recorded deferred revenue of $19.3 million and $18.1 million, respectively, for 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 2026.

KKC Japan License Agreement

In October 2018, we, as licensor, entered into a license agreement with KKC for zandelisib (“the KKC Japan License Agreement”). Under the terms of the KKC Japan License Agreement, KKC was granted the exclusive right to develop and commercialize zandelisib in Japan. We also granted KKC the right to purchase supply of zandelisib for commercial requirements at cost plus a pre-negotiated percentage, as well as manufacturing rights in Japan. In return, we received an upfront payment of $10.0 million and were eligible to receive additional development and commercialization milestones, as well as royalties on net sales of zandelisib in Japan. In April 2020, we and KKC agreed to terminate the KKC Japan License Agreement. The KKC Japan License Agreement was replaced with the KKC Commercialization Agreement. Pursuant to the terms of the KKC Commercialization Agreement, we agreed to collaborate with KKC on the development, manufacturing and commercialization of zandelisib in Japan.

We assessed the KKC Japan License Agreement in accordance with ASC 606 and determined that our performance obligations comprised the license, research and development obligations, and our obligation to provide clinical trial materials to KKC. We determined that the transaction price amounted to the upfront payment of $10.0 million.

We determined that control of the license was transferred to KKC during the year ended June 30, 2019. Revenue allocated to the research and development obligations was recognized based on the proportional performance of these research and development activities. Revenue allocated to providing clinical trial materials was recognized upon delivery.

Helsinn License Agreement

In August 2016, we entered into an exclusive worldwide license, development, manufacturing and commercialization agreement with Helsinn Healthcare SA, a Swiss pharmaceutical corporation (“Helsinn”) for pracinostat in acute myeloid leukemia (“AML”), myelodysplastic syndrome (“MDS”) and other potential indications (the “Helsinn License Agreement”). Under the terms of the agreement, Helsinn was granted a worldwide exclusive license to develop, manufacture and commercialize pracinostat, and is primarily responsible for funding its global development and commercialization. As compensation for such grant of rights, we received payments of $20.0 million.

We determined that the agreement contains multiple performance obligations for purposes of revenue recognition. Revenue related to the research and development elements of the arrangement is recognized based on the extent of progress toward completion of each performance obligation. Revenue is recognized on a gross basis as we are the primary obligor and have discretion in supplier selection. During the three months ended September 30, 2020, our only remaining performance obligation under the agreement is the conduct of a Phase 2 dose-optimization study of pracinostat in combination with azacitidine in patients with high and very high risk MDS who are previously untreated with hypomethylating agents (the “POC study”), for which Helsinn has agreed to share third-party expenses.

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.

CyDex License Agreement

We are party to a license agreement with CyDex Pharmaceuticals, Inc. ("CyDex"). Under the license agreement, CyDex granted to us an exclusive, nontransferable license to intellectual property rights relating to Captisol® for use with our isoflavone-based drug compounds (currently ME-344). We agreed to pay to CyDex a non-refundable license issuance fee, future milestone payments, and royalties at a low, single-digit percentage rate on future sales of our approved drugs utilizing Captisol. Contemporaneously with the license agreement, CyDex entered into a commercial supply agreement with us, pursuant to which we agreed to purchase 100% of our requirements for Captisol from CyDex. We may terminate both the license agreement and the supply agreement at any time upon 90 days' prior written notice.

Note 4. 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 ("BTK"), 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 5. 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, 2020 and 2019. 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,	
	2020	2019
Net loss - basic	$ (2,092)	$(2,994)
Change in fair value of warrant liability	(13,224)	—
Net loss - diluted	$(15,316)	$(2,994)

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 (in thousands) that have been excluded from the calculation of net loss per share because of their anti-dilutive effect:

	Three Months Ended September 30,	
	2020	**2019**
Stock options	15,128	10,930
Restricted stock units	429	—
Warrants	—	16,062
Total anti-dilutive shares	15,557	26,992

Note 6. 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 3, 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, 2020, we have not accrued any amounts for potential future payments.

*S*Bio Purchase Agreement*

We are party to a definitive asset purchase agreement with S*Bio, pursuant to which we acquired certain assets comprised of intellectual property and technology including rights to pracinostat. We agreed to make certain milestone payments to S*Bio based on the achievement of certain clinical, regulatory and net sales-based milestones, as well as to make certain contingent earnout payments to S*Bio. Milestone payments will be made to S*Bio up to an aggregate amount of $74.5 million if certain U.S., E.U. and Japanese regulatory approvals are obtained and if certain net sales thresholds are met in North America, the E.U. and Japan. As of September 30, 2020, we have not accrued any amounts for potential future payments.

CyDex License Agreement

As discussed in Note 3, we are party to a license agreement with CyDex under which we may be required to make future payments upon the achievement of certain milestones, as well as potential future royalties based upon net sales. Contemporaneously with the license agreement, CyDex entered into a commercial supply agreement with us, pursuant to which we agreed to purchase 100% of our requirements for Captisol from CyDex. As of September 30, 2020, we have not accrued any amounts for potential future payments.

COVID-19

In January 2020, the World Health Organization (“WHO”) announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China (the “COVID-19 outbreak”) and the risks to the international community. In March 2020, the WHO classified the COVID-19 outbreak as a pandemic, based on the rapid increase in exposure globally. As a result of the COVID-19 pandemic, which continues to rapidly evolve, “shelter in place” orders and other public health guidance measures have been implemented across much of the United States, Europe and Asia, including in the locations of our offices, clinical trial sites, key vendors and partners. While we continue to enroll and dose patients in our clinical trials, we expect our clinical development program timelines to be negatively affected by COVID-19. The extent to which the outbreak impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease and to minimize its economic impact.

CARES Act

On March 27, 2020, President Trump signed into law the “Coronavirus Aid, Relief, and Economic Security (CARES) Act.” The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations, increased limitations on qualified charitable contributions, and technical corrections to tax depreciation methods for qualified improvement property. Regulatory guidance has indicated that public companies are ineligible to participate in certain of the loan programs provided by the CARES Act. We do not expect that the CARES Act will have a material impact on our financial condition, results of operation, or liquidity.

Legal Proceedings

On August 10, 2020, Guy Bahat, an individual who allegedly purchased 50 shares of our common stock filed a putative securities class action lawsuit (the “Securities Class Action”) in the United States District Court for the Southern District of California against the Company, Daniel P. Gold, and Brian G. Drazba, asserting claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exhange Act”) and Rule 10b-5 thereunder. The plaintiff seeks to sue on behalf of all purchasers of our securities from August 2, 2017 through July 1, 2020 and alleges, among other things, that we made false and misleading statements relating to pracinostat during the proposed class period. We believe that the claims are without merit, as to both the facts and the law, and intend to vigorously defend the case.

On October 21, 2020, Peter D’Arcy, an individual who alleges that he is a Company stockholder, filed a putative stockholder derivative action nominally on behalf of the Company in the United States District Court for the District of Delaware (the “Derivative

Action") against Dr. Gold, Mr. Drazba, Mr. Charles V. Baltic, III, Dr. Kevan E. Clemens, Mr. Frederick W. Driscoll, Dr. Nicholas R. Glover, Ms. Tamar D. Howson, Dr. Thomas C. Reynolds, Mr. William D. Rueckert, and Dr. Christine A. White, and naming the Company as a nominal defendant. The Derivative Action is based upon the pracinostat-related allegations in the Securities Class Action described above, and alleges claims under Section 14(a) of the Exchange Act and claims for breach of fiduciary duty, unjust enrichment, corporate waste, and contribution. We believe the plaintiff in the Derivative Action lacks standing to sue on behalf of the Company.

At this stage, we cannot predict the ultimate outcome of the Securities Class Action or the Derivative Action or whether they will result in any loss. Accordingly, we have not accrued an amount for any potential loss associated with these actions.

Note 7. Leases

In December 2019, we entered into a lease agreement for approximately 32,800 square feet of office space in San Diego, California. We have accounted for the lease as an operating lease. The contractual lease term began in July 2020 and is scheduled to expire in March 2028. The lease contains an option to renew and extend the lease terms. We have not included the lease extension within the ROU asset and lease liability on the balance sheet as it is not reasonably certain to be exercised. The lease includes variable non-lease components (e.g. common area maintenance, maintenance, etc.) that are not included in the ROU asset and lease liability and are reflected as an expense in the period incurred. We do not have any other operating or finance leases. Upon commencement of the lease, we recognized an operating lease ROU asset of $8.7 million and a corresponding operating lease liability of $8.7 million.

The following is a schedule of the future minimum rental payments for our operating lease, reconciled to the lease liability as of September 30, 2020 (in thousands):

	September 30, 2020
2021	$ 1,240
2022	1,531
2023	1,576
2024	1,209
2025	1,596
Thereafter	4,403
Total	11,555
Less: Present value discount	(2,881)
Lease liability	$ 8,674
Other Balance Sheet Information-Operating Lease	
Weighted average remaining lease term (in years)	7.5
Weighted average discount rate	7.50%

Note 8. Short-Term Investments

As of September 30, 2020 and June 30, 2020, our short-term investments consisted of $165.2 million and $170.3 million, respectively, in U.S. government securities. The short-term investments held as of September 30, 2020 and June 30, 2020 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, 2020 and June 30, 2020, the gross holding gains and losses were immaterial.

Note 9. Stockholders' Equity

Equity Transactions

At-The-Market Equity Offering

On November 8, 2017, we entered into an At-The-Market Equity Offering Sales Agreement (the "ATM Sales Agreement"), pursuant to which we may sell an aggregate of up to $30.0 million of our common stock pursuant to the shelf registration statement. During the three months ended September 30, 2020, we sold 958,083 shares under the ATM Sales Agreement for net proceeds of $3.1 million, after costs of $0.1 million. The ATM Sales Agreement expired on November 8, 2020. There are no amounts remaining available under the ATM Sales Agreement.

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, replacing our prior shelf registration statement that was filed and declared effective in May 2017, and carrying forward approximately $107.5 million of unsold securities registered under the prior shelf registration statement. As of September 30, 2020, there is $175.7 million aggregate value of securities available under the shelf registration statement.

Warrants

As of September 30, 2020, we have outstanding warrants to purchase 16,061,602 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 Sheet. Therefore, we are required to account for the warrants as liabilities and record them at fair value. The warrants were revalued as of September 30, 2020 at $27.3 million and as of June 30, 2020 at $40.5 million; the changes in fair value were recorded in our Condensed Statement of Operations. No warrants were exercised during the three months ended September 30, 2020.

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 (“2008 Plan”), as amended and restated in 2011, 2013, 2014, 2015, 2016 and 2018, under which 19,089,794 shares of common stock are authorized for issuance. The 2008 Plan provides for the grant of options and/or other stock-based or stock-denominated awards to our non-employee directors, officers, employees and advisors. As of September 30, 2020, there were 1,791,137 shares available for future grant under the 2008 Plan.

Total share-based compensation expense for all stock awards consists of the following, (in thousands):

	Three Months Ended September 30,	
	2020	2019
Research and development	$ 1,129	$ 781
General and administrative	1,813	1,332
Total share-based compensation	$ 2,942	$ 2,113

Stock Options

Stock option activity for the three months ended September 30, 2020 was as follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at June 30, 2020	11,252,976	$ 2.81		
Granted	4,280,300	3.46		
Exercised	(50,229)	2.46		
Forfeited / Cancelled	(70,937)	3.46		
Expired	—	—		
Outstanding at September 30, 2020	15,412,110	2.99	8.2	$ 6,818,933
Vested and exercisable at September 30, 2020	6,636,348	2.68	7.0	$ 4,895,136

The fair value of each stock option granted during the three months ended September 30, 2020 is estimated on the grant date under the fair value method using a Black-Scholes valuation model. Stock options granted to employees during the three months ended September 30, 2020 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 during the three months ended September 30, 2020 vest ratably each month for a period of 12 months from the date of grant and expire ten years from the date of grant. The estimated fair values of the stock options, including the effect of estimated forfeitures, are expensed over the service period.

The following weighted-average assumptions were used to determine the fair value of options granted during the period:

	Three Months Ended September 30,	
	2020	2019
Risk-free interest rate	0.4%	1.8%
Expected life (years)	6.0	6.0
Expected volatility	80.6%	73.6%
Dividend yield	0.0%	0.0%
Weighted-average grant date fair value	$ 2.35	$ 1.63

As of September 30, 2020, there was $11.9 million of unrecognized compensation expense related to the unvested portion of stock options. Such compensation expense is expected to be recognized over a weighted-average period of 1.8 years.

Restricted Stock Units

In July 2020, we granted 442,650 RSUs to employees. Each RSU represented the contingent right to receive one share of our common stock. The RSUs will vest in periods of either one year or two years from the date of grant. The fair value of the RSUs was measured at $3.49 per unit. Under the terms of the 2008 Plan, each of the RSUs is calculated as 1.25 shares of common stock for purposes of determining the number of shares available for future grant. There were forfeitures of 6,000 RSUs during the three months ended September 30, 2020, and 436,650 unvested RSUs were outstanding as of September 30, 2020. As of September 30, 2020, unrecognized compensation expense related to the unvested portion of our RSUs was approximately $1.3 million and is expected to be recognized over approximately 1.5 years.

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

This Quarterly Report on Form 10-Q 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 2020 Annual Report, and elsewhere in this report, including, among other things:

- the outbreak of the novel coronavirus disease, COVID-19, or other pandemic, epidemic or outbreak of an infectious disease, and government responses thereto, may materially and adversely impact our business, including our preclinical studies and clinical trials;
- costs and delays in our clinical development programs and/or receipt of FDA or other required foreign and domestic governmental or regulatory approvals, or the failure to obtain such approvals, for our product candidates;
- our inability to obtain required additional financing or financing available to us on acceptable terms, or at all, whether as a result of weaknesses in the capital markets or otherwise, which may cause us to delay, scale-back or eliminate plans related to development of our drug candidates;
- KKC, Helsinn and other parties with which we have entered into collaboration, license, development and/or commercialization agreements may not satisfy their obligations under the agreements which could impact future revenues;
- our payment obligations under the Presage License Agreement and the S*Bio Purchase Agreement, which may reduce our cash available for other development efforts, and other obligations and risks related to the Presage License Agreement and the S*Bio Purchase Agreement;
- clinical studies by their nature typically have a high level of risk and may not produce successful results;
- 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;
- our inability to maintain or enter into, and the risks resulting from our dependence upon, contractual arrangements necessary for the clinical development, manufacture, commercialization, marketing, sales and distribution of our product candidates;
- the FDA's interpretation and our interpretation of data from preclinical and clinical studies may differ significantly;
- our failure to successfully commercialize our product candidates;
- pricing regulations, third-party reimbursement practices and healthcare reform initiatives;
- the failure of any products to gain market acceptance;
- our reliance on third parties to conduct our clinical trials and manufacture our products;
- our inability to control the costs of manufacturing our products;
- our reliance on acquisitions or licenses from third parties to expand our pipeline of drug candidates;
- competition and competitive factors;
- our inability to protect our patents or proprietary rights and obtain necessary rights to third party patents and intellectual property to operate our business;
- our inability to operate our business without infringing the patents and proprietary rights of others;
- costs stemming from litigation, including the pending securities class action or our defense against third party intellectual property infringement claims;
- our exposure to potential product liability claims and other claims may exceed our insurance limits;
- 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;
- 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 ability to attract and retain key employees;
- technological changes;
- cybersecurity;
- general economic conditions;
- government regulation generally;
- changes in industry practice; and
- one-time events.

These risks are not exhaustive. Other sections of this report and our other filings with the 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 COVID-19 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 on Form 10-Q and the audited financial statements and notes thereto included in our 2020 Annual Report, as filed with the SEC. Operating results are not necessarily indicative of results that may occur in future periods.

Overview and Recent Developments

We are a late-stage pharmaceutical company focused on leveraging our extensive development and oncology expertise to identify and advance new therapies intended to meaningfully improve the treatment of cancer. Our portfolio of drug candidates contains four clinical-stage assets, including zandelisib (formerly known as ("f/k/a") ME-401), currently in an ongoing Phase 2 clinical trial that, subject to the results upon completion of the trial, we intend to submit to the U.S. Food and Drug Administration ("FDA") to support accelerated approval of a marketing application. Our common stock is listed on the NASDAQ Capital Market under the symbol "MEIP."

Our approach to building our pipeline is to license promising cancer agents and build value in programs through development, commercialization and strategic partnerships, as appropriate.

In January 2020, the World Health Organization ("WHO") announced a global health emergency because of a new strain of coronavirus (the "COVID-19 outbreak") and the risks to the international community. In March 2020, the WHO classified the COVID-19 outbreak as a pandemic based on the rapid increase in exposure globally. As a result of the ongoing and rapidly evolving COVID-19 pandemic, various public health orders and guidance measures have been implemented across much of the United States, and across the globe, including in the locations of our office, clinical trial sites, key vendors and partners. While we continue to enroll and dose patients in our clinical trials, our clinical development program timelines have been negatively affected by COVID-19. The extent to which the ongoing pandemic continues to impact our business, including our preclinical studies, chemistry, manufacturing and controls ("CMC") studies and clinical trials, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease and to minimize its economic impact.

In light of the COVID-19 outbreak, the FDA issued a number of new guidance documents. Specifically, as a result of the potential effect of the COVID-19 outbreak on many clinical trial programs in the US and globally, the FDA issued guidance concerning potential impacts on clinical trial programs, changes that may be necessary to such programs if they proceed, considerations regarding trial suspensions and discontinuations, the potential need to consult with or make submissions to relevant ethics committees, Institutional Review Boards ("IRBs"), and the FDA, the use of alternative drug delivery methods, and considerations with respect the outbreak's impacts on endpoints, data collection, study procedures, and analysis. In addition, the European Medicines Agency ("EMA") as well as various country regulatory authorities have issued similar guidance. We have adapted the FDA and EMA guidance for study procedures, data collection, and oversight resulting from the pandemic.

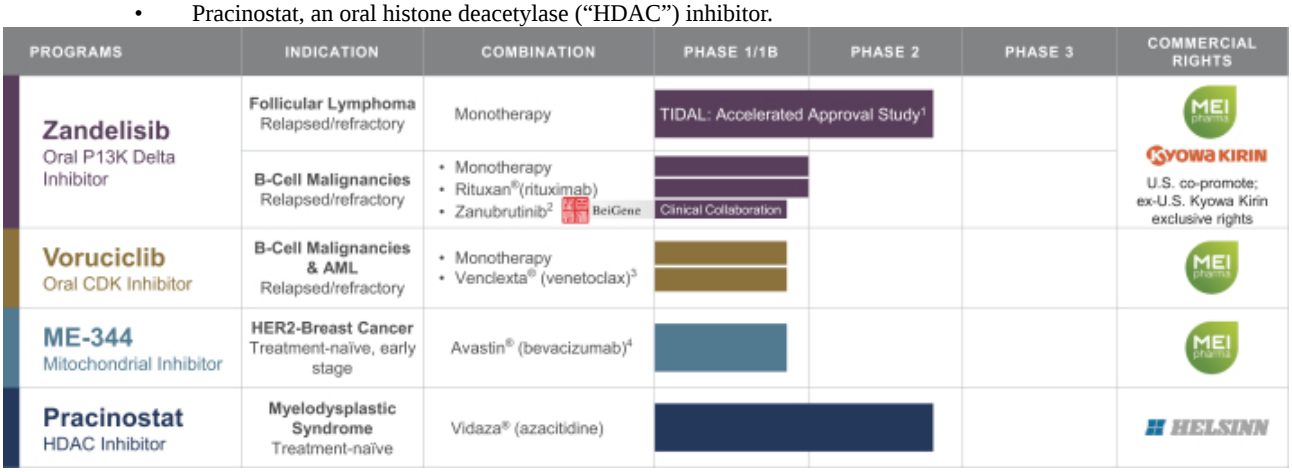
On March 27, 2020, President Trump signed into law the "Coronavirus Aid, Relief, and Economic Security ("CARES") Act." The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations, increased limitations on qualified charitable contributions, and technical corrections to tax depreciation methods for qualified improvement property. Regulatory guidance has indicated that public companies are ineligible to participate in certain of the loan programs provided by the CARES Act. We continue to examine the impact that the CARES Act may have on our business. Currently, we do not expect that the CARES Act will have a material impact on our financial condition, results of operations, or liquidity.

Clinical Development Programs

Our approach to building our pipeline is to license promising cancer agents and build value in programs through development, commercialization and strategic partnerships, as appropriate. Our drug candidate pipeline includes:

- Zandelisib (f/k/a ME-401), an oral phosphatidylinositol 3-kinase ("PI3K") delta inhibitor;
- Voruciclib, an oral cyclin-dependent kinase ("CDK") inhibitor;

- ME-344, a mitochondrial inhibitor targeting the oxidative phosphorylation ("OXPHOS") complex; and
- Pracinostat, an oral histone deacetylase ("HDAC") inhibitor.



1. Phase 2 study intended to support an accelerated approval marketing application with FDA.
2. Study arm conducted under clinical collaboration with BeiGene, Ltd.
3. Initiation of clinical studies is subject to opening of a new Investigational New Drug application with FDA.
4. Investigator-initiated trial; completed.

Zandelisib (f/k/a ME-401): PI3Kd Inhibitor in a Phase 2 Trial Intended to Support an Accelerated Approval in Relapsed or Refractory Follicular Lymphoma

Zandelisib is an oral, once-daily, selective PI3Kd inhibitor in clinical development for the treatment of B-cell malignancies. In April 2020, we entered a global license, development and commercialization agreement to further develop and commercialize zandelisib with Kyowa Kirin Co., Ltd. ("KKC"). MEI and KKC will co-develop and co-promote zandelisib in the U.S., with MEI 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 including TIDAL (Trials of PI3K DeltA in Non-Hodgkin's Lymphoma), a Phase 2 clinical trial currently evaluating zandelisib as a monotherapy for the treatment of adults with relapsed or refractory ("r/r") follicular lymphoma ("FL") after failure of at least two prior systemic therapies including chemotherapy and an anti-CD20 antibody. Subject to the results, upon completion of TIDAL, we are planning a submission with the FDA to support an accelerated approval of a marketing application under 21 CFR Part 314.500, Subpart H. 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, being conducted by KKC, evaluating zandelisib as a monotherapy in patients in Japan with indolent B-cell malignancy, pursuant to the 2018 license, development and commercialization agreement with respect to development and commercialization in Japan that was superseded by the KKC Commercialization Agreement (as defined below).

While PI3Kd inhibitors as a group are a clinically validated class for the treatment of B-cell malignancies, the FDA approved orally administered products, idelalisib (marketed as Zydelig®) and duvelisib (marketed as COPIKTRA®), and the intravenously administered PI3Kd/α inhibitor copanlisib (marketed as Aliqopa®), are challenged by dose-limiting toxicities 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 better maximize the therapeutic potential of PI3Kd inhibition by limiting toxicities, which hinder clinical utility.

The molecular structure and pharmacodynamic characteristics of zandelisib are distinct from the FDA approved PI3Kd inhibitors. Zandelisib is characterized by 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. These properties of zandelisib allow exploration of flexible dosing regimens such as an intermittent dosing schedule, which has demonstrated the potential to maintain clinical benefit while minimizing immune-related toxicities common to other PI3Kd agents, either as a monotherapy or in combination with other therapies.

KKC License, Development and Commercialization Agreement

In April 2020, we entered a License, Development and Commercialization Agreement with KKC (the "KKC Commercialization Agreement"). 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., 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 United States (the "Ex-U.S"). KKC grants 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 and KKC will co-develop and co-promote zandelisib in the U.S., with us recording all revenue from U.S. sales. We and KKC will share U.S. profits and costs (including development costs) on a 50-50 basis. 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 million in May 2020. Of the $100 million paid by KKC, $20.4 million was remitted by KKC to the Japanese taxing authorities as a result of the U.S. Internal Revenue Service being closed due to the COVID pandemic, and therefore being unable to provide necessary documentation to support an exemption from the required foreign withholding. We received the amount remitted to the Japanese taxing authorities in October 2020. 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 PI3Kd 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 d 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

We are conducting multiple ongoing studies evaluating zandelisib including TIDAL, a global Phase 2 trial evaluating patients with relapsed or refractory follicular lymphoma intended to support an accelerated approval of a marketing application with the FDA, and a multi-arm, open-label, Phase 1b dose escalation and expansion trial as a monotherapy and in combination with other therapies in patients with FL and other B-cell malignancies. Additionally, KKC has initiated Phase 1 and Phase 2 studies evaluating zandelisib as a monotherapy in patients in Japan with indolent B-cell malignancy; the Phase 2 study is intended to support marketing authorization in Japan.

We are also in the process of expanding the zandelisib clinical development program under the KKC Commercialization Agreement. Expansion plans include adding an arm evaluating patients with relapsed or refractory marginal zone lymphoma to the TIDAL study. We are also planning to initiate a Phase 3 study of zandelisib in combination with rituximab evaluating follicular lymphoma and MZL patients who received one or more prior lines of treatment; this study would act as the required confirmatory study for the potential accelerated approval of zandelisib in patients with relapsed FL who have received at least two prior systemic therapies. In addition to other planned clinical studies sponsored by us, we also plan to support select investigator-initiated studies, including one being conducted at the Cleveland Clinic evaluating zandelisib combined with standard of care (“R-CHOP”) in patients with newly diagnosed diffuse large B-cell lymphoma (“DLBCL”).

Phase 1b Multi-arm Trial

In May 2020, we reported updated data from the ongoing Phase 1b clinical trial evaluating zandelisib as a monotherapy and in combination with rituximab in patients with relapsed or refractory B-cell malignancies as featured in a poster discussion at the American Society of Clinical Oncology 2020 Virtual Scientific Program.

Data were reported from a total of 57 patients treated with zandelisib, including 36 patients with r/r FL, 10 patients with r/r chronic lymphocytic leukemia (“CLL”), and 11 patients with other B-cell malignancies. Zandelisib was administered once daily at 60 mg for two 28-day cycles and then on an intermittent schedule (“IS”) of once daily dosing for the first seven days of each subsequent 28-day cycle. A previous cohort of 39 patients in the trial was treated with zandelisib at 60 to 180 mg administered continuously once daily (“CS”) or were switched to the IS in later cycles.

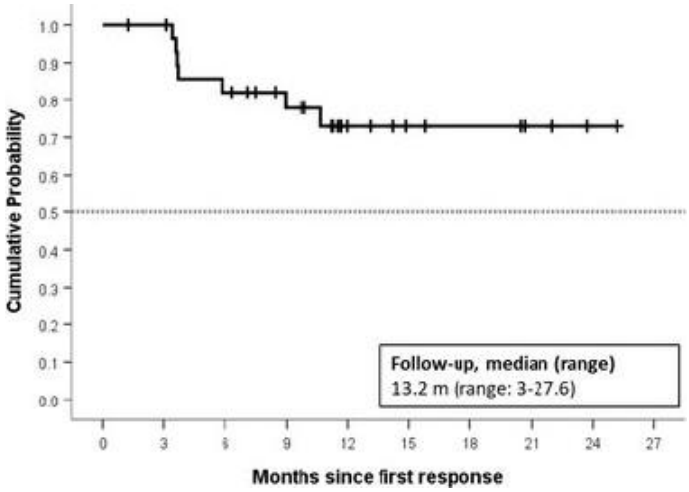
The overall response rate in the 36 patients with r/r FL was 83%, with 22% achieving a complete response. The overall response rate was 76% in 17 patients administered zandelisib as a monotherapy and 89% in 19 patients administered zandelisib in combination with rituximab. The overall response rate in nine evaluable patients with CLL was 89%.

Overall Response Rates ("ORR")

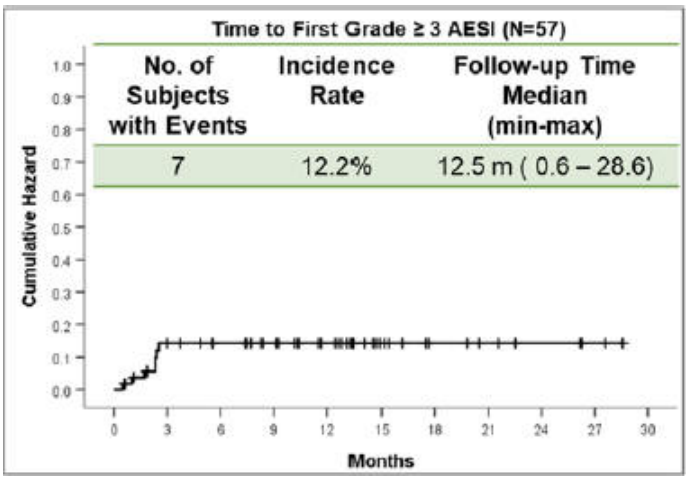
Diagnosis	Evaluable Subjects N	ORR N (%)
FL	36	30 (83%)
By treatment group		
zandelisib monotherapy	17	13 (76%)
zandelisib + rituximab	19	17 (89%)
By prior lines of therapy		
1 prior	16	13 (81%)
³ 2 prior	20	17 (85%)
CLL SLL		
By treatment group	9	8 (89%)
zandelisib monotherapy	3	3 (100%)
zandelisib + rituximab	6	5 (83%)

Median duration of response in patients with FL has not yet been reached and median follow-up was 13.2 months (range: 3.0-27.6). Responses appeared durable across patient subsets analyzed (prior lines of therapy (1 vs ³ 2), treatment group (i.e. monotherapy or in combination with rituximab) or tumor bulk (< 5 cm vs ³5 cm)).

Duration of Response: Follicular Lymphoma Patients (N=30)



Zandelisib was generally well-tolerated. The rate of drug related grade 3 Adverse Events of Special Interest ("AESI") was: diarrhea 3.5% (2/57); colitis 3.5% (2/57); rash 1.8% (1/57); alanine aminotransferase ("ALT")/ aspartate aminotransferase ("AST") elevation 1.8% (1/57); non-infectious pneumonitis 1.8% (1/57). No grade ³3 AESI was reported after Cycle 3, when patients are treated with the IS, and the discontinuation rate due to adverse events was 7% (4/57). There were no isolated grade 3 elevations in ALT and AST: such elevations were transient and in each case were associated with grade 3 diarrhea or rash.



The Phase 1b trial is additionally evaluating zandelisib (60 mg) in combination with zanubrutinib (marketed as Brukinsa®), an inhibitor of Bruton's tyrosine kinase ("BTK") developed by BeiGene, Ltd. ("BeiGene"). Pursuant to a collaboration initiated with

BeiGene in October 2018, we began evaluating the safety and efficacy of zandelisib in combination with zanubrutinib for the treatment of patients with various relapsed or refractory B-cell malignancies. The cost of the combination trial is being equally shared. 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.

Phase 2 Trial Intended to Support an Accelerated Approval Marketing Application

We are recruiting patients in TIDAL, a global Phase 2 trial currently evaluating the efficacy, safety, and tolerability of zandelisib in patients with FL after failure of at least two prior systemic therapies including chemotherapy and anti-CD20 antibody. This study is intended to support an FDA accelerated approval New Drug Application ("NDA"). The study is evaluating zandelisib administered once daily at 60 mg for two 28-day cycles and then on an intermittent schedule of once daily dosing for the first seven days of each subsequent 28-day cycle (i.e. IS). Approximately 120 patients will be enrolled and treated with the IS regimen; the primary efficacy endpoint will be the rate of objective responses to therapy and other endpoints will include duration of response and tolerability of zandelisib. Additionally, we have added an arm to this study evaluating patients with relapsed or refractory marginal zone lymphoma.

Impact of COVID-19 on the Phase 2 TIDAL Study

While the extent to which the COVID-19 pandemic will impact the completion of the TIDAL study is subject to future developments, which are highly uncertain and cannot be predicted with confidence, currently the integrity of the study remains intact and patient enrollment continues, although at a reduced rate. At this time, TIDAL enrollment is projected to be completed in the first calendar quarter of 2021. 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 and guidance from other regulatory authorities, as we may deem appropriate.

Voruciclib: CDK Inhibitor with CDK9 Inhibition in Phase 1 Studies

Voruciclib is an orally administered CDK inhibitor differentiated by its potent in vitro inhibition of CDK9 in addition to CDK6, 4 and 1. Voruciclib is being evaluated in a Phase 1b trial evaluating dose and schedule in patients with acute myeloid leukemia ("AML") and B-cell malignancies.

Voruciclib Scientific Overview: Cell Cycle Signaling

The CDK family of proteins are important cell cycle regulators. 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®).

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. (Scientific Reports. (2017) 7:18007. DOI:10.1038/s41598-017-18368-w).

Additionally, a peer reviewed manuscript published in 2020 by Luedtke et al, concluded that the inhibition of CDK9 by voruciclib synergistically enhances cell death induced by the Bcl-2 selective inhibitor venetoclax in preclinical models of acute myeloid leukemia. (Sig Transduct Target Ther 5, 17 (2020). https://doi.org/10.1038/s41392-020-0112-3.

CDK9 is also a transcriptional regulator of MYC proto-oncogene protein ("MYC"), a transcription factor regulating cell proliferation and growth which contributes to many human cancers and is frequently associated with poor prognosis and unfavorable patient survival. Targeting MYC directly has historically been difficult, but CDK9 is a transcriptional regulator of MYC and is a promising approach to target this oncogene.

Clinical Program

We are evaluating patients with hematological malignancies in a Phase 1b clinical trial evaluating the dose and schedule of voruciclib. The trial is initially intended to evaluate the dose and schedule of voruciclib as a monotherapy in patients with relapsed and/or refractory B-cell malignancies or AML after failure of prior standard therapies to determine the safety, preliminary efficacy and maximum tolerated dose. Once initial safe dose levels and schedules have been established, we plan in parallel, subject to FDA agreement, to evaluate the dose and schedule of voruciclib in combination with a BCL2 inhibitor such as venetoclax to assess synergies and the opportunity for combination treatments, initially in patients with AML and subsequently across multiple indications.

Voruciclib was previously evaluated in more than 70 patients with solid tumors in multiple Phase 1 studies with a tolerability profile consistent with other drugs in its class. In pre-clinical studies, voruciclib shows dose-dependent suppression of MCL1 at concentrations achievable with doses that appear to be generally well tolerated in earlier Phase 1 studies. Pre-clinical studies additionally show inhibition of MYC protein expression.

Impact of COVID-19 on the Voruciclib Clinical Development Program

While the extent to which the COVID-19 pandemic will impact the progress of the voruciclib clinical development program, including the ongoing Phase 1b study, is subject to future developments, which are highly uncertain and cannot be predicted with confidence, the study remains ongoing and is continuing to enroll patients, although at a reduced rate. 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: Mitochondrial Inhibitor with Combinatorial Potential

ME-344 is our novel and tumor selective, isoflavone-derived mitochondrial inhibitor drug candidate. It directly targets the OXPHOS complex 1, a pathway involved in 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 ®) in 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 adenosine triphosphate ("ATP"). The two major sources of ATP are the specialized cellular organelles termed mitochondria and through the metabolism of carbohydrates, proteins and lipids.

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 for 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 issue 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.

Pracinostat: HDAC Inhibitor Candidate in a Phase 2 Clinical Trial

Pracinostat is an oral HDAC inhibitor being evaluated in a Phase 2 trial in patients with high or very high-risk *myelodysplastic syndrome* ("MDS") who are previously untreated with hypomethylating agents (the "POC study").

In August 2016, we entered into an exclusive worldwide license, development, manufacturing and commercialization agreement with Helsinn Healthcare SA, a Swiss pharmaceutical corporation ("Helsinn") for pracinostat (the "Helsinn License Agreement") as a treatment for patients with MDS or AML. Under the agreement, Helsinn is primarily responsible for funding global development and commercialization costs for pracinostat. We are responsible for conducting the POC study, the cost of which is being shared equally with Helsinn. Any future development and commercialization costs after the completion of the Phase 2 trial will be the responsibility of Helsinn.

Pracinostat Scientific Overview; Epigenetics

HDACs play a key role in epigenetic regulation of gene expression by regulating chromatin structure. Acetylation of positively charged lysine residues present in histone proteins by the histone acetyltransferase ("HATs") reduces the affinity between histones and negatively charged DNA, resulting in the opening of the chromatin structure. This makes it easier for the transcriptional machinery to access the DNA, enhancing RNA transcription. Conversely, deacetylation by the HDACs closes the chromatin structure leading to a repression of gene transcription. In normal cells, HDACs and HATs together control histone acetylation levels to maintain a balance. In diseases such as cancer, this regulation can be disturbed. HDAC inhibitors cause accumulation of acetylated histones, enhance transcription and result in changes to a variety of cellular responses including differentiation, proliferation, migration, survival and response to metabolic and hypoxic stress. In general, tumor cells are more susceptible than normal cells to the anti-proliferative and pro-apoptotic effects of HDAC inhibitors.

There are currently three HDAC inhibitors, one oral and two injectable, approved by the FDA for the treatment of T-cell lymphoma and a fourth orally administered HDAC inhibitor approved for multiple myeloma. Other HDAC inhibitors are being evaluated in clinical trials as monotherapies and in combination for the treatment of various hematologic diseases and solid tumors.

Pracinostat is an orally available, potent HDAC inhibitor that we believe has potentially improved physicochemical, pharmaceutical and pharmacokinetic properties when compared to other compounds of this class, including increased bioavailability and increased half-life.

Clinical Program

Pracinostat is being investigated in a Phase 2 dose optimization trial evaluating patients with high and very high-risk MDS who are previously untreated with hypomethylating agents. This patient group represents the highest unmet need in MDS, with median survival estimates of 1.6 years and 0.8 years, respectively (Greenberg et al, *Blood 2012*). The ongoing Phase 2 open-label trial is evaluating a 45 mg dose of pracinostat in combination with the standard dose of azacitidine. The trial is designed to evaluate tolerability of the combination, with the intent of maintaining patient enrollment longer than in an earlier Phase 2 trial evaluating a 60 mg dose. A prolonged treatment may result in a systemic exposure to pracinostat and azacitidine sufficient to achieve the desired treatment effect; data from the earlier Phase 2 trial suggested that insufficient exposure to treatment may have limited the treatment effect of the combination.

A pre-planned interim analysis of the ongoing Phase 2 MDS trial demonstrated a 10% discontinuation rate among the first 20 evaluable patients treated, meeting the predefined threshold in the first 3 treatment cycles. The 10% rate is consistent with the discontinuation rate for azacitidine given as a monotherapy in earlier studies with pracinostat. Having met this threshold, the trial expanded open-label enrollment to a total of 60 patients in the study. An interim analysis presented at the 2018 ASH meeting demonstrated a discontinuation rate due to adverse events in the first three cycles of 4%, substantially lower than the rate of 26% reported in our prior Phase 2 trial.

The ongoing Phase 2 trial completed enrollment and patients have been followed for at least one year to evaluate safety and efficacy. The primary endpoints of the trial are 1) safety and tolerability and 2) overall response rate, defined as complete remission ("CR"), partial remission ("PR") and marrow CR. Secondary endpoints include CR rate, overall hematologic improvement ("HI") response rate, clinical benefit rate (defined as rate of CR + PR + HI + Marrow CR), rate of cytogenetic complete response/remission, duration of response, rate of leukemic transformation, event-free survival, progression-free survival and overall survival.

Data from the ongoing Phase 2 study (n=64) presented as part of the American Society of Clinical Oncology 2020 Virtual Scientific Program in June 2020 demonstrated an estimated median overall survival ("OS") rate of 23.5 months with a one-year OS rate of 77%. The median follow-up was 17.6 months (range, 15.7–18.8) and the overall response rate ("ORR") was 33% (21/64), all of which are complete responses ("CR"). The clinical benefit rate (CR, mCR plus hematologic improvement ("HI"), mCR with no HI, or HI with no mCR) was 77% (49/64). Twenty seven percent of patients (17/64) proceeded to a stem cell transplant while on study. Eleven percent of patients discontinued treatment because of adverse events. The most common grade ³3 treatment emergent adverse events were hematologic, and included decreased neutrophil count (50%), anemia (39%), febrile neutropenia (34%), decreased platelet count (33%), thrombocytopenia (27%), and decreased white blood cell count (20%).

A Phase 3 study evaluating pracinostat in combination with azacitidine in patients with AML who are unfit to receive standard intensive chemotherapy was discontinued by Helsinn, the study sponsor, in July 2020 after an interim futility analysis

undertaken by the study Independent Data Monitoring Committee demonstrated it was unlikely to meet the primary endpoint of overall survival compared to the control group. In connection with the discontinuation of the Phase 3 study, Helsinn has withdrawn the breakthrough therapy designation FDA granted for pracinostat in combination with azacitidine for the treatment of patients with AML. Following the discontinuation of the Phase 3 AML study, Helsinn communicated to us their plan to continue therapy and observation of the patients currently in the Phase 2 MDS study and that further development of pracinostat, including for the treatment of MDS, is under review.

Results of Operations

Comparison of Three Months Ended September 30, 2020 and 2019

We had a loss from operations of $15.6 million for the three months ended September 30, 2020 compared to a loss from operations of $12.6 million for the three months ended September 30, 2019.

Revenue: We recognized revenue of $3.8 million for the three months ended September 30, 2020 compared to $1.2 million for the three months ended September 30, 2019. Revenue increased primarily due to our license agreement with KKC and resulted from the partial satisfaction of our research and development obligations. Revenue related to the license agreement with KKC was $3.6 million for the three months ended September 30, 2020 compared to $0.8 million for the three months ended September 30, 2019. Revenue also includes recognition of fees allocated to performance obligations in accordance with the Helsinn License Agreement. Revenue related the Helsinn License Agreement was $0.3 million for the three months ended September 30, 2020 compared to $0.4 million for the three months ended September 30, 2019 due to decreased costs associated with the POC study.

Cost of Revenue: We recognized cost of revenue of $0.5 million for the three months ended September 30, 2020 compared to $0.7 million for the three months ended September 30, 2019. The cost of revenue includes external costs paid to third-party contractors to perform research, conduct clinical trials and develop and manufacture drug materials, and internal compensation and related personnel expenses associated with pracinostat. Costs of revenue relate to expenses for pracinostat incurred in connection with our development activities in accordance with the Helsinn License Agreement, including both Helsinn's share and our share of costs related to the POC study, which we are responsible for conducting. Cost of revenue decreased due to decreased costs associated with the POC study.

***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	**2020**	**2019**
Zandelisib	$ 7,996	$ 4,952
Voruciclib	784	543
ME-344	65	—
Other	4,151	3,467
Total research and development expenses	$ 12,996	$ 8,962

Research and development expenses consist primarily of clinical trial costs (including payments to 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. Research and development expenses were $13.0 million for the three months ended September 30, 2020 compared to $9.0 million for the three months ended September 30, 2019. Costs related to zandelisib for the three months ended September 30, 2020 reflected an increase of $3.0 million of increased clinical trial costs, primarily as a result of increased activity in the Phase 2 study and start-up costs related to the Phase 3 study. Costs related to voruciclib increased for the three months ended September 30, 2020 compared with the three months ended September 30, 2019, due to increased drug manufacturing costs. Other research and development costs increased for the three months ended September 30, 2020 due to higher levels of personnel costs ($0.5 million) and share-based compensation ($0.3 million) associated with increased headcount to support our clinical activities, offset by decreased consulting fees ($0.2 million).

***General and Administrative*:** General and administrative expenses increased by $1.8 million to $5.9 million for the three months ended September 30, 2020 compared to $4.1 million for the three months ended September 30, 2019. The increase is primarily due to increased personnel costs ($0.4 million) and share-based compensation ($0.5 million) associated with increased headcount to support our activities, as well as external professional services and legal costs ($0.4 million) and corporate overhead costs ($0.5 million).

Other income or expense: We recorded a non-cash gain of $13.2 million during the three months ended September 30, 2020 due to a change in the fair value of our warrant liability for warrants issued in connection with the May 2018 Private Placement. The change in the warrant liability is primarily due to changes in our stock price. Additionally, we received interest and dividend income of $0.3 million for the three months ended September 30, 2020 compared to $0.4 million for the three months ended September 30, 2019. The decrease was due to lower yields during the three months ended September 30, 2020 compared to the three months ended September 30, 2019.

Liquidity and Capital Resources

We have accumulated losses of $279.3 million since inception and expect to incur operating losses and generate negative cash flows from operations for the foreseeable future. As of September 30, 2020, we had $176.1 million in cash and cash equivalents, and short-term investments. Additionally, we had a receivable of $20.4 million from the Japanese taxing authorities that had been withheld from the $100 million upfront payment associated with the KKC Commercialization Agreement. The receivable was received in October 2020. We believe that these resources will be sufficient to fund our operations into fiscal year 2022 and beyond. 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 operations for the three months ended September 30, 2020 was $9.1 million. Net cash used in operating activities for the three months ended September 30, 2019 was $14.1 million. The decrease in cash used in operating activities year over year is due to changes in working capital balances.

Net cash provided by investing activities for the three months ended September 30, 2020 was $4.5 million compared to $5.0 million provided by investing activities for the three months ended September 30, 2019. The change was primarily due to increased purchases of short-term investments in 2020, net of maturities, as a result of cash received associated with the KKC License Agreement.

Net cash provided by financing activities during the three months ended September 30, 2020 was $3.3 million compared with $5.5 million provided by financing activities during the quarter ended September 30, 2019. Cash raised during the three months ended September 30, 2020 reflected $3.1 million of net proceeds from the issuance of common stock. Cash raised during the quarter ended September 30, 2019 reflected $0.2 million from the issuance of common stock and $5.3 million of proceeds from the collection of common stock proceeds receivable.

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 have leased approximately 32,800 square feet of office space in San Diego, California. The contractual lease term is from July 2020 through March 2028. The average annual lease payments over the term of the lease will approximate $1.5 million, plus a pro rata share of certain building expenses. Our total contractual obligation over the term of the lease is approximately $11.6 million.

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, 2020, we have not accrued any amounts for potential future payments.

*S*Bio Purchase Agreement*

We are party to a definitive asset purchase agreement with S*Bio, pursuant to which we acquired certain assets comprised of intellectual property and technology including rights to pracinostat. We agreed to make certain milestone payments to S*Bio based on the achievement of certain clinical, regulatory and net sales-based milestones, as well as to make certain contingent earnout payments to S*Bio. Milestone payments will be made to S*Bio up to an aggregate amount of $74.5 million if certain U.S., E.U. and Japanese regulatory approvals are obtained and if certain net sales thresholds are met in North America, the E.U. and Japan. The first milestone payment of $200,000 plus 166,527 shares of our common stock having a value of $500,000 was paid in August 2017 upon the first dosing of a patient in a Phase 3 clinical trial. Subsequent milestone payments will be due upon certain regulatory approvals and sales-based events. As of September 30, 2020, we have not accrued any amounts for potential future payments.

CyDex License Agreement

We are party to a license agreement with CyDex. Under the license agreement, CyDex granted to us an exclusive, non-transferable license to intellectual property rights relating to Captisol® for use with our two isoflavone-based drug compounds (currently ME-344). We agreed to pay to CyDex a non-refundable license issuance fee, future milestone payments, and royalties at a low, single-digit percentage rate on future sales of our approved drugs utilizing Captisol. Contemporaneously with the license agreement, CyDex entered into a commercial supply agreement with us, pursuant to which we agreed to purchase 100% of our requirements for Captisol from CyDex. We may terminate both the license agreement and the supply agreement for convenience at any time upon 90 days' prior written notice. As of September 30, 2020, we have not accrued any amounts for potential future payments.

COVID-19

In January 2020, the World Health Organization ("WHO") announced a global health emergency because of a new strain of coronavirus (the "COVID-19 outbreak") and the risks to the international community. In March 2020, the WHO classified the COVID-19 outbreak as a pandemic based on the rapid increase in exposure globally. While we continue to enroll and dose patients in our clinical trials, our clinical development program timelines have been negatively affected by COVID-19. The extent to which the ongoing pandemic continues to impact our business, including our preclinical studies, chemistry, manufacturing, and control ("CMC") studies and clinical trials, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease and to minimize its economic impact.

In light of the COVID-19 outbreak, the FDA issued a number of new guidance documents. Specifically, as a result of the potential effect of the COVID-19 outbreak on many clinical trial programs in the U.S. and globally, the U.S. FDA issued guidance concerning potential impacts on clinical trial programs, changes that may be necessary to such programs if they proceed, considerations regarding trial suspensions and discontinuations, the potential need to consult with or make submissions to relevant ethics committees, IRBs, and the FDA, the use of alternative drug delivery methods, and considerations with respect the outbreak's impacts on endpoints, data collection, study procedures, and analysis. In addition, the European Medicines Agency ("EMA") as well as country regulatory authorities have issued similar guidance.

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 2020 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 2020 Annual Report. There have been no changes in our significant accounting policies or critical accounting estimates since June 30, 2020.

Recent Accounting Pronouncements

There are no recent accounting pronouncements that we anticipate adopting.

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

At the end of the period covered by this Quarterly Report on Form 10-Q, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective to ensure that the information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

There were no changes in our internal control over financial reporting during the period covered by this Quarterly Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1: Legal Proceedings

See our financial statements, Note 6 — Commitments and Contingencies – Legal Proceedings.

Item 1A: Risk Factors

There have been no material changes in our risk factors from those included in our 2020 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	
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	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase 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 10, 2020

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 10, 2020

/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. Our 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 10, 2020

/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, 2020, (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 10, 2020

/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)