
**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 March 31, 2021

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
(State or other jurisdiction of
incorporation or organization)

51-0407811
(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 May 4, 2021, the number of shares outstanding of the issuer’s common stock, \$0.00000002 par value, was 112,591,778.

MEI PHARMA, INC.

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PART I FINANCIAL INFORMATION**Item 1: Condensed Financial Statements – Unaudited**

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

| | March 31, 2021 (unaudited) | June 30, 2020 |
|--|----------------------------------|-------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 9,745 | \$ 12,331 |
| Short-term investments | 154,879 | 170,299 |
| Total cash, cash equivalents and short-term investments | 164,624 | 182,630 |
| Receivable for foreign tax withholding | — | 20,420 |
| Prepaid expenses and other current assets | 11,937 | 5,594 |
| Total current assets | 176,561 | 208,644 |
| Operating lease right-of-use asset | 7,992 | — |
| Property and equipment, net | 1,569 | 1,084 |
| Total assets | <u>\$ 186,122</u> | <u>\$ 209,728</u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 5,571 | \$ 2,437 |
| Accrued liabilities | 7,762 | 6,090 |
| Deferred revenue | 19,143 | 14,777 |
| Operating lease liability | 900 | — |
| Total current liabilities | 33,376 | 23,304 |
| Deferred revenue, long-term | 70,734 | 67,723 |
| Operating lease liability, long-term | 7,608 | — |
| Warrant liability | 29,442 | 40,483 |
| Total liabilities | <u>141,160</u> | <u>131,510</u> |
| 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; 112,592 and 111,514 shares issued and outstanding at March 31, 2021 and June 30, 2020, respectively | — | — |
| Additional paid-in capital | 367,055 | 355,452 |
| Accumulated deficit | (322,093) | (277,234) |
| Total stockholders' equity | 44,962 | 78,218 |
| Total liabilities and stockholders' equity | <u>\$ 186,122</u> | <u>\$ 209,728</u> |

See accompanying notes to condensed financial statements.

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

| | Three Months Ended | | Nine Months Ended | |
|--|--------------------|-------------------|--------------------|--------------------|
| | March 31, | | March 31, | |
| | 2021 | 2020 | 2021 | 2020 |
| Revenue | \$ 2,418 | \$ 1,244 | \$ 15,419 | \$ 3,409 |
| Operating expenses: | | | | |
| Cost of revenue | 405 | 860 | 1,408 | 2,189 |
| Research and development | 17,884 | 8,963 | 53,104 | 26,206 |
| General and administrative | 6,215 | 3,864 | 17,780 | 12,189 |
| Total operating expenses | <u>24,504</u> | <u>13,687</u> | <u>72,292</u> | <u>40,584</u> |
| Loss from operations | (22,086) | (12,443) | (56,873) | (37,175) |
| Other income (expense): | | | | |
| Change in fair value of warrant liability | (9,272) | 7,732 | 11,035 | 8,562 |
| Interest and dividend income | 58 | 382 | 497 | 1,074 |
| Other income (expense) | (13) | — | 482 | (1) |
| Net loss | <u>\$ (31,313)</u> | <u>\$ (4,329)</u> | <u>\$ (44,859)</u> | <u>\$ (27,540)</u> |
| Net loss: | | | | |
| Basic | <u>\$ (31,313)</u> | <u>\$ (4,329)</u> | <u>\$ (44,859)</u> | <u>\$ (27,540)</u> |
| Diluted | <u>\$ (31,313)</u> | <u>\$ (4,329)</u> | <u>\$ (65,166)</u> | <u>\$ (27,540)</u> |
| Net loss per share: | | | | |
| Basic | <u>\$ (0.28)</u> | <u>\$ (0.04)</u> | <u>\$ (0.40)</u> | <u>\$ (0.32)</u> |
| Diluted | <u>\$ (0.28)</u> | <u>\$ (0.04)</u> | <u>\$ (0.57)</u> | <u>\$ (0.32)</u> |
| Shares used in computing net loss per share: | | | | |
| Basic | <u>112,557</u> | <u>105,999</u> | <u>112,505</u> | <u>85,995</u> |
| Diluted | <u>112,557</u> | <u>105,999</u> | <u>113,991</u> | <u>85,995</u> |

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, net | 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 |
| Net loss | — | — | (11,454) | (11,454) |
| Exercise of stock options | 6 | 15 | — | 15 |
| Share-based compensation expense | — | 2,609 | — | 2,609 |
| Balance at December 31, 2020 | 112,528 | 364,278 | (290,780) | 73,498 |
| Net loss | — | — | (31,313) | (31,313) |
| Exercise of stock options | 63 | 126 | — | 126 |
| Exercise of warrants | 1 | 6 | — | 6 |
| Share-based compensation expense | — | 2,645 | — | 2,645 |
| Balance at March 31, 2021 | <u>112,592</u> | <u>\$367,055</u> | <u>\$ (322,093)</u> | <u>\$ 44,962</u> |
| | 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, net | 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 |
| Net loss | — | — | (20,217) | (20,217) |
| Issuance of common stock, net | 32,344 | 48,451 | — | 48,451 |
| Share-based compensation expense | — | 1,771 | — | 1,771 |
| Balance at December 31, 2019 | 105,999 | 331,714 | (254,429) | 77,285 |
| Net loss | — | — | (4,329) | (4,329) |
| Issuance of common stock, net | — | (8) | — | (8) |
| Share-based compensation expense | — | 1,550 | — | 1,550 |
| Balance at March 31, 2020 | <u>105,999</u> | <u>\$333,256</u> | <u>\$ (258,758)</u> | <u>\$ 74,498</u> |

See accompanying notes to condensed financial statements.

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

| | Nine Months Ended | |
|--|--------------------------|-----------------|
| | March 31, | |
| | 2021 | 2020 |
| Cash flows from operating activities: | | |
| Net loss | \$ (44,859) | \$(27,540) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Change in fair value of warrant liability | (11,035) | (8,562) |
| Share-based compensation | 8,196 | 5,434 |
| Depreciation and amortization | 215 | 90 |
| Non-cash lease expense | 697 | — |
| Changes in operating assets and liabilities: | | |
| Receivable for foreign tax withholding | 20,420 | — |
| Prepaid expenses and other current assets | (6,343) | (169) |
| Accounts payable | 3,134 | (2,295) |
| Accrued liabilities | 1,672 | 667 |
| Deferred revenue | 7,377 | (2,479) |
| Operating lease liability | (181) | — |
| Net cash used in operating activities | <u>(20,707)</u> | <u>(34,854)</u> |
| Cash flows from investing activities: | | |
| Purchases of property and equipment | (700) | (785) |
| Purchases of short-term investments | (325,162) | (90,324) |
| Proceeds from maturity of short-term investments | 340,582 | 69,863 |
| Net cash provided by (used in) investing activities | <u>14,720</u> | <u>(21,246)</u> |
| Cash flows from financing activities: | | |
| Proceeds from exercise of stock options | 265 | 72 |
| Proceeds from issuance of common stock, net | 3,136 | 48,602 |
| Collection of common stock proceeds receivable | — | 5,274 |
| Net cash provided by financing activities | <u>3,401</u> | <u>53,948</u> |
| Net decrease in cash and cash equivalents | (2,586) | (2,152) |
| Cash and cash equivalents at beginning of the period | 12,331 | 9,590 |
| Cash and cash equivalents at end of the period | <u>\$ 9,745</u> | <u>\$ 7,438</u> |
| Supplemental disclosures: | | |
| Income taxes paid | \$ (8) | \$ (1) |
| Operating lease right-of-use assets obtained in exchange for operating lease liabilities | \$ 8,689 | \$ — |
| Warrants issued pursuant to cashless exercise | \$ 6 | \$ — |

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 and ME-344, and to develop new compounds. The actual amount of funds that will be needed will depend upon 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 \$322.1 million since inception and expect to incur operating losses and generate negative cash flows from operations for the foreseeable future. As of March 31, 2021, we had \$164.6 million in cash and cash equivalents and short-term investments. We believe that these resources will be sufficient to meet our obligations and fund our liquidity and capital expenditure requirements for at least the next 12 months from the issuance of these financial statements. Our current business operations are focused on continuing the clinical development of our drug candidates. Changes to our research and development plans or other changes affecting our operating expenses may affect actual future use of existing cash resources. Our research and development expenses are expected to increase in the foreseeable future. We cannot determine with certainty costs associated with ongoing and future clinical trials or the regulatory approval process. The duration, costs and timing associated with the development of our product candidates will depend on a variety of factors, including uncertainties associated with the results of our clinical trials.

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

Basis of Presentation

The accompanying unaudited financial statements have been prepared in accordance with accounting principles generally accepted in the 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 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 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”)

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 or usage-based royalty revenue from license agreements.

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

| | Three Months Ended March 31, | | Nine Months Ended March 31, | |
|--------------------------------|---------------------------------|----------------|--------------------------------|----------------|
| | 2021 | 2020 | 2021 | 2020 |
| KKC License Agreements | \$2,321 | \$ 812 | \$14,979 | \$2,282 |
| Helsinn License Agreement | 97 | 432 | 440 | 1,127 |
| | <u>\$2,418</u> | <u>\$1,244</u> | <u>\$15,419</u> | <u>\$3,409</u> |
| Timing of Revenue Recognition: | | | | |
| Services performed over time | \$2,418 | \$1,244 | \$15,419 | \$3,409 |
| | <u>\$2,418</u> | <u>\$1,244</u> | <u>\$15,419</u> | <u>\$3,409</u> |

The KKC Commercialization Agreement and KKC Japan License Agreement (Note 3) include other distinct performance obligations that will be satisfied over time, and accordingly we recognized \$2.3 million and \$0.8 million related to our progress toward satisfying those obligations during the three months ended March 31, 2021 and 2020, respectively, and \$15.0 million and \$2.3 million during the nine months ended March 31, 2021 and 2020, 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 \$0.1 million and \$0.4 million related to our progress toward satisfying those obligations during the three months ended March 31, 2021 and 2020, respectively, and \$0.4 million and \$1.1 million during the nine months ended March 31, 2021 and 2020, 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 nine months ended March 31, 2021 and 2020 (in thousands):

| | Nine Months Ended March 31, | |
|---|--------------------------------|-----------------|
| | 2021 | 2020 |
| Receivables | | |
| Receivables, beginning of period | \$ 2,605 | \$ — |
| Amounts billed | 15,744 | 1,088 |
| Payments received | (18,349) | (1,014) |
| Receivables, end of period | <u>\$ —</u> | <u>\$ 74</u> |
| Contract assets | | |
| Contract assets, beginning of period | \$ 335 | \$ 511 |
| Billable amounts | 22,841 | 930 |
| Amounts billed | (15,744) | (1,088) |
| Contract assets, end of period | <u>\$ 7,432</u> | <u>\$ 353</u> |
| Contract liabilities | | |
| Contract liabilities, beginning of period | \$ 82,497 | \$ 7,771 |
| Net change | 7,380 | (2,479) |
| Contract liabilities, end of period | <u>\$ 89,877</u> | <u>\$ 5,292</u> |

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.

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As of March 31, 2021, we had \$7.4 million of contract assets related to our remaining performance obligations under the KKC Commercialization Agreement and no contract assets related to the Helsinn License Agreement as the remaining performance obligations have been completed. During the nine months ended March 31, 2021, contract assets increased by \$22.8 million, primarily due the recognition of revenue related to the satisfaction or partial satisfaction of performance obligations for which we had not yet billed KKC or Helsinn, partially offset by billings of \$15.7 million to KKC and Helsinn.

As of March 31, 2021, we had \$89.9 million of deferred revenue associated with our remaining performance obligations under the KKC Commercialization Agreement, of which \$64.5 million relates to the U.S. License which is a unit of account under the scope of Topic 808 and is not a deliverable under Topic 606, and \$25.4 million relates to the Ex-U.S. license and development services performance obligations which are under the scope of Topic 606. For the three and nine months ended March 31, 2021, we recognized revenue of \$2.4 million and \$15.4 million, respectively, that was included in the contract liabilities balance at June 30, 2020 related to performance obligations under ASC 606. In addition, as a result of a change in estimated cost of completion related to our remaining performance obligations, we decreased deferred revenue by \$2.1 million. To date we have not recognized any amounts related to units of account under Topic 808. For the three and nine months ended March 31, 2020, we recognized revenue of \$0.8 million and \$2.6 million, respectively, that was included in the contract liabilities balance at June 30, 2019 related to performance obligations under ASC 606 under the KKC Japan License Agreement and Helsinn License Agreement which are described in Note 3.

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 March 31, 2021 and 2020, 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 nine months ended March 31, 2021.

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

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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):

| | March 31, 2021 | | | June 30, 2020 | | |
|-------------------|----------------|---------|------------|---------------|---------|------------|
| | Level 1 | Level 2 | Level 3 | Level 1 | Level 2 | Level 3 |
| Warrant liability | \$— | \$— | \$(29,442) | \$— | \$— | \$(40,483) |
| Total | \$— | \$— | \$(29,442) | \$— | \$— | \$(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 and nine months ended March 31, 2021 and 2020, respectively.

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

| | March 31, 2021 | June 30, 2020 |
|--------------------------|-------------------|------------------|
| Risk-free interest rate | 0.1% | 0.2% |
| Expected life (years) | 2.1 | 2.9 |
| Expected volatility | 82.4% | 77.4% |
| Dividend yield | 0.0% | 0.0% |
| Black-Scholes Fair Value | \$1.83 | \$2.52 |

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The following table sets forth a summary of changes in the estimated fair value of our Level 3 warrant liability for the nine months ended March 31, 2021 and 2020 (in thousands):

| | Fair Value of Warrants Using Significant Unobservable Inputs (Level 3) | |
|--|--|--------------------------|
| | 2021 | 2020 |
| Balance at July 1, | \$(40,483) | \$(17,613) |
| Reclassification of derivative liability to equity upon exercise of warrants | 6 | — |
| Change in estimated fair value of liability classified warrants | 11,035 | 830 |
| Balance at March 31, | <u>\$(29,442)</u> | <u>\$(16,783)</u> |

Note 3. License Agreements

KKC License, Development and Commercialization Agreement

In April 2020, we entered into the License, Development and Commercialization Agreement (the “KKC Commercialization Agreement”) with Kyowa Kirin Company (“KKC”). 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 will co-develop and co-promote zandelisib with KKC in the U.S., with the Company recording all revenue from U.S. sales. We will share U.S. profits and costs (including development costs) on a 50-50 basis with KKC. We will also provide to KKC certain drug supplies necessary for the development and commercialization of zandelisib in the Ex-U.S., with the understanding that KKC will assume responsibility for manufacturing for the Ex-U.S. as soon as practicable.

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

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 (as defined below). During the nine months ended March 31, 2021, we updated our initial assessment to reflect estimated development cost-sharing of \$94.9 million. We included the amount of estimated variable consideration that is not constrained for development cost-sharing in the transaction price. Any variable consideration related to sales-based royalties and commercial milestones related to licenses of intellectual property will be determined when the sale or usage occurs, and is therefore excluded from the transaction price. In addition, we are eligible to receive future development and regulatory milestones upon the achievement of certain criteria; however, these amounts are excluded from variable consideration as the risk of significant revenue reversal will only be resolved depending on future research and development and/or regulatory approval outcomes. We re-evaluate the estimated variable consideration included in the transaction price and any related constraints at the end of each reporting period.

We allocated the transaction price 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.

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We determined that control of the U.S. License and Ex-U.S. License were transferred to KKC during the year ended June 30, 2020, and recognized revenue of \$21.0 million related to the Ex-U.S. License. The \$64.5 million transaction price allocated to the U.S. License obligation accounted for under Topic 808 is recorded as non-current deferred revenue and will begin to be recognized upon future commercialization as non-ASC 606 revenue. As of March 31, 2021 and June 30, 2020, we recorded deferred revenue of \$25.4 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 nine months ended March 31, 2021, our only remaining performance obligation under the agreement was 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. As of March 31, 2021, our performance obligations related to the Helsinn License Agreement have been met, and no future revenue or costs of revenue will be recognized.

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, 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 and nine months ended March 31, 2021 and 2020. 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 March 31, | | Nine Months Ended March 31, | |
|---|---------------------------------|------------------|--------------------------------|-------------------|
| | 2021 | 2020 | 2021 | 2020 |
| Net loss – basic | \$(31,313) | \$(4,329) | \$(44,859) | \$(27,540) |
| Change in fair value of warrant liability | — | — | (20,307) | — |
| Net loss – diluted | <u>\$(31,313)</u> | <u>\$(4,329)</u> | <u>\$(65,166)</u> | <u>\$(27,540)</u> |

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

| | Three Months Ended March 31, | | Nine Months Ended March 31, | |
|---|---------------------------------|----------------|--------------------------------|---------------|
| | 2021 | 2020 | 2021 | 2020 |
| Weighted average shares used in calculating basic net loss per share | 112,557 | 105,999 | 112,505 | 85,995 |
| Effect of potentially dilutive common shares from equity awards and liability-classified warrants | — | — | 1,486 | — |
| Weighted average shares used in calculating diluted net loss per share | <u>112,557</u> | <u>105,999</u> | <u>113,991</u> | <u>85,995</u> |

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

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

| | Three Months Ended March 31, | | Nine Months Ended March 31, | |
|----------------------------|---------------------------------|---------------|--------------------------------|---------------|
| | 2021 | 2020 | 2021 | 2020 |
| Stock options | 16,161 | 11,064 | 15,618 | 10,974 |
| Restricted stock units | 430 | — | 430 | — |
| Warrants | 16,060 | 16,062 | 5,354 | 16,062 |
| Total anti-dilutive shares | <u>32,651</u> | <u>27,126</u> | <u>21,402</u> | <u>27,036</u> |

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 March 31, 2021, we have not accrued any amounts for potential future payments as achievement of the milestones has not been met.

*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 March 31, 2021, we have not accrued any amounts for potential future payments as achievement of the milestones has not been met.

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 March 31, 2021, 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. Despite the relaxation of many governmental orders in mid-2020, the “second wave” of the COVID-19 outbreak has resulted in the re-imposition of many of these measures. In addition, although the FDA has authorized vaccines for the treatment of COVID-19, the effectiveness and timing of distribution of the vaccines remains highly uncertain. The COVID-19 virus has also mutated into different strains, which could be more contagious or severe or for which treatments are unavailable. While we continue to enroll and dose patients in our clinical trials, our clinical development program timelines continue to be subject to potential negative impacts from the ongoing pandemic. 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, the effectiveness and timing of distribution of treatments for COVID-19, 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, the Coronavirus Aid, Relief, and Economic Security (“CARES”) Act was signed into law. 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. There is substantial uncertainty with respect to the scope, content or timing of any further economic stimulus programs to address the economic downturn related to the COVID-19 outbreak. 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, Dr. Daniel P. Gold, and Mr. Brian G. Drazba, asserting claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 thereunder. Mr. Bahat did not seek appointment as lead plaintiff, and the court appointed another

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individual, Ramesh Mahalingham, as lead plaintiff. 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. On February 16, 2021, the lead plaintiff filed a notice of voluntary dismissal without prejudice, thereby concluding the class action litigation.

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. Additional putative stockholder derivative suits were filed in the same court naming the same defendants plus Dr. Robert D. Mass on December 2, 2020 and December 15, 2020 by Gerald Wright and William Trablicy, respectively, who also allege that they are Company stockholders, and these additional suits were consolidated into the Derivative Action by court order. 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. On February 24, 2021, following the resolution of the class action litigation, the parties stipulated request for voluntary dismissal without prejudice, which the court granted on February 25, 2021.

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 total operating lease costs were as follows (in thousands):

| | Three Months Ended March 31, | | Nine Months Ended March 31, | |
|----------------------|---------------------------------|-------|--------------------------------|-------|
| | 2021 | 2020 | 2021 | 2020 |
| Operating lease cost | \$377 | \$201 | \$1,130 | \$603 |

Supplemental cash flow information related to our operating leases were as follows (in thousands):

| | Three Months Ended March 31, | | Nine Months Ended March 31, | |
|---|---------------------------------|-------|--------------------------------|-------|
| | 2021 | 2020 | 2021 | 2020 |
| Cash paid for amounts included in the measurement of lease liabilities: | | | | |
| Operating cash flows from operating leases | \$369 | \$201 | \$ 615 | \$603 |
| Right-of-use assets obtained in exchange for operating lease obligations: | — | — | 8,689 | — |

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The following is a schedule of the future minimum rental payments for our operating lease, reconciled to the lease liability as of March 31, 2021 (in thousands):

| | March 31, 2021 |
|--|-------------------|
| Remainder of fiscal year ending June 30, 2021 | \$ 368 |
| Years ending June 30, | |
| 2022 | 1,519 |
| 2023 | 1,565 |
| 2024 | 1,612 |
| 2025 | 1,168 |
| 2026 | 1,710 |
| Thereafter | 3,122 |
| Total lease payments | 11,064 |
| Less: Present value discount | (2,556) |
| Total operating lease liability | <u>\$ 8,508</u> |
| Balance Sheet Classification – Operating Lease | |
| Operating lease liability | \$ 900 |
| Operating lease liability, long-term | 7,608 |
| Total operating lease liability | <u>\$ 8,508</u> |
| Other Balance Sheet Information – Operating Lease | |
| Weighted average remaining lease term (in years) | 7.0 |
| Weighted average discount rate | 7.50% |

Note 8. Short-Term Investments

As of March 31, 2021 and June 30, 2020, our short-term investments consisted of \$154.9 million and \$170.3 million, respectively, in U.S. government securities. The short-term investments held as of March 31, 2021 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 March 31, 2021 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 10, 2020, we entered into an At-The-Market Equity Offering Sales Agreement (the “2020 ATM Sales Agreement”), pursuant to which we may sell an aggregate of up to \$60.0 million of our common stock pursuant to the shelf registration statement. We had previously entered into an At-The-Market Equity Offering Sales Agreement in November 2017 (the “2017 ATM Sales Agreement”), pursuant to which we could sell an aggregate of up to \$30.0 million of our common stock pursuant to the shelf registration statement. The 2017 ATM Sales Agreement expired on November 8, 2020. During the nine months ended March 31, 2021, we sold 958,083 shares under the 2017 ATM Sales Agreement for net proceeds of \$3.1 million, after costs of \$0.1 million. As of March 31, 2021, there is \$60.0 million remaining available under the 2020 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 March 31, 2021, there is \$175.7 million aggregate value of securities available under the shelf registration statement, including up to \$60.0 million remaining available under the 2020 ATM Sales Agreement.

Warrants

As of March 31, 2021, we have outstanding warrants to purchase 16,058,985 shares of our common stock. The warrants are fully vested, exercisable at a price of \$2.54 per share and expire in May 2023. Pursuant to the terms of the warrants, we could be required to settle the warrants in cash in the event of an acquisition of the Company and, as a result, the warrants are required to be

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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 March 31, 2021 at \$29.4 million and as of June 30, 2020 at \$40.5 million; the changes in fair value were recorded in our Condensed Statement of Operations. During the nine months ended March 31, 2021, a warrant holder completed a cashless exercise of 2,617 warrants for 964 shares of common stock. No warrants were exercised during the nine months ended March 31, 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, 2018 and 2020, under which 29,014,794 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 March 31, 2021, there were 10,284,365 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 March 31, | | Nine Months Ended March 31, | |
|--------------------------------|---------------------------------|----------------|--------------------------------|----------------|
| | 2021 | 2020 | 2021 | 2020 |
| Research and development | \$1,207 | \$ 696 | \$3,496 | \$2,220 |
| General and administrative | 1,438 | 854 | 4,700 | 3,214 |
| Total share-based compensation | <u>\$2,645</u> | <u>\$1,550</u> | <u>\$8,196</u> | <u>\$5,434</u> |

Stock Options

Stock option activity for the nine months ended March 31, 2021 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 | 5,763,300 | 3.40 | | |
| Exercised | (119,042) | 2.22 | | |
| Forfeited / Cancelled | (223,828) | 3.65 | | |
| Outstanding at March 31, 2021 | <u>16,673,406</u> | 3.01 | 7.9 | \$9,775,096 |
| Vested and exercisable at March 31, 2021 | 7,802,361 | 2.74 | 6.7 | \$7,006,856 |

The fair value of each stock option granted during the nine months ended March 31, 2021 is estimated on the grant date under the fair value method using a Black-Scholes valuation model. Stock options granted to employees during the nine months ended March 31, 2021 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 nine months ended March 31, 2021 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:

| | Nine Months Ended March 31, | |
|--|--------------------------------|--------|
| | 2021 | 2020 |
| Risk-free interest rate | 0.5% | 1.8% |
| Expected life (years) | 6.0 | 6.0 |
| Expected volatility | 81.1% | 73.6% |
| Dividend yield | 0.0% | 0.0% |
| Weighted-average grant date fair value | \$2.32 | \$1.60 |

As of March 31, 2021, there was \$10.2 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 1.7 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 12,000 RSUs during the nine months ended March 31, 2021, and 430,650 unvested RSUs were outstanding as of March 31, 2021. As of March 31, 2021, unrecognized compensation expense related to the unvested portion of our RSUs was approximately \$0.8 million and is expected to be recognized over approximately 1.1 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 on Form 10-K, as filed with the Securities and Exchange Commission on September 9, 2020, 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 including but not limited to the ability of FDA to conduct necessary audit functions, 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 securities class action and stockholder derivative litigation, our defense against third party intellectual property infringement claims, or other litigation;
- 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, including changes to government regulation as a result of a new U.S. President and congressional majorities;
- changes in industry practice; and
- one-time events.

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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 our lead drug candidate, 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”) as part of a marketing application to support accelerated approval. 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. Despite the relaxation of many governmental orders in mid-2020, the “second wave” of the COVID-19 outbreak has resulted in the re-imposition of many of these measures. In addition, although the FDA has authorized vaccines for the treatment of COVID-19, the effectiveness and timing of distribution of the vaccines remains highly uncertain. The COVID-19 virus has also mutated into different strains, which could be more contagious or severe or for which treatments are unavailable. While we continue to enroll and dose patients in our clinical trials, our clinical development program timelines continue to be subject to potential negative impacts from the ongoing pandemic. The extent to which the ongoing pandemic continues to impact our business, including our preclinical studies, chemistry, manufacturing and controls (“CMC”) studies, manufacturing, 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, the effectiveness and timing of distribution of treatments for COVID-19, 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, including vaccination rates and effectiveness.

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

Not only might the COVID-19 outbreak impact the conduct of our clinical trials, but it may also impact our ability to procure the necessary supply of our investigational drug products, as well as any ancillary supplies necessary for the conduct of our studies. This could happen for a variety of reasons, including manufacturing shortages or shutdowns, or a manufacturer need to prioritize other products or customers over us, including under the Defense Production Act. Third party manufacturers may also need to implement measures and changes, or deviate from typical manufacturing requirements that may otherwise adversely impact our product candidates.

In light of the 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, which guidance FDA has continually updated. 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.


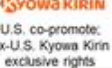




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On March 27, 2020, the “Coronavirus Aid, Relief, and Economic Security (“CARES”) Act” was signed into law. The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer side social security 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. There is substantial uncertainty with respect to the scope, content or timing of any further economic stimulus programs to address the economic downturn related to the COVID-19 outbreak. 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.

| PROGRAMS | INDICATION | COMBINATION | PHASE 1/1B | PHASE 2 | PHASE 3 | COMMERCIAL RIGHTS |
|--|--|--|--------------------------|---------|---------|---|
| Zandelisib Oral PI3K Delta Inhibitor | Follicular & Marginal Zone Lymphomas Relapsed/refractory | Monotherapy | TIDAL Study ¹ | | |   U.S. co-promote; ex-U.S. Kyowa Kirin exclusive rights |
| | B-Cell Malignancies Relapsed/refractory | • Monotherapy • Rituxan [®] (rituximab) • Zanubrutinib ²  BeiGene | Clinical Collaboration | | | |
| Voruciclib Oral CDK Inhibitor | B-Cell Malignancies & AML Relapsed/refractory | • Monotherapy • Venclexta [®] (venetoclax) ³ | | | |  |
| ME-344 Mitochondrial Inhibitor | Solid Tumors | Avastin [®] (bevacizumab) ¹ | | | |  |
| Pracinostat HDAC Inhibitor | Myelodysplastic Syndrome Treatment-naïve | Vidaza [®] (azacitidine) | | | |  |

1. Phase 2 study intended to support a marketing application for FDA accelerated approval.
2. Study arm conducted under clinical collaboration with BeiGene, Ltd.
3. Initiation of clinical studies in combination with venetoclax is subject to FDA approval.
4. Investigator-initiated trial; completed.

Zandelisib (f/k/a ME-401): PI3Kd Inhibitor in a Phase 2 Trial Intended to Support Accelerated Approvals in Relapsed or Refractory Follicular and Marginal Zone Lymphomas

Zandelisib is an oral, once-daily, selective PI3Kd inhibitor in clinical development for the treatment of B-cell malignancies. In March 2020, the FDA granted zandelisib Fast Track designation for the treatment of adult patients with relapsed or refractory follicular lymphoma who have received at least two prior systemic therapies. In April 2020, we entered into a global license, development and commercialization agreement to further develop and commercialize zandelisib with Kyowa Kirin Co., Ltd. (“KKC”). MEI 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 evaluating zandelisib as a monotherapy for the treatment of adults with relapsed or refractory (“r/r”) follicular lymphoma (“FL”) and r/r marginal zone lymphoma (“MZL”) after failure of at least two prior systemic therapies including chemotherapy and an anti-CD20 antibody. Subject to the results, upon completion of each study arm in TIDAL, we are planning marketing application submissions with the FDA to support accelerated approval 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 our agreement with KKC (as described below).

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

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[®]) duvelisib (marketed as COPIKTRA[®]), and umbralisib (marketed as UKONIQ[™]), and the intravenously administered PI3Kd/α inhibitor copanlisib (marketed as Aliqopa[®]), are challenged by dose-

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limiting toxicities, modest efficacy and/or inconvenience of administration route. We believe this provides an opportunity for the development of a next-generation candidate with pharmaceutical properties that may better maximize the therapeutic potential of PI3Kd inhibition by limiting toxicities and improving upon modest efficacy, which together hinder clinical utility.

The molecular structure and pharmacodynamic characteristics of zandelisib are distinct from the FDA approved PI3Kd inhibitors. Zandelisib's distinct characteristics include prolonged target binding, preferential cellular accumulation, high volume of distribution throughout the body tissues, and an approximately 28-hour half-life suitable for once daily oral administration. The properties of zandelisib support exploration of flexible dosing regimens such as an intermittent dosing schedule, which has clinically demonstrated to date 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 into 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 will co-develop and co-promote zandelisib with KKC in the U.S., with the Company recording all revenue from U.S. sales. We will share U.S. profits and costs (including development costs) on a 50-50 basis with KKC. We will also provide to KKC certain drug supplies necessary for the development and commercialization of zandelisib in the Ex-U.S. pursuant to supply agreements to be entered into on customary terms, with the understanding that KKC will assume responsibility for manufacturing for the Ex-U.S. as soon as practicable.

Under the terms of the KKC Commercialization Agreement, KKC paid us an initial payment of \$100 million. 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, the global Phase 2 trial evaluating patients with t/r FL and MZL intended to support FDA marketing applications for accelerated approval, 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.

The Phase 1b trial includes an arm exploring zandelisib in combination with zanubrutinib (marketed as BRUKINSA®), an inhibitor of Bruton's tyrosine kinase developed by BeiGene, Ltd. ("BeiGene"). This study arm completed the safety evaluation stage in patients with B-cell malignancies and has expanded into disease specific B-cell malignancy cohorts. The evaluation of zandelisib in combination with zanubrutinib is conducted under a collaboration established with BeiGene in October 2018, pursuant to which the cost of the combination trial is being equally shared, and each company is supplying its own investigational agent. We retain all commercial rights to zandelisib (subject to the KKC Commercialization Agreement) and BeiGene retains all commercial rights to zanubrutinib. Additionally, ongoing studies include Phase 1 and Phase 2 studies initiated by KKC evaluating zandelisib as a monotherapy in patients in Japan with indolent B-cell malignancies; the Phase 2 study is intended to support marketing authorization in Japan.

We are also in the process of expanding the zandelisib clinical development program pursuant to the KKC Commercialization Agreement. Expansion plans include initiating, around mid-calendar year 2021, COASTAL, (COmbination of

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Rituximab and PI3-Kinase Delta Inhibitor in iNH Lymphoma) a Phase 3 study of zandelisib in combination with rituximab evaluating follicular lymphoma and marginal zone lymphoma patients who received one or more prior lines of treatment; this study is intended to support FDA approval for additional indications and act as the required confirmatory study for the potential accelerated approval of zandelisib in patients with relapsed follicular lymphoma or marginal zone lymphoma who 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 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 r/r 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. The objective of this portion of the study was to evaluate the safety, tolerability and efficacy of zandelisib given at 60 mg on IS as monotherapy or in combination with rituximab. 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.

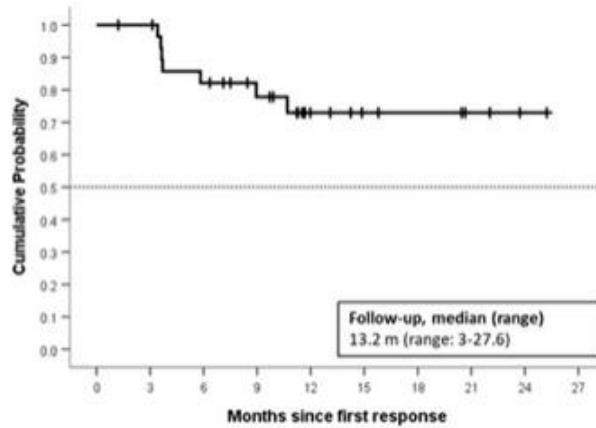
The overall response rate in the 36 patients with r/r FL was 83%, with 22% achieving a complete response. The overall response rate was 76% in 17 patients administered zandelisib as a monotherapy and 89% in 19 patients administered zandelisib in combination with rituximab. The overall response rate in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

Overall Response Rates (“ORR”)

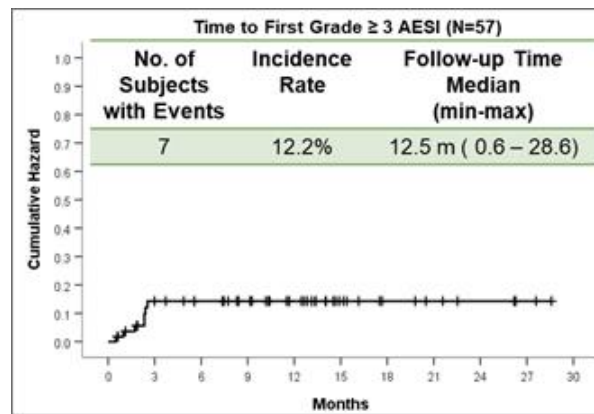
| Diagnosis | Evaluable Subjects N | ORR N (%) |
|---------------------------|---------------------------------|----------------------|
| FL | 36 | 30 (83%) |
| By treatment group | | |
| zandelisib monotherapy | 17 | 13 (76%) |
| zandelisib + rituximab | 19 | 17 (89%) |
| By prior lines of therapy | | |
| 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 ³ 5 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 3 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).



Phase 2 Trial Intended to Support Accelerated Approval of Marketing Applications

We are recruiting patients in TIDAL, the global Phase 2 trial evaluating zandelisib as a monotherapy across two study arms: the first study arm for the treatment of adults with r/r FL and the second study arm for r/r MZL, in both cases after failure of at least two prior systemic therapies including chemotherapy and an anti-CD20 antibody. Subject to the results and discussions with FDA, data from each study arm are intended to be submitted to FDA to support marketing applications for accelerated approval under 21 CFR Part 314.500, Subpart H. 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). 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. The primary efficacy population sample size for r/r FL is 91 patients and the primary efficacy population sample size for r/r MZL is 64 patients. Complete enrollment of the FL primary efficacy population was announced in April 2021. MEI will maintain the total study enrollment in the FL arm to 120 patients to provide additional safety data for the registration application.

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. Topline data from the Phase 2 TIDAL study is expected in the fourth calendar quarter of 2021. We will continue to closely monitor for potential negative impacts on the study related to the ongoing COVID-19 pandemic. We will also 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 is also being evaluated in pre-clinical studies to explore the potential synergistic activity in various solid tumor cancers of voruciclib in combination with drug-candidates that directly inhibit KRAS as well as other targets in the RAS signaling pathway.

Voruciclib Scientific Overview: Cell Cycle Signaling

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

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

Voruciclib: Inhibition of MCL1

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

The research presented suggests that voruciclib could be an attractive therapeutic target for treating cancers in combination with venetoclax or other BCL-2 inhibitors.

Voruciclib: Inhibition of MYC

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

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

The research presented suggests that voruciclib could be an attractive therapeutic target for cancers driven by KRAS mutations.

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.

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Preliminary data to date from the Phase 1b study evaluating voruciclib as a monotherapy at the doses studied demonstrates that voruciclib has not been associated with drug related gastrointestinal toxicity or neutropenia. Also, favorable pharmacokinetics have been observed, including a half-life supporting once-a-day oral dosing, dose proportional C-max and a high volume of distribution suggesting broad entry into tissues. Our projections suggest that doses of 150-200 mg may be sufficient to achieve plasma concentrations sufficient to inhibit the molecular target. Early signs of biological activity have also been observed in patients with AML.

Voruciclib was also previously evaluated in more than 70 patients with solid tumors in multiple Phase 1 studies. The totality of the clinical data, along with data from pre-clinical studies, suggests voruciclib's ability to inhibit its molecular target at a projected dose as low as 150 mg daily. In one clinical study, voruciclib was evaluated in combination with vemurafenib (marketed as Zelboraf®) in 9 patients with BRAF mutated advanced/inoperable malignant melanoma. Three of three BRAF/MEK naive patients achieved a response: two partial responses and one complete response. In this study voruciclib was dosed at 150 mg daily plus vemurafenib 720 mg or 960 mg twice daily in 28-day cycles. The most common adverse events were fatigue, constipation, diarrhea, arthralgia and headache. One instance of grade 3 fatigue was dose limiting and no serious adverse events related to voruciclib were reported. Other clinical studies evaluated voruciclib at doses up to 850 mg in patients with solid tumors, demonstrating additional evidence of potential biologic activity and an adverse event profile generally consistent with other drugs in its class.

Impact of COVID-19 on the Voruciclib Clinical Development Program

While the extent to which the 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 deem appropriate.

ME-344: Clinical Stage Mitochondrial Inhibitor with Combinatorial Potential

ME-344 is our novel and tumor selective, isoflavone-derived mitochondrial inhibitor drug candidate. It 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. We are planning to advance ME-344 in combination with anti-angiogenic therapies in a Phase 2 study evaluating patients with solid tumors.

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”). All patients in the study have completed therapy and analyses are ongoing in preparation of a final study report.

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 POC study 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 the POC study, which is a Phase 2 dose optimization trial evaluating patients with high and very high-risk MDS who are previously untreated with hypomethylating agents. All patients in the study have completed therapy and analyses are ongoing in preparation of a final study report. 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 POC Study is an open-label trial 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 POC study 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 POC study completed enrollment and patients were followed for at least two years 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 POC 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 3 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%). The POC study results have reached maturity leading to closing the study; as of the end of December 2020 no patients are being treated or followed in the study.

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 March 31, 2021 and 2020

We had a loss from operations of \$22.1 million for the three months ended March 31, 2021 compared to a loss from operations of \$12.4 million for the three months ended March 31, 2020.

Revenue: We recognized revenue of \$2.4 million for the three months ended March 31, 2021 compared to \$1.2 million for the three months ended March 31, 2020. Revenue increased primarily due to amounts recognized under 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 \$2.3 million for the three months ended March 31, 2021 compared to \$0.8 million for the three months ended March 31, 2020. Revenue also includes recognition of fees allocated to performance obligations in accordance with the Helsinn License Agreement. Revenue related to the Helsinn License Agreement was \$0.1 million for the three months ended March 31, 2021 compared to \$0.4 million for the three months ended March 31, 2020 due to decreased costs associated with the POC study. As of March 31, 2021, our performance obligations related to the Helsinn License Agreement have been met, and no future revenue or costs of revenue will be recognized.

Cost of Revenue: We recognized cost of revenue of \$0.4 million for the three months ended March 31, 2021 compared to \$0.9 million for the three months ended March 31, 2020. 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.

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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.

| Research and development expenses | Three Months Ended March 31, | |
|---|---------------------------------|----------------|
| | 2021 | 2020 |
| Zandelisib | \$11,460 | \$4,572 |
| Voruciclib | 694 | 524 |
| ME-344 | 212 | 18 |
| Other | 5,518 | 3,849 |
| Total research and development expenses | <u>\$17,884</u> | <u>\$8,963</u> |

Research and development expenses consist primarily of clinical trial costs (including payments to contract research organizations “CROs”), pre-clinical study costs, and costs to manufacture our drug candidates for non-clinical and clinical studies. Other research and development expenses consist primarily of salaries and personnel costs, share-based compensation, legal costs, and other costs not allocated to specific drug programs. Research and development expenses were \$17.9 million for the three months ended March 31, 2021 compared to \$9.0 million for the three months ended March 31, 2020. Costs related to zandelisib for the three months ended March 31, 2021 reflected an increase in clinical trial costs (\$5.3 million) primarily as a result of increased activity in the Phase 2 study and start-up costs related to the Phase 3 study, an increase in drug manufacturing costs (\$1.0 million), and increased consulting fees (\$0.6 million). Costs related to voruciclib increased for the three months ended March 31, 2021 compared with the three months ended March 31, 2020, due to increased drug manufacturing costs. Other research and development costs increased for the three months ended March 31, 2021 due to higher levels of personnel costs (\$1.2 million) and share-based compensation (\$0.5 million) associated with increased headcount to support our clinical activities.

General and Administrative: General and administrative expenses increased by \$2.3 million to \$6.2 million for the three months ended March 31, 2021 compared to \$3.9 million for the three months ended March 31, 2020. The increase is primarily due to increased external professional services and legal costs (\$0.9 million), as well as share-based compensation (\$0.6 million) and personnel costs (\$0.5 million) associated with increased headcount to support our activities, including preparation for commercial launch of zandelisib, and corporate overhead costs (\$0.3 million).

Other income or expense: We recorded a non-cash loss of \$9.3 million during the three months ended March 31, 2021 due to a change in the fair value of our warrant liability. The change in the warrant liability is primarily due to changes in our stock price. Additionally, we received interest and dividend income of \$58,000 for the three months ended March 31, 2021 compared to \$0.4 million for the three months ended March 31, 2020. The decrease was due to lower yields during the three months ended March 31, 2021 compared to the three months ended March 31, 2020.

Comparison of Nine Months Ended March 31, 2021 and 2020

We had a loss from operations of \$56.9 million for the nine months ended March 31, 2021 compared to a loss from operations of \$37.2 million for the nine months ended March 31, 2020.

Revenue: We recognized revenue of \$15.4 million for the nine months ended March 31, 2021 compared to \$3.4 million for the nine months ended March 31, 2020. Revenue increased primarily due to amounts recognized under 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 \$15.0 million for the nine months ended March 31, 2021 compared to \$2.3 million for the nine months ended March 31, 2020. Revenue also includes recognition of fees allocated to performance obligations in accordance with the Helsinn License Agreement. Revenue related to the Helsinn License Agreement was \$0.4 million for the nine months ended March 31, 2021 compared to \$1.1 million for the nine months ended March 31, 2020 due to decreased costs associated with the POC study.

Cost of Revenue: We recognized cost of revenue of \$1.4 million for the nine months ended March 31, 2021 compared to \$2.2 million for the nine months ended March 31, 2020. 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.

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| Research and development expenses | Nine Months Ended March 31, | |
|---|--------------------------------|-----------------|
| | 2021 | 2020 |
| Zandelisib | \$36,350 | \$13,741 |
| Voruciclib | 2,215 | 1,524 |
| ME-344 | 433 | 27 |
| Other | 14,106 | 10,914 |
| Total research and development expenses | <u>\$53,104</u> | <u>\$26,206</u> |

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 \$53.1 million for the nine months ended March 31, 2021 compared to \$26.2 million for the nine months ended March 31, 2020. Costs related to zandelisib for the nine months ended March 31, 2021 reflected an increase in clinical trial costs (\$19.9 million) primarily as a result of increased activity in the Phase 2 study and start-up costs related to the Phase 3 study, an increase in drug manufacturing costs (\$1.5 million), and increased consulting fees (\$1.2 million). Costs related to voruciclib increased for the nine months ended March 31, 2021 compared with the nine months ended March 31, 2020, due to increased drug manufacturing costs. Other research and development costs increased for the nine months ended March 31, 2021 due to higher levels of personnel costs (\$2.3 million) and share-based compensation (\$1.3 million) associated with increased headcount to support our clinical activities, offset by decreased legal, consulting, and administrative costs (\$0.4 million).

General and Administrative: General and administrative expenses increased by \$5.6 million to \$17.8 million for the nine months ended March 31, 2021 compared to \$12.2 million for the nine months ended March 31, 2020. The increase is primarily due to increased external professional services and legal costs (\$1.8 million), as well as share-based compensation (\$1.5 million) and personnel costs (\$1.1 million) associated with increased headcount to support our activities, including preparation for commercial launch of zandelisib, and corporate overhead costs (\$1.2 million).

Other income or expense: We recorded a non-cash gain of \$11.0 million during the nine months ended March 31, 2021 due to a change in the fair value of our warrant liability. The change in the warrant liability is primarily due to changes in our stock price. Additionally, we received interest and dividend income of \$0.5 million for the nine months ended March 31, 2021 compared to \$1.1 million for the nine months ended March 31, 2020. The decrease was due to lower yields during the nine months ended March 31, 2021 compared to the nine months ended March 31, 2020. We also recognized a \$0.5 million gain related to foreign currency exchange rate changes on a tax receivable from the Japanese government for tax withholdings related to the KKC Commercialization Agreement.

Liquidity and Capital Resources

We have accumulated losses of \$322.1 million since inception and expect to incur operating losses and generate negative cash flows from operations for the foreseeable future. As of March 31, 2021, we had \$164.6 million in cash and cash equivalents, and short-term investments. 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 operating activities for the nine months ended March 31, 2021 was \$20.7 million. Net cash used in operating activities for the nine months ended March 31, 2020 was \$34.9 million. The decrease in cash used in operating activities year over year reflects the receipt in October 2020 of our \$20.4 million receivable from the Japanese government for tax withholdings related to the KKC Commercialization Agreement, as well as other changes in working capital.

Net cash provided by investing activities for the nine months ended March 31, 2021 was \$14.7 million compared to \$21.2 million used in investing activities for the nine months ended March 31, 2020. The change was primarily due to decreased purchases of short-term investments in 2021, net of maturities.

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Net cash provided by financing activities during the nine months ended March 31, 2021 was \$3.4 million compared with \$53.9 million provided by financing activities during the nine months ended March 31, 2020. Cash raised during the nine months ended March 31, 2021 reflected \$3.1 million of net proceeds from the issuance of common stock. Cash raised during the nine months ended March 31, 2020 reflected \$48.6 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 trial 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 payment over the remaining term of the lease is \$1.6 million, plus a pro rata share of certain building expenses. Our total contractual obligation over the remaining term of the lease is \$11.1 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 March 31, 2021, we have not accrued any amounts for potential future payments as achievement of the milestones has not been met.

*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 March 31, 2021, we have not accrued any amounts for potential future payments as achievement of the milestones has not been met.

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 March 31, 2021, we have not accrued any amounts for potential future payments.

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

| <u>Exhibits</u> | |
|-----------------|---|
| 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: May 6, 2021

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: May 6, 2021

/s/ Daniel P. Gold

Daniel P. Gold

Chief Executive Officer

(Principal Executive Officer)

CERTIFICATION

I, Brian G. Drazba, certify that:

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

Date: May 6, 2021

/s/ Brian G. Drazba

Brian G. Drazba

Chief Financial Officer

(Principal Financial Officer)

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 March 31, 2021, (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: May 6, 2021

/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)