## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, DC 20549** 

**FORM 10-Q** 

		•		
	k One)	CECTION 42 OD 45(4) OF THE CEC	-	
$\boxtimes$	QUARTERLY REPORT PURSUANT TO S	` ,		
	Fo	or the quarterly period ended Decem	ber 31, 2022	
		OR		
	TRANSITION REPORT PURSUANT TO S	SECTION 13 OR 15(d) OF THE SEC	CURITIES EXCHANGE ACT OF 1934	
	For the tra	ansition period from	to	
		Commission File Number: 000-5	50484 	
	<b>(E</b> )	MEI Pharma, I		
			_	
	DELAWARE		51-0407811	
	(State or other jurisdiction of incorporation or organization)		(I.R.S. Employer Identification No.)	
		11455 El Camino Real, San Diego, CA (Address of principal executive offices) (Zip		
		(858) 369-7100 (Registrant's telephone number, including are	a code)	
		Securities registered pursuant to Section	n 12(b) of the Act:	
	Title of each class	Trading Symbol(s)	Name of each exchange on which registered	
	Common Stock, \$0.00000002 par value	MEIP	The Nasdaq Stock Market LLC	
	onths (or for such shorter period that the registrant wa		B or 15(d) of the Securities Exchange Act of 1934 during the poeen subject to such filing requirements for the past 90 days.	oreceding Yes ⊠
	•		required to be submitted pursuant to Rule 405 of Regulation S t was required to submit such files). Yes $\boxtimes$ No $\square$	-T
			relerated filer, smaller reporting company, or an emerging growny," and "emerging growth company" in Rule 12b-2 of the Ex	
Large	e accelerated filer $\ \square$		Accelerated filer	
	accelerated filer ⊠ 'ging growth company □		Smaller reporting company	X
If an			ended transition period for complying with any new or revised	
	ate by check mark whether the registrant is a shell con	-	nange Act). Yes □ No ⊠	
	ate by check mark whether the registrant has filed all o equent to the distribution of securities under a plan con		y Sections 12, 13 or 15(d) of the Securities Exchange Act of 1	1934
As of	February 6, 2023, the number of shares outstanding of	of the issuer's common stock, \$0.00000002	par value, was 133,260,865.	

#### MEI PHARMA, INC.

#### **Table of Contents**

		Page
PART I	FINANCIAL INFORMATION	3
Item 1.	Condensed Financial Statements (Unaudited)	3
	Condensed Balance Sheets as of December 31, 2022 and June 30, 2022	3
	Condensed Statements of Operations for the three and six months ended December 31, 2022 and 2021	4
	Condensed Statements of Stockholders' Equity for the three and six months ended December 31, 2022 and 2021	5
	Condensed Statements of Cash Flows for the six months ended December 31, 2022 and 2021	6
	Notes to Condensed Financial Statements	7
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	20
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	30
Item 4.	Controls and Procedures	30
PART II	OTHER INFORMATION	32
Item 1.	<u>Legal Proceedings</u>	32
Item 1A.	Risk Factors	32
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	32
Item 3.	Defaults upon Senior Securities	32
Item 4.	Mine Safety Disclosures	32
Item 5.	Other Information	32
Item 6.	<u>Exhibits</u>	33
SIGNATUR	RES.	34

#### PART I FINANCIAL INFORMATION

#### **Item 1. Condensed Financial Statements**

## MEI PHARMA, INC. CONDENSED BALANCE SHEETS

(In thousands, except par value data)

	D	ecember 31, 2022		June 30, 2022
ASSETS	(	Unaudited)		
Current assets:				
Cash and cash equivalents	\$	10,917	\$	15,740
Short-term investments	Ψ	113,256	Ψ	137,512
Total cash, cash equivalents and short-term investments		124,173		153,252
Unbilled receivables		5,704		10,044
Prepaid expenses and other current assets		3,568		3,830
Total current assets		133,445	_	167,126
Operating lease right-of-use asset		12,698		9,054
Property and equipment, net		1,456		1,660
Total assets	\$	147,599	\$	177,840
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$	4,067	\$	7,918
Accrued liabilities		14,346		10,820
Deferred revenue		2,897		4,834
Operating lease liability		1,343		871
Total current liabilities		22,653		24,443
Deferred revenue, long-term		64,545		90,610
Operating lease liability, long-term		12,027		8,771
Warrant liability		_		1,603
Total liabilities		99,225		125,427
Commitments and contingencies (Note 7)				
Stockholders' equity:				
Preferred stock, \$0.01 par value; 100 shares authorized; none outstanding		_		_
Common stock, \$0.00000002 par value; 226,000 shares authorized; 133,261 and 133,152 shares issued and outstanding at December 31, 2022 and June 30, 2022, respectively		_		_
Additional paid-in capital		428,904		426,572
Accumulated deficit		(380,530)		(374,159)
Total stockholders' equity		48,374		52,413
Total liabilities and stockholders' equity	\$	147,599	\$	177,840

See accompanying notes to condensed financial statements.

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

	Three Months Ended December 31,			Six Months En December 3			ed
	2022		2021		2022		2021
Revenue	\$ 32,735	\$	11,832	\$	41,465	\$	19,589
Operating expenses:							
Research and development	15,313		21,531		34,776		41,484
General and administrative	8,496		7,926		15,982		15,835
Total operating expenses	23,809		29,457		50,758		57,319
Income (loss) from operations	 8,926		(17,625)		(9,293)	-	(37,730)
Other income (expense):							
Change in fair value of warrant liability	486		5,458		1,603		8,046
Interest and dividend income	845		11		1,325		18
Other expense, net	 (4)		<u> </u>		(6)		_
Net income (loss)	\$ 10,253	\$	(12,156)	\$	(6,371)	\$	(29,666)
Net income (loss):	_						_
Basic	\$ 10,253	\$	(12,156)	\$	(6,371)	\$	(29,666)
Diluted	\$ 10,253	\$	(17,614)	\$	(6,371)	\$	(37,712)
Net income (loss) per share:							
Basic	\$ 0.08	\$	(0.10)	\$	(0.05)	\$	(0.26)
Diluted	\$ 0.08	\$	(0.14)	\$	(0.05)	\$	(0.32)
Shares used in computing net income (loss) per share:	 						
Basic	 133,261		126,725		133,258		115,982
Diluted	 133,261		128,160		133,258		118,657

 $See\ accompanying\ notes\ to\ condensed\ financial\ statements.$ 

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

(Unaudited)

	Common Shares	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at June 30, 2022	133,152	\$ 426,572	\$ (374,159)	\$ 52,413
Net loss	_	_	(16,624)	(16,624)
Issuance of common stock for vested restricted stock units	109	(40)	_	(40)
Share-based compensation expense	_	1,559	_	1,559
Balance at September 30, 2022	133,261	428,091	(390,783)	37,308
Net income	_	_	10,253	10,253
Share-based compensation expense	_	813	_	813
Balance at December 31, 2022	133,261	\$ 428,904	\$ (380,530)	\$ 48,374
Balance at June 30, 2021	Common Shares	Additional Paid-In Capital \$ 369.171	Accumulated Deficit	Total Stockholders' Equity \$ 49.466
Balance at June 30, 2021 Net loss	Common Shares 112,615		Deficit \$ (319,705)	Stockholders' Equity \$ 49,466
		Paid-In Capital \$ 369,171 —	Deficit	\$ 49,466 (17,510)
Net loss Issuance of common stock for vested restricted stock units	112,615	Paid-In Capital  \$ 369,171  — (194)	Deficit \$ (319,705)	Stockholders' Equity \$ 49,466
Net loss Issuance of common stock for vested restricted stock units Share-based compensation expense	112,615	Paid-In Capital \$ 369,171 —	Deficit \$ (319,705)	Stockholders' Equity  \$ 49,466  (17,510)  (194)
Net loss Issuance of common stock for vested restricted stock units	112,615 — 63 —	Paid-In Capital  \$ 369,171  (194) 2,539	Deficit \$ (319,705)	Stockholders' Equity  \$ 49,466  (17,510)  (194)  2,539
Net loss Issuance of common stock for vested restricted stock units Share-based compensation expense Balance at September 30, 2021	112,615 — 63 —	Paid-In Capital  \$ 369,171  (194) 2,539	Deficit \$ (319,705)	Stockholders' Equity  \$ 49,466 (17,510) (194) 2,539 34,301
Net loss Issuance of common stock for vested restricted stock units Share-based compensation expense Balance at September 30, 2021 Net loss	112,615 — 63 — 112,678	Paid-In Capital \$ 369,171	Deficit \$ (319,705)	Stockholders' Equity  \$ 49,466 (17,510) (194) 2,539 34,301 (12,156)
Net loss Issuance of common stock for vested restricted stock units Share-based compensation expense  Balance at September 30, 2021 Net loss Issuance of common stock, net of issuance costs of \$3,672	112,615 — 63 — 112,678 — 20,125	Paid-In Capital \$ 369,171  — (194) 2,539 371,516 — 48,653	Deficit \$ (319,705)	Stockholders' Equity  \$ 49,466 (17,510) (194) 2,539 34,301 (12,156) 48,653

See accompanying notes to condensed financial statements.

## MEI PHARMA, INC. CONDENSED STATEMENTS OF CASH FLOWS

(In thousands) (Unaudited)

		mber 31,		
		2022		2021
Cash flows from operating activities:				
Net loss	\$	(6,371)	\$	(29,666)
Adjustments to reconcile net loss to net cash used in operating activities:				
Change in fair value of warrant liability		(1,603)		(8,046)
Share-based compensation expense		2,372		4,863
Depreciation and amortization		191		152
Non-cash lease expense		703		449
Changes in operating assets and liabilities:				
Unbilled receivables		4,340		(2,569)
Prepaid expenses and other current assets		262		(1,014)
Accounts payable		(3,851)		(99)
Accrued liabilities		3,526		1,363
Deferred revenue		(28,002)		18,736
Operating lease liability		(619)		(456)
Net cash used in operating activities		(29,052)		(16,287)
Cash flows from investing activities:				
Purchases of short-term investments		(67,862)		(173,300)
Proceeds from maturity of short-term investments		92,118		144,983
Proceeds from (purchases) of property and equipment		13		(59)
Net cash provided by (used in) investing activities		24,269		(28,376)
Cash flows from financing activities:				
Payment of RSU tax withholdings in exchange for common shares surrendered by RSU holders		(40)		(194)
Proceeds from exercise of stock options		_		212
Proceeds from issuance of common stock, gross		_		52,325
Payment of issuance costs		_		(3,672)
Net cash (used in) provided by financing activities		(40)		48,671
Net (decrease) increase in cash and cash equivalents		(4,823)	-	4,008
Cash and cash equivalents at beginning of the period		15,740		8,543
Cash and cash equivalents at end of the period	\$	10,917	\$	12,551
Supplemental disclosures:			_	
Operating lease right-of-use assets obtained in exchange for operating lease liabilities	\$	4,347	\$	_
operating reasonable of the assets obtained in chemistre for operating reasonables	Ψ	1,5 17	<u> </u>	

See accompanying notes to condensed financial statements.

### MEI PHARMA, INC. NOTES TO CONDENSED FINANCIAL STATEMENTS

(Unaudited)

#### Note 1. The Company and Summary of Significant Accounting Policies

#### The Company

MEI Pharma, Inc. (Nasdaq: MEIP) is a clinical stage pharmaceutical company focused on developing potential new therapies for cancer. MEI Pharma's portfolio of drug candidates includes drug candidates with differentiated or novel mechanisms of action intended to address unmet medical needs and deliver improved benefit to patients, either as standalone treatments or in combination with other therapeutic options. Our common stock is listed on the Nasdaq Capital Market under the symbol "MEIP."

#### **Clinical Development Programs**

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

- Voruciclib, an oral cyclin-dependent kinase ("CDK") inhibitor;
- · ME-344, an intravenous small molecule targeting the oxidative phosphorylation pathway; and
- Zandelisib, an oral phosphatidylinositol 3-kinase delta ("PI3Kδ") 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 voruciclib and ME-344 and to develop new compounds we might license or acquire. The actual amount of funds that will be needed are determined by a number of factors, some of which are beyond our control. Negative U.S. and global economic conditions may pose challenges to our business strategy, which relies on funding from the financial markets or collaborators.

#### **Reduction in Force and Current Events**

In November 2022, we and Kyowa Kirin Co., Ltd. ("KKC") met with the U.S. Food and Drug Administration ("FDA") in a follow-up meeting to the March 2022 end of Phase 2 meeting. At this meeting, the FDA provided further guidance regarding the design and statistical analysis for the COASTAL trial. Following the November meeting, the companies jointly concluded that a clinical trial consistent with the recent FDA guidance, including modification of the ongoing COASTAL trial, would likely not be feasible to complete within a time period that would support further investment or with sufficient certainty of the regulatory requirements for approval to justify continued global development efforts. As a result, we and KKC jointly decided to discontinue global development of zandelisib for indolent forms of non-Hodgkin lymphoma outside of Japan.

The discontinuation of zandelisib development outside of Japan was a business decision based on the most recent regulatory guidance from the FDA and is not related to the zandelisib clinical data generated to date. KKC is continuing certain ongoing Japanese clinical trials, including the Phase 2 MIRAGE trial evaluating Japanese patients with relapsed or refractory indolent B-cell non-Hodgkin lymphomas, and will explore submitting the MIRAGE and TIDAL trials for marketing authorization in Japan. MIRAGE is a Phase 2 trial, similar in design to the global Phase 2, single-arm, TIDAL trial. In November 2022, we and KKC announced positive topline data from the Phase 2 MIRAGE trial.

We and KKC have begun closing all ongoing zandelisib clinical studies outside of Japan, including the Phase 3 COASTAL trial, the Phase 2 TIDAL trial, and the Phase 2 CORAL trial. Depending on the achievement of certain regulatory and commercial milestones in Japan, MEI may be eligible for additional payments from KKC under the current agreement. We are entitled to royalties on any sales of zandelisib in Japan.

In December 2022, we announced a plan to streamline our organization towards the continued clinical development of voruciclib and ME-344. As a result, we initiated a staggered workforce reduction, initially affecting 28 employees in December 2022 (representing approximately 27% of our workforce). In connection with the reduction in force, we incurred termination costs, which include severance, benefits, and related costs of approximately \$1.2 million, of which \$0.8 million was research and development expense and \$0.4 million was general and administrative expense. We have accrued these termination benefits as of December 31, 2022 and paid the associated benefits in January 2023.

#### Liquidity

We have accumulated losses of \$380.5 million since inception and expect to incur operating losses and generate negative cash flows from operations for the foreseeable future. As of December 31, 2022, we had \$124.2 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 operations and operating expenses may affect actual future use of existing cash resources. We cannot determine with certainty costs associated with ongoing and future clinical trials or the regulatory approval process. The duration, costs and timing associated with the development of our product candidates will depend on a variety of factors, including uncertainties associated with the results of our clinical trials.

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

#### **Basis of Presentation**

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

The accompanying unaudited financial statements for the quarterly period ended December 31, 2022 should be read in conjunction with the audited financial statements and notes thereto as of and for the fiscal year ended June 30, 2022, included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on September 8, 2022 ("2022 Annual Report"). Interim results are not necessarily indicative of results for a full year.

#### **Use of Estimates**

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

#### **Fair Value Measurements**

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

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

#### **Revenue Recognition**

Revenues from Customers

In accordance with Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("Topic 606"), we recognize revenue when control of the promised goods or services is transferred to our customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. For enforceable contracts with our customers, we

first identify the distinct performance obligations – or accounting units – within the contract. Performance obligations are commitments in a contract to transfer a distinct good or service to the customer.

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

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

Stand-alone selling price is the price at which we would sell a promised good or service separately to the customer. When not directly observable, we typically estimate the stand-alone selling price for each distinct performance obligation. Variable consideration that relates specifically to our efforts to satisfy specific performance obligations is allocated entirely to those performance obligations. Other components of the transaction price are allocated based on the relative stand-alone selling price, over which management has applied significant judgment. We develop assumptions that require judgment to determine the stand-alone selling price for license-related performance obligations, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical, regulatory and commercial success. We estimate stand-alone selling price for research and development performance obligations by forecasting the expected costs of satisfying a performance obligation plus an appropriate margin.

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

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

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

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

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

	Three Months Ended December 31,					led ,				
		2022		2021 2022		2022		2022		2021
Revenue	\$	32,735	\$	11,832	\$	41,465	\$	19,589		
Timing of Revenue Recognition:										
Services performed over time	\$	32,473	\$	9,625	\$	40,832	\$	16,810		
Pass through services at a point in time		262		2,207		633		2,779		
	\$	32,735	\$	11,832	\$	41,465	\$	19,589		

#### Contract Balances

Accounts receivable are included in "Prepaid expenses and other current assets", and contract liabilities are included in "Deferred revenue" and "Deferred revenue, long-term" on our Condensed Balance Sheets. The following table presents changes in accounts receivable, unbilled receivables and contract liabilities accounted for under Topic 606 for the periods presented (in thousands):

C' M d E l l

	Six Months Ended December 31,				
		2022		2021	
Accounts receivable					
Accounts receivable, beginning of period	\$	_	\$	_	
Amounts billed		17,803		35,757	
Payments received		(17,803)		(35,757)	
Accounts receivable, end of period	\$	_	\$		
Unbilled receivables					
Unbilled receivables, beginning of period	\$	10,044	\$	7,582	
Billable amounts		13,463		38,326	
Amounts billed		(17,803)		(35,757)	
Unbilled receivables, end of period	\$	5,704	\$	10,151	
Contract liabilities					
Contract liabilities, beginning of period	\$	30,900	\$	14,677	
Payments received		_		20,000	
Revenue recognized		(2,831)		(1,264)	
Revenue recognized from change in estimate for performance obligations that are being					
closed		(16,565)		_	
Revenue recognized for performance obligations that will no longer commence		(8,607)		<u> </u>	
Contract liabilities, end of period	\$	2,897	\$	33,413	

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

As of December 31, 2022 and June 30, 2022, we had \$67.4 million and \$95.4 million, respectively, of deferred revenue associated with the KKC Commercialization Agreement, of which \$64.5 million relates to the U.S. license which is a unit of account under the scope of ASC Topic 808, *Collaborative Arrangements* ("Topic 808") and is not a performance obligation under Topic 606. The remaining balance of deferred revenue as of December 31, 2022 and June 30, 2022 of \$2.9 million and \$30.9 million, respectively, relates to the development services performance obligations which are under the scope of Topic 606. The decrease in deferred revenue comes as a result of our beginning the close down of all zandelisib studies outside of Japan. We updated our estimated costs to complete each of the performance obligations, resulting in a higher progress towards completion based on the ratio of costs incurred to date to the total estimated costs. Additionally, we recognized revenue related to non-refundable payments for performance obligations that have not commenced and will no longer be initiated.

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

#### Revenues from Collaborators

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

#### **Research and Development Costs**

Research and development costs are expensed as incurred and include costs paid to third-party contractors to perform research, conduct clinical trials and develop and manufacture drug materials. Clinical trial costs, including costs associated with third-party contractors, are a significant component of research and development expenses. We expense research and development costs based on work performed. In determining the amount to expense, management relies on estimates of total costs based on contract components completed, the enrollment of subjects, the completion of trials, and other events. Costs incurred related to the purchase or licensing of in-process research and development for early-stage products or products that are not commercially viable and ready for use, or have no alternative future use, are charged to expense in the period incurred.

#### Leases

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

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

#### **Share-Based Compensation**

Share-based compensation expense stock options and restricted stock units ("RSUs") granted to employees and directors is recognized in the Condensed Statements of Operations based on estimated amounts. The cost of stock options is measured at the grant

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

#### **Income Taxes**

Our income tax expense consists of current and deferred income tax expense or benefit. Current income tax expense or benefit is the amount of income taxes expected to be payable or refundable for the current year. A deferred income tax asset or liability is recognized for the future tax consequences attributable to tax credits and loss carryforwards and to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. As of December 31, 2022, we have established a valuation allowance to fully reserve our net deferred tax assets. Tax rate changes are reflected in income during the period such changes are enacted. Changes in our ownership may limit the amount of net operating loss carryforwards that can be utilized in the future to offset taxable income.

There have been no material changes in our unrecognized tax benefits since June 30, 2022, and, as such, the disclosures included in our 2022 Annual Report continue to be relevant for the six months ended December 31, 2022.

#### **Recent Accounting Pronouncement**

In June 2016, the Financial Accounting Standards Board issued Accounting Standards Update 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), as amended. The amendments in ASU 2016-13 require, among other things, financial assets measured at amortized cost basis to be presented at the net amount expected to be collected as compared to previous U.S. GAAP which delayed recognition until it was probable a loss had been incurred. The amendments in ASU 2016-13 are effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact that adoption of ASU 2016-13 will have on our financial statements and related disclosures.

#### **Note 2. Fair Value Measurements**

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

In May 2018, we issued warrants in connection with our private placement of shares of common stock. Pursuant to the terms of the warrants, we could be required to settle the warrants in cash in the event of an acquisition of the Company and, as a result, the warrants are required to be measured at fair value and reported as a liability in the Condensed Balance Sheet. We recorded the fair value of the warrants upon issuance using the Black-Scholes valuation model and are required to revalue the warrants at each reporting date with any changes in fair value recorded on our Condensed Statement of Operations. The valuation of the warrants is considered under Level 3 of the fair value hierarchy due to the need to use assumptions in the valuation that are both significant to the fair value measurement and unobservable. Inputs used to determine estimated fair value of the warrant liabilities include the estimated fair value of the underlying stock at the valuation date, the estimated term of the warrants, risk-free interest rates, expected dividends and the expected volatility of the underlying stock. The significant unobservable inputs used in the fair value measurement of the warrant liabilities were the volatility rate and the estimated term of the warrants. Generally, increases (decreases) in the fair value of the underlying stock and estimated term would result in a directionally similar impact to the fair value measurement. The change in the fair value of the Level 3 warrant liability is reflected in the Condensed Statements of Operations for the three and six months ended December 31, 2022 and 2021, respectively.

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

	December 202		June 30, 2022
Risk-free interest rate		4.7 %	2.8 %
Expected life (years)		0.4	0.9
Expected volatility		101.7%	139.4%
Dividend yield		0.0%	0.0%
Black-Scholes Fair Value	\$	— \$	0.10

The following table sets forth a summary of changes in the estimated fair value of our Level 3 warrant liability for the six months ended December 31, 2022 and 2021 (in thousands):

	Fair Value of Warrants Using Significant Unobservable Inputs (Level 3)					
	2022		2021			
Balance at July 1,	\$ 1,603	\$	22,355			
Change in estimated fair value of liability classified warrants	(1,603)		(8,046)			
Balance at December 31,	\$ _	\$	14,309			

#### **Note 3. Short-Term Investments**

As of December 31, 2022, and June 30, 2022, our short-term investments consisted of \$113.3 million and \$137.5 million, respectively, in U.S. government securities. The short-term investments held as of December 31, 2022 and June 30, 2022 had maturity dates of less than one year, are considered to be "held to maturity" and are carried at amortized cost. As of December 31, 2022, and June 30, 2022, the gross holding gains and losses were immaterial.

#### **Note 4. License Agreements**

KKC License, Development and Commercialization Agreement

In April 2020, we entered into the KKC Commercialization Agreement under which we granted to KKC a co-exclusive, sublicensable, payment-bearing license under certain patents and know-how controlled by us to develop and commercialize zandelisib and any pharmaceutical product containing zandelisib for all human indications in the U.S. (the "U.S. License"), and an exclusive (subject to certain retained rights to perform obligations under the KKC Commercialization Agreement), sublicensable, payment-bearing, license under certain patents and know-how controlled by us to develop and commercialize zandelisib and any pharmaceutical product containing zandelisib for all human indications in countries outside of the U.S. (the "Ex-U.S." and the "Ex-U.S. License"). KKC granted to us a co-exclusive, sublicensable, license under certain patents and know-how controlled by KKC to develop and commercialize zandelisib for all human indications in the U.S., and a co-exclusive, sublicensable, royalty-free, fully paid license under certain patents and know-how controlled by KKC to perform our obligations in the Ex-U.S. under the KKC Commercialization Agreement. KKC paid us an initial payment of \$100.0 million. Additionally, in Japan, where development is now focused, the KKC Commercialization Agreement included potential regulatory and commercialization milestone payments plus royalties on net sales of zandelisib in Japan, which are tiered beginning in the teens.

KKC is responsible for the development and commercialization of zandelisib in the Ex-U.S. and, subject to certain exceptions, is solely responsible for all costs related thereto. We provide to KKC certain drug supplies necessary for the development and commercialization of zandelisib in the Ex-U.S., with the understanding that KKC will assume responsibility for manufacturing for the Ex-U.S. as soon as practicable.

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

As discussed in Note 1, we and KKC jointly decided to discontinue zandelisib development in the U.S. As of December 31, 2022, we updated our assessment of the total transaction price from the KKC Commercialization Agreement to be \$216.3 million, comprised of the upfront payment of \$100.0 million, milestone payments of \$20.0 million, estimated development cost-sharing of

\$91.1 million, and deferred revenue of \$5.2 million. As of December 31, 2022, the updated assessment reflects a decrease in estimated variable consideration related to development cost sharing of \$143.8 million from June 30, 2022. We decreased our estimate for variable consideration related to development cost sharing primarily as a result of us discontinuing our zandelisib program. As a result, we recognized revenue of \$16.6 million from the change in estimate. Additionally, we recognized \$8.6 million of revenue related to non-refundable payments for performance obligations that have not commenced and will no longer be initiated. Any variable consideration related to sales-based royalties and commercial milestones related to licenses of intellectual property will be determined when the sale or usage occurs, and is therefore excluded from the transaction price. In addition, we are eligible to receive future development and regulatory milestones upon the achievement of certain criteria; however, these amounts are excluded from variable consideration as the risk of significant revenue reversal will only be resolved depending on future research and development and/or regulatory approval outcomes. We re-evaluate the estimated variable consideration included in the transaction price and any related constraints at the end of each reporting period.

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

We determined that control of the U.S. License and Ex-U.S. License were transferred to KKC during the year ended June 30, 2020, and recognized revenue of \$21.0 million related to the Ex-U.S. License. The \$64.5 million transaction price allocated to the U.S. License obligation accounted for under Topic 808 is included as non-current deferred revenue and will begin to be recognized upon completion of the collaborative arrangement as non-ASC 606 revenue. As of December 31, 2022 and June 30, 2022, we have deferred revenue of \$2.9 million and \$30.9 million, respectively, related to the transaction price allocated to the Development Services performance obligations and are recognizing this revenue based on the proportional performance of these development activities, which we expect to recognize through fiscal year 2024.

#### Presage License Agreement

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

#### Note 5. BeiGene Collaboration

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

#### Note 6. Net Income (Loss) Per Share

Basic and diluted net income (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 six months ended December 31, 2022 and 2021. Diluted net income (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 income (loss) used to calculate basic income (loss) and diluted income (loss) per share (in thousands):

	Three Months Ended December 31,				Six Months Ended December 31,			
	 2022		2021		2022		2021	
Net income (loss) – basic	\$ 10,253	\$	(12,156)	\$	(6,371)	\$	(29,666)	
Change in fair value of warrant liability	_		(5,458)		_		(8,046)	
Net income (loss) – diluted	\$ 10,253	\$	(17,614)	\$	(6,371)	\$	(37,712)	

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

	Three Mon Decemb		Six Month Decemb	
	2022	2021	2022	2021
Weighted average shares used in calculating basic net income (loss) per share	133,261	126,725	133,258	115,982
Effect of potentially dilutive common shares from equity awards and liability-classified warrants		1,435		2,675
Weighted average shares used in calculating diluted net income (loss) per share	133,261	128,160	133,258	118,657

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 income (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 income (loss) per share because of their anti-dilutive effect (in thousands):

	Three Mont Decemb		Six Months Ended December 31,		
	2022	2021	2022	2021	
Stock options	27,452	20,460	27,606	20,671	
Warrants	16,059	_	16,059	_	
Restricted stock units	_	229	5	244	
Total anti-dilutive shares	43,511	20,689	43,670	20,915	

#### Note 7. Commitments and Contingencies

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

#### Presage License Agreement

As discussed in Note 4, we are party to a license agreement with Presage under which we may be required to make future payments upon the achievement of certain development, regulatory and commercial milestones, as well as potential future royalties based upon net sales. As of December 31, 2022, we had not accrued any amounts for potential future payments as achievement of the milestones had not been met.

#### COVID-19

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

We have experienced enrollment delays and suspensions, patient withdrawals, postponement of planned clinical or preclinical studies, redirection of site resources from studies, and study deviations or noncompliance. We may also need to maintain or implement study modifications, suspensions, or terminations, the introduction of additional remote study procedures and modified informed

consent procedures, study site changes, direct delivery of investigational products to patient homes or alternative sites, which may require state licensing, and changes or delays in site monitoring. The foregoing may require that we consult with relevant review and ethics committees, Institutional Review Boards and the FDA. The foregoing may also impact the integrity of our study data. The ongoing COVID-19 pandemic may further increase the need for clinical trial patient monitoring and regulatory reporting of adverse effects, and may delay regulatory authority meetings, inspections, or the regulatory review of marketing or investigational applications or submissions.

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

Nasdaq Bid Price Letter

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

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

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

Torreya Partners

In October 2022, we engaged Torreya Partners as a financial advisor to help explore additional strategic opportunities. As part of this engagement, we have agreed to issue warrants to acquire shares of our common stock having a value equal to \$0.5 million at the time of issuance. To date these warrants have not been issued and have been accrued for as of December 31, 2022. We will also pay Torreya Partners a transaction fee equal to 20% of aggregate consideration, up to a maximum of \$2.0 million, in connection with a potential strategic transaction. As of December 31, 2022, we have not accrued any amount for potential future transaction fees.

#### Note 8. Leases

In July 2020, we entered into a lease agreement (the "Initial Lease Agreement") for approximately 32,800 square feet of office space in San Diego, California. The Initial Lease Agreement was extended to November 30, 2029, in accordance with the amended lease agreement that we entered into in January 2022 (the "Amended Lease Agreement"). The Amended Lease Agreement, which began on July 1, 2022 and expires on November 30, 2029, provides for an additional 12,300 square feet of office space adjacent to our current office in San Diego, for a total of approximately 45,100 square feet of office space. Upon taking control of the additional 12,300 square feet of office space adjacent to our current office in San Diego on July 1, 2022, we recognized operating lease ROU assets obtained in exchange for operating lease liabilities of \$4.3 million. The Initial Lease Agreement and Amended Lease Agreement are collectively referred to as the "Lease Agreements" and have been accounted for as operating leases.

The following is a schedule of the future minimum lease payments under the Lease Agreements, reconciled to the operating lease liability, as of December 31, 2022 (in thousands):

	Dec	ember 31, 2022
Remainder of fiscal year ending June 30, 2023	\$	1,133
Years ending June 30,		
2024		2,335
2025		1,913
2026		2,477
2027		2,551
2028		2,715
Thereafter		4,386
Total lease payments		17,510
Less: Present value discount		(4,140)
Total operating lease liability	\$	13,370
Balance Sheet Classification – Operating Leases		
Operating lease liability	\$	1,343
Operating lease liability, long-term		12,027
Total operating lease liability	\$	13,370
Other Balance Sheet Information – Operating Leases		
Weighted average remaining lease term (in years)		6.9
Weighted average discount rate		7.50 %

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

The total operating lease costs and supplemental cash flow information related to our operating leases were as follows (in thousands):

	Three Mo Decen	nths En iber 31,		Six Months Ended December 31,		
	 2022		2021	 2022		2021
Operating lease expense	\$ 608	\$	377	\$ 1,217	\$	753
Operating cash flows from operating leases	\$ 567	\$	380	\$ 1,133	\$	760

#### Note 9. Stockholders' Equity

#### **Equity Transactions**

Shelf Registration Statement

We have a shelf registration statement that permits us to sell, from time to time, up to \$200.0 million of common stock, preferred stock and warrants. The shelf registration was filed and declared effective in May 2020, and carried forward approximately \$107.5 million of unsold securities registered under the prior shelf registration statement. As of December 31, 2022, there was \$123.4 million aggregate value of securities available under the shelf registration statement, including \$60.0 million remaining available under the 2020 ATM Sales Agreement described below.

At-The-Market Equity Offering

On November 10, 2020, we entered into an At-The-Market Equity Offering Sales Agreement (the "2020 ATM Sales Agreement"), pursuant to which we may sell an aggregate of up to \$60.0 million of our common stock pursuant to the shelf registration statement. As of December 31, 2022, there was \$60.0 million remaining available under the 2020 ATM Sales Agreement.

#### Warrants

As of December 31, 2022, we have outstanding warrants to purchase 16,058,985 shares of our common stock related to a private placement equity financing that we closed in May 2018. The warrants are fully vested, exercisable at a price of \$2.54 per share and expire in May 2023. Pursuant to the terms of the warrants, we could be required to settle the warrants in cash in the event of an

acquisition of the Company and, as a result, the warrants are required to be measured at fair value and reported as a liability in the Condensed Balance Sheets. The warrants were revalued as of December 31, 2022 and June 30, 2022 at zero and \$1.6 million, respectively. The change in fair value of \$0.5 million and \$1.6 million was recorded on the Condensed Statement of Operations for the three and six months ended December 31, 2022.

#### Note 10. Share-based Compensation

We use equity-based compensation programs to provide long-term performance incentives for our employees. These incentives consist primarily of stock options and RSUs. In December 2008, we adopted the MEI Pharma, Inc. 2008 Stock Omnibus Equity Compensation Plan ("Omnibus Plan"), as amended and restated from time-to-time, under which 29,014,794 shares of common stock are authorized for issuance. The Omnibus Plan provides for the grant of options and/or other stock-based or stock-denominated awards to our non-employee directors, officers, and employees. As of December 31, 2022, there were 3,335,415 shares available for future grant under the Omnibus Plan. In January 2023, our stockholders approved the increase of 8,000,000 additional shares available for future grant under the Omnibus Plan.

In May 2021, we adopted the 2021 Inducement Plan ("Inducement Plan"), under which 2,500,000 shares of common stock are authorized for issuance. The Inducement Plan is intended to assist us in attracting and retaining selected individuals to serve as employees who are expected to contribute to our success, by providing an inducement for such individuals to enter into employment with us, and to achieve long-term objectives that will benefit stockholders of the Company. As of December 31, 2022, there were 491,397 shares available for future grant under the Inducement Plan.

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

	Three Months Ended December 31,				Six Months Ended December 31,		
	2022 2021		2022 202		2021		
Research and development	\$ 201	\$	658	\$	850	\$	1,280
General and administrative	612		1,666		1,522		3,583
Total share-based compensation expense	\$ 813	\$	2,324	\$	2,372	\$	4,863

Stock Options

Stock options granted to employees vest 25% one year from the date of grant and ratably each month thereafter for a period of 36 months and expire ten years from the date of grant. Stock options granted to directors vest ratably each month for a period of 12 months from the date of grant and expire ten years from the date of grant. Of the total options outstanding of 25,404,860 as of December 31, 2022, 23,396,257 were granted under the Omnibus Plan and 2,008,603 were granted under the Inducement Plan.

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

	Number of Options	Weighted- Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Valu	ıe_
Outstanding at June 30, 2022	19,934,007	\$ 2.85			
Granted	9,220,410	0.53			
Expired	(156,667)	2.63			
Forfeited/Cancelled	(3,592,890)	2.05			
Outstanding at December 31, 2022	25,404,860	2.12	7.7	\$	_
Vested and exercisable at December 31, 2022	12,242,063	2.89	6.3	\$	

As of December 31, 2022, the aggregate intrinsic value of outstanding options was calculated as the difference between the exercise price of the underlying options and the closing price of our common stock of \$0.24 on that date.

Unrecognized compensation expense related to non-vested stock options totaled \$5.2 million as of December 31, 2022. Such compensation expense is expected to be recognized over a weighted average period of 1.6 years. As of December 31, 2022, we expect all options to vest.

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

	Six Months Ended December 31,			
	2022	2021		
Risk-free interest rate	2.9 %	1.1 %		
Expected life (years)	6.0	6.0		
Expected volatility	84.1 %	68.0 %		
Dividend yield	0.0 %	0.0 %		
Weighted average grant date fair value	\$ 0.39 \$	1.78		

#### Restricted Stock Units

A summary of our RSU activity and related data for the six months ended December 31, 2022 was as follows:

	Number of RSUs	Weighted Average Grant Date Fair Value
Non-vested at June 30, 2022	184,400	\$ 3.49
Vested	(184,400)	\$ 3.49
Non-vested at December 31, 2022		\$ _

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

This Quarterly Report on Form 10-Q ("Quarterly Report") includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding the future financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," and similar expressions, as they relate to us, are intended to identify forward-looking statements. We have based these forward-looking statements largely on current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, without limitation, those described in "Risk Factors" in our 2022 Annual Report on Form 10-K ("2022 Annual Report"), as filed with the Securities and Exchange Commission on September 8, 2022. Set forth below is a summary of the principal risks we face:

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

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

similar actions may be brought only in the Court of Chancery in the State of Delaware and, if brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder's counsel, which may have the effect of discouraging lawsuits against our directors, officers, other employees or stockholders; and

Our executive officers and directors may sell shares of their stock, and these sales could adversely affect our stock price.

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

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

#### Overview

MEI Pharma, Inc. (Nasdaq: MEIP) is a clinical stage pharmaceutical company focused on developing potential new therapies for cancer. MEI Pharma's portfolio of drug candidates includes clinical-stage candidates with differentiated or novel mechanisms of action intended to address unmet medical needs and deliver improved benefit to patients, either as standalone treatments or in combination with other therapeutic options. Our common stock is listed on the Nasdaq Capital Market under the symbol "MEIP."

In November 2022, we announced plans to realign our clinical development efforts following the discontinuation of zandelisib global development efforts outside Japan. Zandelisib, an oral PI3K delta inhibitor, was our lead drug candidate being developed globally under a partnership with Kyowa Kirin Co., Ltd ("KKC"). The decision to discontinue zandelisib development outside of Japan was a joint decision with KKC. The costs of the close of the zandelisib development program outside of Japan are shared with KKC. Our focus going forward will be the development of our two earlier clinical-stage assets, voruciclib and ME-344.

In connection with the realignment, we initiated a staggered workforce reduction, initially affecting 28 employees in December 2022 (representing approximately 27% of our workforce). Following completion of the close of the zandelisib development program and associated workforce reductions, MEI expects that, along with any additional workforce reductions to be determined to fully align resources going forward, its existing cash, cash equivalents and short-term investments will be sufficient to fund operations for at least 12 months. In connection with the realignment, we also announced that we are exploring additional strategic opportunities in conjunction with Torreya Partners as a financial advisor.

#### **Clinical Development Programs**

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

- Voruciclib, an oral cyclin-dependent kinase 9 ("CDK9") inhibitor; and
- ME-344, an intravenous small molecule targeting the oxidative phosphorylation pathway; and
- Zandelisib, an oral phosphatidylinositol 3-kinase delta ("PI3Kδ") inhibitor.

#### Voruciclib: Potent Orally Administered CDK9 Inhibitor in Phase 1 Studies

Voruciclib is a potent orally administered CDK9 inhibitor. Voruciclib is being evaluated in a Phase 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 targets in the RAS signaling pathway, including KRAS.

Voruciclib Scientific Overview: Cell Cycle Signaling

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

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

Voruciclib: Inhibition of MCL1

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

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

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

Voruciclib: Inhibition of MYC

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

Results in a rapid decrease in the phosphorylation of proteins that promote MYC transcription;

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

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

#### Clinical Program

We are evaluating patients with hematological malignancies in a Phase 1b clinical trial evaluating the dose and schedule of voruciclib. The trial started with the evaluation of dose and schedule of voruciclib as a monotherapy in patients with relapsed and refractory B-cell malignancies and AML after failure of prior standard therapies to determine the safety, preliminary efficacy and maximum tolerated dose. We are now also starting to evaluate the dose and schedule of voruciclib in combination with venetoclax, a BCL2 inhibitor, initially in patients with AML and subsequently across multiple indications where BCL2 inhibition has been shown to be effective. The primary goal of the Phase 1b study is to assess the safety, and possible synergies, of voruciclib administered in combination with venetoclax. We are planning to report key interim clinical data from this trial around calendar year-end 2023.

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

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

#### Impact of COVID-19 on the Voruciclib Clinical Development Program

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

#### ME-344: Clinical Stage Mitochondrial Inhibitor with Combinatorial Potential

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

#### ME-344 Scientific Overview: Cancer Metabolism

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

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

#### Clinical Program

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

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

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

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

- In ME-344 treated patients, mean absolute Ki67 decreases were 13.3 compared to an increase of 1.1 in the bevacizumab monotherapy group (P=0.01).
- In ME-344 treated patients, mean relative Ki67 decreases were 23% compared to an increase of 186% in the bevacizumab monotherapy group (P < 0.01).
- The mean relative Ki67 reduction in patients experiencing vascular normalization in the ME-344 treated patients was 33%, compared to an increase of 11.8% in normalized patients from the bevacizumab monotherapy group (P=0.09). Approximately one-third of patients in each arm had vascular normalization.

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

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

We are planning to advance ME-344 in combination with the anti-angiogenic antibody bevacizumab in a Phase 1b study evaluating patients with relapsed colorectal cancer in the first half of calendar year 2023. The study will enroll patients with progressive disease after failure of standard therapies with patients treated until disease progression or intolerance. The primary objective is progression free survival. Secondary endpoints include overall response rate, duration of response, overall survival and safety. We are planning to report key interim clinical data from this trial around calendar year-end 2023.

Additionally, ME-344 may also have clinical potential against hematological malignancies. At the AACR Annual Meeting 2022, a poster presentation reported results from preclinical studies exploring the ability of ME-344 to enhance the activity of venetoclax against AML. Data from the in vitro and in vivo preclinical studies evaluating the combination of ME-344 with venetoclax

in standard-of-care-resistant AML cell lines and relapsed or refractory AML patient samples suggest that ME-344, both alone and in combination with venetoclax, inhibits purine biosynthesis, suppresses oxidative phosphorylation, induces apoptosis and decreases MCL-1, which together target metabolic vulnerabilities of AML cells. The data demonstrated that ME-344 and venetoclax prolong survival in MV4-11 and MV4-11/AraC-R-derived xenograft AML models. The poster concludes that ME-344 enhances venetoclax activity against AML cells including resistant AML.

#### Zandelisib: PI3Kδ Inhibitor Overview

Zandelisib is an oral, once-daily, selective PI3Kδ inhibitor clinically evaluated for the treatment of B-cell malignancies. In April 2020, we entered into a global license, development and commercialization agreement to further develop and commercialize zandelisib with KKC.

In March 2022, MEI Pharma and KKC reported the outcome of an end of Phase 2 meeting with the FDA wherein the agency discouraged a filing based on data from a single-arm Phase 2 trial, called TIDAL, evaluating zandelisib in patients with relapsed or refractory follicular lymphoma. At this meeting, the FDA stated that a randomized trial should be used to support an initial zandelisib registration in patients with indolent non-Hodgkin lymphoma and, accordingly, data generated from single arm studies such as the Phase 2 TIDAL trial are insufficient to adequately assess the risk/benefit of PI3K inhibitors evaluating indolent non-Hodgkin lymphoma. At that time the FDA emphasized that the companies continue efforts with the ongoing randomized Phase 3 COASTAL trial evaluating patients with relapsed or refractory follicular or marginal zone lymphomas. Subsequently, at an April 2022 meeting of the FDA Oncology Drugs Advisory Committee, the committee voted that future approvals of PI3K inhibitors for hematologic malignancies should be supported by randomized data.

In November 2022, MEI Pharma and KKC met with the FDA in a follow-up meeting to the March 2022 end of Phase 2 meeting. At this meeting, the FDA provided further guidance regarding the design and statistical analysis for the COASTAL trial. Following the November meeting, the companies jointly concluded that a clinical trial consistent with the recent FDA guidance, including modification of the ongoing COASTAL trial, would likely not be feasible to complete within a time period that would support further investment or with sufficient certainty of the regulatory requirements for approval to justify continued global development efforts. As a result, MEI and KKC jointly decided to discontinue global development of zandelisib for indolent forms of non-Hodgkin lymphoma outside of Japan.

The discontinuation of zandelisib development outside of Japan was a business decision based on the most recent regulatory guidance from the FDA and is not related to the zandelisib clinical data generated to date. KKC is continuing certain ongoing Japanese clinical trials including the Phase 2 MIRAGE trial evaluating Japanese patients with relapsed or refractory indolent B-cell non-Hodgkin lymphomas and will explore submitting the MIRAGE and TIDAL trials for marketing authorization in Japan. MIRAGE is a Phase 2 trial, similar in design to the global Phase 2, single-arm, TIDAL trial. In November 2022 KKC and MEI announced positive topline data from the Phase 2 MIRAGE trial.

MEI and KKC have begun closing all ongoing zandelisib clinical studies outside of Japan, including the Phase 3 COASTAL trial, the Phase 2 TIDAL trial, and the Phase 2 CORAL trial. Depending on the achievement of certain regulatory and commercial milestones in Japan, MEI may be eligible for additional payments from KKC under the current agreement. MEI may also be entitled to royalties on any sales of zandelisib in Japan.

#### KKC License, Development and Commercialization Agreement

In April 2020, we entered into the KKC Commercialization Agreement under which we granted to KKC a co-exclusive, sublicensable, payment-bearing license under certain patents and know-how controlled by us to develop and commercialize zandelisib and any pharmaceutical product containing zandelisib for all human indications in the U.S. (the "U.S. License"), and an exclusive (subject to certain retained rights to perform obligations under the KKC Commercialization Agreement), sublicensable, payment-bearing, license under certain patents and know-how controlled by us to develop and commercialize zandelisib and any pharmaceutical product containing zandelisib for all human indications in countries outside of the U.S. (the "Ex-U.S." and the "Ex-U.S. License"). KKC granted to us a co-exclusive, sublicensable, license under certain patents and know-how controlled by KKC to develop and commercialize zandelisib for all human indications in the U.S., and a co-exclusive, sublicensable, royalty-free, fully paid license under certain patents and know-how controlled by KKC to perform our obligations in the Ex-U.S. under the KKC Commercialization Agreement. KKC paid us an initial payment of \$100.0 million. Additionally, in Japan, where development is now focused, the KKC Commercialization Agreement included potential regulatory and commercialization milestone payments plus royalties on net sales of zandelisib in Japan, which are tiered beginning in the teens.

KKC is responsible for the development and commercialization of zandelisib in the Ex-U.S. and, subject to certain exceptions, is solely responsible for all costs related thereto. 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.

#### **Results of Operations**

#### Comparison of three months ended December 31, 2022 and 2021

**Revenue:** We recognized revenue of \$32.7 million for the three months ended December 31, 2022 compared to \$11.8 million for the three months ended December 31, 2021. As a result of the discontinuation of the zandelisib program, we updated our estimated costs to complete each performance obligation, resulting in a higher progress towards completion based on the ratio of costs incurred to date to the total estimated costs, resulting in the recognition of \$16.6 million of previously deferred revenue related to performance obligations that are being closed. We also recognized \$8.6 million of previously deferred revenue related to performance obligations associated with clinical trials that have not commenced and will no longer be initiated.

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

	Three Months Ended December 31,			
Research and development expenses	2022 202			2021
Zandelisib	\$	8,265	\$	14,620
Voruciclib		428		1,545
ME-344		64		1,144
Other		6,556		4,222
Total research and development expenses	\$	15,313	\$	21,531

Research and development expenses consist primarily of clinical trial costs (including payments to contract research organizations "CROs"), preclinical study costs, and costs to manufacture our drug candidates for non-clinical and clinical studies. Other research and development expenses consist primarily of salaries and personnel costs, share-based compensation, legal costs, and other costs not allocated to specific drug programs. Costs related to zandelisib decreased primarily as a result of lower drug manufacturing costs, lower professional services costs, and lower clinical costs as we began the discontinuation of the zandelisib program during the three months ended December 31, 2022. Costs related to voruciclib decreased due to lower drug manufacturing costs and clinical costs in the Phase 1b study. Costs related to ME-344 decreased due to decreased drug manufacturing costs and clinical costs related to the Phase 1b study. The increase in other research and development costs is primarily due to personnel costs, including severance costs related to the reduction in force, offset by lower share-based compensation expenses.

**General and Administrative:** General and administrative expenses increased by \$0.6 million to \$8.5 million for the three months ended December 31, 2022 compared to \$7.9 million for the three months ended December 31, 2021. The increase is primarily due to severance costs related to the reduction in force, professional services and legal costs, and corporate overhead costs, offset by decreased share-based compensation costs related to the reduction in force.

**Other income or expense:** We recorded a non-cash gain of \$0.5 million during the three months ended December 31, 2022 due to a change in the fair value of our warrant liability. The change in the warrant liability is primarily due to changes in our stock price. Additionally, we received interest and dividend income of \$0.8 million for the three months ended December 31, 2022 compared to \$11,000 for the three months ended December 31, 2021. The increase is primarily due to higher yields during the three months ended December 31, 2022 compared to the three months ended December 31, 2021.

#### Comparison of six months ended December 31, 2022 and 2021

**Revenue:** We recognized revenue of \$41.5 million for the six months ended December 31, 2022 compared to \$19.6 million for the six months ended December 31, 2021. As a result of the discontinuation of the zandelisib program, we updated our estimated costs to complete each performance obligation, resulting in a higher progress towards completion based on the ratio of costs incurred to date to the total estimated costs, resulting in the recognition of \$16.6 million of previously deferred revenue related to performance obligations that are being closed. We also recognized \$8.6 million of previously deferred revenue related to performance obligations associated with clinical trials that have not commenced and will no longer be initiated.

**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.

		Decem			
Research and development expenses		2022	2021		
Zandelisib	\$	19,871	\$	27,012	
Voruciclib		1,161		2,586	
ME-344		849		1,784	
Other		12,895		10,102	
Total research and development expenses	\$	34,776	\$	41,484	

Research and development expenses consist primarily of clinical trial costs (including payments to contract research organizations "CROs"), preclinical study costs, and costs to manufacture our drug candidates for non-clinical and clinical studies. Other research and development expenses consist primarily of salaries and personnel costs, share-based compensation, legal costs, and other costs not allocated to specific drug programs. Costs related to zandelisib decreased primarily as a result of lower drug manufacturing costs, lower professional services costs, and lower clinical costs as we began the discontinuation of the zandelisib program during the six months ended December 31, 2022. Costs related to voruciclib decreased for the due to lower drug manufacturing costs and clinical costs related to the Phase 1b study. Costs related to ME-344 decreased due to decreased drug manufacturing costs and clinical costs related to the Phase 1b study. The increase in other research and development costs is primarily due to personnel costs, including severance costs related to the reduction in force, offset by lower share-based compensation expenses.

*General and Administrative*: General and administrative expenses increased by \$0.2 million to \$16.0 million for the six months ended December 31, 2022 compared to \$15.8 million for the six months ended December 31, 2021. The increase is primarily due to severance costs related to the reduction in force and corporate overhead costs, offset by decreased share-based compensation costs related to the reduction in force.

Other income or expense: We recorded a non-cash gain of \$1.6 million during the six months ended December 31, 2022 due to a change in the fair value of our warrant liability. The change in the warrant liability is primarily due to changes in our stock price. Additionally, we received interest and dividend income of \$1.3 million for the six months ended December 31, 2022 compared to \$18,000 for the six months ended December 31, 2021. The increase is primarily due to higher yields during the six months ended December 31, 2022 compared to the six months ended December 31, 2021.

#### **Liquidity and Capital Resources**

We have accumulated losses of \$380.5 million since inception and expect to incur operating losses and generate negative cash flows from operations for the foreseeable future. As of December 31, 2022, we had \$124.2 million in cash and cash equivalents, and short-term investments. We believe that these resources will be sufficient to fund our operations for at least 12 months from the issuance of this Quarterly Report. Our current business operations are focused on continuing the clinical development of our drug candidates. Changes to our research and development plans or other changes affecting our operations and operating expenses may affect actual future use of existing cash resources. 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 six months ended December 31, 2022 was \$29.1 million as compared to net cash used in operating activities of \$16.3 million for the six months ended December 31, 2021. The increase in net cash used in operating activities period over period reflects the receipt of two \$10.0 million milestones during the six months ended December 31, 2021, related to the KKC Commercialization Agreement, with no corresponding receipt for the six months ended December 31, 2022, as well as other changes in working capital.

Net cash provided by investing activities for the six months ended December 31, 2022 was \$24.3 million as compared to \$28.4 million used in investing activities for the six months ended December 31, 2021. The change was primarily due to increased proceeds from maturities of short-term investments in 2022, net of purchases.

Net cash used in financing activities during the six months ended December 31, 2022 was \$40,000 compared with \$48.7 million provided by financing activities during the six months ended December 31, 2021. Cash used during the six months ended December 31, 2022 was due to the payment of RSU tax withholdings in exchange for common shares surrendered by RSU holders. Cash raised during the six months ended December 31, 2021 reflected \$48.7 million of net proceeds from the issuance of common stock.

#### **Contractual Obligations**

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

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

#### Presage License Agreement

In September 2017, we entered into the Presage License Agreement. Under the terms of the Presage License Agreement, Presage granted to us exclusive worldwide rights to develop, manufacture and commercialize voruciclib, a clinical-stage, oral and selective CDK inhibitor, and related compounds. In exchange, we paid Presage \$2.9 million. With respect to the first indication, an incremental \$2.0 million payment, due upon dosing the first subject in the first registration trial will be owed to Presage, for total payments of \$4.9 million prior to receipt of marketing approval of the first indication in the U.S., E.U. or Japan. Additional potential payments of up to \$179 million will be due upon the achievement of certain development, regulatory and commercial milestones. We will also pay mid-single-digit tiered royalties on the net sales of any product successfully developed. As an alternative to milestone and royalty payments related to countries in which we sublicense product rights, we will pay to Presage a tiered percent (which decreases as product development progresses) of amounts received from such sublicensees. As of December 31, 2022, we had not accrued any amounts for potential future payments.

#### COVID-19

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

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

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

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

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

#### **Critical Accounting Policies and Management Estimates**

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

#### **Recent Accounting Pronouncement**

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

#### Item 3. Quantitative and Qualitative Disclosures about Market Risk

#### **Interest Rate Risk**

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

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

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

#### **Item 4. Controls and Procedures**

#### (a) Disclosure Controls and Procedures

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

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

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

#### Plan for Remediation of Material Weakness

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

#### Changes in Internal Control over Financial Reporting

Other than the ongoing remediation efforts related to the material weakness discussed above, there were no changes in our internal control over financial reporting (as such term is defined by Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the most recent fiscal quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

#### PART II OTHER INFORMATION

#### **Item 1. Legal Proceedings**

None.

#### **Item 1A. Risk Factors**

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

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

None.

#### Item 3. Defaults upon Senior Securities

None.

#### **Item 4. Mine Safety Disclosures**

Not applicable.

#### **Item 5. Other Information**

None.

#### Item 6. Exhibits

#### **Exhibit Index**

Exhibits	
31.1	Rule 13a-14(a) or Rule 15d-14(a) Certification of Principal Executive Officer.
31.2	Rule 13a-14(a) or Rule 15d-14(a) Certification of Principal Financial Officer.
32.1	Certification of Principal Executive Officer and Principal Financial Officer required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C 1350).
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

#### **SIGNATURES**

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

MEI Pharma, Inc.

/s/ Daniel P. Gold

Daniel P. Gold

President and Chief Executive Officer

Date: February 9, 2023

#### **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: February 9, 2023

/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: February 9, 2023 /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 December 31, 2022, (the "Form 10-Q") to which this Certification is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2. The information contained in the Form 10-Q fairly presents, in all material respects, the financial condition of the Registrant at the end of the period covered by the Form 10-Q and results of operations of the registrant for the period covered by the Form 10-Q.

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

Dated: February 9, 2023		
/s/ Daniel P. Gold	/s/ Brian G. Drazba	
Daniel P. Gold	Brian G. Drazba	
Chief Executive Officer	Chief Financial Officer	
(Principal Executive Officer)	(Principal Financial Officer)	