

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2022

OR

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

For the transition period from _____ to _____

Commission file number: 000-31141

INFINITY PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

33-0655706
(I.R.S. Employer
Identification No.)

1100 Massachusetts Avenue, Floor 4, Cambridge, Massachusetts 02138

(Address of principal executive offices) (Zip code)

(617) 453-1000

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value	INFI	Nasdaq Global Select Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer <input type="checkbox"/>	Non-accelerated filer <input checked="" type="checkbox"/>	Smaller reporting company	Emerging growth company <input type="checkbox"/>
<input type="checkbox"/>			<input checked="" type="checkbox"/>	

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

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

Number of shares of the registrant's Common Stock, \$0.001 par value, outstanding on August 2, 2022: 89,277,873

INFINITY PHARMACEUTICALS, INC.
FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2022

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Cautionary Note Regarding Forward-Looking Information

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1999. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth, are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. The forward-looking statements contained in this Quarterly Report on Form 10-Q are based upon information available to us as of the date such statements are made and, while we believe such information forms a reasonable basis for such statements at the time made, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information.

There are a number of important risks and uncertainties that could cause actual results or events to differ materially from those indicated by forward-looking statements made herein. These risks and uncertainties include those inherent in pharmaceutical research and development, such as adverse results in our drug discovery and clinical development activities, decisions made by the U.S. Food and Drug Administration, or FDA, and other regulatory authorities with respect to the development and commercialization of our product candidates, our ability to obtain, maintain and enforce intellectual property rights for our product candidates, our dependence on our alliance partners, our competitive position, our ability to obtain any necessary financing to conduct our planned activities, our ability to implement our strategic plans, our ability to achieve cost-savings benefits from our restructuring and other risks described herein. These risks also include the direct and indirect impact of COVID-19 on our business operations and financial results.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Quarterly Report on Form 10-Q. Important factors that could cause actual results to differ materially from those in these forward-looking statements include the factors discussed under the heading “Summary of Risk Factors” and the risk factors detailed further in Item 1A, “Risk Factors” of Part I of our Annual Report on Form 10-K for the year ended December 31, 2021 and those included under Part II, Item 1A of this Quarterly Report on Form 10-Q. Unless required by law, we do not undertake any obligation to update any forward-looking statements.

This Quarterly Report on Form 10-Q also may include statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties as well as our own estimates. All of the market data used in this Quarterly Report on Form 10-Q involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our estimates of the potential market opportunities for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research and other surveys, which may be based on a small sample size and may fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions.

PART I. FINANCIAL INFORMATION**Item 1. Unaudited Condensed Consolidated Financial Statements****INFINITY PHARMACEUTICALS, INC.****Condensed Consolidated Balance Sheets
(unaudited)****(in thousands, except share and per share amounts)**

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 45,838	\$ 80,726
Available-for-sale securities	10,737	—
Prepaid expenses and other current assets	3,035	1,542
Total current assets	59,610	82,268
Property and equipment, net	1,017	1,241
Restricted cash, less current portion	158	158
Operating lease right-of-use assets	887	1,064
Other assets	185	54
Total assets	<u>\$ 61,857</u>	<u>\$ 84,785</u>
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	\$ 1,813	\$ 2,320
Accrued expenses and other current liabilities	12,526	10,980
Total current liabilities	14,339	13,300
Liabilities related to sale of future royalties, net, less current portion (Note 9)	47,955	48,727
Operating lease liability, less current portion	633	917
Other liabilities	37	270
Total liabilities	62,964	63,214
Commitments and contingencies		
Stockholders' (deficit) equity:		
Preferred Stock, \$0.001 par value; 1,000,000 shares authorized, no shares issued and outstanding at June 30, 2022 and December 31, 2021	—	—
Common Stock, \$0.001 par value; 200,000,000 shares authorized; 89,277,873 and 89,155,311 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	89	89
Additional paid-in capital	834,827	833,065
Accumulated deficit	(836,005)	(811,583)
Accumulated other comprehensive loss	(18)	—
Total stockholders' (deficit) equity	<u>(1,107)</u>	<u>21,571</u>
Total liabilities and stockholders' (deficit) equity	<u>\$ 61,857</u>	<u>\$ 84,785</u>

The accompanying notes are an integral part of these unaudited, condensed consolidated financial statements.

INFINITY PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Royalty revenue	\$ 686	\$ 512	\$ 1,338	\$ 979
Operating expenses:				
Research and development	8,795	7,957	17,785	16,158
General and administrative	3,495	3,498	7,171	7,064
Royalty expense (Note 11)	414	308	807	590
Total operating expenses	<u>12,704</u>	<u>11,763</u>	<u>25,763</u>	<u>23,812</u>
Loss from operations	(12,018)	(11,251)	(24,425)	(22,833)
Other income (expense):				
Investment and other income	77	27	93	25
Non-cash interest expense (Note 9)	(45)	(45)	(90)	(90)
Total other income (expense)	<u>32</u>	<u>(18)</u>	<u>3</u>	<u>(65)</u>
Net loss	<u>\$ (11,986)</u>	<u>\$ (11,269)</u>	<u>\$ (24,422)</u>	<u>\$ (22,898)</u>
Basic and diluted loss per common share:	<u>\$ (0.13)</u>	<u>\$ (0.13)</u>	<u>\$ (0.27)</u>	<u>\$ (0.28)</u>
Basic and diluted weighted average number of common shares outstanding:	<u>89,161,777</u>	<u>88,661,934</u>	<u>89,158,562</u>	<u>82,230,784</u>
Other comprehensive loss:				
Net unrealized holding gains (losses) on available-for-sale securities arising during the period	2	—	(18)	1
Comprehensive loss	<u>\$ (11,984)</u>	<u>\$ (11,269)</u>	<u>\$ (24,440)</u>	<u>\$ (22,897)</u>

The accompanying notes are an integral part of these unaudited, condensed consolidated financial statements.

INFINITY PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	Six Months Ended June 30,	
	2022	2021
Operating activities		
Net loss	\$ (24,422)	\$ (22,898)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	241	239
Stock-based compensation	1,682	1,202
Non-cash royalty revenue	(708)	(518)
Non-cash interest expense	90	90
Other, net	66	24
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,624)	(543)
Operating lease right-of-use assets	177	175
Accounts payable, accrued expenses and other liabilities	616	(571)
Operating lease liability	(248)	(238)
Net cash used in operating activities	(24,130)	(23,038)
Investing activities		
Purchases of property and equipment	(17)	—
Purchases of available-for-sale securities	(16,019)	—
Proceeds from maturities of available-for-sale securities	5,250	5,500
Net cash (used in) provided by investing activities	(10,786)	5,500
Financing activities		
Proceeds from public offering, net	—	85,838
Proceeds from issuances of common stock, net	28	365
Net cash provided by financing activities	28	86,203
Net (decrease) increase in cash, cash equivalents and restricted cash	(34,888)	68,665
Cash, cash equivalents and restricted cash at beginning of period	80,884	28,908
Cash, cash equivalents and restricted cash at end of period	\$ 45,996	\$ 97,573
Reconciliation of cash, cash equivalents, and restricted cash to the condensed consolidated balance sheets		
Cash and cash equivalents	\$ 45,838	\$ 97,258
Restricted cash included in prepaid expenses and other current assets	—	150
Restricted cash, less current portion	158	165
Total cash, cash equivalents and restricted cash	\$ 45,996	\$ 97,573

The accompanying notes are an integral part of these unaudited, condensed consolidated financial statements.

INFINITY PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Stockholders' (Deficit) Equity
(unaudited)
(in thousands, except share amounts)

	<u>Common Stock</u>		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance at March 31, 2022	89,155,311	\$ 89	\$ 833,932	\$ (824,019)	\$ (20)	\$ 9,982
Stock-based compensation expense			815			815
Issuance of common stock, net	122,562	—	80			80
Unrealized gain on marketable securities					2	2
Net loss				(11,986)		(11,986)
Balance at June 30, 2022	<u>89,277,873</u>	<u>\$ 89</u>	<u>\$ 834,827</u>	<u>\$ (836,005)</u>	<u>\$ (18)</u>	<u>\$ (1,107)</u>

	<u>Common Stock</u>		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balance at March 31, 2021	88,647,241	\$ 89	\$ 829,907	\$ (777,950)	\$ —	\$ 52,046
Exercise of stock options	29,494	—	41			41
Stock-based compensation expense			672			672
Issuance of common stock, net	42,804	—	50			50
Net loss				(11,269)		(11,269)
Balance at June 30, 2021	<u>88,719,539</u>	<u>\$ 89</u>	<u>\$ 830,670</u>	<u>\$ (789,219)</u>	<u>\$ —</u>	<u>\$ 41,540</u>

The accompanying notes are an integral part of these unaudited, condensed consolidated financial statements.

INFINITY PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Stockholders' (Deficit) Equity
(unaudited)
(in thousands, except share amounts)

	<u>Common Stock</u>		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockhold Equity (D
	Shares	Amount				
Balance at December 31, 2021	89,155,311	\$ 89	\$ 833,065	\$ (811,583)	\$ —	\$
Stock-based compensation expense			1,682			
Issuance of common stock, net	122,562	—	80			
Unrealized loss on marketable securities					(18)	
Net loss				(24,422)		(2
Balance at June 30, 2022	<u>89,277,873</u>	<u>\$ 89</u>	<u>\$ 834,827</u>	<u>\$ (836,005)</u>	<u>\$ (18)</u>	<u>\$</u>
	<u>Common Stock</u>					
	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Income	Total Stockhold (Deficit) E
Balance at December 31, 2020	64,320,244	\$ 64	\$ 743,269	\$ (766,321)	\$ (1)	\$ (2
Exercise of stock options	206,491	1	335			
Stock-based compensation expense			1,202			
Issuance of common stock related to public offering, net of issuance costs	24,150,000	24	85,814			
Issuance of common stock, net	42,804	—	50			
Unrealized gain on marketable securities					1	
Net loss				(22,898)		(2
Balance at June 30, 2021	<u>88,719,539</u>	<u>\$ 89</u>	<u>\$ 830,670</u>	<u>\$ (789,219)</u>	<u>\$ —</u>	<u>\$</u>

The accompanying notes are an integral part of these unaudited, condensed consolidated financial statements.

Infinity Pharmaceuticals, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Organization

Infinity Pharmaceuticals, Inc., is a clinical-stage innovative biopharmaceutical company dedicated to developing novel medicines for people with cancer. As used throughout these unaudited, condensed consolidated financial statements, the terms “Infinity,” “we,” “us,” and “our” refer to the business of Infinity Pharmaceuticals, Inc., and its wholly-owned subsidiaries.

2. Basis of Presentation

These condensed consolidated financial statements include the accounts of Infinity and its wholly-owned subsidiaries. We have eliminated all significant intercompany accounts and transactions in consolidation.

The accompanying condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring accruals and revisions of estimates, considered necessary for a fair presentation of the accompanying condensed consolidated financial statements have been included. Interim results for the three and six months ended June 30, 2022 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2022.

The information presented in the condensed consolidated financial statements and related footnotes at June 30, 2022, and for the three and six months ended June 30, 2022 and 2021, is unaudited, and the condensed consolidated balance sheet amounts and related footnotes at December 31, 2021 have been derived from our audited financial statements. For further information, please refer to the consolidated financial statements and accompanying footnotes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 filed with the U.S. Securities and Exchange Commission, or SEC, on March 29, 2022, which we refer to as our 2021 Annual Report on Form 10-K.

Liquidity

As of June 30, 2022, we had cash, cash equivalents and available-for-sale securities of \$56.6 million. We have primarily incurred operating losses since inception and have relied on our ability to fund our operations through collaboration and license arrangements, or other strategic arrangements, and through the sale of our common stock.

We expect to continue to spend significant resources to fund the development and potential commercialization of eganalisib, also known as IPI-549, an orally administered immuno-oncology product candidate that selectively inhibits the enzyme phosphoinositide-3-kinase-gamma, or PI3K-gamma, and to incur significant operating losses for the foreseeable future.

We believe that our existing cash, cash equivalents and available-for-sale securities at June 30, 2022 will be adequate to satisfy our current operating plans for at least the next twelve months from the issuance date of these financial statements.

3. Significant Accounting Policies

Our significant accounting policies are described in Note 2, “Summary of Significant Accounting Policies,” in “Notes to Consolidated Financial Statements” in our 2021 Annual Report on Form 10-K.

Segment Information

We operate in one business segment, which focuses on drug development. We make operating decisions based upon the performance of the enterprise as a whole and utilize our consolidated financial statements for decision making.

Basic and Diluted Net Loss per Common Share

Basic net loss per share is based upon the weighted average number of common shares outstanding during the period, excluding restricted stock units that have been issued but have not yet vested. Diluted net loss per share is based upon the weighted average number of common shares outstanding during the period plus the effect of additional weighted average common equivalent shares outstanding during the period when the effect of adding such shares is dilutive. Common equivalent shares result from the assumed exercise of outstanding stock options and the exercise of outstanding warrants (the proceeds of which are then assumed to have been used to repurchase outstanding stock using the treasury stock method) and the vesting of restricted shares of common stock. In addition, the assumed proceeds under the treasury stock method include the average unrecognized compensation expense of stock options that are in-the-money. This results in the “assumed” buyback of additional shares, thereby reducing the dilutive impact of stock options. The two-class method is used for outstanding warrants as such warrants are considered to be participating securities, and this method is more dilutive than the treasury stock method. The following outstanding shares of common stock equivalents were excluded from the computation of net loss per share attributable to common stockholders for the periods presented because including them would have been antidilutive:

	At June 30,	
	2022	2021
Stock options	15,091,829	12,583,847
Unvested restricted stock units	50,000	—

New Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update, or ASU, No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Statements*, or ASU No. 2016-13, which requires that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and it establishes additional disclosure requirements related to credit risks. For available-for-sale debt securities with expected credit losses, this standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. In November 2019, the FASB subsequently issued ASU 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates*, whereby the effective date of this standard for smaller reporting companies was deferred to annual reporting periods beginning after December 15, 2022, including interim periods within those annual reporting periods, and early adoption is still permitted. We are currently evaluating the impact of ASU No. 2016-13 on our consolidated financial statements and related disclosures.

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity*, or ASU No. 2020-06, which simplifies the guidance on an issuer’s accounting for convertible instruments and contracts in its own equity. The provisions of ASU No. 2020-06 are applicable for fiscal years beginning after December 15, 2023, with early adoption permitted no earlier than fiscal years beginning after December 15, 2020. We are currently evaluating the impact of ASU No. 2020-06 on our consolidated financial statements and related disclosures.

In November 2021, the FASB issued ASU No. 2021-10, *Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance*, or ASU No. 2021-10, which requires additional annual disclosures about transactions with a government that are accounted for by applying a grant or contribution accounting model by analogy. The additional disclosures required by this standard include 1) information about the nature of the transactions and the related accounting policy used to account for the transactions, 2) the financial statement line items that are impacted by the transactions and the amounts applicable to each financial statement line item and 3) significant terms and conditions of the transactions, including commitments and contingencies. We adopted this standard effective January 1, 2022 on a prospective basis. The adoption of the standard has not had a material impact on our consolidated financial statements.

4. Stock-Based Compensation

Total stock-based compensation expense related to all equity awards for the three and six months ended June 30, 2022 and 2021 was composed of the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(in thousands)			
Research and development	\$ 279	\$ 165	\$ 554	\$ 316
General and administrative	536	507	1,128	886
Total stock-based compensation expense	\$ 815	\$ 672	\$ 1,682	\$ 1,202

As of June 30, 2022, we had approximately \$6.9 million of total unrecognized compensation cost related to unvested common stock options and awards under our 2013 Employee Stock Purchase Plan, which is expected to be recognized over a weighted-average period of 2.7 years.

Stock Options

During the six months ended June 30, 2022, we granted options to purchase 2,776,324 shares of our common stock at a weighted average fair value of \$1.11 per share and a weighted average exercise price of \$1.37 per share. During the six months ended June 30, 2021, we granted options to purchase 289,040 shares of our common stock at a weighted average fair value of \$2.68 per share and a weighted average exercise price of \$3.37 per share. For the three and six months ended June 30, 2022 and 2021, the fair values were estimated using the Black-Scholes valuation model using the following weighted-average assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Risk-free interest rate	3.0 %	0.8 %	2.0 %	0.9 %
Expected annual dividend yield	—	—	—	—
Expected stock price volatility	102.2 %	106.5 %	105.2 %	105.5 %
Expected term of options	5.5 years	5.5 years	5.9 years	5.6 years

5. Cash, Cash Equivalents and Available-for-Sale Securities

The following is a summary of cash, cash equivalents and available-for-sale securities:

	June 30, 2022			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
(in thousands)				
Cash and cash equivalents	\$ 45,838	\$ —	\$ —	\$ 45,838
Available-for-sale securities:				
U.S. Treasury securities due in one year or less	5,510	—	(8)	5,502
Commercial paper due in one year or less	4,493	—	(8)	4,485
Asset backed securities due in one year or less	752	—	(2)	750
Total available-for-sale securities	\$ 10,755	\$ —	\$ (18)	\$ 10,737
Total cash, cash equivalents and available-for-sale securities	\$ 56,593	\$ —	\$ (18)	\$ 56,575

	December 31, 2021			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
(in thousands)				
Cash and cash equivalents	\$ 80,726	\$ —	\$ —	\$ 80,726
Total cash and cash equivalents	\$ 80,726	\$ —	\$ —	\$ 80,726

We held 11 debt securities at June 30, 2022 classified as available-for-sale securities with original maturity dates greater than three months that were in an unrealized loss position for less than twelve months. The fair value of these securities was \$10.7 million. We held 7 debt securities at June 30, 2022 classified as cash and cash equivalents with original maturity dates less than three months that were in an unrealized loss position. The fair value of these securities was \$5.0 million. We evaluated our securities for other-than-temporary impairments based on quantitative and qualitative factors. We considered the decline in market value for these securities to be primarily attributable to current economic and market conditions. It is not more likely than not that we will be required to sell these securities, and we do not intend to sell these securities before the recovery of their amortized cost basis. Based on our analysis, we do not consider these investments to be other-than-temporarily impaired as of June 30, 2022.

We had no material realized gains or losses on our available-for-sale securities for the three and six months ended June 30, 2022 and 2021. There were no other-than-temporary impairments recognized for the three and six months ended June 30, 2022 and 2021.

6. Fair Value

The following table presents the assets and liabilities carried at fair value measured on a recurring basis as of June 30, 2022 and December 31, 2021:

	June 30, 2022		
	Level 1	Level 2	Level 3
	(in thousands)		
Assets:			
Cash and cash equivalents	\$ 40,844	\$ 4,994	\$ —
U.S. Treasury securities	—	5,502	—
Commercial paper	—	4,485	—
Asset backed securities	—	750	—
Total assets	\$ 40,844	\$ 15,731	\$ —
Liabilities:			
Warrant liability	\$ —	\$ —	\$ 220
Total liabilities	\$ —	\$ —	\$ 220
	December 31, 2021		
	Level 1	Level 2	Level 3
	(in thousands)		
Assets:			
Cash and cash equivalents	\$ 80,726	\$ —	\$ —
Total assets	\$ 80,726	\$ —	\$ —
Liabilities:			
Warrant liability	\$ —	\$ —	\$ 220
Total liabilities	\$ —	\$ —	\$ 220

The fair value of the available-for-sale securities and cash and cash equivalents is based on the following inputs for both U.S. Treasury securities and U.S. government-sponsored enterprise obligations: benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data including TRACE[®] reported trades. For commercial paper, the fair value is based on the three month Treasury bill rate published on the last business day of the month.

There have been no changes to our valuation methods of available-for-sale securities during the six months ended June 30, 2022. We had no available-for-sale securities that were classified as Level 3 at any point during the six months ended June 30, 2022 or during the year ended December 31, 2021.

Warrant liability relates to potential future warrants that may be issued. The fair value of the warrant liability on the date of the commitment and on each re-measurement date for those warrants classified as liabilities was estimated using the Monte Carlo simulation model, which involves a series of simulated future stock price paths over the remaining life of the commitment. The fair value is estimated by taking the average of the fair values under each of many Monte Carlo simulations. The fair value estimate is affected by our stock price, as well as estimated future financing needs, including timing and sources of the financing and subjective variables including expected stock price volatility over the remaining life of the commitment and risk-free interest rate. Due to the nature of these inputs, the valuation of the warrants is considered a Level 3 measurement. The fair value of the warrant liability as of June 30, 2022 has been included in accrued expenses and other current liabilities on our condensed consolidated balance sheet. The fair value of the warrant liability as of December 31, 2021 has been included in other liabilities on our condensed consolidated balance sheet. See Note 9 for further discussion of the accounting for the warrants.

The carrying amounts reflected in the condensed consolidated balance sheets for prepaid expenses and other current assets, other assets, accounts payable and accrued expenses and other current liabilities approximate their fair value due to their short-term maturities.

7. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	June 30, 2022	December 31, 2021
	(in thousands)	
Prepaid expenses	\$ 2,646	\$ 1,143
Other current assets	389	399
Total prepaid expenses and other current assets	<u>\$ 3,035</u>	<u>\$ 1,542</u>

8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	June 30, 2022	December 31, 2021
	(in thousands)	
Accrued clinical	\$ 4,303	\$ 4,998
Accrued compensation and benefits	2,289	2,835
Accrued development	2,820	755
Liability related to sale of future royalties, net, current portion	1,051	897
Operating lease liability, current portion	555	519
Other	1,508	976
Total accrued expenses and other current liabilities	<u>\$ 12,526</u>	<u>\$ 10,980</u>

9. Liabilities Related to Sale of Future Royalties

HCR Agreement

In 2016, we and Verastem Inc., or Verastem, entered into an amended and restated license agreement, or the Verastem Agreement, under which we granted to Verastem an exclusive worldwide license in oncology indications for the research, development, commercialization, and manufacture of duvelisib, or Copiktra[®], an oral, dual inhibitor of PI3K delta and gamma, and products containing duvelisib, which we refer to as Licensed Products. In September 2020, Verastem completed a disposition of its rights, title, and interest in and to duvelisib to Secura Bio, Inc., or Secura Bio, whereby Secura Bio assumed all liabilities and obligations under the Verastem Agreement. We now refer to the Verastem Agreement as the Secura Bio Agreement.

Secura Bio is obligated to pay us royalties on worldwide net sales of Licensed Products ranging from the mid-single digits to the high-single digits, a portion of which we are obligated to share with Takeda Pharmaceuticals Company Limited, or Takeda, as described in Note 11.

In March 2019, we entered into a royalty purchase agreement, or the HCR Agreement, with HealthCare Royalty Partners III, L.P., or HCR, providing for the acquisition by HCR of our interest in certain royalty payments based on worldwide annual net sales of Licensed Products under the Secura Bio Agreement for gross proceeds of \$30.0 million, which is non-refundable. Under the HCR Agreement, HCR obtained the right to receive the royalty payments up to agreed upon thresholds of royalties, the amount of which depends on when the aggregate royalties received by HCR reach specified thresholds. If the specified threshold has been met through royalty payments from Secura Bio or if we elect to make a payment to meet the threshold amount, the HCR Agreement will automatically terminate and all rights to the royalty stream under the HCR Agreement will revert back to us. If the specified threshold has not been achieved by June 30, 2025, the HCR Agreement will continue through the term of the Secura Bio Agreement.

We recognized the receipt of the \$30.0 million payment from HCR as a liability, net of debt discount and issuance costs of approximately \$2.4 million. As the basis for our determination, we considered, in accordance with the relevant accounting guidance, the potential for the royalty stream to revert back to us if specified royalty thresholds have been met and our right to terminate the HCR Agreement by making a payment to achieve the threshold. We are not obligated to repay any of the proceeds received under the HCR Agreement. In order to determine the amortization of the liability, we are required to estimate the total amount of future net royalty payments to be made to HCR over the term of the HCR Agreement. The total threshold of net royalties to be paid, less the net proceeds received, will be recorded as interest expense over the life of the liability. We impute interest on the unamortized portion of the liability using the effective interest method. Interest and debt discount amortization expense is reflected as non-cash interest expense in the condensed consolidated statements of operations and comprehensive loss. Over the course of the HCR Agreement, the actual interest rate will be affected by the amount and timing of royalty revenue recognized and changes in forecasted royalty revenue. On a quarterly basis, we reassess the effective interest rate and adjust the rate prospectively as needed.

The following table shows the activity within the liability account for the six months ended June 30, 2022:

	<u>June 30, 2022</u>	
	<u>(in thousands)</u>	
Liability related to sale of future royalties, net - beginning balance	\$	28,038
Non-cash royalty revenue		(708)
Non-cash interest expense recognized		77
Liability related to sale of future royalties, net - ending balance		27,407
Less: current portion		(1,051)
Liability related to sale of future royalties, net, less current portion	\$	<u>26,356</u>

As royalties are due to HCR by Secura Bio, the balance of the recognized liability will be effectively repaid over the life of the HCR Agreement. There are a number of factors that could materially affect the amount and timing of royalty payments from Secura Bio, none of which are within our control.

BVF Agreement

On January 8, 2020, or the BVF Closing Date, we entered into a funding agreement, or the BVF Funding Agreement, with BVF Partners, L.P., or BVF, and Royalty Security, LLC, a wholly-owned subsidiary of BVF, or the Buyer. BVF was subsequently replaced as a party to the BVF Funding Agreement with Royalty Security Holdings, LLC. The BVF Funding Agreement provides for the acquisition by the Buyer of our interest in all royalty payments based on worldwide annual net sales of a clinical-stage product candidate IPI-926, or patidegib, part of the hedgehog inhibitor program we licensed to PellePharm Inc., or PellePharm, in 2013, or the BVF Licensed Product, excluding relevant Trailing Mundipharma Royalties, as defined in Note 11, which is related to patidegib. We refer to all BVF Licensed Product royalties owed to us less Trailing Mundipharma Royalties as the Royalty or Royalties. Such Royalties are owed to us pursuant to the PellePharm Agreement, as defined in Note 11, entered into by and between us and PellePharm.

Pursuant to the BVF Funding Agreement, we received a non-refundable payment of \$20.0 million, or the Upfront Purchase Price, less certain transaction expenses. We transferred to the Buyer (i) the Royalty, (ii) the PellePharm Agreement (subject to our rights to milestone payments and rights to equity in PellePharm under the PellePharm Agreement), and (iii) certain patent rights established in the BVF Funding Agreement, with (i), (ii), and (iii) together referred to as Transferred Assets. We preserved our rights under the PellePharm Agreement to receive potential regulatory, commercial, and success-based milestone payments. We have the option to terminate the BVF Funding Agreement by purchasing 100% of the outstanding equity interests of the Buyer under specified terms for a specified amount under the BVF Funding Agreement through January 8, 2023. In addition, the BVF Funding Agreement may be terminated by mutual written agreement between us and the Buyer.

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We recognized the proceeds received under the BVF Funding Agreement as a related party liability that will be amortized using the effective interest method over the life of the arrangement. We recorded the receipt of the \$20.0 million Upfront Purchase Price as a liability, net of debt issuance costs of approximately \$0.4 million and warrant liability of \$0.3 million. The related party liability has since been reclassified to liabilities related to sale of future royalties since Biotechnology Value Fund, L.P. is no longer considered our related party. We are not obligated to repay any of the proceeds received under the BVF Funding Agreement. In order to determine the amortization of the liability, we are required to estimate the total amount of potential future net royalty payments to be made by PellePharm to the Buyer over the term of the BVF Funding Agreement. The total estimated net royalties to be paid, less the net proceeds received, will be recorded as interest expense over the life of the liability. Interest and debt discount amortization expense is reflected as non-cash interest expense for the three and six months ended June 30, 2022 and 2021 in our condensed consolidated statements of operations and comprehensive loss. Over the course of the BVF Funding Agreement, the actual interest rate will be affected by the amount and timing of royalty revenue recognized, if any, and changes in forecasted royalty revenue. There are a number of factors that could materially affect the amount and timing of royalty payments from PellePharm, none of which are within our control. On a quarterly basis, we will reassess the effective interest rate and adjust the rate prospectively as needed.

The following table shows the activity within the liability account for the six months ended June 30, 2022:

	June 30, 2022	
	(in thousands)	
Liability related to sale of future royalties, net - beginning balance	\$	21,586
Non-cash interest expense recognized		13
Liability related to sale of future royalties, net - ending balance	<u>\$</u>	<u>21,599</u>

For so long as we have not exercised an option to repurchase the Buyer's equity interest under the BVF Funding Agreement, (a) if, during the 36-month period following the BVF Closing Date, we issue a specified number of shares of our common stock, which we refer to as the Warrant Threshold, and (b) any shares in excess of the Warrant Threshold are issued for consideration to us of less than \$3.75 per share (as adjusted for any stock splits, reverse stock splits or other similar recapitalization events), or the Threshold Price, then we are obligated to issue to BVF warrants to purchase a number of shares of our common stock. Such warrants would equal 50% of the number of qualifying shares at an exercise price equal to 1.5 times the price per share of such qualifying shares issued. The requirement to issue warrants to BVF does not apply to certain issuances of our common stock. As of June 30, 2022, the Warrant Threshold has been met, and any future qualifying shares of our common stock issued below the Price Threshold will result in warrants to purchase our common stock to be issued to BVF. No warrants have been issued to BVF as of June 30, 2022.

We determined that the commitment to issue warrants represents a freestanding financial instrument and accounted for it as a liability as of the BVF Closing Date. The fair value of the warrant liability was estimated using the Monte Carlo simulation model. The fair value of the warrant liability as of June 30, 2022 has been included in accrued expenses and other current liabilities on our condensed consolidated balance sheet. We will re-measure the warrant liability at each reporting date. Changes in fair value of the warrant liability are included in investment and other income in our condensed consolidated statements of operations and comprehensive loss. See Note 6 for further discussions of the fair value of the warrants.

10. Commitments and Contingencies

On April 5, 2019, we entered into a lease agreement, or the Lease, with Sun Life Assurance Company of Canada, or the Landlord, effective April 3, 2019, or the Commencement Date, for the lease of approximately 10,097 square feet of office space at 1100 Massachusetts Avenue, Cambridge, Massachusetts, or the Leased Premises. The term of the Lease commenced on the Commencement Date and expires on August 1, 2024, or the Expiration Date, approximately five years after the Rent Commencement Date as defined below.

Beginning August 1, 2019, or the Rent Commencement Date, the total base rent of the Lease was \$47,961 per month and increases by approximately 3% on each anniversary of the Rent Commencement Date until the Expiration Date. In addition to the base rent, we are also responsible for our share of the operating expenses, insurance, real estate taxes and certain capital costs, and we are responsible for utility expenses in the Leased Premises, all in accordance with the terms of the Lease. Pursuant to the terms of the Lease, we provided a security deposit in the form of a letter of credit in the initial amount \$300,000, which was reduced to \$150,000 during the year ended December 31, 2021 in accordance with the terms of the Lease. The remaining portion of the security deposit plus the associated bank fee of \$7,500 is included on our condensed consolidated balance sheet as restricted cash as of June 30, 2022. The Landlord provided a lease incentive allowance of \$0.6 million to fund certain improvements made by us to the Leased Premises.

As of June 30, 2022, future minimum lease payments of our operating lease liabilities are approximately \$1.3 million.

11. Strategic Agreements

We have worldwide development and commercialization rights to eganelisib, subject to certain obligations to our licensor, Takeda Pharmaceutical Company Limited, or Takeda, as described in more detail below. Additionally, we are obligated to pay Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue, a 4% royalty in the aggregate on worldwide net sales of products that were previously subject to our strategic alliance with Mundipharma and Purdue that was terminated in 2012. Such products include eganelisib; duvelisib, the PI3K delta and gamma inhibitor that we licensed to Verastem in 2016, the rights to which Verastem sold to Secura Bio in 2020; and IPI-926, or patidegib, part of the hedgehog inhibitor program we licensed to PellePharm in 2013. We refer to such royalties as Trailing Mundipharma Royalties. After Mundipharma and Purdue have recovered approximately \$260.0 million in royalty payments from all products that were previously subject to the strategic alliance, which represents the funding paid to us for research and development services performed by us under this strategic alliance, the Trailing Mundipharma Royalties will be reduced to a 1% royalty on net sales in the United States of such products.

PellePharm

In June 2013, we entered into a license agreement with PellePharm, under which we granted PellePharm exclusive global development and commercialization rights to our hedgehog inhibitor program, including patidegib. We refer to our license agreement with PellePharm as the PellePharm Agreement and products covered by the PellePharm Agreement as Hedgehog Products. We assessed this arrangement in accordance with Accounting Standard Codification 606 and concluded that at the date of contract inception there was only one performance obligation, consisting of the license, which was satisfied at contract inception.

Under the PellePharm Agreement, PellePharm is obligated to pay us up to \$9.0 million in remaining regulatory and commercial-based milestone payments through the first commercial sale of a Hedgehog Product. PellePharm is also obligated to pay us up to \$37.5 million in success-based milestone payments upon the achievement of certain annual net sales thresholds, as well as a share of certain revenue received by PellePharm in the event that PellePharm sublicenses its rights under the PellePharm Agreement and tiered royalties on annual net sales of Hedgehog Products subject to specified conditions. The remaining milestones have not been recognized as they represent variable consideration that is constrained. In making this assessment, we considered numerous factors, including the fact that achievement of the milestones is outside of our control and contingent upon the future success of clinical trials, PellePharm's actions, and the receipt of regulatory approval. As the single performance obligation was previously satisfied, all regulatory and commercial-based milestones will be recognized as revenue in full in the period in which the constraint is removed. Any consideration related to sales-based milestone payments, including royalties, will be recognized when the related sales occur as these amounts have been determined to relate predominantly to the license granted to PellePharm and therefore are recognized at the later of when the performance obligation is satisfied or the related sales occur.

PellePharm is also obligated to pay us tiered royalties on annual net sales of Hedgehog Products, which are subject to reduction after a certain aggregate funding threshold has been achieved. On January 8, 2020, we entered into the BVF Funding Agreement, as further described in Note 9, pursuant to which we sold our interest in all royalty payments based on worldwide annual net sales of the BVF Licensed Product excluding Trailing Mundipharma Royalties related to patidegib.

Takeda

In July 2010, we entered into a development and license agreement with Intellikine, Inc., or Intellikine, under which we obtained rights to discover, develop and commercialize pharmaceutical products targeting the gamma and/or delta isoforms of PI3K, including eganelisib and duvelisib. In January 2012, Intellikine was acquired by Takeda. In December 2012, we amended and restated our development and license agreement with Takeda and further amended the agreement in July 2014, September 2016, July 2017, and March 2019. We refer to the amended and restated development and license agreement, as amended, as the Takeda Agreement.

Duvelisib

Pursuant to the Takeda Agreement, prior to March 4, 2019, we were obligated to share equally with Takeda all revenue arising from certain qualifying transactions for duvelisib, including the Secura Bio Agreement, subject to certain exceptions including revenue we receive as reimbursement for duvelisib research and development expenses. On March 4, 2019, we entered into the fourth amendment to the Takeda Agreement, or the Takeda Amendment. Pursuant to the Takeda Amendment, Takeda agreed (i) to the sale of certain royalty payments based on worldwide annual net sales of Licensed Products under the Secura Bio Agreement to HCR, (ii) to forego its rights to an equal share of the royalties due from Secura Bio during the term of the HCR Agreement, and (iii) not to seek any payment from HCR with respect to the royalties owed to Takeda. As consideration for the Takeda Amendment, we paid Takeda \$6.7 million representing 25% of the \$30.0 million in gross proceeds we received from the closing of the HCR Agreement, net of 25% of the expenses incurred by us in connection with the HCR Agreement. In addition, we agreed to pay Takeda 25% of the royalties that would have been payable to us by Secura Bio but for the consummation of the HCR Agreement, which we refer to as the Interim Obligation. During the six months ended June 30, 2022 and 2021, we recognized \$0.2 million and \$0.1 million of Interim Obligation amounts owed to Takeda as royalty expense, respectively.

We have the right to extinguish the Interim Obligation by payment to Takeda of an amount equal to (i) the \$6.7 million payment multiplied by a specified multiple corresponding to the time period in which such extinguishing payment is made, minus (ii) any payments made to Takeda pursuant to the Interim Obligation. The Interim Obligation shall expire upon the termination of the HCR Agreement and the reversion of related royalties to us, at which time our obligations to share the royalties payable under the Secura Bio Agreement equally with Takeda shall be reinstated.

Eganelisib

Pursuant to the Takeda Agreement, we are obligated to pay Takeda up to \$3.0 million in remaining success-based development milestone payments and up to \$165.0 million in remaining regulatory and commercial-based milestone payments for one product candidate other than duvelisib, which could be eganelisib.

12. Stockholders' (Deficit) Equity

Common Stock Sales Facility

On June 28, 2019, we entered into a Capital on Demand Sales Agreement with JonesTrading Institutional Services LLC, or JonesTrading, and on July 29, 2019 we amended and restated the sales agreement to add B. Riley Securities (f/k/a B. Riley FBR, Inc.), or B. Riley Securities, as a party to the agreement. On July 27, 2021, we entered into an amendment to the agreement to increase the maximum aggregate offering price of the shares of common stock that we may issue and sell from time to time under the agreement by \$75.0 million to an aggregate of \$95.0 million. We refer to the amended and restated sales agreement, as amended, as the ATM Sales Agreement. During the six months ended June 30, 2022, a portion of the aggregate offering price totaling \$11.8 million expired without sale. As of June 30, 2022, we had an aggregate of \$75.0 million available for future sales. Pursuant to the ATM Sales Agreement we may offer and sell shares of our common stock from time to time through JonesTrading or B. Riley Securities, each acting as our sales agent. We have agreed to pay commissions to the sales agents for their services in acting as agents in the sale of our common stock in the amount of up to 3.0% of the gross proceeds from sales of our common stock pursuant to the ATM Sales Agreement. Sales of shares of our common stock under the ATM Sales Agreement may be made by any method that is deemed to be an "at-the-market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. With our prior written approval, JonesTrading or B. Riley Securities may also sell the shares by any other method permitted by law, including in negotiated transactions. We and JonesTrading or B. Riley Securities may suspend or terminate the offering of shares upon notice to the other parties and subject to other conditions. During the three and six months ended June 30, 2022 and 2021, we did not sell any shares under the ATM Sales Agreement.

Public Offering

On February 11, 2021, we entered into a purchase agreement with Piper Sandler & Co., as representative of the underwriters named therein, pursuant to which we issued and sold to the underwriters in an underwritten public offering an aggregate of 24,150,000 shares of our common stock, including 3,150,000 shares of common stock sold in connection with the exercise in full of a 15% over-allotment option by the underwriters. The public offering price was \$3.80 per share. The gross proceeds to us from this offering were approximately \$91.8 million. After underwriting discounts and commissions and offering expenses, we received net proceeds from the offering of approximately \$85.8 million.

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

The following discussion of our financial condition and results of operations should be read in conjunction with the Condensed Consolidated Financial Statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis and set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements, based on current expectations and related to future events and our future financial and operational performance, that involve risks and uncertainties. You should review the discussion under the heading “Summary of Risk Factors” and the risk factors detailed further in Item 1A, “Risk Factors” of Part I of our Annual Report on Form 10-K for the year ended December 31, 2021, and those included under Part II, Item 1A of this Quarterly Report on Form 10-Q for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Business Overview

We are a clinical-stage innovative biopharmaceutical company dedicated to developing novel medicines for people with cancer. We combine proven scientific expertise with a passion for developing novel small molecule drugs that target disease pathways for potential applications in oncology. We are focused on advancing eganelisib, also known as IPI-549, an orally administered, clinical-stage, immuno-oncology product candidate that reprograms macrophages through selective inhibition of the enzyme phosphoinositide-3-kinase-gamma, or PI3K-gamma. We have retained worldwide development and commercialization rights to eganelisib.

Clinical Development Program

At this stage in eganelisib’s clinical development, and given the current market environment, we are prioritizing establishing potential partnerships before beginning new efficacy studies, including MARIO-4 in triple negative breast cancer, or TNBC, and the MARIO-P platform study. We believe this approach will allow us to focus our current resources on our ongoing clinical trials, extend our cash runway, and will provide the flexibility necessary to accommodate potential partners’ input on the prioritization and design of our potential next studies.

MARIO-3

MARIO-3 is a multi-arm Phase 2 study designed to evaluate eganelisib in the front-line treatment for mTNBC or metastatic renal cell carcinoma, or mRCC. The mTNBC cohort is evaluating eganelisib in combination with atezolizumab, an anti-PD-L1 monoclonal antibody also known as Tecentriq[®], and nab-paclitaxel, an albumin-bound chemotherapy drug also known as Abraxane[®], in approximately 60 patients with unresectable locally advanced or metastatic TNBC. The RCC cohort is evaluating eganelisib in combination with atezolizumab and bevacizumab, also known as Avastin[®], in approximately 30 patients with RCC. Using the same cutoff standard used in the F. Hoffmann-La Roche Ltd., or Roche, benchmark IMpassion130 study for PD-L1, we refer to patients with tumors that test below 1% PD-L1 at baseline as “PD-L1(-) patients” and those with tumors that test equal to or greater than 1% as “PD-L1(+) patients.” We entered into clinical supply agreements with Roche, under which Roche has agreed to supply atezolizumab and bevacizumab for our use in MARIO-3.

On December 10, 2021, we presented data at the 2021 San Antonio Breast Cancer Symposium, or SABCS, from the mTNBC cohort of MARIO-3 study. As of the October 2, 2021 data cutoff date for the presentation, we had enrolled 44 evaluable patients and 50 patients total, with a median duration of follow up of 9.9 months. The MARIO-3 data presented at SABCS and an investor event following SABCS include the following findings:

- Of evaluable patients, tumor reduction was observed in 92.8% of patients with PD-L1(+) tumors and 85.2% of patients with PD-L1(-) tumors
- Disease control rate (DCR)
 - 92.8% (13/14) DCR in patients with PD-L1(+) tumors, complete response (CR) 14.3% (2/14), partial response (PR) 57.1% (8/14), stable disease (SD) 21.4% (3/14)
 - 81.4% (22/27) DCR in patients with PD-L1(-) tumors, CR 0% (0/27), PR 48.1% (13/27), SD 33.3% (9/27)
- Progression free survival (PFS)
 - In patients with PD-L1(+) tumors, median PFS in MARIO-3 was 11.0 months, a 47% improvement in median PFS compared to the 7.5 months reported for the atezolizumab and nab-paclitaxel doublet in IMpassion130
 - In patients with PD-L1(-) tumors, median PFS in MARIO-3 was 7.3 months, a 30% improvement compared to the 5.6 months reported for the atezolizumab and nab-paclitaxel doublet in IMpassion130
- 67% of the PD-L1(-) patients who reached the median PFS of 7.3 months remained on treatment

The MARIO-3 mTNBC cohort did not demonstrate any new safety signals compared to benchmark trials, and its safety profile was consistent with expectations for the three component drugs. The most common Grade 3 or higher treatment-related treatment emergent adverse events (TEAEs) were hepatic adverse events (18%); neutropenia adverse events (16%); skin adverse events (12%); fatigue, diarrhea and peripheral sensory neuropathy (6% each); and vomiting and weight decreased (2% each). Seven patients (14%) discontinued treatment for treatment-related TEAEs and nine patients (18%) had treatment-related serious adverse events. There was one Grade 4 and no Grade 5 treatment-related TEAEs.

Translational data presented at SABCS are supportive of eganelisib's immune modulation mechanism. Quantification across 11 paired tumor biopsies showed increased immune activation and decreased immune suppression, including an increase in CD8+ T cells, activated T cells, and anti-tumor M1 macrophages and a decrease in tumor cells and pro-tumor M2 macrophages resulting in an increase in the M1:M2 ratio. Further, paired tumor biopsy data show that treatment with eganelisib combination for two months led to increased expression of PD-L1 in 5 of 8 patients with PD-L1(-) tumors at baseline, reaching levels above the 1% PD-L1 cutoff of the standard PD-L1 biomarker assay used in MARIO-3 and the benchmark IMpassion130 study. PD-L1 expression also increased in the three patients with PD-L1(+) tumors.

We expect to provide updated data from the MARIO-3 mTNBC cohort in the second half of 2022.

MARIO-275

MARIO-275 is our global, randomized, placebo-controlled Phase 2 study evaluating the effect of adding eganelisib to nivolumab, also known as Opdivo[®], in checkpoint-naïve advanced urothelial cancer, or UC, patients whose cancer has progressed or recurred following treatment with platinum-based chemotherapy. Nivolumab is an immune checkpoint inhibitor therapy commercialized by Bristol Myers Squibb Company, or BMS, that targets programmed death receptor 1, or PD-1, a checkpoint protein that helps regulate the body's immune system. We presented MARIO-275 data at the American Society of Clinical Oncology Genitourinary Cancers Symposium, or ASCO GU, in February 2021, and presented updates on overall survival data in July 2021 and January 2022, as well as a two-year landmark analysis announced in a press release issued on August 9, 2022. The data from the 49 patients enrolled in the trial include the following findings:

- At a two-year landmark survival analysis as of July 29, 2022, 45% of patients in the eganelisib plus nivolumab arm are alive compared to 24% of patients in the nivolumab control arm. Durable survival benefit was also seen in the PD-L1(-) subgroup, with 38% of patients alive at two years in the eganelisib plus nivolumab arm versus 17% in the control group. No new safety signals were observed during the extended period on treatment.
- Median overall survival (mOS) in the intent to treat population as of July 2021 was 15.4 months (6.2, NE) on the eganelisib plus nivolumab combination arm as compared to 7.9 months (2.3, NE) on the control arm of nivolumab alone with a hazard ratio (HR) 0.62 (0.28, 1.36), reflecting a 38% lower probability of death.
- The mOS in PD-L1(-) patients, as updated in January 2022, was 15.3 months (4.7, NE) on the eganelisib plus nivolumab arm versus 7.9 months (1.9, NE) on the nivolumab control arm with an HR 0.58 (0.21, 1.66), reflecting a 42% lower probability of death.

The most common TEAEs for the eganelisib plus nivolumab combination arm across all doses, all causality, were pyrexia (33.3%), decreased appetite (30.3%), pruritus (27.3%), asthenia (27.3%), rash (27.3%), and increased alanine aminotransferase (24.2%); and the most common \geq Grade 3 TEAEs across all doses, all causality, were anemia (12.1%), and hepatic AEs including hepatotoxicity (15.2%), increased ALT (12.1%), and increased AST (12.1%) with no Hy's Law. No treatment-related Grade 5 AEs were reported.

Data presented at ASCO GU demonstrated the greatest benefit of the combination of eganelisib and nivolumab was observed in the patient population (n=23) with tumors expressing low levels of PD-L1, with improvement over nivolumab monotherapy (n=7) in ORR (26% vs. 14%); DCR (57% vs. 14%); and best responses of CR (9% vs. 0%) and SD (30% vs. 0%). Of patients with PD-L1 low tumors in the combination arm, 58% (11 of 19) achieved a reduction in tumor burden, compared to 17% (1 of 6) in the nivolumab plus placebo arm.

Business Update Regarding COVID-19

In December 2019, a novel strain of coronavirus surfaced causing the respiratory disease COVID-19. This disease has spread worldwide and was deemed a "pandemic" by the World Health Organization on March 11, 2020. The following guidance regarding the impact of the COVID-19 pandemic on our business operations is highly uncertain and subject to change. We cannot know with certainty what the ultimate impact of the pandemic will be.

We do not anticipate disruptions to drug supply due to COVID-19. The safety and well-being of our employees remains a top priority, and we are working to mitigate risk while minimizing disruptions. However, variants of the SARS-COV-2 virus have continued to develop, and future variants could be potentially more virulent or more contagious than variants to date. Such variants may worsen or prolong the impact of the COVID-19 pandemic, and may be so extreme that we cannot fully mitigate their impact on our manufacturing timeline or other business interests.

Alliances, Collaborations, and Other Arrangements

We have primarily incurred operating losses since inception and will continue to fund our operations through collaboration and license arrangements or other strategic arrangements, as well as through the sale of securities or incurring debt, until such time as we are able to generate significant revenue from product sales, if ever. Such arrangements have provided access to breakthrough science, significant research and development support and funding, supply of clinical trial materials, and innovative drug development programs, all intended to help us realize the full potential of our product pipeline.

In July 2010, we entered into a development and license agreement with Intellikine, Inc., or Intellikine, under which we obtained rights to discover, develop and commercialize pharmaceutical products targeting the gamma and/or delta isoforms of PI3K, including eganelisib and duvelisib, or Copiktra[®], an oral, dual inhibitor of PI3K delta and gamma. We licensed our rights related to the development of duvelisib to Verastem Inc., or Verastem, in 2016. In September 2020, Verastem completed a disposition of its rights, title, and interest in and to duvelisib to Secura Bio, Inc., or Secura Bio, wherein Secura Bio assumed all liabilities and obligations under the Verastem Agreement. We now refer to the Verastem Agreement as the Secura Bio Agreement. In January 2012, Intellikine was acquired by Takeda Pharmaceutical Company Limited, or Takeda. In December 2012, we amended and restated our development and license agreement with Takeda and further amended the agreement in July 2014, September 2016, July 2017, and March 2019. We refer to the amended and restated development and license agreement, as amended, as the Takeda Agreement. We are obligated to pay Takeda up to \$3.0 million in remaining success-based development milestone payments and up to \$165.0 million in remaining regulatory and commercialization success-based milestone payments, for one product candidate other than duvelisib, which could be eganelisib.

Financial Overview

Revenue

To date, all our revenue has been generated under collaboration agreements, including payments to us of upfront license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales.

We recognize revenue when we transfer goods or services to customers in an amount that reflects the consideration that we expect to receive for those goods or services. These principles are applied using a five-step model: 1) identify the customer contract; 2) identify the contract's performance obligations; 3) determine the transaction price; 4) allocate the transaction price to the performance obligations; and 5) recognize revenue when or as a performance obligation is satisfied. We evaluate all promised goods and services within a customer contract and determine which of those are separate performance obligations. This evaluation includes an assessment of whether the good or service is capable of being distinct and whether the good or service is separable from other promises in the contract. When a performance obligation is satisfied, we recognize as revenue the amount of the transaction price, excluding estimates of variable consideration that are constrained, that is allocated to that performance obligation. For contracts that contain variable consideration, such as milestone payments, we estimate the amount of variable consideration by using either the expected value method or the most likely amount method. In making this assessment, we evaluate factors such as the clinical, regulatory, commercial and other risks that must be overcome to achieve the milestone. Each reporting period we re-evaluate the probability of achievement of such milestones and any related constraints. We will include variable consideration, without constraint, in the transaction price to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

We recognize sales-based milestones and royalty revenue based upon net sales by the licensee of licensed products in licensed territories, and in the period the sales occur under the sales- and usage-based royalty exception when the sole or predominate item to which the royalty relates is a license to intellectual property.

In the event of an early termination of a collaboration agreement, any contract liabilities would be recognized in the period in which all our obligations under the agreement have been fulfilled.

Research and Development Expense

We are a drug development company. Our research and development expense has historically consisted primarily of the following:

- compensation of personnel associated with research and development activities;
- clinical testing costs, including payments made to contract research organizations;
- costs of combination and comparator drugs used in clinical studies;
- costs of manufacturing product candidates for preclinical testing and clinical studies;
- costs associated with the licensing of research and development programs;
- preclinical testing costs, including costs of toxicology studies;
- fees paid to external consultants;
- fees paid to professional service providers for independent monitoring and analysis of our clinical trials;
- costs for collaboration partners to perform research and development activities, including development milestones for which a payment is due when achieved;
- depreciation of equipment; and
- allocated costs of facilities.

General and Administrative Expense

General and administrative expense primarily consists of compensation of personnel in executive, finance, accounting, legal and intellectual property, information technology infrastructure, corporate communications, and human resources functions. Other costs include facilities costs not otherwise included in research and development expense and professional fees for legal and accounting services.

Royalty Expense

Royalty expense represents the expense associated with amounts owed to third parties as a result of royalty revenue recognized and the amounts owed by us to Takeda in relation to the sale of future royalties.

Other Income and Expense

Other income and expense typically consist of interest earned on cash, cash equivalents and available-for-sale securities, non-cash interest expense, and changes in fair value of the warrant liability.

Critical Accounting Policies and Significant Judgments and Estimates

The discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make judgments, estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates, including those related to cumulative revenue related to variable consideration, accrued expenses and estimates of future net royalty payments used in the calculation of our liability related to the sale of future royalties. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ from those estimates.

There have been no material changes to our critical accounting policies during the six months ended June 30, 2022. Please refer to Part II, Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of our 2021 Annual Report on Form 10-K for a discussion of our critical accounting policies and significant judgments and estimates.

Results of Operations

The following table summarizes our results of operations for each of the three and six months ended June 30, 2022 and 2021, together with the change in these items in dollars and as a percentage:

	Three Months Ended June 30,		\$ Change	% Change
	2022	2021		
	(in thousands)			
Royalty revenue	\$ 686	\$ 512	\$ 174	34 %
Research and development expense	8,795	7,957	838	11 %
General and administrative expense	3,495	3,498	(3)	— %
Royalty expense	414	308	106	34 %
Investment and other income	77	27	50	185 %
Non-cash interest expense	(45)	(45)	—	— %
Net loss	(11,986)	(11,269)	(717)	6 %

	Six Months Ended June 30,		\$ Change	% Change
	2022	2021		
	(in thousands)			
Royalty revenue	\$ 1,338	\$ 979	\$ 359	37 %
Research and development expense	17,785	16,158	1,627	10 %
General and administrative expense	7,171	7,064	107	2 %
Royalty expense	807	590	217	37 %
Investment and other income	93	25	68	272 %
Non-cash interest expense	(90)	(90)	—	— %
Net loss	(24,422)	(22,898)	(1,524)	7 %

Revenue

Royalty revenue for both the three and six months ended June 30, 2022 and 2021 is related to royalties from Secura Bio and Verastem on net sales of duvelisib. A portion of royalties received is owed to Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue. We refer to such portion as the Trailing Mundipharma Royalties (see Note 11 of the notes to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q). We and HealthCare Royalty Partners III, L.P., or HCR, entered into a purchase and sale agreement in March 2019, or the HCR Agreement, pursuant to which HCR acquired our interest in royalties received from Verastem on net sales of duvelisib, less the Trailing Mundipharma Royalties (see Note 9 of the notes to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q).

Research and Development Expense

Research and development expense increased for the three months ended June 30, 2022 as compared to the three months ended June 30, 2021 due to an increase in compensation and hiring expenses of \$1.3 million due primarily to new hires during the period and an increase in consulting expenses of \$0.5 million to support the continued development of eganelisib, partially offset by a decrease in clinical development expenses of \$1.1 million.

Research and development expense increased for the six months ended June 30, 2022 as compared to the six months ended June 30, 2021 due to an increase in compensation and hiring expenses of \$2.3 million due primarily to new hires during the period, an increase in consulting expenses of \$0.4 million to support the continued development of eganelisib and an increase in information technology support expenses of \$0.2 million, partially offset by a decrease in clinical development expenses of \$1.5 million.

We track and accumulate expenses by major program. These expenses primarily relate to payroll and related expenses for personnel working on our programs, process development and manufacturing, preclinical toxicology studies, clinical trial costs and allocated costs of facilities. During the three months ended June 30, 2022 and 2021, we estimated that we incurred \$8.8 million and \$8.0 million, respectively, on eganelisib. During the six months ended June 30, 2022 and 2021, we estimated that we incurred \$17.8 million and \$16.2 million of research and development expense, respectively, on eganelisib.

We do not believe that the historical costs associated with our drug development programs are indicative of the future costs associated with these programs. Due to the variability in the length of time and scope of activities necessary to develop a product candidate and uncertainties related to our cost estimates and our ability to obtain marketing approval for our product candidates, accurate and meaningful estimates of the total costs required to bring our product candidates to market are not available.

Because of the risks inherent in drug development, we cannot reasonably estimate or know:

- the nature, timing and estimated costs of the efforts necessary to complete the development of our programs;
- the completion dates of these programs; or
- the period in which material net cash inflows are expected to commence, if at all, from the programs described above and any potential future product candidates.

There is significant uncertainty regarding our ability to successfully develop any product candidates. These risks include the uncertainty of:

- the scope, rate of progress and cost of our clinical trials that we are currently conducting or may commence in the future;
- clinical trial results;
- the cost of establishing clinical supplies of any product candidates;
- the cost and availability of combination and comparator drugs, such as the current global shortage of the MARIO-3 combination drug nab-paclitaxel. Although we expect our current supply of nab-paclitaxel to be adequate to meet MARIO-3 demand through the study completion, the global shortage could impact MARIO-3 if the shortage persists beyond our current supply;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights relating to our programs under development;
- the terms and timing of any collaborations, licensing and other arrangements that we have or may establish in the future relating to our programs under development;
- the cost and timing of regulatory approvals;
- the effect of competing technological and market developments; and
- the impact of the COVID-19 pandemic.

General and Administrative Expense

General and administrative expense was comparable for the three and six months ended June 30, 2022 as compared to the three and six months ended June 30, 2021.

Royalty Expense

Royalty expense for both periods is related to royalties paid to Mundipharma, Purdue and Takeda on net sales of duvelisib by Secura Bio and Verastem.

Investment and Other Income (Expense)

Investment and other income increased for the three and six months ended June 30, 2022 as compared to the three and six months ended June 30, 2021 primarily as a result of higher yields on our cash and investments.

Non-cash Interest Expense

Non-cash interest expense for the three and six months ended June 30, 2022 was the result of the sale of future royalties in relation to the HCR Agreement and BVF Funding Agreement, which we recognized as liabilities that are being amortized using the effective interest method over the life of the arrangements (see Note 9 of the notes to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q). Over the course of the arrangements, the non-cash interest expense will be affected by the amount and timing of estimated royalty revenue, if any. We reassess the effective interest rate on a quarterly basis and adjust the rate prospectively as needed.

Liquidity and Capital Resources

We have not generated any revenue from product sales to date, and we do not expect to generate any such revenue for the foreseeable future, if at all. We have instead relied on the proceeds from sales of equity securities, sales of future royalties, issuances of debt, interest on investments, upfront license fees, expense reimbursements, milestones, royalties and cost sharing under our collaborations to fund our operations. Because eganalisib is in clinical development, and the outcome of this effort is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidate or whether, or when, we may achieve profitability.

The following table summarizes the components of our financial condition:

	June 30, 2022		December 31, 2021	
	(in thousands)			
Cash, cash equivalents and available-for-sale securities	\$	56,575	\$	80,726
Working capital		45,271		68,968
	Six Months Ended June 30,			
		2022		2021
	(in thousands)			
Cash (used in) provided by:				
Operating activities	\$	(24,130)	\$	(23,038)
Investing activities		(10,786)		5,500
Financing activities		28		86,203

Cash Flows

For the six months ended June 30, 2022 compared to the six months ended June 30, 2021, our cash used in operating activities increased primarily due to increased operating expenses as we continue clinical development of eganalisib. Our cash used in operating activities in future periods may vary significantly.

Net cash provided by investing activities decreased during the six months ended June 30, 2022 primarily due to net purchases of available-for-sale securities of \$10.8 million as compared to net proceeds from available-for-sale securities of \$5.5 million for the six months ended June 30, 2021.

Net cash provided by financing activities for the six months ended June 30, 2022 was due to proceeds from the issuance of common stock to employees during the period. Net cash provided by financing activities for the six months ended June 30, 2021 was due to \$85.8 million in net proceeds from our public offering in February 2021.

Operating Capital Requirements

As of June 30, 2022, we had cash, cash equivalents and available-for-sale securities of \$56.6 million. We believe that our existing cash, cash equivalents and available-for-sale securities at June 30, 2022 will be adequate to satisfy our capital needs for at least the next twelve months from the issuance date of the financial statements included in this Quarterly Report on Form 10-Q based on our current operational plans. We expect to continue to spend significant resources to fund the development and potential commercialization of eganalisib and to incur significant operating losses for the foreseeable future.

Our estimate as to how long we expect our existing cash and cash equivalents to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate. Our future funding requirements, both short-term and long-term, will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of developing eganelisib, currently in clinical development;
- the impact of delays in patient enrollment and site activation related to the COVID-19 pandemic;
- the timing of, and the costs involved in, obtaining regulatory approvals for eganelisib;
- subject to receipt of marketing approval, revenue, if any, received from commercial sales of eganelisib;
- the timing and amount of additional revenues, if any, received from strategic agreements and funding arrangements;
- the timing and amount of additional royalty and milestone payments owed to Takeda;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- any breach, acceleration event or event of default under any agreements with third parties;
- the outcome of any lawsuits that could be brought against us;
- the cost of acquiring raw materials for, and of manufacturing, eganelisib is higher than anticipated;
- the cost or quantity required of comparator or combination drugs used in clinical studies increases;
- the effect of competing technological and market developments;
- any federal government shutdown that prevents or delays the SEC from processing any future registration statements we may file to register shares for capital raising purposes; and
- a loss in our investments due to general market conditions or other reasons.

We may seek additional funds through arrangements with collaborators or other third parties, or through project financing. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or product candidates, and we may not be able to enter into such agreements on acceptable terms, if at all. We may also seek additional funding through public or private financings of equity or debt securities, but such financings may not be available on acceptable terms, if at all. In addition, the terms of our financings may be dilutive to, or otherwise adversely affect, holders of our common stock, and such terms may impact our ability to make capital expenditures or incur additional debt. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all of our development programs or to scale back, suspend or terminate our business operations.

Equity Offerings

On June 28, 2019, we entered into a Capital on Demand Sales Agreement with JonesTrading Institutional Services LLC, or JonesTrading, and on July 29, 2019 we amended and restated the sales agreement to add B. Riley Securities (f/k/a B. Riley FBR, Inc.), or B. Riley Securities, as a party to the agreement. On July 27, 2021, we entered into an amendment to the agreement to increase the maximum aggregate offering price of the shares of common stock that we may issue and sell from time to time under the agreement by \$75.0 million to an aggregate of \$95.0 million. We refer to the amended and restated sales agreement, as amended, as the ATM Sales Agreement. During the six months ended June 30, 2022, a portion of the aggregate offering price totaling \$11.8 million expired without sale. As of June 30, 2022, we had an aggregate of \$75.0 million available for future sales. Pursuant to the ATM Sales Agreement we may offer and sell shares of our common stock from time to time through JonesTrading or B. Riley Securities, each acting as our sales agent. We have agreed to pay commissions to the sales agents for their services in acting as agents in the sale of our common stock in the amount of up to 3.0% of the gross proceeds from sales of our common stock pursuant to the ATM Sales Agreement. Sales of shares of our common stock under the ATM Sales Agreement may be made by any method that is deemed to be an “at-the-market offering” as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. With our prior written approval, JonesTrading or B. Riley Securities may also sell the shares by any other method permitted by law, including in negotiated transactions. We and JonesTrading or B. Riley Securities may suspend or terminate the offering of shares upon notice to the other parties and subject to other conditions. During the three and six months ended June 30, 2022 and 2021, we did not sell any shares under the ATM Sales Agreement.

On February 11, 2021, we entered into a purchase agreement with Piper Sandler & Co., as representative of the underwriters named therein, pursuant to which we issued and sold to the underwriters in an underwritten public offering an aggregate of 24,150,000 shares of our common stock, including 3,150,000 shares of common stock sold in connection with the exercise in full of a 15% over-allotment option by the underwriters. The public offering price was \$3.80 per share. The gross proceeds to us from this offering were approximately \$91.8 million. After underwriting discounts and commissions and offering expenses, we received net proceeds from the offering of approximately \$85.8 million.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, or the Exchange Act, and are not required to provide the information under this item.

Item 4. Controls and Procedures

Our management, with the participation of our principal executive and financial officers, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2022. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2022, our principal executive and financial officers concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter ended June 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1A. Risk Factors

For a detailed discussion of our potential risks or uncertainties, please see the sections entitled “Summary of Risk Factors” and “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, which we refer to as our 2021 Annual Report, as well as in the section entitled “[Management’s Discussion and Analysis of Financial Condition and Results of Operations](#)” in Part I, Item 2 of this Quarterly Report on Form 10-Q. The risk factor set forth below represents a material change to the similarly titled risk factor included in the section entitled “Risk Factors” in our 2021 Annual Report.

If we fail to meet the requirements for continued listing on the Nasdaq Global Select Market, our common stock could be delisted from trading, which would decrease the liquidity of our common stock and our ability to raise additional capital.

Our common stock is currently listed for quotation on the Nasdaq Global Select Market. We are required to meet specified requirements in order to maintain our listing on the Nasdaq Global Select Market, including, among other things, a minimum bid price of \$1.00 per share under Nasdaq Listing Rule 5450(a)(1), or the Minimum Bid Requirement, and Minimum Bid Price, respectively. On May 24, 2022, we received a deficiency letter from the Listing Qualifications Department of the Nasdaq Stock Market, LLC, or Nasdaq, notifying us that, for the previous 30 consecutive business days, the bid price for our common stock had closed below the Minimum Bid Price.

The Notice has no immediate effect on the listing of our common stock. We have 180 calendar days, or until November 21, 2022, to regain compliance with the Minimum Bid Requirement. To regain compliance, the closing bid price of our common stock must be at least \$1.00 per share for a minimum of ten consecutive business days during this 180-day period. We intend to actively monitor the closing bid price of our common stock and will evaluate available options to regain compliance with the Minimum Bid Requirement. If we fail to do so within the initial 180 calendar day period, we may be eligible for an additional 180 calendar day compliance period. However, there can be no assurance that we can secure such additional compliance period, that we will be able to regain compliance with the Minimum Bid Requirement, or that we can maintain compliance with the other listing requirements.

If we fail to satisfy the Nasdaq Global Select Market's continued listing requirements, including the Minimum Bid Requirement, we may transfer to the Nasdaq Capital Market, which generally has lower financial requirements for initial listing, to avoid delisting, or, if we fail to meet its listing requirements, the OTC Bulletin Board. A transfer of our listing to the Nasdaq Capital Market or having our common stock trade on the OTC Bulletin Board could adversely affect the liquidity of our common stock. Any such event could make it more difficult to dispose of, or obtain accurate quotations for the price of, our common stock, and there also would likely be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further. We may also face other material adverse consequences in such event, such as negative publicity, a decreased ability to obtain additional financing, diminished investor and/or employee confidence, and the loss of business development opportunities, some or all of which may contribute to a further decline in our stock price.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We may seek additional funding through public or private financings of equity or debt securities, but such financing may not be available on acceptable terms, if at all. If we raise additional funds through the issuance of additional debt or equity securities, as we did in 2020 under our common stock sales facility as well as in February 2021 through a public offering of our common stock, we may not be able to raise capital at the price we desire, as underscored by our current noncompliance with the Minimum Bid Requirement. Any public offering could result in dilution to our existing stockholders, increased fixed payment obligations and the existence of securities with rights that may adversely affect the rights of our existing stockholders including liquidation or other preferences and anti-dilution protections.

In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

We may also seek additional funds through arrangements with collaborators or other third parties, or through project financing. These arrangements would generally require us to relinquish or encumber valuable rights to our technologies, future revenue streams, or product candidates, and we may not be able to enter into such agreements on acceptable terms, if at all.

If we are unable to obtain additional funding on a timely basis, we may be required to curtail, terminate, sell or license rights to develop and market eganalisib that we would otherwise prefer to develop and market ourselves, or to scale back, suspend, or terminate our business operations. For example, we are currently in discussions with potential partners regarding the future development of eganalisib and have opted to defer initiation of any new clinical trials until such time that we have entered into a potential partnership or have otherwise raised additional capital.

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Item 6. Exhibits

Exhibit No.	Description	Incorporated by Reference			Filed with this 10-Q
		Form	SEC Filing date	Exhibit Number	
3.1	Restated Certificate of Incorporation of the Registrant, as amended.	10-Q	7/30/2020	3.1	
3.2	Amended and Restated Bylaws of the Registrant.	8-K	3/17/2009	3.1	
4.1	Form of Common Stock Certificate.	10-K	3/14/2008	4.1	
10.1*	2019 Equity Incentive Plan of Infinity Pharmaceuticals, Inc., as amended by Amendment No. 1 and No. 2	S-8	6/16/2022	99.1	
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.				X
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.				X
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).				X

*Indicates management contract or compensatory plan.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: August 9, 2022

INFINITY PHARMACEUTICALS, INC.

By: _____ /s/ Lawrence E. Bloch

Lawrence E. Bloch, M.D., J.D.

President

(Principal Financial Officer & Principal Accounting Officer)

**CERTIFICATION PURSUANT TO RULES 13A-14(A) AND 15D-14(A)
UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED**

I, Adelene Q. Perkins, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Infinity Pharmaceuticals, Inc. (the "Registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;

4. The Registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. The Registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: August 9, 2022

/s/ Adelene Q. Perkins

Adelene Q. Perkins
Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO RULES 13A-14(A) AND 15D-14(A)
UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED**

I, Lawrence E. Bloch, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Infinity Pharmaceuticals, Inc. (the "Registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;

4. The Registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. The Registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: August 9, 2022

/s/ Lawrence E. Bloch

Lawrence E. Bloch, M.D., J.D.

President

(Principal Financial Officer & Principal Accounting Officer)

**STATEMENT PURSUANT TO 18 U.S.C. §1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to 18 U.S.C. §1350, the undersigned certifies that, to her knowledge, this Quarterly Report on Form 10-Q for the period ended June 30, 2022 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in this report fairly presents, in all material respects, the financial condition and results of operations of Infinity Pharmaceuticals, Inc.

Date: August 9, 2022

/s/ Adelene Q. Perkins

Adelene Q. Perkins
Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to Infinity Pharmaceuticals, Inc. and will be retained by Infinity Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

**STATEMENT PURSUANT TO 18 U.S.C. §1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to 18 U.S.C. §1350, the undersigned certifies that, to his knowledge, this Quarterly Report on Form 10-Q for the period ended June 30, 2022 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in this report fairly presents, in all material respects, the financial condition and results of operations of Infinity Pharmaceuticals, Inc.

Date: August 9, 2022

/s/ Lawrence E. Bloch

Lawrence E. Bloch, M.D., J.D.

President

(Principal Financial Officer & Principal Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to Infinity Pharmaceuticals, Inc. and will be retained by Infinity Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.