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 March 31, 2021**

☐ **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: 001-37990

LEAP THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**27-4412575**
State or other jurisdiction of incorporation or organization	(I.R.S. Employer Identification No.)
47 Thorndike St, Suite B1-1, Cambridge, MA	**02141**
Address of Principal Executive Offices	Zip Code

(617) 714-0360
Registrant's Telephone Number, Including Area Code

N/A
Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report

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, par value $0.001 per share	LPTX	Nasdaq Global 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 ☐

Non-accelerated filer ☒

Smaller reporting company ☒
Emerging growth company ☒

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

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

As of May 10, 2021 there were 59,672,014 shares of the registrant's common stock, par value $0.001 per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Quarterly Report on Form 10-Q (this "Quarterly Report") contains forward-looking statements which reflect our current views with respect to, among other things, our operations and financial performance. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "will" or the negative of such terms or any other comparable terminology. Forward-looking statements appear in a number of places throughout this Quarterly Report and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, that the initiation, conduct, and completion of clinical trials, laboratory operations, manufacturing campaigns, and other studies may be delayed, adversely affected, or impacted by COVID-19 related issues; our ability and plan to develop and commercialize DKN-01; status, timing and results of preclinical studies and clinical trials; the potential benefits of DKN-01; the timing of our development programs and seeking regulatory approval of DKN-01; our ability to obtain and maintain regulatory approval; our estimates of expenses and future revenues and profitability; our estimates regarding our capital requirements and our needs for additional financing; our estimates of the size of the potential markets for DKN-01; the benefits to be derived from our agreement with BeiGene, Ltd. ("BeiGene") or any other collaborations, license agreements, or other acquisition efforts, including those relating to the development and commercialization of DKN-01; sources of revenues and anticipated revenues, including contributions from our agreement with BeiGene or any other collaborations or license agreements for the development and commercialization of products; our ability to create an effective sales and marketing infrastructure if we elect to market and sell DKN-01 directly; the rate and degree of market acceptance of DKN-01; the timing and amount of reimbursement for DKN-01; the success of other competing therapies that may become available; the manufacturing capacity for DKN-01; our intellectual property position; our ability to maintain and protect our intellectual property rights; our results of operations, financial condition, liquidity, prospects, growth and strategies; the industry in which we operate; and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change, and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report. In addition, even if our results of operations, financial condition and liquidity, and events in the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report, they may not be predictive of results or developments in future periods. You should carefully read this Quarterly Report and the documents that we have filed as exhibits to this Quarterly Report completely.

You should refer to Part II, Item 1A, Risk Factors in this Quarterly Report and Part I, Item 1A, Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission on March 12, 2021 for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Quarterly Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all. Any forward-looking statement that we make in this Quarterly Report speaks only as of the date of such statement, and, except to the extent required by applicable law, we undertake no obligation to update such statements to reflect events or circumstances after the date of this Quarterly Report or to reflect the occurrence of unanticipated events. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data.

DKN-01 is an investigational drug undergoing clinical development and has not been approved by the U.S. Food and Drug Administration (the "FDA"), nor has it been submitted to the FDA for approval. DKN-01 has not been, and may never be, approved by any regulatory agency or marketed anywhere in the world. Statements contained in this Quarterly Report should not be deemed to be promotional.

INTRODUCTORY COMMENT

References to Leap

Throughout this Quarterly Report on Form 10-Q, the "Company," "Leap," "Leap Therapeutics," "we," "us," and "our," except where the context requires otherwise, refer to Leap Therapeutics, Inc. and its consolidated subsidiaries, and "our board of directors" refers to the board of directors of Leap Therapeutics, Inc.

Part I — FINANCIAL INFORMATION

Item 1. Financial Statements

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	March 31, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 43,491	$ 52,071
Research and development incentive receivable	22	73
Prepaid expenses and other current assets	266	130
Total current assets	43,779	52,274
Property and equipment, net	56	65
Right of use assets, net	433	528
Research and development incentive receivable, net of current portion	70	-
Deferred tax assets	178	179
Deferred costs	311	345
Deposits	980	980
Total assets	$ 45,807	$ 54,371
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,514	$ 2,717
Accrued expenses	2,335	2,747
Deferred revenue	1,125	1,500
Lease liability - current portion	418	408
Total current liabilities	7,392	7,372
Non current liabilities:		
Restricted stock liability	-	204
Lease liability, net of current portion	36	144
Total liabilities	7,428	7,720
Stockholders' equity:		
Common stock, $0.001 par value; 240,000,000 shares authorized; 59,669,722 and 59,657,742 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	60	60
Additional paid-in capital	271,002	270,155
Accumulated other comprehensive loss	(564)	(579)
Accumulated deficit	(232,119)	(222,985)
Total stockholders’ equity	38,379	46,651
Total liabilities and stockholders' equity	$ 45,807	$ 54,371

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended March 31,	
	2021	**2020**
License revenue	$ 375	$ 375
Operating expenses:		
Research and development	6,807	4,603
General and administrative	2,740	2,153
Total operating expenses	9,547	6,756
Loss from operations	(9,172)	(6,381)
Interest income	2	68
Interest expense	(14)	(12)
Australian research and development incentives	71	85
Foreign currency loss	(21)	(991)
Loss before income taxes	(9,134)	(7,231)
Dividend attributable to down round feature of warrants	-	(303)
Dividends attributable to Series A & B convertible preferred stock	-	(372)
Series A & B convertible preferred stock - beneficial conversion feature	-	(9,399)
Net loss attributable to common stockholders	$ (9,134)	$ (17,305)
Net loss per share		
Basic & diluted	$ (0.12)	$ (0.55)
Weighted average common shares outstanding		
Basic & diluted	76,378,569	31,632,213

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2021	**2020**
Net loss	$ (9,134)	$ (7,231)
Other comprehensive income:		
Foreign currency translation adjustments	15	912
Comprehensive loss	$ (9,119)	$ (6,319)

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY For the Three Months Ended March 31, 2021 and 2020

(In thousands, except share amounts)

(Unaudited)

	Series A Redeemable Convertible Preferred Stock,		Series B Convertible Preferred Stock,		Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	Equity
Balances at December 31, 2019	-	$ -	-	$ -	24,194,877	$ 24	$ 193,319	$ 76	$ (195,168)	$ (1,749)
Issuance of convertible preferred stock, net of underwriting discounts and commissions of $1,664	1,421,801	14,062	1,137,442	11,260	-	-	-	-	-	-
Series A & B Convertible Preferred Stock discount - beneficial conversion feature	-	(5,226)	-	(4,173)	-	-	9,399	-	-	9,399
Series A & B Convertible Preferred Stock accrued dividends	-	207	-	165	-	-	(372)	-	-	(372)
Conversion of Series A & B Convertible Preferred Stock dividends to prefunded warrants and common stock	-	(207)	-	(165)	156,713	1	371	-	-	372
Conversion of Series A Convertible Preferred Stock to prefunded warrants	(1,421,801)	(8,836)	-	-	-	-	8,836	-	-	8,836
Conversion of Series B Convertible Preferred Stock to common stock	-	-	(1,137,442)	(7,087)	11,374,420	11	7,076	-	-	7,087
Issuance of common stock upon exercise of stock options	-	-	-	-	7,778	-	12	-	-	12
Issuance of common stock upon exercise of warrants	-	-	-	-	65,700	-	128	-	-	128
Dividend attributable to the down round feature of 2017 Warrants	-	-	-	-	-	-	303	-	(303)	-
Foreign currency translation adjustment	-	-	-	-	-	-	-	912	-	912
Stock-based compensation	-	-	-	-	-	-	570	-	-	570
Net loss	-	-	-	-	-	-	-	-	(7,231)	(7,231)
Balances at March 31, 2020	-	$ -	-	$ -	35,799,488	$ 36	$ 219,642	$ 988	$ (202,702)	$ 17,964

	Series A Redeemable Convertible Preferred Stock,		Series B Convertible Preferred Stock,		Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	Equity
Balances at December 31, 2020	-	$ -	-	$ -	59,657,742	$ 60	$ 270,155	$ (579)	$ (222,985)	$ 46,651
Issuance of common stock upon exercise of warrants	-	-	-	-	11,980	-	14	-	-	14
Foreign currency translation adjustment	-	-	-	-	-	-	-	15	-	15
Stock-based compensation	-	-	-	-	-	-	833	-	-	833
Net loss	-	-	-	-	-	-	-	-	(9,134)	(9,134)
Balances at March 31, 2021	-	$ -	-	$ -	59,669,722	$ 60	$ 271,002	$ (564)	$ (232,119)	$ 38,379

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (9,134)	$ (7,231)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	7	10
Amortization of contract asset	34	34
Amortization on right-of-use asset	95	191
Stock-based compensation expense	833	570
Foreign currency loss	21	991
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(133)	362
Research and development incentive receivable	(20)	(86)
Contract acquisition costs	-	(270)
Accounts payable and accrued expenses	387	(770)
Deferred revenue	(375)	2,625
Restricted stock liability	(204)	(159)
Lease liability	(98)	(193)
Net cash used in operating activities	(8,587)	(3,926)
Cash flows from financing activities:		
Proceeds from the issuance of Series A convertible preferred stock commissions and discounts	-	14,986
Proceeds from the issuance of Series B convertible preferred stock commissions and discounts	-	12,000
Proceeds from the exercise of common stock warrants	14	128
Proceeds from the exercise of stock options	-	11
Payment of deferred offering costs	-	(1,520)
Net cash provided by financing activities	14	25,605
Effect of exchange rate changes on cash and cash equivalents	(7)	(105)
Net increase (decrease) in cash and cash equivalents	(8,580)	21,574
Cash and cash equivalents at beginning of period	52,071	3,891
Cash and cash equivalents at end of period	$ 43,491	$ 25,465
Supplemental disclosure of non-cash financing activities:		
Dividend attributable to down round feature of warrants	$ -	$ 303
Offering costs included in accounts payable and accrued expenses	$ -	$ 144
Conversion of Series A convertible preferred stock to prefunded warrants	$ -	$ 8,836
Conversion of Series B convertible preferred stock to common stock	$ -	$ 7,087
Beneficial conversion feature from Series A convertible preferred stock	$ -	$ 5,226
Beneficial conversion feature from Series B convertible preferred stock	$ -	$ 4,173

See notes to condensed consolidated financial statements.

1. Nature of Business, Basis of Presentation and Liquidity

Nature of Business

Leap Therapeutics, Inc. was incorporated in the state of Delaware on January 3, 2011. During 2015, HealthCare Pharmaceuticals Pty Ltd. ("HCP Australia") was formed and is a wholly owned subsidiary of the Company.

The Company is a biopharmaceutical company acquiring and developing novel therapeutics at the leading edge of cancer biology. The Company's approach is designed to target compelling tumor-promoting and immuno-oncology pathways to generate durable clinical benefit and enhanced outcomes for patients. The Company's programs are monoclonal antibodies that target key cellular pathways that enable cancer to grow and spread and specific mechanisms that activate the body's immune system to identify and attack cancer.

Basis of Presentation

The accompanying condensed consolidated financial statements as of March 31, 2021 and for the three months ended March 31, 2021 and 2020 have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2020 included in the Company's Annual Report on Form 10-K filed with the SEC on March 12, 2021.

The condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements. In the opinion of management, the accompanying condensed consolidated financial statements contain all adjustments which are necessary for the fair presentation of the Company's financial position as of March 31, 2021, statements of operations and statements of comprehensive loss for the three months ended March 31, 2021 and 2020 and statements of cash flows for the three months ended March 31, 2021 and 2020. Such adjustments are of a normal and recurring nature. The results of operations for the three months ended March 31, 2021 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2021.

Liquidity

Since inception, the Company has been engaged in organizational activities, including raising capital, and research and development activities. The Company does not yet have a product that has been approved by the Food and Drug Administration (the "FDA"), has not generated any product sales revenues and has not yet achieved profitable operations, nor has it ever generated positive cash flows from operations. There is no assurance that profitable operations, if achieved, could be sustained on a continuing basis. Further, the Company's future operations are dependent on the success of the Company's efforts to raise additional capital, its research and commercialization efforts, regulatory approval, and, ultimately, the market acceptance of the Company's products.

In accordance with Accounting Standards Codification ("ASC") 205-40, Going Concern, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern for a period of at least one year after the date that the condensed consolidated financial statements are issued. As of March 31, 2021, the Company had cash and cash equivalents of $43,491. Additionally, the Company had an accumulated deficit of $232,119 at March 31, 2021, and during the three months ended March 31, 2021, the Company incurred a net loss of $9,134. The Company expects to continue to generate operating losses for the foreseeable future. The Company believes that its cash and cash equivalents of $43,491 as of March 31, 2021 will be sufficient to fund its operating expenses for at least the next 12 months from issuance of these financial statements.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions are eliminated upon consolidation.

Use of Estimates

The presentation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Research and development incentive income and receivable

The Company recognizes other income from Australian research and development incentives when there is reasonable assurance that the income will be received, the relevant expenditure has been incurred, and the consideration can be reliably measured. The research and development incentive is one of the key elements of the Australian Government's support for Australia's innovation system and is supported by legislative law primarily in the form of the Australian Income Tax Assessment Act 1997, as long as eligibility criteria are met.

Management has assessed the Company's research and development activities and expenditures to determine which activities and expenditures are likely to be eligible under the research and development incentive regime described above. At each period end, management estimates the refundable tax offset available to the Company based on available information at the time.

Under the program, a percentage of eligible research and development expenses incurred by the Company through its subsidiary in Australia are reimbursed. The percentage was 43.5% for the year ended December 31, 2020 and for the three months ended March 31, 2021.

The research and development incentive receivable represents an amount due in connection with the above program. The Company has recorded a research and development incentive receivable of $92 and $73 as of March 31, 2021 and December 31, 2020, respectively, in the condensed consolidated balance sheets and other income from Australian research and development incentives of $71 and $85, respectively, for the three months ended March 31, 2021 and 2020.

The following table shows the change in the research and development incentive receivable from January 1, 2020 to March 31, 2021 (in thousands):

The following table shows the change in the research and development incentive receivable from January 1, 2020 to March 31, 2021:

Balance at January 1, 2020	185
Australian research and development incentive income, net	231
Cash received for 2019 eligible expenses	(331)
Foreign currency translation	(12)
Balance at December 31, 2020	$ 73
Australian research and development incentive income, net	71
Cash received for eligible expenses	(51)
Foreign currency translation	(1)
Balance at March 31, 2021	$ 92

Foreign Currency Translation

The financial statements of the Company's Australian subsidiary are measured using the local currency as the functional currency. Assets and liabilities of this subsidiary are translated into U.S. dollars at an exchange rate as of the consolidated balance sheet date. Equity is translated at historical exchange rates. Revenues and expenses are translated into U.S. dollars at average rates of exchange in effect during the period. The resulting cumulative translation adjustments have been recorded as a separate component of stockholders' equity. Realized foreign currency transaction gains and losses are included in the results of operations.

Deferred Costs

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process equity financings as deferred costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity (deficiency) as a reduction of additional paid-in capital generated as a result of the offering.

The Company also capitalizes certain contract acquisition costs. During the three months ended March 31, 2020, the Company incurred contract acquisition costs which were capitalized under ASC 340-40 as incremental costs of obtaining the contract with BeiGene. This cost is amortized on a straight-line basis over the performance period of the research and development services.

As of March 31, 2021 and December 31, 2020 there was $311 and $345, respectively, of deferred costs.

Deposits

As of March 31, 2021 and December 31, 2020, $980 of deposits made by the Company with certain service providers that are to be applied to future payments due under the service agreements or returned to the Company if not utilized were recorded in the condensed consolidated balance sheets.

Warrants

The Company will recognize on a prospective basis the value of the effect of the down round feature in the 2017 Warrants when it is triggered (i.e., when the exercise price is adjusted downward). This value is measured as the difference between (1) the financial instrument’s fair value (without the down round feature) using the pre-trigger exercise price and (2) the financial instrument’s fair value (with the down round feature) using the reduced exercise price. The value of the effect of the down round feature will be treated as a dividend and a reduction to income available to common stockholders in the basic EPS calculation. In connection with the private placement of common stock completed in January 2020 (the “January 2020 Private Placement”), when the 2017 Warrants were repriced from $1.75 to $1.055 as a result of a down round, the Company recorded a dividend of $303 during the three months ended March 31, 2020.

Fair Value of Financial Instruments

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.

- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

During the periods presented, the Company has not changed the manner in which it values assets and liabilities that are measured at fair value using Level 3 inputs. There were no transfers within the hierarchy during the three months ended March 31, 2021 or the year ended December 31, 2020.

A summary of the assets and liabilities carried at fair value in accordance with the hierarchy defined above is as follows (in thousands):

	Total	Level 1	Level 2	Level 3
March 31, 2021				
Assets:				
Cash equivalents	$ 42,506	$ 42,506	$ -	$ -
Total assets	$ 42,506	$ 42,506	$ -	$ -
December 31, 2020				
Assets:				
Cash equivalents	$ 51,116	$ 51,116	$ -	$ -
Total assets	$ 51,116	$ 51,116	$ -	$ -
Liabilities:				
Restricted stock liability	$ 204	$ -	$ 204	$ -
Total liabilities	$ 204	$ -	$ 204	$ -

Cash equivalents of $42,506 and $51,116 as of March 31, 2021 and December 31, 2020, respectively, consisted of overnight investments and money market funds and are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices in active markets.

The carrying values of the research and development incentive receivable, accounts payable and accrued liabilities approximate their fair value due to the short-term nature of these assets and liabilities.

Leases

The Company accounts for leases in accordance with Accounting Standards Codification, or ASC, Topic 842, *Leases*.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Most leases with a term greater than one year are recognized on the balance sheet as right-of-use assets, lease liabilities and, if applicable, long-term lease liabilities. The Company has elected not to recognize on the balance sheet leases with terms of one year or less. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. The Company has determined that the rate implicit in the lease is not determinable and the Company does not have borrowings with similar terms and collateral. Therefore, the Company considered a variety of factors, including observable debt yields from comparable companies and the volatility in the debt market for securities with similar terms, in determining that 8% was reasonable to use as the incremental borrowing rate for purposes of the calculation of lease liabilities.

In accordance with the guidance in Topic 842, components of a lease should be split into three categories: lease components (e.g. land, building, etc.), non-lease components (e.g. common area maintenance, maintenance, consumables, etc.), and non-components (e.g. property taxes, insurance, etc.). Then the fixed and in-substance fixed contract consideration (including any related to non-components) must be allocated based on fair values to the lease components and non-lease components.

Although separation of lease and non-lease components is required, certain practical expedients are available. Entities may elect the practical expedient to not separate lease and non-lease components. Rather, they would account for each lease component and the related non-lease component together as a single component. The Company has elected to account for the lease and non-lease components of each of its operating leases as a single lease component and allocate all of the contract consideration to the lease component only. The lease component results in an operating right-of-use asset being recorded on the consolidated balance sheets and amortized such that lease expense is recorded on a straight line basis over the term of the lease.

Revenue Recognition

The Company records revenue in accordance with ASC Topic 606, *Revenue From Contracts with Customers.* This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

License revenue. The Company's performance obligations under its license agreements may include providing intellectual property licenses, performing technology transfer, performing research and development consulting services and notifying the customer of any enhancements to licensed technology or new technology that it discovers, among others. The Company determined that its performance obligations under its license agreements as evaluated at contract inception were not distinct and represented a single performance obligation. Upfront payments are amortized to revenue on a straight-line basis over the performance period. Upfront payment contract liabilities resulting from the Company's license agreements do not represent a financing component as the payment is not financing the transfer of goods or services, and the technology underlying the licenses granted reflects research and development expenses already incurred by the Company. Generally, all amounts received or due other than sales-based milestones and royalties are classified as license revenues. Sales-based milestones and royalties under the Company's license agreements will be recognized as royalty revenue in the period the related sale occurred. The Company generally invoices its licensees upon the completion of the effort or achievement of a milestone, based on the terms of each agreement. Deferred revenue arises from amounts received in advance of the culmination of the earnings process and is recognized as revenue in future periods as performance obligations are satisfied. Deferred revenue expected to be recognized within the next twelve months is classified as a current liability.

Research and Development Services. The promises under the Company's license agreements may include research and development services to be performed by the Company on behalf of the customer. Payments or reimbursements resulting from the Company's research and development efforts are recognized as the services are performed and presented on a gross basis because the Company is the principal for such efforts.

Customer Options. If an arrangement is determined to contain customer options that allow the customer to acquire additional goods or services, the goods and services underlying the customer options that are not determined to be material rights are not considered to be performance obligations at the outset of the arrangement, as they are contingent upon option exercise. The Company evaluates the customer options for material rights, or options to acquire additional goods or services for free or at a discount. If the customer options are determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. The Company allocates the transaction price to material rights based on the relative standalone selling price, which is determined based on the identified discount and the probability that the customer will exercise the option. Amounts allocated to a material right are not recognized as revenue until (1) the option is exercised and the additional goods or services are transferred or (2) the option expires.

Milestone Payments. At the inception of each arrangement that includes research or development milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Royalties. For arrangements that include sales-based royalties, including milestone payments upon first commercial sales and milestone payments based on a level of sales, which are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

Collaborative Arrangements

The Company analyzes its collaboration arrangements to assess whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities and therefore within the scope of ASC Topic 808, Collaborative Arrangements (ASC 808). This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and which elements of the collaboration are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to ASC 606. Amounts that are owed to collaboration partners are recognized as an offset to collaboration revenues as such amounts are incurred by the collaboration partner. Where amounts owed to a collaboration partner exceed the Company's collaboration revenues in each quarterly period, such amounts are classified as research and development expense. Reimbursements from and payments to the customer that are the result of a collaborative relationship with a partner, instead of a customer relationship, such as co-development activities, are recorded as a reduction to research and development expense. For those elements of the arrangement that are accounted for pursuant to ASC 606, the Company applies the five-step model described above under ASC 606.

See Note 3 for a complete discussion of the revenue recognition for the Company's license agreement.

Net Loss per Share

Basic net loss per share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed using the weighted average number of common shares outstanding during the period and, if dilutive, the weighted average number of potential shares of common stock, including the assumed exercise of stock options and warrants.

Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence for certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated as required.

Recent Accounting Pronouncements

The Company's significant accounting policies are described in Note 2, "Summary of Significant Accounting Policies", in the Company's previously filed Annual Report on Form 10-K for the year ended December 31, 2020.

3. BeiGene Exclusive Option and License Agreement

Terms of Agreement

On January 3, 2020, the Company entered into an exclusive option and license agreement (the "BeiGene Agreement") with BeiGene, Ltd. ("BeiGene") for the clinical development and commercialization of DKN-01, in Asia (excluding Japan), Australia, and New Zealand. The Company retains exclusive rights for the development, manufacturing, and commercialization of DKN-01 for the rest of the world.

Pursuant to the BeiGene Agreement, the Company received an upfront cash payment of $3,000 from BeiGene in exchange for granting BeiGene an option to an exclusive license to develop and commercialize DKN-01 in Asia (excluding Japan), Australia, and New Zealand. The Company is eligible to receive up to $132,000 in future option exercise and milestone payments, based upon the achievement of certain development, regulatory, and sales milestones, as well as tiered royalties on any product sales of DKN-01 in the licensed territory.

The Company is responsible for conducting development activities prior to the exercise of the option. After the option is exercised, BeiGene is solely responsible for the development and commercialization of DKN-01 in the territory. The BeiGene Agreement continues in effect until the earlier of: (i) 120 days after the end of the option period, if BeiGene has not exercised the option by such date; and (ii) on a country-by country and Licensed Product-by-Licensed Product (as defined in the BeiGene Agreement) basis, the expiration of the Royalty Term (as defined in the BeiGene Agreement) applicable to such licensed product in such country. At any time, BeiGene may terminate the agreement by providing at least 60 days written notice of termination to the Company. Upon termination of the License Agreement, all rights granted by the Company to BeiGene terminate.

Revenue Recognition

The Company evaluated the BeiGene Agreement to determine whether it is a collaborative arrangement for purposes of ASC 808. The Company concluded that because both parties were active participants and were exposed to the risks and rewards of the BeiGene Agreement, that such activities are under the scope of ASC 808. The Company concluded that BeiGene was a customer with regard to the combined license and research and development activities and as such the contract should be evaluated under ASC 606.

In determining the appropriate amount of revenue to be recognized under ASC 606 as the Company fulfills its obligations under the BeiGene Agreement, the Company performs the following steps: (i) identifies the promised goods or services in the contract; (ii) determines whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measures the transaction price, including any constraints on variable consideration; (iv) allocates the transaction price to the performance obligations; and (v) recognizes revenue when (or as) the Company satisfies each performance obligation.

The Company identified the following material promises under the BeiGene Agreement: (1) option to an exclusive license to develop and commercialize DKN-01 in Asia (excluding Japan), Australia, and New Zealand, (2) participation in a joint development committee, (3) technology transfer services and (4) pre-option research and development services. The Company determined that the option to an exclusive license in the territory does not represent a material right. Additionally, the Company determined that the participation in the joint development committee, research and development services and technology transfer services are not distinct from each other, as each has limited value without the other. As such, for the purposes of ASC 606, the Company determined that these four material promises, described above, should be combined into a single performance obligation.

The Company determined the transaction price is equal to the up-front fee of $3,000. The transaction price was fully allocated to the single performance obligation and is recognized as revenue on a straight-line basis over the performance period of the research and development services. During each of the three months ended March 31, 2021 and 2020, the Company recognized $375 of license revenue related to the up-front fee received from BeiGene.

Cost of contract acquisition

The Company incurred contract acquisition costs of $270 which were capitalized under ASC 340-40 as incremental costs of obtaining the contract with BeiGene. This cost is amortized on a straight-line basis over the performance period of the research and development services. The total amount of amortization expense during the three months ended March 31, 2021 and 2020 was $34 and the closing balance recorded in deferred costs as of March 31, 2021 was $101.

Royalties

As the license is deemed to be the predominant item to which sales-based royalties relate, the Company will recognize revenue when the related sales occur. No royalty revenue was recognized during the three months ended March 31, 2021 and 2020.

The following table presents a summary of the activity in the Company's contract liabilities, related to the upfront cash payment received of $3,000, from January 1, 2020 through March 31, 2021 (in thousands):

Contract Liabilities:	
Balance at January 1, 2020	$ -
Additions	3,000
Deductions	(1,500)
Balance at December 31, 2020	$ 1,500
Deductions	(375)
Balance at March 31, 2021	$ 1,125

4. Accrued Expenses

Accrued expenses consist of the following:

	March 31, 2021	December 31, 2020
Clinical trials	$ 1,676	$ 795
Professional fees	117	255
Payroll and related expenses	542	1,697
Accrued expenses	$ 2,335	$ 2,747

5. Leases

The Company has operating leases for real estate in the United States and does not have any finance leases. The Company’s leases may contain options to renew and extend lease terms and options to terminate leases early. Reflected in the right-of-use asset and lease liability on the Company’s consolidated balance sheets are the periods provided by renewal and extension options that the Company is reasonably certain to exercise, as well as the periods provided by termination options that the Company is reasonably certain to not exercise.

The Company has existing leases that include variable lease and non-lease components that are not included in the right-of-use asset and lease liability and are reflected as an expense in the period incurred. Such payments primarily include common area maintenance charges and increases in rent payments that are driven by factors such as future changes in an index (e.g., the Consumer Price Index).

In calculating the present value of future lease payments, the Company utilized its incremental borrowing rate based on the remaining lease term at the date of adoption. The Company has elected to account for each lease component and its associated non-lease components as a single lease component and has allocated all of the contract consideration across lease components only. This will potentially result in the initial and subsequent measurement of the balances of the right-of-use asset and lease liability for leases being greater than if the policy election was not applied. The Company has existing net leases in which the non-lease components (e.g. common area maintenance, maintenance, consumables, etc.) are paid separately from rent based on actual costs incurred and therefore are not included in the right-of-use asset and lease liability and are reflected as an expense in the period incurred. As of March 31, 2021, a right-of-use asset of $433 and lease liability of $454 are reflected on the condensed consolidated balance sheets. The Company recorded rent expense of $105 and $198, respectively, during the three months ended March 31, 2021 and 2020.

Future lease payments under non-cancelable operating leases as of March 31, 2021 are detailed as follows:

Future Operating Lease Payments

2021	$	327
2022		146
Total Lease Payments		**473**
Less: imputed interest		(19)
Total operating lease liabilities	**$**	**454**

6. Warrants

As of March 31, 2021, outstanding warrants to purchase common stock, all of which are classified as equity warrants, consisted of the following:

	March 31, 2021		
Description	Number of Shares Issuable	Exercise Price	Expiration Date
1/23/2017	54,516	$ 0.01	Upon M&A event
2017 Warrants	2,539,409	$ 1.055	November 2024
2019 Warrants	7,489,893	$ 1.95	February 2026
March 2020	14,413,902	$ 0.001	March 2027
March 2020	25,945,035	$ 2.11	March 2027
June 2020	2,250,000	$ 0.001	June 2027
	52,692,755		

2017 Warrants

The 2017 Warrants contain full ratchet anti-dilution protection provisions. The Company will recognize on a prospective basis the value of the effect of the down round feature in the 2017 Warrants when it is triggered (i.e., when the exercise price is adjusted downward). This value is measured as the difference between (1) the financial instrument's fair value (without the down round feature) using the pre-trigger exercise price and (2) the financial instrument's fair value (with the down round feature) using the reduced exercise price. The value of the effect of the down round feature will be treated as a dividend and a reduction to income available to common stockholders in the basic EPS calculation. In connection with the January 2020 Private Placement, when the 2017 Warrants were repriced from $1.75 to $1.055, the Company recorded a dividend of $303 during the three months ended March 31, 2020.

2019 Warrants

On February 5, 2019, in connection with the 2019 Public Offering, the Company issued immediately exercisable warrants (the "2019 Warrants") to purchase 7,557,142 shares of common stock to investors. The 2019 Warrants have an exercise price of $1.95 per share and expire on February 5, 2026. The 2019 Warrants qualify for equity classification.

March 2020 Warrants

On January 3, 2020, the Company entered into a Securities Purchase Agreement with investors, providing for a private placement transaction exempt from the Securities Act of 1933, as amended, pursuant to which the Company issued and sold 1,421,801 shares of its Series A Preferred Stock, at a purchase price of $10.54 per share, and 1,137,442 shares of its Series B Preferred Stock at a purchase price of $10.55 per share, and one (1) share of the Company's Special Voting Stock entitling the purchaser of Series A Preferred Stock to elect one member of the Company's board of directors.

On March 5, 2020, the Company's stockholders approved the conversion of the Series A Preferred Stock into a pre-funded warrant to purchase 14,413,902 shares of common stock at an exercise price of $0.001 (the "March 2020 Pre-funded Warrants") and the conversion of the Series B Preferred Stock into 11,531,133 shares of common stock. Each investor also received a warrant to purchase an equal number of shares of common stock at an exercise price of $2.11 per share (the "Coverage Warrants"). The March 2020 Pre-funded Warrants and the Coverage Warrants expire on March 5, 2027 and qualify for equity classification.

June 2020 Warrants

On June 22, 2020, the Company completed a public offering ("the 2020 Public Offering") whereby the Company issued 20,250,000 shares of its common stock, at $2.00 per share and, in lieu of common stock, offered pre-funded warrants (the "June 2020 Pre-funded Warrants") to purchase up to 2,250,000 shares of its common stock to certain investors. The June 2020 Pre-funded Warrants have an exercise price of $0.001 per share, expire on June 22, 2027 and qualify for equity classification.

7. Common Stock

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to the preferential dividend rights of the preferred stockholders. Through March 31, 2021, no dividends have been declared for shares of common stock.

Lincoln Park Purchase Agreement

On July 10, 2019, the Company entered into a Commitment Purchase Agreement and a Registration Rights Agreement with Lincoln Park, pursuant to which the Company has the right to sell to Lincoln Park up to $20,000 in shares of its common stock, subject to certain limitations and conditions set forth in the Commitment Purchase Agreement. The Lincoln Park Purchase Agreement expires in July 2021. As consideration for Lincoln Park's commitment to purchase shares of common stock pursuant to the Commitment Purchase Agreement, the Company issued to Lincoln Park 330,000 shares of common stock. The Company did not receive any cash proceeds from the issuance of such shares. During the three months ended March 31, 2021 and 2020, the Company did not issue any shares under the Commitment Purchase Agreement.

January 2020 Private Placement

On January 3, 2020, the Company issued and sold 1,421,801 shares of its Series A Preferred Stock at a purchase price of $10.54 per share, and 1,137,442 shares of its Series B Preferred Stock at a purchase price of $10.55 per share, and one (1) share of its Special Voting Stock, entitling the purchaser of Series A Preferred Stock to elect one member of the Company's board of directors, for aggregate net proceeds to the Company of approximately $25,322.

On March 5, 2020, the Company's stockholders approved the conversion of the Series A Preferred Stock into a pre-funded warrant to purchase 14,413,902 shares of common stock at an exercise price of $0.001 per share and the conversion of the Series B Preferred Stock into 11,531,133 shares of its common stock, par value $0.001 per share. Each investor also received the Coverage Warrants to purchase an equal number of shares at an exercise price of $2.11 per share.

In connection with the January 2020 Private Placement, Series A Preferred Stock holders and Series B Preferred Stock holders were entitled to cash dividends at fixed cumulative percentage of 8% per annum plus any dividends declared on outstanding common stock on an as-converted basis, effective on the issuance date of the Series A Preferred Stock and Series B Preferred Stock. The cash dividends were converted to shares of common stock upon the conversion of the Series A Preferred Stock to pre-funded warrants and Series B Preferred Stock to common stock. During the three months ended March 31, 2020, the Company recorded $372 of Series A Preferred Stock and Series B Preferred Stock dividends, which qualify as cumulative dividends, and in the calculation of EPS are subtracted from net income in arriving at income attributable to common stockholders.

The Company determined that the embedded conversion features of the Series A Preferred Stock and Series B Preferred Stock to receive the Coverage Warrants each met the definition of a contingent beneficial conversion feature and should be accounted for separately as a derivative. The recognition of the beneficial conversion feature occurred upon the conversion of the Series A Preferred Stock into pre-funded warrants and Series B Preferred Stock into common stock and the issuance of the Coverage Warrants. The Company measured the contingent beneficial conversion features' intrinsic values on January 3, 2020 and determined that the beneficial conversion features were valued at $5,226 for Series A and $4,173 for Series B, respectively. Upon conversion, the discount originated by the contingent beneficial conversion feature, at its intrinsic value for Series A Preferred Stock and Series B Preferred Stock, was immediately recognized as a dividend. The dividend is reflected as an adjustment to basic and diluted net loss per share attributable to common stockholders.

Public Offering of Common Stock — June 2020

On June 22, 2020, the Company completed the 2020 Public Offering, whereby the Company issued 20,250,000 shares of its common stock at $2.00 per share and, in lieu of common stock, issued certain investors 2,250,000 of its June 2020 Pre-funded Warrants. The June 2020 Pre-funded Warrants have an exercise price of $0.001 per share, expire on June 22, 2027 and qualify for equity classification.

On June 25, 2020, the underwriters exercised their right to purchase 3,375,000 additional shares of the Company's common stock at the public offering price per share of common stock, less underwriting discounts and commissions. The aggregate net proceeds received by the Company from the 2020 Public Offering were approximately $48,276, net of underwriting discounts and commissions and estimated offering expenses payable by the Company.

8. Equity Incentive Plans

Equity Incentive Plans

In September 2012, the Company adopted the 2012 Equity Incentive Plan, as amended, which provides designated employees of the Company and its affiliates, certain consultants and advisors who perform services for the Company and its affiliates, and nonemployee members of the board of directors of the Company and its affiliates with the opportunity to receive grants of incentive stock options, nonqualified stock options and stock awards.

On January 20, 2017, the Company's stockholders approved the 2016 Equity Incentive Plan (the "2016 Plan"). Beginning on January 1, 2018, the number of shares of common stock authorized for issuance pursuant to the 2016 Plan was increased each January 1 by an amount equal to four percent (4%) of the Company's outstanding common stock as of the end of the immediately preceding calendar year or such other amount as determined by the compensation committee of the Company's board of directors.

As of March 31, 2021, there were 1,094,999 shares available for grant under the Company's equity incentive plans.

A summary of stock option activity under the Equity Plans is as follows:

	Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Life in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2020	6,393,853	$ 5.29	7.96	$ 1,961
Granted	1,556,500	$ 2.50		
Forfeited	(200,046)	$ 2.57		
Outstanding at March 31, 2021	7,750,307	$ 4.80	7.99	$ 912
Options exercisable at March 31, 2021	3,907,038	$ 7.25	6.81	$ 456
Options vested and expected to vest at March 31, 2021	7,750,307	$ 4.80	7.99	$ 912

The grant date fair value of the options granted during the three months ended March 31, 2021 and 2020 was estimated at the date of grant using the Black-Scholes option valuation model. The expected life was estimated using the "simplified" method as defined by the SEC's Staff Accounting Bulletin 107, Share-Based Payment. The expected volatility was based on the historical volatility of comparable public companies from a representative peer group selected based on industry and market capitalization data. The risk-free interest rate was based on the continuous rates provided by the U.S. Treasury with a term approximating the expected life of the option. The expected dividend yield was 0% because the Company does not expect to pay any dividends for the foreseeable future. The Company elected the straight-line attribution method in recognizing the grant date fair value of options issued over the requisite service periods of the awards, which are generally the vesting periods.

The weighted average grant date fair value for the stock options granted during the three months ended March 31, 2021 and 2020 was $1.57 and $1.48 per share, respectively.

The assumptions that the Company used to determine the grant-date fair value of stock options granted to employees and directors during the three months ended March 31, 2021 and 2020 were as follows, presented on a weighted average basis:

	Three Months Ended March 31, 2021	Three Months Ended March 31, 2020
Expected volatility	66.94%	66.94%
Weighted average risk-free interest rate	0.66%	0.89%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	6.86	6.81

Stock options generally vest over a three or four year period, as determined by the compensation committee of the board of directors at the time of grant. The options expire ten years from the grant date. As of March 31, 2021, there was approximately $5,340 of unrecognized compensation cost related to non-vested stock options, which is expected to be recognized over a remaining weighted-average period of approximately 2.24 years.

The Company recognized stock-based compensation expense related to the issuance of stock option awards to employees and non-employees in the condensed consolidated statements of operations as follows:

	Three Months Ended March 31,	
	2021	2020
Research and development	$ 330	$ 189
General and administrative	384	368
Total	$ 714	$ 557

Restricted Stock Units

During the year ended December 31, 2020, the Company issued 92,500 restricted stock units ("RSUs") to employees under the 2016 Plan. Upon vesting of the RSUs, the Company has the option to settle the award by either issuing shares of the Company's common stock or paying an amount of cash equal to the fair value of the Company's common stock on the settlement date. In January 2021, the Company cash settled 92,500 RSUs. As of December 31, 2020, these RSUs are classified as restricted stock liability in the condensed consolidated balance sheets of $204, as they contain a cash settlement option.

During the three months ended March 31, 2021 and 2020, the Company granted 275,000 and 660,606, respectively, of RSUs to executive officers that will cliff vest and will be settled after three years of continuous service, or upon a change of control of the Company, whichever is earlier, pursuant to the 2016 Plan. During the three months ended March 31, 2021 and 2020, the Company recognized $119 and $13, respectively, of stock based compensation expense related to equity classified RSUs, as they do not contain a cash settlement option.

The following table presents a summary of outstanding RSUs under the 2016 Plan as of March 31, 2021:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2020	753,106	$ 1.52
Awarded	275,000	$ 2.57
Settled in cash	(92,500)	$ 1.97
Outstanding at March 31, 2021	935,606	$ 1.76

As of March 31, 2021, there were 935,606 shares outstanding covered by RSUs that are expected to vest and the weighted average grant date fair value of these shares of restricted stock was $1.76 per share and the aggregate grant date fair value of these shares of restricted stock was approximately $1,645. As of March 31, 2021, there was approximately $1,278 of unrecognized compensation costs related to RSUs granted to employees, which are expected to be recognized as expense over a remaining weighted average period of 2.41 years.

9. Net Loss Per Share

Basic and diluted net loss per share for the three months ended March 31, 2021 and 2020 was calculated as follows (in thousands except share and per share amounts).

	Three Months Ended March 31,	
	2021	2020
Numerator:		
Net loss	$ (9,134)	$ (7,231)
Dividend attributable to down round feature of warrants	-	(303)
Dividend attributable to Series A & B convertible preferred stock	-	(372)
Series A & B convertible preferred stock - beneficial conversion feature	-	(9,399)
Net loss attributable to common stockholders for basic and diluted loss per share	$ (9,134)	$ (17,305)
Denominator:		
Weighted average number of common shares outstanding - basic and diluted	76,378,569	31,632,213
Net loss per share attributable to common stockholders - basic and diluted	$ (0.12)	$ (0.55)

Included within weighted average common shares outstanding are 16,718,418 common shares issuable upon the exercise of the pre-funded warrants as the warrants are exercisable at any time for nominal consideration, and as such, the shares are considered outstanding for the purpose of calculating basic and diluted net loss per share attributable to common stockholders.

The Company's potentially dilutive securities include RSUs, stock options and warrants. These securities were excluded from the computations of diluted net loss per share for the three months ended March 31, 2021 and 2020, as the effect would be to reduce the net loss per share. The following table includes the potential shares of common stock, presented based on amounts outstanding at each period end, that were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Three Months Ended March 31,	
	2021	**2020**
Restricted stock units to purchase common stock	935,606	660,606
Options to purchase common stock	7,750,307	5,091,209
Warrants to purchase common stock	35,974,337	36,249,087
	44,660,250	42,000,902

10. Commitments and Contingencies

Manufacturing Agreements—The Company is party to manufacturing agreements with vendors to manufacture DKN-01, its lead product candidate, for use in clinical trials. As of March 31, 2021, there were $2,030 noncancelable commitments under these agreements.

License and Service Agreement—On January 3, 2011, the Company entered into a license agreement with Eli Lilly and Company ("Lilly"), a shareholder, to grant a license to the Company for certain intellectual property rights relating to pharmaceutically active compounds that may be useful in the treatment of bone healing, cancer and, potentially, other medical conditions. As defined in the license agreement, the Company would be required to pay royalties to Lilly based upon a percentage in the low single digits of net sales of developed products, if and when achieved. However, there can be no assurance that clinical or commercialization success of developed products will occur, and no royalties have been paid or accrued through March 31, 2021.

License Agreement—On May 28, 2015, the Company entered into a license agreement with Lonza Sales AG ("Lonza"), pursuant to which Lonza granted the Company a world-wide, non-exclusive license for certain intellectual property relating to a gene expression system for manufacturing DKN-01. As defined in the license agreement, the Company would be required to pay royalties to Lonza based on a percentage in the low single digits of net sales of DKN-01, if and when achieved. However, there can be no assurance that clinical or commercialization success will occur, and no royalties have been paid or accrued through March 31, 2021.

Legal Proceedings—At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to its legal proceedings.

A patent covering the TRX518 antibody and its uses in methods of inducing or enhancing an immune response in a subject was granted in 2013 to the Company by the European Patent Office (EPO). Three notices of opposition to this patent were filed: two by major pharmaceutical companies and a third by an individual, possibly on behalf of a major pharmaceutical company. At the conclusion of the opposition proceedings before the Opposition Division of the EPO, the Opposition Division issued a decision indicating that the Company's patent was maintained with modified claims that differ from the claims as originally granted. These narrowed claims cover the TRX518 antibody and uses of the TRX518 antibody in methods of inducing or enhancing an immune response in a subject. The Company filed an appeal of the decision of the Opposition Division seeking to obtain broader claims that more closely reflect the claims as granted in the patent. A hearing before the EPO Boards of Appeal took place on September 16, 2020, which resulted in the Boards of Appeal dismissing the appeal and maintaining the Decision of the Opposition Division. A written Decision by the Boards of Appeal was issued on September 25, 2020.

In 2016, a patent covering the use of the TRX518 antibody in combination with a chemotherapeutic agent for treating cancer was granted to the Company by the EPO. In March 2017, notices of opposition to this patent were filed at the EPO by ten different entities, including several major pharmaceutical companies. Oral proceedings at the EPO took place on December 4 and 5, 2018. At the conclusion of the oral proceedings, the Opposition Division decided that the patent should be revoked in its entirety on the ground that the claims as granted contained added matter. Subsequently, the Opposition Division issued an interlocutory decision restating its conclusion that the claims as granted contained added matter and revoking the patent. The Company has filed an appeal of the decision of the Opposition Division seeking to obtain a reversal of the Opposition Division's decision on added matter. The EPO Board of Appeal has not yet scheduled the appeal hearing.

In December of 2019, a patent covering the use of the TRX518 antibody in combination with the chemotherapeutic agent, gemcitabine, for treating a colon tumor or adenocarcinoma of the colon, was granted to the Company by the EPO. A Notice of Opposition was filed against the patent by a single opponent, Sanofi, on September 25, 2020. The EPO issued a Communication on October 9, 2020 setting a deadline of February 9, 2021 for the Patentee to file a response to the Notice of Opposition. The Company filed a timely reply to the opponent's Notice of Opposition on February 9, 2021. Oral proceedings at the EPO have not yet been scheduled.

Indemnification Agreements—In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements, and it has not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of March 31, 2021 or December 31, 2020.

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") is intended to help the reader understand our results of operations and financial condition. This MD&A is provided as a supplement to, and should be read in conjunction with, our condensed consolidated financial statements and the accompanying notes thereto and other disclosures included in this Quarterly Report on Form 10-Q, including the disclosures under Part II, Item IA "Risk Factors," and our audited condensed consolidated financial statements and the accompanying notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the Securities and Exchange Commission, or the SEC, on March 12, 2021. Our condensed consolidated financial statements have been prepared in accordance with U.S. GAAP and, unless otherwise indicated, amounts are presented in U.S. dollars.

Company Overview

We are a biopharmaceutical company developing novel therapies designed to treat patients with cancer by inhibiting fundamental tumor-promoting pathways and by harnessing the immune system to attack cancer cells. Our strategy is to identify, acquire, and develop molecules that will rapidly translate into high impact therapeutics that generate durable clinical benefit and enhanced patient outcomes.

Our lead clinical stage program is DKN-01, a monoclonal antibody that inhibits Dickkopf-related protein 1, or DKK1. DKK1 is a protein that regulates the Wnt signaling pathways and enables tumor cells to proliferate and spread, as well as suppresses the immune system from attacking the tumor. When DKN-01 binds to DKK1, an anti-tumor effect can be generated. DKN-01-based therapies have generated responses and clinical benefit in several patient populations. We are currently studying DKN-01 in multiple ongoing clinical trials in patients with esophagogastric cancer, hepatobiliary cancer, gynecologic cancers, or prostate cancer. We entered into an exclusive option and license agreement (the "BeiGene Agreement") with BeiGene, Ltd., or BeiGene, which granted BeiGene the right to develop and commercialize DKN-01 in Asia (excluding Japan), Australia, and New Zealand.

Recent Developments

Since December 31, 2020, we have continued to make progress with the clinical development and regulatory strategy of DKN-01:

Completion of Enrollment in First-Line Cohort in the DisTinGuish Study of DKN-01 plus Tislelizumab and chemotherapy in Gastric Cancer: We announced the completion of enrollment for the first-line patient cohort in the DisTinGuish study, a clinical trial evaluating DKN-01 in combination with tislelizumab, BeiGene Ltd.'s anti-PD-1 antibody, with or without chemotherapy, in patients with gastric or gastroesophageal junction cancer (G/GEJ). The study, which is being conducted in two parts in the United States and the Republic of Korea, enrolled 25 patients with first-line G/GEJ cancer and will enroll up to 48 patients with second-line G/GEJ cancer whose tumors express high levels of DKK1. Initial data is expected in the second half of 2021. We are conducting this combination study as part of an exclusive option and license agreement with BeiGene for the development of DKN-01 in Asia (excluding Japan), Australia, and New Zealand.

Presented Final Data for DKN-01 in Gynecologic Cancers: At the Society of Gynecologic Oncology 2021 Annual Meeting on Women's Cancer, we presented the final data from our study of DKN-01 as a monotherapy or in combination with paclitaxel in groups composed of epithelial endometrial cancer (EEC), epithelial ovarian cancer (EOC), or carcinosarcoma (MMMT) patients. The key findings from the study were:

- ***EEC patients and patients with Wnt activating mutations express higher levels of DKK1:*** EEC patients expressed higher levels of DKK1 and had a higher frequency of Wnt activating mutations than patients with EOC. Within EEC, patients with endometrioid histology had higher DKK1 expression than those with non-endometrioid histology. Patients whose tumors had Wnt activating mutations expressed 14.4 times higher levels of DKK1.

- ***DKN-01 has enhanced activity in patients whose tumors express high levels of DKK1:*** In the group of 22 EEC patients treated with DKN-01 monotherapy for whom DKK1 expression data was available, patients with DKK1-high tumors (n=7) had greater ORR (14% vs. 0%), DCR (57% vs. 7%), and median PFS (3.0 months vs. 1.8 months [HR 0.39; 95% CI: 0.14, 1.1]) compared to patients with DKK1-low tumors (n=15). Additionally, seven patients did not have DKK1 expression results available, of whom one had a complete response (14%) and five (72%) had a best response of stable disease, including three patients with Wnt activating mutations. In the group of 24 EEC patients treated with DKN-01 plus paclitaxel, 72% of whom had received three or more prior systemic therapies, DKK1-high patients (n=11) had improved median PFS (5.4 months vs. 1.8 months [HR 0.34; 95% CI: 0.12, 0.97]) compared to DKK1-low patients (n=9). Four patients did not have DKK1 expression data available.

Presented DKK1 Biomarker Assay Validation Data: At the American Association for Cancer Research Annual Meeting 2021, we and our clinical laboratory partner, Flagship Biosciences, presented data on the validation of a DKK1 RNAscope chromogenic in situ hybridization (CISH) assay and digital image analysis solution. We and Flagship have demonstrated that the DKK1 RNAscope assay and accompanying digital image analysis solution is specific, sensitive, accurate and reproducible according to Clinical Laboratory Improvements Amendments (CLIA) guidelines. The assay is currently being used to prospectively identify G/GEJ patients with elevated tumoral expression of DKK1 in our ongoing DisTinGuish clinical trial.

Financial Overview

Revenues

Our revenues relate to our performance obligations under the BeiGene Agreement and may include such things as providing intellectual property licenses, performing technology transfer, performing research and development consulting services and notifying the customer of any enhancements to licensed technology or new technology that we discover, among others. We have determined that our performance obligations under the BeiGene Agreement, as evaluated at contract inception, were not distinct and represented a single performance obligation. Upfront payments are amortized to revenue on a straight-line basis over the performance period. Upfront payment contract liabilities resulting from the BeiGene Agreement do not represent a financing component as the payment is not financing the transfer of goods or services, and the technology underlying the license granted reflects research and development expenses already incurred by us. Generally, all amounts received or due other than sales-based milestones and royalties are classified as license revenues. Sales-based milestones and royalties under the BeiGene Agreement will be recognized as royalty revenue in the period the related sale occurred. We generally invoice our licensee upon the completion of the effort or achievement of a milestone, based on the terms of the BeiGene Agreement. Deferred revenue arises from amounts received in advance of the culmination of the earnings process and is recognized as revenue in future periods as performance obligations are satisfied. Deferred revenue expected to be recognized within the next twelve months is classified as a current liability.

Research and Development Expenses

Our research and development activities have included conducting nonclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for DKN-01 and TRX518. We recognize research and development expenses as they are incurred. Our research and development expenses consist primarily of:

- salaries and related overhead expenses for personnel in research and development functions, including costs related to stock-based compensation;
- fees paid to consultants and CROs for our nonclinical and clinical trials, and other related clinical trial fees, including but not limited to laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis;
- costs related to acquiring and manufacturing clinical trial material; and
- costs related to compliance with regulatory requirements.

We plan to increase our research and development expenses for the foreseeable future as we continue the development of DKN-01 and any other product candidates, subject to the availability of additional funding.

Our direct research and development expenses are tracked on a program-by-program basis and consist primarily of internal and external costs, such as employee costs, including salaries and stock-based compensation, other internal costs, fees paid to consultants, central laboratories, contractors and CROs in connection with our clinical and preclinical trial development activities. We use internal resources to manage our clinical and preclinical trial development activities and perform data analysis for such activities.

We participate, through our subsidiary in Australia, in the Australian government's research and development ("R&D") Incentive program, such that a percentage of our eligible research and development expenses are reimbursed by the Australian government as a refundable tax offset and such incentives are reflected as other income.

The table below summarizes our research and development expenses incurred by development program and the R&D Incentive income for the three months ended March 31, 2021 and 2020:

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Direct research and development by program:		
DKN-01 program	$ 6,615	$ 3,443
TRX518 program	192	1,160
Total research and development expenses	$ 6,807	$ 4,603
Australian research and development incentives	$ 71	$ 85

The successful development of our clinical product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the remainder of the development of any of our product candidates or the period, if any, in which material net cash inflows from these product candidates may commence. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our ongoing, as well as any additional, clinical trials and other research and development activities;
- future clinical trial results; and
- the timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a product candidate could result in a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in executive, finance and administrative functions. General and administrative expenses also include direct and allocated facility-related costs as well as professional fees for legal, patent, consulting, accounting and audit services.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance, director and officer insurance costs as well as investor and public relations expenses associated with being a public company.

Interest income

Interest income consists primarily of interest income earned on cash and cash equivalents.

Research and development incentive income

Research and development incentive income includes payments under the R&D Incentive program from the government of Australia. The R&D Incentive program is one of the key elements of the Australian Government's support for Australia's innovation system. It was developed to assist businesses in recovering some of the costs of undertaking research and development. The research and development tax incentive provides a tax offset to eligible companies that engage in research and development activities.

Companies engaged in research and development may be eligible for either:

- a 43.5% refundable tax offset for entities with an aggregated turnover of less than A$20 million per annum, or
- a 38.5% non-refundable tax offset for all other entities.

We recognize as income the amount we expect to be reimbursed for qualified expenses.

Foreign currency translation adjustment

Foreign currency translation adjustment consists of gains (losses) due to the revaluation of foreign currency transactions attributable to changes in foreign currency exchange rates associated with our Australian subsidiary.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

Revenue Recognition

We recognize revenue in accordance with Accounting Standards Codification, or ASC, Topic 606, Revenue from Contracts with Customers, using the full retrospective transition method. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer. At contract inception, once the contract is determined to be within the scope of Topic 606, we assess the goods or services promised within each contract, determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. We utilize key assumptions to determine a stand-alone selling price for performance obligations, which may include revenue forecasts, expected development timelines, discount rates, probabilities of technical and regulatory success and costs for manufacturing clinical supplies.

Our critical accounting policies are described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations— Critical Accounting Policies and Significant Judgments and Estimates" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 12, 2021 and the notes to the condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. We believe that of our critical accounting policies, the following accounting policies involve the most judgment and complexity:

- revenue recognition;
- accrued research and development expenses;
- research and development incentive receivable; and
- stock-based compensation.

Results of Operations

Comparison of the Three Months Ended March 31, 2021 and 2020

The following table summarizes our results of operations for the three months ended March 31, 2021 and 2020:

	Three Months Ended March 31,		
	2021	2020	Change
	(in thousands)		
License revenue	$ 375	$ 375	$ -
Operating expenses:			
Research and development	6,807	4,603	2,204
General and administrative	2,740	2,153	587
Total operating expenses	9,547	6,756	2,791
Loss from operations	(9,172)	(6,381)	(2,791)
Interest income	2	68	(66)
Interest expense	(14)	(12)	(2)
Australian research and development incentives	71	85	(14)
Foreign currency loss	(21)	(991)	970
Net loss	$ (9,134)	$ (7,231)	$ (1,903)

Revenues

License revenues for the three months ended March 31, 2021 and 2020, were $0.4 million and $0.4 million, respectively, and relate to the BeiGene Agreement for the development and commercialization of DKN-01 in Asia (excluding Japan), Australia, and New Zealand. The BeiGene Agreement became effective January 3, 2020.

Research and Development Expenses

	Three Months Ended March 31,		Increase (Decrease)
	2021	2020	
	(in thousands)		
Direct research and development by program:			
DKN-01 program	$ 6,615	$ 3,443	$ 3,172
TRX518 program	192	1,160	(968)
Total research and development expenses	$ 6,807	$ 4,603	$ 2,204

Research and development expenses were $6.8 million for the three months ended March 31, 2021, compared to $4.6 million for the three months ended March 31, 2020. The increase of $2.2 million in research and development expenses was primarily due to an increase of $0.8 million in payroll and other related expenses due to an increase in headcount of our research and development full time employees, an increase of $0.6 million in manufacturing costs related to clinical trial material and an increase of $0.8 million in clinical trial costs due to timing of patient enrollment.

General and Administrative Expenses

General and administrative expenses were $2.7 million for the three months ended March 31, 2021, compared to $2.2 million for the three months ended March 31, 2020. The increase of $0.5 million in general and administrative expenses was due to a $0.3 million increase in payroll and other related expenses during the three months ended March 31, 2021 as compared to the same period in 2020 and a $0.2 million increase in professional fees primarily due to increased recruiting and information technology costs.

Interest Income

We recorded interest income of $0.1 million in the three months ended March 31, 2020. During the three months ended March 31, 2021, we recorded an immaterial amount of interest income.

Australian Research and Development Incentives

We recorded R&D incentive income of $0.1 million during the three months ended March 31, 2021 and 2020, based upon the applicable percentage of eligible research and development activities under the Australian Incentive Program, which expenses included the cost of manufacturing clinical trial material.

The R&D incentive receivable has been recorded as “Research and development incentive receivable” in the condensed consolidated balance sheets.

Foreign Currency Gains (loss)

During the three months ended March 31, 2020, we recorded foreign currency loss of $1.0 million. During the three months ended March 31, 2021, we recorded an immaterial amount of foreign currency loss. Foreign currency gains and losses are due to changes in the Australian dollar exchange rate related to activities of the Australian entity.

Financial Position, Liquidity and Capital Resources

Since our inception, we have been engaged in organizational activities, including raising capital, and research and development activities. We do not yet have a product that has been approved by the Food and Drug Administration (the “FDA”), have not yet achieved profitable operations, nor have we ever generated positive cash flows from operations. There is no assurance that profitable operations, if achieved, could be sustained on a continuing basis. Further, our future operations are dependent on the success of efforts to raise additional capital, our research and commercialization efforts, regulatory approval, and, ultimately, the market acceptance of our products.

In accordance with ASC 205-40, Going Concern, we have evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued. As of March 31, 2021, we had cash and cash equivalents of $43.5 million. Additionally, we had an accumulated deficit of $232.1 million at March 31, 2021, and during the three months ended March 31, 2021, we incurred a net loss of $9.1 million. We expect to continue to generate operating losses in the foreseeable future. We believe that our cash and cash equivalents of $43.5 million as of March 31, 2021 will be sufficient to fund our operating expenses for at least 12 months from issuance of these financial statements.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	Three Months Ended March 31,	
	2021	**2020**
	(in thousands)	
Cash used in operating activities	$ (8,587)	$ (3,926)
Cash provided by financing activities	14	25,605
Effect of exchange rate changes on cash and cash equivalents	(7)	(105)
Net increase (decrease) in cash and cash equivalents	$ (8,580)	$ 21,574

Operating activities. Net cash used in operating activities for the three months ended March 31, 2021 was primarily related to our net loss from the operation of our business of $9.1 million and net changes in working capital, including a decrease of $0.4 million in deferred revenue, an increase of $0.1 million in prepaid expenses and other assets, a decrease in lease liabilities of $0.1 million and a $0.2 million decrease related to a noncash change in restricted stock liability. These changes were partially offset by an increase in accounts payable and accrued expenses of $0.4 million, noncash stock based compensation expense of $0.8 million and amortization on right-of-use assets of $0.1 million.

Net cash used in operating activities for the three months ended March 31, 2020 was primarily related to our net loss from the operation of our business of $7.2 million and net changes in working capital, including a decrease in accounts payable and accrued expenses of $0.8 million, an increase in contract acquisition costs of $0.3 million, a decrease in lease liabilities of $0.2 million and an increase in research and development receivable of $0.1 million. There was also a decrease of $0.2 million related to a noncash change in restricted stock liability. These changes were partially offset by a decrease of $0.4 million in prepaid expenses and other assets, an increase of $2.7 million in deferred revenue, noncash foreign currency losses of $1.0 million related to activities in our Australian entity due to changes in the Australian dollar exchange rate, noncash stock based compensation expense of $0.6 million and noncash lease expense of $0.2 million.

Investing Activities. There were no investing activities during the three months ended March 31, 2021 and 2020.

Financing Activities. Net cash provided by financing activities for the three months ended March 31, 2021 consisted of proceeds from the exercise of common stock warrants.

Net cash provided by financing activities for the three months ended March 31, 2020 consisted of $27.0 million in proceeds from the issuance of Series A Preferred Stock and Series B Preferred Stock in connection with the January 2020 Private Placement and $0.1 million in proceeds from the issuance of common stock upon the exercise of warrants. These increases were partially offset by payments of $1.5 million for deferred costs.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not Applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities and Exchange Act of 1934, as amended (the "Exchange Act") is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our President and Chief Executive Officer, who is also serving as Chief Financial Officer and therefore currently serves as both our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

As of March 31, 2021, our management, with the participation of our Chief Executive Officer, who is also serving as Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control—Integrated Framework (2013 Framework). Our 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. Our principal executive officer and principal financial officer has concluded, based upon the evaluation described above, that, as of March 31, 2021, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in reports the Company files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such material information is accumulated and communicated to the Company's management, including its principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

During the three months ended March 31, 2021, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that materially affected, or are reasonably likely to affect, internal control over financial reporting.

Part II — OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

An investment in our ordinary shares involves a high degree of risk. You should carefully consider the risk factors discussed in Part I, Item 1A "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2020 as filed with the SEC on March 12, 2021, which could materially affect our business, financial condition, operating results or cash flows. We operate in a dynamic and rapidly changing industry that involves numerous risks and uncertainties. There have been no material changes from the risk factors described in our Annual Report on Form 10-K for the year ended December 31, 2020.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

See the Exhibit Index immediately prior to the signature page to this Quarterly Report on Form 10-Q for a list of exhibits filed or furnished with this report, which Exhibit Index is incorporated herein by reference.

EXHIBIT INDEX

31.1*	Certification of Chief Executive Officer and Chief Financial Officer Required Under Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following materials from Leap Therapeutics, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets at March 31, 2021 and December 31, 2020, (ii) Condensed Consolidated Statements of Operations for the three months ended March 31, 2021 and 2020, (iii) Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2021 and 2020, (iv) Condensed Consolidated Statements of Stockholders' Equity for the three months ended March 31, 2021 and 2020, (v) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2021 and 2020, and (vi) Notes to Condensed Consolidated Financial Statements, tagged as blocks of text.

* Filed herewith.

**Furnished with this report.

SIGNATURES

Pursuant to the requirements 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.

LEAP THERAPEUTICS, INC.

Date: May 14, 2021

By: /s/ Douglas E. Onsi
Douglas E. Onsi
President, Chief Executive Officer and Chief Financial Officer
(Principal Executive Officer, Principal Financial Officer and Duly Authorized Signatory)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
AND CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Douglas E. Onsi, certify that:

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

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. I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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 my 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. I have disclosed, based on my 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.

May 14, 2021	/s/ DOUGLAS E. ONSI
Date	Douglas E. Onsi President, Chief Executive Officer and Chief Financial Officer (Principal Executive Officer and Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
AND CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Leap Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Douglas E. Onsi, as Chief Executive Officer, President and Chief Financial Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1)The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2)The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 14, 2021

By: /s/ DOUGLAS E. ONSI

Douglas E. Onsi
President, Chief Executive Officer and Chief Financial Officer

(Principal Executive Officer and Principal Financial Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Leap Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Quarterly Report), irrespective of any general incorporation language contained in such filing.