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 September 30, 2020**

☐ **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 November 10, 2020 there were 59,657,742 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, 2019 as filed with the Securities and Exchange Commission on March 16, 2020 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 and TRX518 are investigational drugs undergoing clinical development and have not been approved by the U.S. Food and Drug Administration (the "FDA"), nor been submitted to the FDA for approval. DKN-01 and TRX518 have 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)

	September 30, 2020 (Unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 57,975	$ 3,891
Research and development incentive receivable	209	185
Prepaid expenses and other current assets	217	165
Total current assets	58,401	4,241
Property and equipment, net	73	124
Right of use assets, net	620	1,026
Deferred tax assets	130	127
Deferred costs	379	831
Deposits	941	1,099
Total assets	$ 60,544	$ 7,448
Liabilities and Stockholders' Equity (Deficiency)		
Current liabilities:		
Accounts payable	$ 2,547	$ 4,571
Accrued expenses	2,270	3,441
Deferred revenue - current portion	1,500	-
Lease liability - current portion	398	474
Total current liabilities	6,715	8,486
Non current liabilities:		
Restricted stock liability	66	159
Deferred revenue, net of current portion	375	-
Lease liability, net of current portion	250	552
Total liabilities	7,406	9,197
Stockholders' equity (deficiency):		
Common stock, $0.001 par value; 240,000,000 and 100,000,000 shares authorized as of September 30, 2020 and December 31, 2019, respectively; 59,657,742 and 24,194,877 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	60	24
Additional paid-in capital	269,440	193,319
Accumulated other comprehensive income (loss)	(87)	76
Accumulated deficit	(216,275)	(195,168)
Total stockholders’ equity (deficiency)	53,138	(1,749)
Total liabilities and stockholders' equity (deficiency)	$ 60,544	$ 7,448

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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
License revenue	$ 375	$ -	$ 1,125	$ -
Operating expenses:				
Research and development	5,369	5,772	15,322	18,698
General and administrative	2,514	2,151	7,188	6,481
Total operating expenses	7,883	7,923	22,510	25,179
Loss from operations	(7,508)	(7,923)	(21,385)	(25,179)
Interest income	3	80	91	281
Interest expense	(17)	(5)	(42)	(21)
Australian research and development incentives	228	(7)	343	129
Foreign currency gains (loss)	237	(80)	189	(114)
Loss before income taxes	(7,057)	(7,935)	(20,804)	(24,904)
Income taxes	-	-	-	-
Net loss	(7,057)	(7,935)	(20,804)	(24,904)
Dividend attributable to down round feature of warrants	-	-	(303)	(359)
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	$ (7,057)	$ (7,935)	$ (30,878)	$ (25,263)
Net loss per share				
Basic	$ (0.09)	$ (0.33)	$ (0.58)	$ (1.15)
Diluted	$ (0.09)	$ (0.33)	$ (0.58)	$ (1.15)
Weighted average common shares outstanding				
Basic	76,321,644	23,923,196	53,548,902	22,039,386
Diluted	76,321,644	23,923,196	53,548,902	22,039,386

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net loss	$ (7,057)	$ (7,935)	$ (20,804)	$ (24,904)
Other comprehensive income (loss):				
Foreign currency translation adjustments	(208)	5	(163)	25
Comprehensive loss	$ (7,265)	$ (7,930)	$ (20,967)	$ (24,879)

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Three and Nine Months Ended September 30, 2019

(In thousands, except share amounts)

(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at June 30, 2019	22,949,064	$ 23	$ 189,831	$ 322	$ (179,237)	$ 10,939
Issuance of common stock through ATM sales	344,384	-	617			617
To record ATM issuance costs in additional paid-in-capital	-	-	(4)	-	-	(4)
Issuance of common stock in connection with July 2019 Lincoln Park Captial Commitment Purchase Agreement	330,000	-	-	-	-	-
Issuance of common stock in connection with July 2019 Lincoln Park Captial Registered Offering Purchase Agreement, net of issuance costs of $10	571,429	1	989	-	-	990
Foreign currency translation adjustment	-	-	-	5	-	5
Stock-based compensation	-	-	950	-	-	950
Net loss	-	-	-	-	(7,935)	(7,935)
Balances at September 30, 2019	24,194,877	$ 24	$ 192,383	$ 327	$ (187,172)	$ 5,562

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2018	14,703,159	$ 15	$ 162,393	$ 302	$ (153,535)	$ 9,175
Issuance of common stock in connection with February 2019 Public Offering, net of issuance costs of $1,102	7,557,142	7	12,115	-	-	12,122
Issuance of common stock through ATM sales	1,033,147	1	1,922			1,923
To record ATM issuance costs in additional paid-in-capital	-	-	(13)	-	-	(13)
Issuance of common stock in connection with July 2019 Lincoln Park Captial Commitment Purchase Agreement	330,000	-	-	-	-	-
Issuance of common stock in connection with July 2019 Lincoln Park Captial Registered Offering Purchase Agreement, net of issuance costs of $10	571,429	1	989	-	-	990
Reclassification of 2017 warrants from liability to equity	-	-	11,822	-	(8,374)	3,448
Dividend attributable to the down round feature of 2017 Warrants	-	-	359	-	(359)	-
Foreign currency translation adjustment	-	-	-	25	-	25
Stock-based compensation	-	-	2,796	-	-	2,796
Net loss	-	-	-	-	(24,904)	(24,904)
Balances at September 30, 2019	24,194,877	$ 24	$ 192,383	$ 327	$ (187,172)	$ 5,562

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY
For the Three and Nine Months Ended September 30, 2020

(In thousands, except share amounts)

(Unaudited)

	Series A Convertible Preferred Stock,		Series B Convertible Preferred Stock,		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at June 30, 2020	-	$ -	-	$ -	59,657,742	$ 60	$ 268,770	$ 121	$ (209,218)	$ 59,733
Foreign currency translation adjustment	-	-	-	-	-	-	-	(208)	-	(208)
Stock-based compensation	-	-	-	-	-	-	670	-	-	670
Net loss	-	-	-	-	-	-	-	-	(7,057)	(7,057)
Balances at September 30, 2020	-	$ -	-	$ -	59,657,742	$ 60	$ 269,440	$ (87)	$ (216,275)	$ 53,138

	Series A Convertible Preferred Stock,		Series B Convertible Preferred Stock,		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2019	-	$ -	-	$ -	24,194,877	$ 24	$ 193,319	$ 76	$ (195,168)	$ (1,749)
Issuance of Series A & B Convertible Preferred Stock, net of underwriting discounts	1,421,801	14,062	1,137,442	11,260	-	-	-	-	-	-
Series A & B Convertible Preferred Stock discount - benefical 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 in connection with June 2020 Public Offering, net of issuance costs of $3,472					23,625,000	24	48,252	-	-	48,276
Issuance of common stock upon exercise of stock options	-	-	-	-	32,778	-	51	-	-	51
Issuance of common stock upon exercise of warrants	-	-	-	-	273,954	-	348	-	-	348
Dividend attributable to the down round feature of 2017 Warrants	-	-	-	-	-	-	303	-	(303)	-
Foreign currency translation adjustment	-	-	-	-	-	-	-	(163)	-	(163)
Stock-based compensation	-	-	-	-	-	-	1,857	-	-	1,857
Net loss	-	-	-	-	-	-	-	-	(20,804)	(20,804)
Balances at September 30, 2020	-	$ -	-	$ -	59,657,742	$ 60	$ 269,440	$ (87)	$ (216,275)	$ 53,138

See notes to condensed consolidated financial statements

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (20,804)	$ (24,904)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	26	37
Amortization of contract asset	101	-
Amortization on right-of-use asset	406	541
Stock-based compensation expense	1,857	2,796
Foreign currency (gain) loss	(189)	-
Change in fair value of restricted stock liability	(94)	159
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	727	280
Research and development incentive receivable	(20)	(128)
Contract acquisition costs	(270)	-
Accounts payable and accrued expenses	(3,206)	717
Deferred revenue	1,875	-
Lease liability	(378)	(506)
Net cash used in operating activities	(19,969)	(21,008)
Cash flows from investing activities:		
Proceeds from the sale of property and equipment	25	-
Purchases of property and equipment	-	(100)
Net cash provided by (used) in investing activities	25	(100)
Cash flows from financing activities:		
Proceeds from issuance of common stock - June 2020 Public Offering	48,518	-
Proceeds from the issuance of Series A convertible preferred stock	14,986	-
Proceeds from the issuance of Series B convertible preferred stock	12,000	-
Proceeds from issuance of common stock	-	12,331
Proceeds from issuance of common stock from ATM sales	-	1,923
Proceeds from issuance of common stock in connection with July 2019 Lincoln Park Capital Registered Offering Purchase Agreement, net of issuance costs	-	999
Proceeds from the exercise of common stock warrants	348	-
Proceeds from the exercise of stock options	51	-
Payment of deferred offering costs	(1,906)	(417)
Net cash provided by financing activities	73,997	14,836
Effect of exchange rate changes on cash and cash equivalents	31	46
Net increase (decrease) in cash and cash equivalents	54,084	(6,226)
Cash and cash equivalents at beginning of period	3,891	16,284
Cash and cash equivalents at end of period	$ 57,975	$ 10,058
Supplemental disclosure of non-cash financing activities:		
Reclassification of 2017 Warrants from liability to equity	$ -	$ 3,448
Dividend attributable to down round feature of warrants	$ 303	$ 359
Offering costs included in accounts payable and accrued expenses - February 2019 Public Offering	$ -	$ 20
Right-of-use asset recorded upon adoption of ASU 2016-02	$ -	$ 1,720
Lease liability recorded upon adoption of ASU 2016-02	$ -	$ 1,720
Prepaid rent reclassified upon adoption of ASU 2016-02	$ -	$ 35
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.

Leap Therapeutics, Inc.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(In thousands, except share and per share amounts)

(Unaudited)

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 September 30, 2020 and for the three and nine months ended September 30, 2020 and 2019 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, 2019 included in the Company's Annual Report on Form 10-K filed with the SEC on March 16, 2020.

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 September 30, 2020, statements of operations and statements of comprehensive loss for the three and nine months ended September 30, 2020 and 2019 and statements of cash flows for the nine months ended September 30, 2020 and 2019. Such adjustments are of a normal and recurring nature. The results of operations for the three and nine months ended September 30, 2020 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2020.

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 within one year after the date that the condensed consolidated financial statements are issued. As of September 30, 2020, the Company had cash and cash equivalents of $57,975. Additionally, the Company had an accumulated deficit of $216,275 at September 30, 2020, and during the nine months ended September 30, 2020, the Company incurred a net loss of $20,804. The Company expects to continue to generate operating losses for the foreseeable future. The Company believes that its cash and cash equivalents of $57,975 as of September 30, 2020, 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. This estimate is also reviewed by external tax advisors on an annual basis.

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, 2019 and for the three and nine months ended September 30, 2020.

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 $209 and $185 as of September 30, 2020 and December 31, 2019, respectively, in the condensed consolidated balance sheets and other income from Australian research and development incentives of $228 for the three months ended September 30, 2020. During the three months ended September 30, 2019, the Australian research and development incentives recognized were offset by an adjustment to the prior year estimated Australian research and development incentives, resulting in a net expense for the period. During the three months ended September 30, 2020, the Company recorded an adjustment to increase Australian research and development incentive income by approximately $150 as the cash received from the Australian Government during the three months ended September 30, 2020 for 2019 eligible expenditures was higher than the prior year estimated Australian research and development incentives. During the nine months ended September 30, 2020 and 2019, the Company recorded $343 and $129, respectively, of other income from Australian research and development incentives.

The following table shows the change in the research and development incentive receivable from December 31, 2018 to September 30, 2020 (in thousands):

Balance at December 31, 2018	$ 836
Australian research and development incentive income, net	132
Cash received for 2018 eligible expenses	(757)
Foreign currency translation	(26)
Balance at December 31, 2019	185
Australian research and development incentive income, net	343
Cash received for 2019 eligible expenses	(331)
Foreign currency translation	12
Balance at September 30, 2020	$ 209

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 nine months ended September 30, 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 September 30, 2020 and December 31, 2019 there was $379 and $831, respectively, of deferred costs.

Deposits

As of September 30, 2020 and December 31, 2019, $941 and $1,099, respectively, 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

On January 1, 2019, the Company adopted ASU No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), and Derivatives and Hedging (Topic 815)* ("ASU 2017-11"), which changes the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. The amendments require entities that present earnings per share ("EPS") in accordance with Topic 260 to recognize the effect of the down round feature when triggered with the effect treated as a dividend and as a reduction of income available to common stockholders in basic EPS.

The Company concluded that the common stock warrants (the "2017 Warrants") issued in connection with the private placement of common stock completed in November 2017 (the "November 2017 Private Placement"), qualify for equity classification under ASU 2017-11. The adoption guidance of ASU 2017-11 provides for a modified retrospective adoption. The Company applied the guidance retrospectively to the 2017 Warrants by means of a cumulative-effect adjustment to its statement of financial position as of the beginning of the interim and annual period beginning January 1, 2019. The Company performed a final remeasurement of the warrant liability as of January 1, 2019 and reclassified $3,448 from warrant liability to equity.

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 public offering, completed in February 2019 (the "2019 Public Offering"), when the 2017 Warrants were repriced from $6.085 to $1.75 as a result of a down round, the Company recorded a dividend of $359 during the nine months ended September 30, 2019. 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 nine months ended September 30, 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 and nine months ended September 30, 2020 or the year ended December 31, 2019.

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
September 30, 2020				
Assets:				
Cash equivalents	$ 57,975	$ 57,975	$ -	$ -
Total assets	$ 57,975	$ 57,975	$ -	$ -
December 31, 2019				
Assets:				
Cash equivalents	$ 3,891	$ 3,891	$ -	$ -
Total assets	$ 3,891	$ 3,891	$ -	$ -

Cash equivalents of $57,975 and $3,891 as of September 30, 2020 and December 31, 2019, 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 value 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

In February 2016, the Financial Accounting Standards Board, or FASB, issued ASU 2016-02, *Leases,* or ASU 2016-02, to enhance the transparency and comparability of financial reporting related to leasing arrangements. The Company adopted ASU 2016-02 on January 1, 2019, or the effective date, and used the effective date as its date of initial application.

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 ASU 2016-02, 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 Accounting Standards Codification, or 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

From time to time, new accounting pronouncements are issued by the FASB, and are early adopted by the Company or adopted as of the specified effective date.

In November 2018, the FASB issued "ASU 2018-18, Clarifying the Interaction between Topic 808 and Topic 606." The objective of the standard is to clarify the interaction between ASC Topic 808--Collaborative Arrangements and ASC Topic 606--Revenue from Contracts with Customers. Currently, ASC Topic 808 does not provide comprehensive recognition or measurement guidance for collaborative arrangements, and the accounting for those arrangements is often based on an analogy to other accounting literature or an accounting policy election. Similarly, aspects of ASC Topic 606 have resulted in uncertainty in practice about the effect of the revenue standard on the accounting for collaborative arrangements. The standard became effective for us beginning on January 1, 2020 and the adoption of this ASU did not have a material impact on our financial condition, results of operations, cash flows, and financial statement disclosures.

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 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 the three and nine months ended September 30, 2020, the Company recognized $375 and $1,125, respectively, of license revenue related to the up-front fee received from BeiGene. The Company did not have any such license revenue during the three and nine months ended September 30, 2019.

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 and nine months ended September 30, 2020 was $34 and $101, respectively, and the closing balance recorded in deferred costs as of September 30, 2020 was $169.

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 and nine months ended September 30, 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, during the nine months ended September 30, 2020 (in thousands):

	Balance at January 1, 2020	Additions	Deductions	Balance at September 30, 2020
Contract liabilities				
Deferred revenue - current	$ -	$ 1,500	$ -	$ 1,500
Deferred revenue - non current	-	1,500	(1,125)	375
Total contract liabilities	$ -	$ 3,000	$ (1,125)	$ 1,875

4. Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2020	December 31, 2019
Clinical trials	$ 1,049	$ 1,828
Professional fees	191	609
Payroll and related expenses	1,030	1,004
Accrued expenses	$ 2,270	$ 3,441

5. Leases

In February 2016, the FASB issued ASU 2016-02, Leases, or ASU 2016-02. ASU 2016-02 requires a lessee to recognize on its balance sheet (for both finance and operating leases) a liability to make lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term. The Company adopted ASU 2016-02 on January 1, 2019, on the effective date, and used the effective date as its date of initial application. As such, the Company did not adjust prior period amounts. The Company also elected to adopt the practical expedients upon transition, which permit companies to not reassess lease identification, classification, and initial direct costs under ASU 2016-02 for leases that commenced prior to the effective date.

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. On January 1, 2019, the Company recorded a right-of-use asset of $1,720 and a lease liability of $1,720 on its consolidated balance sheets and reclassified prepaid rent to the right-of-use asset of $35. As of September 30, 2020, a right-of-use asset of $620 and lease liability of $648 are reflected on the condensed consolidated balance sheets. The Company recorded rent expense of $105 and $211, respectively, during the three months ended September 30, 2020 and 2019 and $445 and $629, respectively, for the nine months ended September 30, 2020.

Future lease payments under non-cancelable operating leases as of September 30, 2020 are detailed as follows:

Future Operating Lease Payments

2020	$	107
2021		434
2022		146
Total Lease Payments		**687**
Less: imputed interest		(39)
Total operating lease liabilities	**$**	**648**

6. Warrants

As of September 30, 2020, outstanding warrants to purchase common stock, all of which are classified as equity warrants, consisted of the following:

September 30, 2020		
Date Exercisable	Number of Shares Issuable	Exercise Price
1/23/2017	54,516	$ 0.01
11/14/2017	2,549,840	$ 1.055
2/5/2019	7,491,442	$ 1.95
3/5/2020	14,413,902	$ 0.001
3/5/2020	25,945,035	$ 2.11
6/22/2020	2,250,000	$ 0.001
	52,704,735	

2017 Warrants

The 2017 Warrants contain full ratchet anti-dilution protection provisions. Prior to January 1, 2019, the Company classified the 2017 Warrants as a liability on its consolidated balance sheet because each warrant represented a freestanding financial instrument that, due to the potential variable nature of the exercise price, is not considered to be indexed to the Company's own shares. The warrant liability was initially recorded at fair value upon entering into the November 2017 Private Placement and has been subsequently remeasured to fair value at each reporting date. Changes in the fair value of the warrant liability were recognized as gains (losses) in the Company's consolidated statement of operations.

On January 1, 2019, the Company adopted ASU 2017-11 and concluded that the 2017 Warrants now qualify for equity classification. The Company applied the guidance retrospectively to the 2017 Warrants by means of a cumulative-effect adjustment to its statement of financial position as of the beginning of the interim and annual period beginning January 1, 2019. The Company performed a final remeasurement of the warrant liability as of January 1, 2019 and reclassified $3,448 to additional paid in capital.

The Company will recognize on a prospective basis the value of the effect of the down round feature in the warrant 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 2019 Public Offering, when the 2017 Warrants were repriced from $6.085 to $1.75, the Company recorded a dividend of $359 during the nine months ended September 30, 2019. 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 nine months ended September 30, 2020.

During the nine months ended September 30, 2020, 208,254 of 2017 Warrants were exercised for cash resulting in gross proceeds to the Company of $220.

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.

During the nine months ended September 30, 2020, 65,700 of 2019 Warrants were exercised for cash resulting in gross proceeds to the Company of $128.

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 September 30, 2020, no dividends have been declared for shares of common stock.

Public Offering of Common Stock — February 2019

On February 5, 2019, the Company completed the 2019 Public Offering whereby the Company issued 7,557,142 shares of its common stock at a price of $1.75 per share, which included 985,714 shares issued pursuant to the underwriters' exercise of their option to purchase additional shares of common stock, each share was issued with a warrant to purchase one share of common stock. Each warrant has an exercise price of $1.95 per share with an exercise period expiring seven years from the date of issuance. The aggregate net proceeds received by the Company from the 2019 Public Offering were approximately $12,122, net of underwriting discounts and commissions and estimated offering expenses payable by the Company.

Issuance of Common Stock under Distribution Agreement

On September 7, 2018, the Company filed a Prospectus Supplement to register the offer and sale of shares of common stock having an aggregate offering price of up to $30,000 pursuant to the terms of a distribution agreement, or the Distribution Agreement, with Raymond James & Associates, Inc. During the year ended December 31, 2019, the Company issued 1,033,147 shares under the Distribution Agreement, for net proceeds of $1,923. In June 2020, the Company terminated the Distribution Agreement and did not issue any shares under the Distribution Agreement during the nine months ended September 30, 2020.

Lincoln Park Purchase Agreements

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. 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 and nine months ended September 30, 2020, the Company did not issue any shares under the Commitment Purchase Agreement.

On July 11, 2019, the Company entered into a Registered Offering Purchase Agreement, under which the Company agreed to sell to Lincoln Park, and Lincoln Park agreed to purchase 571,429 shares of common stock, at a price of $1.75 per share for an aggregate purchase price of $1,000, pursuant to the Company's effective shelf Registration Statement on Form S-3, including the prospectus supplement thereto dated July 11, 2019.

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 nine months ended September 30, 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 (the "Plan"), 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. In 2019, the board of directors and the stockholders approved and authorized an additional 3,000,000 shares of common stock to be added to the shares authorized for issuance under the 2016 Plan.

As of September 30, 2020, there were 455,144 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, 2019	4,024,566	$ 7.48	7.98	$ 2
Granted	2,547,500	$ 2.12		
Exercised	(32,778)	$ 1.53		
Forfeited	(260,435)	$ 6.95		
Outstanding at September 30, 2020	6,278,853	$ 5.35	8.18	$ 1,082
Options exercisable at September 30, 2020	3,113,663	$ 8.45	7.12	$ 359
Options vested and expected to vest at September 30, 2020	6,278,853	$ 5.35	8.18	$ 1,082

The grant date fair value of the options granted during the year ended December 31, 2019 and the nine months ended September 30, 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 assumptions that the Company used to determine the grant-date fair value of stock options granted to employees and directors during the year ended December 31, 2019 and the nine months ended September 30, 2020 were as follows, presented on a weighted average basis:

	Nine Months Ended September 30, 2020	Year Ended December 31, 2019
Expected volatility	66.94%	66.94%
Weighted average risk-free interest rate	0.66%	2.07%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	6.85	6.77

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 September 30, 2020, there was approximately $4,453 of unrecognized compensation cost related to non-vested stock options, which is expected to be recognized over a remaining weighted-average period of approximately 2.21 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development	$ 282	$ 181	$ 720	$ 536
General and administrative	309	769	967	2,260
Total	$ 591	$ 950	$ 1,687	$ 2,796

Restricted Stock Units

During the nine months ended September 30, 2020 and 2019, the Company issued 92,500 and 181,000 restricted stock units ("RSUs"), respectively, 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 each of October 2019 and January 2020, the Company cash settled 90,500 RSUs. As of September 30, 2020 and December 31, 2019, these RSUs are classified as restricted stock liability in the condensed consolidated balance sheets of $66 and $159, respectively, as they contain a cash settlement option.

During the nine months ended September 30, 2020, the Company granted 660,606 RSUs to an executive officer 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 nine months ended September 30, 2020, the Company recognized $170 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 September 30, 2020:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2019	90,500	$ 1.74
Awarded	753,106	$ 1.49
Settled in cash	(90,500)	$ 1.74
Outstanding at June 30, 2020	753,106	$ 1.49

As of September 30, 2020, there were 753,106 shares outstanding covered by RSUs that are expected to vest. The weighted average grant date fair value of these shares of restricted stock was $1.49 per share and the aggregate grant date fair value of these shares of restricted stock was approximately $1,112. As of September 30, 2020, there was approximately $884 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 2.17 years.

9. Net Loss Per Share

Basic and diluted net loss per share for the three and nine months ended September 30, 2020 and 2019 was calculated as follows (in thousands except share and per share amounts).

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Numerator:				
Net loss	$ (7,057)	$ (7,935)	$ (20,804)	$ (24,904)
Dividend attributable to down round feature of warrants	-	-	(303)	(359)
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	$ (7,057)	$ (7,935)	$ (30,878)	$ (25,263)
Denominator:				
Weighted average number of common shares outstanding - basic and diluted	76,321,644	23,923,196	53,548,902	22,039,386
Net loss per share attributable to common stockholders - basic and diluted	$ (0.09)	$ (0.33)	$ (0.58)	$ (1.15)

Included within weighted average common shares outstanding are 16,663,902 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 and nine months ended September 30, 2020 and 2019, 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Restricted stock units to purchase common stock	753,106	-	753,106	-
Options to purchase common stock	6,278,853	4,019,566	6,278,853	4,019,566
Warrants to purchase common stock	36,040,833	10,369,752	36,040,833	10,369,752
	43,072,792	14,389,318	43,072,792	14,389,318

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 September 30, 2020, there were $381 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 September 30, 2020.

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 September 30, 2020.

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. 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 September 30, 2020 or December 31, 2019.

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, 2019, which was filed with the Securities and Exchange Commission, or the SEC, on March 16, 2020. 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 two clinical stage programs are:

- *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 profilerate 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. In January 2020, 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.

- *TRX518:* A monoclonal antibody targeting the glucocorticoid-induced tumor necrosis factor-related receptor, or GITR. GITR is a receptor found on the surface of a wide range of immune cells. GITR stimulation activates tumor fighting white blood cells and decreases the activity of potentially tumor-protective immunosuppressive cells. TRX518 has been specifically engineered to enhance the immune system's anti-tumor response by activating GITR signaling without causing the immune cells to be destroyed. We conducted clinical trials of TRX518 in patients with advanced solid tumors in combination with gemcitabine chemotherapy or with cancer immunotherapies known as PD-1 antagonists. In November 2019, we announced that we have deprioritized continued development of TRX518.

Recent Developments

Since June 30, 2020, we have continued to make progress with the clinical development and regulatory strategy of DKN-01:

- **First Patient Dosed in the DisTinGuish Study of DKN-01 plus Tislelizumab**: We announced that the first patient had been dosed in our study evaluating DKN-01 plus BeiGene's anti-PD-1 antibody, tislelizumab. The DisTinGuish study is a Phase 2a clinical trial evaluating DKN-01 in combination with tislelizumab, BeiGene's anti-PD-1 antibody, with or without chemotherapy, in patients with gastric or gastroesophageal junction cancer (G/GEJ). The study, which will be conducted in two parts, is expected to enroll up to 72 patients. Part A will enroll up to 24 patients with G/GEJ adenocarcinoma who have received no prior systemic treatment in the locally advanced/metastatic setting (first-line treatment), and Part B will enroll up to 48 patients with previously treated, inoperable, locally advanced or metastatic DKK1-high G/GEJ adenocarcinoma (second-line treatment). The study is designed to evaluate safety, tolerability, and efficacy of the combination therapy of intravenous DKN-01 and tislelizumab ± CAPOX (capecitabine + oxaliplatin) in G/GEJ adenocarcinoma patients. Treatment will be conducted in repeating 21-day cycles until the patient meets pre-established criteria for discontinuation or is no longer deriving clinical benefit. Part A and Part B of the study will be conducted concurrently.

- **DKN-01 Receives Fast Track Designation**: We announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to DKN-01 in combination with tislelizumab for the treatment of patients with gastric and gastroesophageal junction (G/GEJ) adenocarcinoma whose tumors express high Dickkopf-1 protein (DKK1), following disease progression on or after prior fluoropyrimidine- and platinum- containing chemotherapy and if appropriate, human epidermal receptor growth factor (HER2)/neu-targeted therapy. The Fast Track program is intended to facilitate the development and expedite the review of drug candidates and vaccines that treat serious conditions and fill an unmet medical need. The purpose of Fast Track is to get important new drugs to the patient earlier. Programs with Fast Track designation may benefit from early and frequent communication with the FDA, in addition to a rolling submission of the marketing application. DKN-01 has also received Orphan Drug Designation for the treatment of gastric and gastroesophageal junction cancer from the FDA.

- **Presented Updated Data for DKN-01 in Esophagogastric Cancer Demonstrating Positive Outcomes in DKK1-high Patients**: At the Society for Immunotherapy of Cancer's 35th Anniversary Annual Meeting, we presented clinical data from the Phase 1b/2a clinical trial of DKN-01 in patients with advanced esophagogastric cancer (EGC). In the study, high levels of tumoral DKK1 expression correlated with improved clinical outcomes in heterogeneous EGC patients treated with DKN-01 monotherapy or in combination with paclitaxel or the anti-PD-1 antibody, pembrolizumab. Important patient subgroups in this study demonstrated consistent benefit in DKK1-high patients, including:

- ***Anti-PD-1/PD-L1 refractory patients (all)***: The four DKK1-high patients had a significantly longer median progression-free survival (PFS) of 12.8 weeks and median overall survival (OS) of 46 weeks as compared to the five DKK1-low patients who experienced PFS of 6 weeks and OS of 16 weeks.
- ***Anti-PD1/PD-L1 refractory GEJ/GC patients***: The three DKK1-high patients had a best response of stable disease (SD) and a longer PFS of 13.4 weeks and OS of 37.4 weeks, as compared to the two DKK1-low patients who both had progressive disease (PD) with a PFS of 3.6 weeks and OS of 11.7 weeks.
- ***Anti-PD-1/PD-L1 naïve GEJ/GC patients***: As previously reported, DKK1-high patients experienced over 22 weeks PFS and nearly 32 weeks OS, with a 50% overall response rate (ORR) and 80% disease control rate (DCR) in ten evaluable patients. DKK1-low patients experienced nearly 6 weeks PFS and over 17 weeks OS, with a 20% DCR in fifteen evaluable patients. PD-L1 Combined Positive Scores (CPS) did not predict efficacy on the combination of DKN-01 plus pembrolizumab. In multi-variate analysis, DKK1-high status correlated with longer PFS independent of PD-L1 CPS scores.

· **Presented Updated Data for DKN-01 in Endometrial Cancer demonstrating Single Agent Activity in Biomarker-selected Patients**: At the American Association for Cancer Research Virtual Meeting on Endometrial Cancer, we presented additional clinical data from the epithelial endometrial cancer (EEC) patients treated with DKN-01 monotherapy as part of our ongoing Phase 2 clinical trial of DKN-01, as both a monotherapy and in combination with paclitaxel chemotherapy, in patients with advanced gynecological malignancies. Twenty-nine EEC patients were enrolled in the DKN-01 monotherapy arm, over 75% of whom had experienced three or more prior lines of therapy. Of those patients, 26 were evaluable for response. Three important biomarker-selected subgroups were the focus of the data presentation:

- ***Patients with Wnt Signaling Alterations*:** Patients with a Wnt signaling alteration had a higher response rate, greater clinical benefit, and longer PFS and OS compared to patients without a Wnt signaling alteration. In the group of 20 patients with a Wnt signaling alteration, one patient (5%) has an ongoing complete response, one patient (5%) had a partial response, eight patients (40%) had a best response of stable disease, and 10 patients (50%) had progressive disease, representing an ORR of 10% and a DCR of 50%. In the group of six patients without any Wnt signaling alterations, one patient (16.6%) had a best response of SD and five patients (83.3%) had PD. The patients with a Wnt signaling alteration experienced PFS of 1.9 months and OS of 15.1 months, compared to the patients without a Wnt signaling alteration who experienced PFS of 1.8 months and OS of 8.4 months.
- ***Patients with Wnt Activating Mutations:*** Patients with Wnt activating mutations had longer PFS and OS than patients without Wnt activating mutations. The nine patients with a Wnt activating mutation experienced PFS of 5.5 months and had not reached a median OS, compared to the 20 patients without a Wnt activating mutation who experienced PFS of 1.8 months and OS of 12.2 months.
- ***Patients expressing high tumor levels of DKK1***: DKK1 expression data was available for 19 EEC patients treated with DKN-01 monotherapy. DKK1-high patients had a higher response rate, greater clinical benefit, and longer PFS than patients who were DKK1-low. In the group of seven patients with DKK1-high tumors, one patient (14.3%) had a partial response, three patients (42.9%) had SD, and 3 patients (42.9%) had PD, representing an ORR of 14.3% and a DCR of 57.1%. In the group of 12 patients with DKK1-low tumors, one patient (8.3%) had SD and 11 patients (91.7%) had PD. The DKK1-high patients experienced PFS of 3.0 months, compared to the DKK1-low patients who experienced PFS of 1.8 months.

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 our license 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 our license 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 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 and nine months ended September 30, 2020 and 2019:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(in thousands)		(in thousands)	
Direct research and development by program:				
DKN-01 program	$ 5,275	$ 3,806	$ 13,273	$ 12,428
TRX518 program	94	1,966	2,049	6,270
Total research and development expenses	$ 5,369	$ 5,772	$ 15,322	$ 18,698
Australian research and development incentives	$ 228	$ (7)	$ 343	$ 129

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.

On January 1, 2019, we adopted ASU No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), and Derivatives and Hedging (Topic 815)* ("ASU 2017-11"), which changes the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features, and Topic 842, Leases, ("ASU 2016-02), which requires lessees to recognize leases on the balance sheet and disclose key information about leasing arrangements.

Revenue Recognition

Effective January 1, 2018, we adopted 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 16, 2020 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 September 30, 2020 and 2019

The following table summarizes our results of operations for the three months ended September 30, 2020 and 2019:

	Three Months Ended September 30,		
	2020	2019	Change
	(in thousands)		
License revenue	$ 375	$ -	$ 375
Operating expenses:			
Research and development	5,369	5,772	(403)
General and administrative	2,514	2,151	363
Total operating expenses	7,883	7,923	(40)
Loss from operations	(7,508)	(7,923)	415
Interest income	3	80	(77)
Interest expense	(17)	(5)	(12)
Australian research and development incentives	228	(7)	235
Foreign currency gains (loss)	237	(80)	317
Net loss	$ (7,057)	$ (7,935)	$ 878

Revenues

License revenues for the three months ended September 30, 2020 were $0.4 million 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. As the BeiGene Agreement is the first such license agreement, no license revenues were recorded during the three months ended September 30, 2019.

Research and Development Expenses

	Three Months Ended September 30,		
	2020	2019	Increase (Decrease)
	(in thousands)		
Direct research and development by program:			
DKN-01 program	$ 5,275	$ 3,806	$ 1,469
TRX518 program	94	1,966	(1,872)
Total research and development expenses	$ 5,369	$ 5,772	$ (403)

Research and development expenses were $5.4 million for the three months ended September 30, 2020, compared to $5.8 million for the three months ended September 30, 2019. The decrease of $0.4 million in research and development expenses was primarily due to a decrease of $0.7 million in clinical trial costs due to deprioritizing the continued development of TRX518 in November 2019 and timing of patient enrollment, partially offset by an increase of $0.3 million in payroll and other related expenses due to an increase in headcount of our research and development full time employees.

General and Administrative Expenses

General and administrative expenses were $2.5 million for the three months ended September 30, 2020, compared to $2.2 million for the three months ended September 30, 2019. The increase of $0.3 million in general and administrative expenses was due to a $0.5 million increase in professional fees primarily due to increased recruiting and information technology costs and a $0.2 million increase in payroll and other related expenses during the three months ended September 30, 2020 as compared to the same period in 2019. These increases were partially offset by a decrease of $0.4 million in stock based compensation expense, primarily due to stock option grants made to our executive officers during the three months ended March 31, 2017 which fully vested in January 2020.

Interest Income

We recorded interest income of $0.1 million in the three months ended September 30, 2019. During the three months ended September 30, 2020, we recorded an immaterial amount of interest income.

Australian Research and Development Incentives

We recorded R&D incentive income of $0.2 million during the three months ended September 30, 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. During the three months ended September 30, 2019, the Australian research and development incentives recognized were offset by an adjustment to the prior year estimated Australian research and development incentives, resulting in a net expense for the period.

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 September 30, 2020 and 2019, we recorded foreign currency gains (losses) of $0.2 million and ($0.1) million, respectively. Foreign currency gains and losses are due to changes in the Australian dollar exchange rate related to activities of the Australian entity.

Comparison of the Nine Months Ended September 30, 2020 and 2019

The following table summarizes our results of operations for the nine months ended September 30, 2020 and 2019:

	Nine Months Ended September 30,		
	2020	**2019**	**Change**
	(in thousands)		
License revenue	$ 1,125	$ -	$ 1,125
Operating expenses:			
Research and development	15,322	18,698	(3,376)
General and administrative	7,188	6,481	707
Total operating expenses	22,510	25,179	(2,669)
Loss from operations	(21,385)	(25,179)	3,794
Interest income	91	281	(190)
Interest expense	(42)	(21)	(21)
Australian research and development incentives	343	129	214
Foreign currency loss	189	(114)	303
Net loss	$ (20,804)	$ (24,904)	$ 4,100

Revenues

License revenues for the nine months ended September 30, 2020 were $1.1 million 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. As the BeiGene Agreement is the first such license agreement, no license revenues were recorded during the nine months ended September 30, 2019.

Research and development expenses

	Nine Months Ended September 30,		Increase
	2020	2019	(Decrease)
	(in thousands)		
Direct research and development by program:			
DKN-01 program	$ 13,273	$ 12,428	$ 845
TRX518 program	2,049	6,270	(4,221)
Total research and development expenses	$ 15,322	$ 18,698	$ (3,376)

Research and development expenses were $15.3 million for the nine months ended September 30, 2020, compared to $18.7 million for the nine months ended September 30, 2019. The decrease of $3.4 million in research and development expenses was primarily due to a decrease of $3.6 million in clinical trial costs due to deprioritizing the continued development of TRX518 in November 2019 and timing of patient enrollment, a $0.2 million decrease in consulting fees associated with research and development activities, and a $0.2 million decrease in rent expense due to the closing of our research laboratory in April of 2020. These decreases were partially offset by an increase of $0.6 million in payroll and other related expenses due to an increase in headcount of our research and development full time employees.

General and Administrative Expenses

General and administrative expenses were $7.2 million for the nine months ended September 30, 2020, compared to $6.5 million for the nine months ended September 30, 2019. The increase of $0.7 million in general and administrative expenses was due to a $0.9 million increase in professional fees primarily due to increased recruiting and information technology costs, a $0.8 million increase in payroll and other related expenses due to an increase in compensation expense during the nine months ended September 30, 2020 as compared to the same period in 2019 and a $0.2 million increase in insurance expense. These increases were partially offset by a decrease of $1.2 million in stock based compensation expense, primarily due to stock option grants made to our executive officers during the three months ended March 31, 2017 which fully vested in January 2020.

Interest Income

We recorded interest income of $0.1 million and $0.3 million, respectively, during the nine months ended September 30, 2020 and 2019.

Australian Research and Development Incentives

We recorded R&D incentive income of $0.3 million and $0.1 million, respectively, in each of the nine months ended September 30, 2020 and 2019, 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 Loss

During the nine months ended September 30, 2020 and 2019, we recorded an immaterial amount of foreign currency losses. Foreign currency 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 Accounting Standards Codification ("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 September 30, 2020, we had cash and cash equivalents of $58.0 million. Additionally, we had an accumulated deficit of $216 million at September 30, 2020, and during the nine months ended September 30, 2020, we incurred a net loss of $20.1 million. We expect to continue to generate operating losses in the foreseeable future. We believe that our cash and cash equivalents of $58.0 million as of September 30, 2020 will be sufficient to fund our operating expenses for at least the next 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:

	Nine Months Ended September 30,	
	2020	**2019**
	(in thousands)	
Cash used in operating activities	$ (19,969)	$ (21,008)
Cash provided by (used) in investing activities	25	(100)
Cash provided by financing activities	73,997	14,836
Effect of exchange rate changes on cash and cash equivalents	31	46
Net increase (decrease) in cash and cash equivalents	$ 54,084	$ (6,226)

Operating activities. Net cash used in operating activities for the nine months ended September 30, 2020 was primarily related to our net loss from the operation of our business of $20.8 million and net changes in working capital, including a decrease in accounts payable and accrued expenses of $3.2 million, an increase in contract acquisition costs of $0.3 million and a decrease in lease liabilities of $0.4 million. There was also a noncash change of $0.2 million due to foreign currency gains and a $0.1 million decrease related to a noncash change in restricted stock liability. These changes were partially offset by a decrease of $0.7 million in prepaid expenses and other assets, an increase of $1.9 million in deferred revenue, noncash stock based compensation expense of $1.9 million, noncash lease expense of $0.4 million and amortization of contract asset of $0.1 million.

Net cash used in operating activities for the nine months ended September 30, 2019 was primarily related to our net loss from the operation of our business of $24.9 million and net changes in working capital, including a decrease in lease liabilities of $0.5 million due to rent payments and an increase in research and development receivable of $0.1 million. These changes were partially offset by an increase in accounts payable and accrued expenses of $0.7 million, a decrease of $0.3 million in prepaid expenses and other assets, noncash stock based compensation expense of $2.8 million, noncash lease expense of $0.5 million and change in restricted stock liability of $0.2 million.

Investing Activities. Net cash provided by investing activities during the nine months ended September 30, 2020 was related to proceeds from the sale of equipment. Net cash used in investing activities during the nine months ended September 30, 2019 was related to purchases of equipment.

Financing Activities. Net cash provided by financing activities for the nine months ended September 30, 2020 consisted of $48.5 million in proceeds from the issuance of common stock in connection with the 2020 Public Offering, $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 $0.4 million in proceeds from the issuance of common stock upon the exercise of stock options and warrants. These increases were partially offset by payments of $1.9 million for offering costs.

Net cash provided by financing activities for the nine months ended September 30, 2019 consisted of $12.3 million in proceeds from the issuance of common stock in connection with the 2019 Public Offering, net of underwriter commissions and discounts, $1.9 million in proceeds from the issuance of common stock under our Distribution Agreement with Raymond James & Associates, Inc. and $1.0 million in proceeds from the issuance of common stock under the Distribution Agreement with Lincoln Park Capital. These increases were partially offset by payments of $0.4 million for deferred offering 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 September 30, 2020, 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 September 30, 2020, 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 nine months ended September 30, 2020, 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, 2019 as filed with the SEC on March 16, 2020, 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.

The information presented below updates, and should be read in conjunction with, the risk factors and information disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019 as filed with the SEC on March 16, 2020. Except as presented below, 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, 2019.

The ongoing outbreak of the Coronavirus could have a material adverse impact on our business and operations, including on our development of our lead product candidate, DKN-01.

As a result of the continuing novel Coronavirus outbreak, or COVID-19, we may experience disruptions that could severely affect our business, including our plans to clinically develop DKN-01, our lead product candidate. For example, our employees are all currently working remotely from our office and unable to work and collaborate physically in person. In addition, widespread business interruptions resulting from the novel Coronavirus may adversely affect our ability to initiate, conduct, and complete critical clinical trials and laboratory operations relating to DKN-01. Specifically, temporary closures or prioritization of COVID-19 related work at certain laboratories, offices, or hospitals at which our nonclinical studies and clinical trials for DKN-01 are conducted, or restrictions on the ability of our employees, clinicians, patients enrolled in our trials, or patients who we would like to recruit to enroll in our trials to travel to or enter into certain facilities due to COVID-19 could adversely affect our operations and our ability to conduct nonclinical studies and clinical trials for DKN-01. Further, governmental health protocols and mandates have restricted the ability of many businesses to operate normally. These measures may have a material adverse impact on the third parties with whom we collaborate, including our clinical trial sites, contract research organizations, contract manufacturing organizations, laboratory service providers, or BeiGene, Ltd., and on their ability to devote sufficient time and resources to us. This could negatively affect our ability to advance DKN-01 and cause delays and increased expenses in our projected development timelines and cost.

We are continuing to monitor and assess the real and potential effects of the COVID-19 pandemic on our business, including with respect to our development of DKN-01. However, the ultimate extent to which the novel Coronavirus impacts our business will depend upon future developments which are highly uncertain and cannot be accurately predicted at this time, such as the ultimate geographic spread of the virus, the severity of the disease, the duration of the current outbreak or subsequent outbreaks, travel restrictions, actions to contain the outbreak or mitigate its impact, and the effectiveness of other actions taken in the United States and other countries to treat the disease.

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

10.1*	Employment Agreement, by and between the Company and Christine Granfield, dated as of August 16, 2020.
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 September 30, 2020, formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets at September 30, 2020 and December 31, 2019, (ii) Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2020 and 2019 , (iii) Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2020 and 2019, (iv) Condensed Consolidated Statements of Stockholders' Equity for the three and nine months ended September 30, 2020 and 2019, (v) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2020 and 2019, 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: November 12, 2020

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 10.1

EXECUTIVE EMPLOYMENT AGREEMENT

This Executive Employment Agreement ("***Agreement***") is made and entered into as of this 16th day of August, 2020 (the "**Effective Date**"), by and between Leap Therapeutics, Inc., a Delaware corporation (the "***Company***"), and Christine Granfield (hereinafter, the "***Executive***").

WITNESSETH:

WHEREAS, the Company desires to employ the Executive as the Vice President, Head of Regulatory Affairs and Quality of the Company effective as of August 16, 2020, and the Executive desires to be employed by the Company as the Vice President, Head of Regulatory Affairs and Quality of the Company effective as of the Effective Date, on the terms herein described.

NOW, THEREFORE, in consideration of the premises and mutual covenants set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are mutually acknowledged, the Company and the Executive hereby agree as follows:

1. ***Definitions***. When used in this Agreement, the following terms shall have the following meanings:

(a) "***Accrued Obligations***" means:

(i) all accrued but unpaid Base Salary through the end of the Term of Employment;

(ii) any unpaid or unreimbursed expenses incurred in accordance with Company policy, including amounts due under Section 5(a) hereof, to the extent incurred during the Term of Employment;

(iii) any accrued but unpaid benefits provided under the Company's employee benefit plans, subject to and in accordance with the terms of those plans;

(iv) any earned and unpaid Bonus in respect to any completed fiscal year that has ended on or prior to the end of the Term of Employment;

(v) any accrued but unpaid rights to indemnification by virtue of the Executive's position as an officer or director of the Company or its subsidiaries and the benefits under any directors' and officers' liability insurance policy maintained by the Company, in accordance with its terms thereof; and

(vi) any accrued but unused vacation pay.

(b) "***Base Salary***" means the salary amount provided for in Section 4(a) hereof or any increase thereto as salary granted to Executive pursuant to Section 4(a) hereof.

(c) "***Beneficial Ownership***" shall have the meaning ascribed to such term in Rule 13d-3 promulgated under the Exchange Act.

(d) "***Board***" means the Board of Directors of the Company.

(e) "***Bonus***" means any bonus earned and payable to the Executive pursuant to Section 4(b) hereof.

(f) "***Cause***" means the occurrence of any of the following: (i) a conviction of the Executive, or a plea of nolo contendere, to a felony (other than a felony related to the operation of a motor vehicle); or (ii) willful misconduct or gross negligence by the Executive resulting, in either case, in material harm to the Company or any Related Entities; or (iii) a willful failure by the Executive to carry out the reasonable and lawful directions of the President and Chief Executive Officer and failure by the Executive to remedy such willful failure within thirty (30) days after receipt of written notice of same from the President and Chief Executive Officer; or (iv) fraud, embezzlement, theft or dishonesty of a material nature by the Executive, or a willful material violation by the Executive of a written policy or procedure of the Company or any Related Entity, resulting, in any case, in material harm to the Company or any Related Entity; (v) the exclusion, suspension or debarment of Executive from participation in a federal health care program or before the United States Food and Drug Administration or other similar regulatory authority or the existence of any pending debarment or similar proceedings against Executive; or (vi) a material breach by the Executive of this Agreement, and failure by the Executive to remedy the material breach within thirty (30) days after receipt of written notice of same, by the President and Chief Executive Officer. For clarity, the inability of Executive to perform any or all of her duties, responsibilities or obligations under this Agreement on account of Executive's death or disability shall not be deemed or treated as a material breach of this Agreement by the Executive and shall not constitute Cause for any purpose of this Agreement.

(g) "***Change in Control***" means:

(i) The acquisition by any Person of Beneficial Ownership of at least twenty percent (20%) of either (A) the value of the then outstanding shares of common stock of the Company (the "***Outstanding Company Common Stock***") or (B) the combined voting power of the then outstanding voting securities of the Company entitled to vote generally in the election of directors (the "***Outstanding Company Voting Securities***") (the foregoing Beneficial Ownership hereinafter being referred to as a "***Controlling Interest***"); *provided, however*, that for purposes of this definition, the following acquisitions shall not constitute or result in a Change in Control: (v) any acquisition directly from the Company; (w) any acquisition by the Company; (x) any acquisition by any person that owns, or by any person that collectively with such person's affiliates own, Beneficial Ownership of a Controlling Interest on the Effective Date; (y) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any subsidiary of the Company; or (z) any acquisition by any corporation or other Person pursuant to a transaction which complies with clauses (A), (B) and (C) of subsection (ii) below; or

(ii) Consummation of a reorganization, merger, statutory share exchange or consolidation or similar corporate transaction involving the Company or any of its subsidiaries, a sale or other disposition of all or substantially all of the assets of the Company, or the acquisition of assets or stock or equity interests of another entity by the Company or any of its subsidiaries (each a "***Business Combination***"), in each case, unless, immediately following such Business Combination, (A) all or substantially all of the Persons who were the Beneficial Owners, respectively, of the Outstanding Company Common Stock and Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than fifty percent (50%) of the then combined voting power of the then outstanding voting securities entitled to vote generally in the election of directors (or equivalent persons) of the corporation or other Person resulting from such Business Combination (including, without limitation, a corporation or other Person which as a result of such transaction owns the Company or all or substantially all of the Company's assets either directly or through one or more subsidiaries) (such resulting or acquiring corporation or other Person is referred to herein as the "***Acquiring Person***") in substantially the same proportions as their beneficial ownership, immediately prior to such Business Combination, of the combined voting power of the Outstanding Company Voting Securities, and (B) at least a majority of the members of the Board of Directors or equivalent body of the corporation or other Person resulting from such Business Combination were members of the incumbent Board at the time of the execution of the initial agreement, or of the action of the Board, providing for such Business Combination; or

(iii) approval by the stockholders of the Company of a complete liquidation or dissolution of the Company.

(h) "***COBRA***" means the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended from time to time.

(i) "***Code***" means the Internal Revenue Code of 1986, as amended.

(j) "***Date of Termination***" means the earliest of: (i) immediately after the Company gives notice to Executive of Executive's termination, with or without Cause, unless the Company specifies a later date, in which case, termination shall be effective as of such later date; (ii) immediately upon the Executive's death; (iii) thirty (30) days after the Company gives notice to Executive of Executive's termination on account of Executive's Disability, unless the Company specifies a later date, in which case, termination shall be effective as of such later date, provided, that Executive has not returned to the full time performance of Executive's duties prior to such date; or (iv) thirty (30) days after the Executive gives written notice to the Company of Executive's resignation with or without Good Reason. Executive will receive compensation through any required notice period. In the event notice of a termination under subsections (i), (iii) and (iv) is given orally, at the other party's request, the party giving notice must provide written confirmation of such notice within five business days of the request in compliance with the requirement of Section 14 below. In the event of a termination for Cause or Good Reason written confirmation shall specify the subsection(s) of the definition of Cause or Good Reason relied on to support the decision to terminate but shall not include further explanation.

(k) "***Disability***" means the Executive's inability, or failure, to perform the essential functions of her position, with or without reasonable accommodation, for any period of ninety (90) consecutive days, or (ii) for one-hundred and eighty (180) days in the aggregate during any twelve (12) month period or based on the written certification by two licensed physicians of the likely continuation of such condition for either such period. This definition shall be interpreted and applied consistent with the Americans with Disabilities Act, the Family and Medical Leave Act, and other applicable law.

(l) ***"Equity Awards***" means any stock options, restricted stock, restricted stock units, stock appreciation rights, phantom stock or other equity-based awards granted by the Company to the Executive.

(m) "***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

(n) "***Excise Tax***" means any excise tax imposed by Section 4999 of the Code, together with any interest and penalties imposed with respect thereto, or any interest or penalties that are incurred by the Executive with respect to any such excise tax.

(o) "***Good Reason***" means the occurrence of any of the following: (i) a material diminution in the Executive's Base Salary; or (ii) the Company's or Related Entity's requiring the Executive to be based at any office or location outside of fifty (50) miles from Cambridge, Massachusetts, except for travel reasonably required in the performance of the Executive's responsibilities; or (iii) any other action or inaction that constitutes a material breach by the Company of this Agreement. For purposes of this Agreement, Good Reason shall not be deemed to exist unless the Executive's termination of employment for Good Reason occurs within one hundred eighty days following the initial existence of one of the conditions specified in clauses (i) through (v) above, the Executive provides the Company with written notice of the existence of such condition within ninety (90) days after the initial existence of the condition, and the Company fails to remedy the condition within thirty (30) days after its receipt of such notice.

(p) "***Person***" shall have the meaning ascribed to such term in Section 3(a)(9) of the Exchange Act and used in Sections 13(d) and 14(d) thereof.

(q) "***Related Entity***" means any Person controlling, controlled by or under common control with the Company or any of its subsidiaries. For this purpose, the terms "controlling," "controlled by" and "under common control with" mean the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, as trustee or executor, by contract or otherwise, including (without limitation) the ownership, directly or indirectly, of securities having the power to elect a majority of the board of directors or similar body governing the affairs of such Person.

(r) "***Severance Amount***" shall mean an amount equal to one-half (1/2) of the Executive's annualized Base Salary, as in effect immediately prior to the Termination Date.

(s) "***Target Bonus***" has the meaning described in Section 4(b).

(t) "***Term of Employment***" means the period during which the Executive shall be employed by the Company pursuant to the terms of this Agreement, which period shall begin effective as of the Effective Date and continue until terminated in accordance with Section 6 hereof.

(u) "***Termination Date***" means the date on which the Term of Employment ends.

2. ***Employment***. The Company hereby agrees to continue to employ the Executive, and the Executive hereby agrees to continue to serve the Company, during the Term of Employment on the terms and conditions set forth herein.

3. ***Duties of Executive***.

(a) ***Position and Position Duties***. During the Term of Employment, the Executive shall be employed and serve as the Vice President, Head of Regulatory Affairs and Quality of the Company.

(b) ***Duties in General***. The Executive shall faithfully and diligently perform all services as may be assigned to her by the President and Chief Executive Officer, and shall exercise such power and authority as may from time to time be delegated to her. The Executive shall devote time, attention and efforts to the performance of her duties under this Agreement, render such services to the best of her ability, and use her reasonable best efforts to promote the interests of the Company. The Executive shall not engage in any other business or occupation during the Term of Employment that (i) conflicts with the interests of the Company or its subsidiaries, (ii) interferes with the proper and efficient performance of her duties for the Company, or (iii) interferes with the exercise of her judgment in the Company's best interests.

(c) ***Company Policies and Procedures***. The employment relationship between the parties also shall be subject to the Company's personnel and compliance policies and procedures as they may be interpreted, adopted, revised or deleted from time to time in the Company's sole discretion. The Company reserves the right to change, alter, or terminate any such policy or procedure in its sole discretion. Notwithstanding the foregoing, in the event that the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement shall control.

4. ***Compensation***.

(a) ***Base Salary***. The Executive shall receive a Base Salary at the annualized rate of $350,000 during the Term of Employment, with such Base Salary payable in installments consistent with the Company's normal payroll schedule, subject to applicable withholding and other taxes. The Base Salary shall be reviewed, at least annually, for merit increases and may, by action and in the discretion of the Board, be increased at any time or from time to time, but may not be decreased from the then current Base Salary.

(b) ***Bonuses***. During the Term of Employment, the Executive shall participate in the Company's annual incentive compensation plan, program and/or arrangements applicable to senior-level executives, as established and modified from time to time by the Compensation Committee of the Board (for the avoidance of doubt, for any period during which there is not a Compensation Committee, all matters under this Agreement shall be addressed by the Board) in its sole discretion. During the Term of Employment, the Executive shall have a target bonus opportunity under such plan or program equal to 30% of her current Base Salary (the "***Target Bonus***"), based on satisfaction of performance criteria to be established by the Compensation Committee of the Board within the first three months of each fiscal year that begins during the Term of Employment. Payment of annual incentive compensation awards shall be made in the same manner and at the same time that other senior-level executives receive their annual incentive compensation awards and, except as otherwise provided herein, will be subject to the Executive's continued employment through the applicable payment date.

(c) ***Equity Awards***. Any and all existing Equity Awards that the Executive has or holds in the Company will be treated consistent with the terms of the applicable plans and agreements under which such Equity Awards have been granted. The Executive may be granted additional Equity Awards from time to time in accordance with the Company's normal business practice and in the sole discretion of the Compensation Committee of the Board. The terms of any future Equity Awards granted to the Executive will be consistent with any plan under which such Equity Awards are granted and the terms of the applicable agreement for such Equity Awards. Notwithstanding the foregoing, any and all outstanding unvested Equity Awards shall automatically become fully vested and exercisable on an accelerated basis immediately prior to any Change of Control that is consummated at any time after the Effective Date.

5. ***Expense Reimbursement and Other Benefits***.

(a) ***Reimbursement of Expenses***. Upon the submission of proper substantiation by the Executive, and subject to such rules and guidelines as the Company may from time to time adopt with respect to the reimbursement of expenses of executive personnel, the Company shall reimburse the Executive for all reasonable expenses actually paid or incurred by the Executive during the Term of Employment in the course of and pursuant to the business of the Company. The Executive shall account to the Company in writing for all expenses for which reimbursement is sought and shall supply to the Company copies of all relevant invoices, receipts or other evidence reasonably requested by the Company.

(b) ***Compensation/Benefit Programs***. During the Term of Employment, the Executive shall be entitled to participate in all benefit plans on the same basis as similarly situated executives in the Company's benefit plans in effect from time to time during Executive's employment. All matters of eligibility for coverage or benefits under any benefit plan shall be determined in accordance with the provisions of such plan.

(c) ***Working Facilities***. During the Term of Employment, the Company shall furnish the Executive with an office, administrative help, and such other facilities and services suitable to her position and adequate for the performance of her duties hereunder. The Executive's principal place of employment (subject to reasonable travel) shall be Cambridge, Massachusetts.

(d) ***Vacation***. The Executive shall be entitled to paid vacation each calendar year during the Term of Employment pursuant to the policies of the Company applicable to Executives, to be taken at such times as the Executive and the Company shall mutually determine and provided that no vacation time shall significantly interfere with the duties required to be rendered by the Executive hereunder.

6. ***Termination***.

(a) ***General***. The Term of Employment shall terminate upon the earliest to occur of (i) the Executive's death, (ii) a termination by the Company by reason of the Executive's Disability, (iii) a termination by the Company with or without Cause, or (iv) a termination by Executive with or without Good Reason. Upon any termination of Executive's employment for any reason, except as may otherwise be requested by the Company in writing and agreed upon in writing by Executive, the Executive shall resign from any and all directorships, committee memberships or any other positions Executive holds with the Company or any of its Related Entities.

(b) ***Termination By Company for Cause.*** In the event the Executive is terminated by the Company for Cause, the Company's obligation to make payments under this Agreement shall cease upon the Date of Termination, except that the Company shall pay Executive any Base Salary earned but unpaid prior to termination, all accrued but unused vacation and any business expenses that were incurred but not reimbursed as of the Date of Termination. Vesting of any unvested stock options and/or other equity securities shall cease on the Date of Termination, unless otherwise provided in any plan, instrument or agreement to which such unvested stock options and/or other equity securities may be subject.

(c) ***Disability***. The Company shall have the option, in accordance with applicable law, to terminate the Term of Employment upon written notice to the Executive, at any time during which the Executive is suffering from a Disability. In the event that the Term of Employment is terminated due to the Executive's Disability, the Executive shall be entitled to (i) the Accrued Obligations, payable as and when those amounts would have been paid had the Term of Employment not ended, and (ii) any insurance benefits to which she and her beneficiaries are entitled as a result of her Disability. Vesting of any unvested stock options and/or other equity securities shall cease on the Date of Termination, unless otherwise provided in any plan, instrument or agreement to which such unvested stock options and/or other equity securities may be subject.

(d) ***Death***. In the event that the Term of Employment is terminated due to the Executive's death, the Executive's estate shall be entitled to (i) the Accrued Obligations, payable as and when those amounts would have been paid had the Term of Employment not ended, and (ii) any insurance benefits to which she and her beneficiaries are entitled as a result of her death. Vesting of any unvested stock options and/or other equity securities shall cease on the Date of Termination, unless otherwise provided in any plan, instrument or agreement to which such unvested stock options and/or other equity securities may be subject.

(e) ***Termination Without Cause or Resignation With Good Reason***. The Company may terminate the Term of Employment without Cause, and the Executive may terminate the Term of Employment for Good Reason, at any time upon written notice, and upon compliance with Section 6(g) below. If the Term of Employment is terminated by the Company without Cause (other than due to the Executive's death or Disability) or by the Executive for Good Reason, the Executive shall be entitled to the following:

(i) The Accrued Obligations, payable as and when those amounts would have been paid had the Term of Employment not ended;

(ii) The Severance Amount, payable in equal installments consistent with the Company's normal payroll schedule over the six (6)-month period beginning with the first regularly scheduled payroll date that occurs more than thirty (30) days following the Termination Date; and

(iii) Provided that the Executive timely elects continued coverage under COBRA, the Company will reimburse the Executive for the monthly COBRA cost of continued health and dental coverage of the Executive and her qualified beneficiaries paid by the Executive under the health and dental plans of the Company, less the amount that the Executive would be required to contribute for health and dental coverage if the Executive were an active employee of the Company, for six (6) months (or, if less, for the duration that such COBRA coverage is available to Executive), payable in equal installments consistent with the Company's normal payroll schedule over the six (6)-month period beginning with the first regularly scheduled payroll date that occurs more than thirty (30) days following the Termination Date.

(f) ***Termination by Executive Without Good Reason***. The Executive may terminate her employment without Good Reason at any time by providing the Company 30 days' written notice of such termination. In the event of a termination of employment by the Executive under this Section 6(f), the Executive shall be entitled only to the Accrued Obligations payable as and when those amounts would have been payable had the Term of Employment not ended. In the event of termination of the Executive's employment under this Section 6(f), the Company may, in its sole and absolute discretion, by written notice, accelerate the Date of Termination and still have it treated as a termination without Good Reason.

(g) ***Release***. All rights, payments and benefits due to the Executive under this Article 6 (other than the Accrued Obligations) shall be conditioned on the Executive's execution of a general release of claims against the Company and its affiliates substantially in the form attached hereto as Exhibit A within 60 days of the Date of Termination (the "***Release***") and on that Release becoming irrevocable within sixty (60) days following the Termination Date.

(h) ***Section 280G Certain Reductions of Payments by the Company***.

(i) In the event that a Change in Control occurs at any time during the Term of Employment, and the severance and other benefits provided for in this Agreement or otherwise payable to Executive (a) constitute "parachute payments" within the meaning of Section 280G of the Code and (b) but for this Section, would be subject to the excise tax imposed by Section 4999 of the Code, then Executive's severance and other benefits constituting parachute payments will be either:

(1) delivered in full, or

(2) delivered as to such lesser extent which would result in no portion of such severance and other benefits being subject to the excise tax under Section 4999 of the Code,

whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the excise tax imposed by Section 4999 of the Code, results in the receipt by Executive, on an after-tax basis, of the greatest amount of severance and other benefits, notwithstanding that all or some portion of such severance and other benefits may be taxable under Section 4999 of the Code. If a reduction in the severance and other benefits constituting "parachute payments" is necessary so that no portion of such severance and other benefits is subject to the excise tax under Section 4999 of the Code, the reduction shall occur in the following order: (a) reduction of the cash severance payments; (b) cancellation of accelerated vesting of equity awards; and (c) reduction of continued employee benefits. In the event that acceleration of vesting of equity award compensation is to be reduced, such acceleration of vesting shall be cancelled in the reverse order of the date of grant of Executive's equity awards.

(ii) A nationally recognized certified professional services firm selected by the Company, the Company's legal counsel or such other person or entity to which the parties mutually agree (the "**Firm**") shall perform the foregoing calculations related to the Excise Tax. The Company shall bear all expenses with respect to the determinations by the Firm required to be made hereunder. For purposes of making the calculations required by this Section 6(h), the Firm may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Company and Executive will furnish to the Firm such information and documents as the Firm may reasonably request in order to make a determination under this Section 6(h). The Firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to the Company and Executive within 15 calendar days after the date on which Executive's right to the severance benefits or other payments is triggered (if requested at that time by the Company or Executive) or such other time as requested by the Company or Executive. Any good faith determinations of the Firm made hereunder shall be final, binding, and conclusive upon the Company and Executive.

(i) ***Cooperation***. Following the Term of Employment, the Executive shall give her assistance and cooperation willingly, upon reasonable advance notice with due consideration for her other business or personal commitments, in any matter relating to her position with the Company, or her expertise or experience as the Company may reasonably request, including her attendance and truthful testimony where deemed appropriate by the Company, with respect to any investigation or the Company's defense or prosecution of any existing or future claims or litigations or other proceedings relating to matters in which he was involved or potentially had knowledge by virtue of her employment with the Company. In no event shall her cooperation materially interfere with her services for a subsequent employer or other similar service recipient. To the extent permitted by law, the Company agrees that (i) it shall promptly reimburse the Executive for her reasonable and documented expenses in connection with her rendering assistance and/or cooperation under this Section 6(i) upon her presentation of documentation for such expenses and (ii) the Executive shall be reasonably compensated for any continued material services as required under this Section 6(i).

(j) ***Return of Company Property***. Following the Termination Date, the Executive or her personal representative shall immediately return all Company property in her possession, including but not limited to all computer equipment (hardware and software), telephones, facsimile machines, tablets and other communication devices, credit cards, office keys, security access cards, badges, identification cards and all copies (including drafts) of any documentation or information (however stored) relating to the business of the Company, its customers and clients or its prospective customers and clients (provided that the Executive may retain a copy of the addresses contained in her rolodex, smartphone or similar device or the Company and, at the Executive's request, the Company shall provide a thumb drive of her contacts).

(k) ***Compliance with Section 409A***.

(i) ***General***. It is the intention of both the Company and the Executive that the benefits and rights to which the Executive could be entitled pursuant to this Agreement comply with Section 409A of the Code and the Treasury Regulations and other guidance promulgated or issued thereunder ("***Section 409A***"), to the extent that the requirements of Section 409A are applicable thereto, and the provisions of this Agreement shall be construed in a manner consistent with that intention.

(ii) ***Distributions on Account of Separation from Service***. If and to the extent required to comply with Section 409A, no payment or benefit required to be paid under this Agreement on account of termination of the Executive's employment shall be made unless and until the Executive incurs a "separation from service" within the meaning of Section 409A.

(iii) ***Six Month Delay for Specified Employees***. If the Executive is a "specified employee" (within the meaning of Section 409A(a)(2)(B)(i) of the Code), then no payment or benefit that is payable on account of the Executive's "separation from service", as that term is defined for purposes of Section 409A, shall be made before the date that is six (6) months after the Executive's "separation from service" (or, if earlier, the date of the Executive's death) if and to the extent that such payment or benefit constitutes deferred compensation (or may be nonqualified deferred compensation) under Section 409A and such deferral is required to comply with the requirements of Section 409A. Any payment or benefit delayed by reason of the prior sentence shall be paid out or provided in a single lump sum at the end of such required delay period in order to catch up to the original payment schedule.

(iv) ***Treatment of Each Installment as a Separate Payment***. For purposes of applying the provisions of Section 409A to this Agreement, each separately identified amount to which the Executive is entitled under this Agreement shall be treated as a separate payment. In addition, any series of installment payments under this Agreement shall be treated as a right to a series of separate payments.

(v) ***Taxable Reimbursements and In-Kind Benefits***.

(A) Any reimbursements by the Company to the Executive of any eligible expenses under this Agreement that are not excludable from the Executive's income for Federal income tax purposes (the "***Taxable Reimbursements***") shall be made by no later than the last day of the taxable year of the Executive following the year in which the expense was incurred.

(B) The amount of any Taxable Reimbursements, and the value of any in-kind benefits to be provided to the Executive, during any taxable year of the Executive shall not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year of the Executive.

(C) The right to Taxable Reimbursement, or in-kind benefits, shall not be subject to liquidation or exchange for another benefit.

(vi) ***Company Discretion***. Notwithstanding the foregoing, if at any time the Company determines, in its sole discretion, that the payment of the COBRA premiums under Section 6(e)(iv) above would result in a violation of the nondiscrimination rules of Section 105(h)(2) of the Code or any statute or regulation of similar effect (including but not limited to the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of providing the COBRA premiums, the Company may instead pay Executive, fully taxable cash payments equal to and paid at the same time as the COBRA premiums that otherwise would have been paid, subject to applicable tax withholdings. In the event the COBRA premium reimbursement is made on an after-tax basis, the Company will provide a tax gross-up to the Executive equal to the amount of taxes withheld on the COBRA premium reimbursement with such amount to be paid at the same time of the COBRA premium reimbursement. To receive the payments under Section 6(e)(ii) above, Executive's termination or resignation must constitute a "separation from service**"** within the meaning of Section 409A, and Executive must execute and allow the Release to become effective within sixty (60) days of Executive's termination or resignation. Such payments shall not be paid prior to the sixtieth (60th) day following Executive's termination or resignation, rather, subject to the aforementioned conditions, on the sixtieth (60th) day following Executive's termination or resignation, the Company will pay Executive such payments in a lump sum that Executive would have received on or prior to such date under the original schedule, with the balance of such payments being paid as originally scheduled.

(vii) ***Timing of Payment and Execution of Release.*** Notwithstanding any provision of this Agreement to the contrary, in no event shall the timing of the execution of the Release, directly or indirectly, result in the Executive designating the calendar year of a payment, and if a payment that is subject to execution of the Release could be made in more than one taxable year, payment shall be made in the later taxable year to the extent required under Section 409A. In no event may the Executive, directly or indirectly, designate the calendar year of a payment.

(viii) ***No Guaranty of 409A Compliance***. Notwithstanding the foregoing, the Company does not make any representation to the Executive that the payments or benefits provided under this Agreement are exempt from, or satisfy, the requirements of Section 409A, and the Company shall have no liability or other obligation to indemnify or hold harmless the Executive or any beneficiary of the Executive for any tax, additional tax, interest or penalties that the Executive or any beneficiary of the Executive may incur in the event that any provision of this Agreement, or any amendment or modification thereof, or any other action taken with respect thereto, is deemed to violate any of the requirements of Section 409A.

7. ***Proprietary Information, Invention, Non-Competition, and Non-Solicitation***. The Executive and the Company have previously entered into that certain Employee Proprietary Information, Invention, Non-Competition and Non-Solicitation Agreement, dated as of August 16, 2020, between the Company and the Executive (the "Confidentiality Agreement"), and the terms and provisions of the Confidentiality Agreement shall be incorporated into this Agreement by reference for all purposes.

8. ***Representations and Warranties of Executive***. The Executive represents and warrants to the Company that:

(a) The Executive's employment has not conflicted with or resulted in, and will not conflict with or result in, her breach of any agreement to which she is a party or otherwise may be bound;

(b) The Executive has not violated, and in connection with her employment with the Company will not violate, any non-solicitation, non-competition or other similar covenant or agreement of a prior employer by which she is or may be bound; and

(c) In connection with Executive's employment with the Company, she has not used, and will not use, any confidential or proprietary information that she may have obtained in connection with employment with any prior employer.

9. ***Taxes***. All payments or transfers of property made by the Company to the Executive or her estate or beneficiaries shall be subject to the withholding of such amounts relating to taxes as the Company may reasonably determine it should withhold pursuant to any applicable law or regulation.

10. ***Assignment***. The Company shall have the right to assign this Agreement and its rights and obligations hereunder in whole, but not in part, to any corporation or other entity with or into which the Company may hereafter merge or consolidate or to which the Company may transfer all or substantially all of its assets, if in any such case said corporation or other entity shall by operation of law or expressly in writing assume all obligations of the Company hereunder as fully as if it had been originally made a party hereto, but may not otherwise assign this Agreement or its rights and obligations hereunder. The Executive may not assign or transfer this Agreement or any rights or obligations hereunder.

11. ***Governing Law***. This Agreement shall be governed by and construed and enforced in accordance with the internal laws of the Commonwealth of Massachusetts, without regard to principles of conflict of laws.

12. ***Jurisdiction and Venue***. The parties acknowledge that a substantial portion of the negotiations, anticipated performance and execution of this Agreement occurred or shall occur in Cambridge, Massachusetts, and that, therefore, without limiting the jurisdiction or venue of any other federal or state courts, each of the parties irrevocably and unconditionally (i) agrees that any suit, action or legal proceeding arising out of or relating to this Agreement which is expressly permitted by the terms of this Agreement to be brought in a court of law, may be brought in the courts of record of the Commonwealth of Massachusetts (Middlesex or Suffolk Counties) or the court of the United States, District of Massachusetts; (ii) consents to the jurisdiction of each such court in any such suit, action or proceeding; (iii) waives any objection which it or he may have to the laying of venue of any such suit, action or proceeding in any of such courts; and (iv) agrees that service of any court papers may be effected on such party by mail, as provided in this Agreement, or in such other manner as may be provided under applicable laws or court rules in such courts.

13. ***Entire Agreement; Termination of Other Employment Agreement; Amendment***. This Agreement, together with the exhibit attached hereto, constitutes the entire agreement between the patties hereto with respect to the subject matter hereof and, upon its effectiveness, shall supersede all prior agreements, understandings and arrangements, both oral and written, between the Executive and the Company (or any of its Related Entities) with respect to such subject matter, including, without limitation, any other employment agreement currently in effect between the Company and the Executive. The Company and the Executive hereby agree that any other employment agreement currently in effect between the Company and the Executive is hereby terminated immediately upon the execution and delivery of this Agreement. This Agreement may not be modified in any way unless by a written instrument signed by both the Company and the Executive.

14. ***Notices***. All notices required or permitted to be given hereunder shall be in writing and shall be personally delivered by courier, sent by registered or certified mail, return receipt requested or sent by confirmed facsimile transmission addressed as set forth herein. Notices personally delivered, sent by facsimile or sent by overnight courier shall be deemed given on the date of delivery and notices mailed in accordance with the foregoing shall be deemed given upon receipt by the addressee, as evidenced by the return receipt thereof. Notice shall be sent (i) if to the Company, addressed to its headquarters, Attention: President, and (ii) if to the Executive, to her address as reflected on the payroll records of the Company, or to such other address as either party shall request by notice to the other in accordance with this provision.

15. ***Benefits; Binding Effect.*** This Agreement shall be for the benefit of and binding upon the parties hereto and their respective heirs, personal representatives, legal representatives, successors and, where permitted and applicable, assigns, including, without limitation, any successor to the Company, whether by merger, consolidation, sale of stock, sale of assets or otherwise.

16. ***Right to Consult with Counsel; No Drafting Party***. The Executive acknowledges having read and considered all of the provisions of this Agreement carefully, and having had the opportunity to consult with counsel of her own choosing, and, given this, the Executive agrees that the obligations created hereby are not unreasonable. The Executive acknowledges that he has had an opportunity to negotiate any and all of these provisions and no rule of construction shall be used that would interpret any provision in favor of or against a party on the basis of who drafted the Agreement.

17. ***Severability***. The invalidity of any one or more of the words, phrases, sentences, clauses, provisions, sections or articles contained in this Agreement shall not affect the enforceability of the remaining portions of this Agreement or any part thereof, all of which are inserted conditionally on their being valid in law, and, in the event that any one or more of the words, phrases, sentences, clauses, provisions, sections or articles contained in this Agreement shall be declared invalid, this Agreement shall be construed as if such invalid word or words, phrase or phrases, sentence or sentences, clause or clauses, provisions or provisions, section or sections or article or articles had not been inserted. If such invalidity is caused by length of time or size of area, or both, the otherwise invalid provision will be considered to be reduced to a period or area which would cure such invalidity.

18. ***Waivers***. The waiver by either party hereto of a breach or violation of any term or provision of this Agreement shall not operate nor be construed as a waiver of any subsequent breach or violation.

19. ***Damages; Attorneys' Fees***. Nothing contained herein shall be construed to prevent the Company or the Executive from seeking and recovering from the other damages sustained by either or both of them as a result of its or her breach of any term or provision of this Agreement. Each party shall bear its own costs and attorneys' fees.

20. ***Waiver of Jury Trial***. The Executive hereby knowingly, voluntarily and intentionally waives any right that the Executive may have to a trial by jury in respect of any litigation based hereon, or arising out of, under or in connection with this Agreement and any agreement, document or instrument contemplated to be executed in connection herewith, or any course of conduct, course of dealing statements (whether verbal or written) or actions of any party hereto.

21. ***No Set-off or Mitigation***. The Company's obligation to make the payments provided for in this Agreement and otherwise to perform its obligations hereunder shall not be affected by any set- off, counterclaim, recoupment, defense or other claim, right or action which the Company may have against the Executive or others. In the event of any termination of the Executive's employment under this Agreement, he shall be under no obligation to seek other employment or otherwise in any way to mitigate the amount of any payment provided for hereunder.

22. **Defend Trade Secrets Act**. Pursuant to 18 U.S.C. § 1833(b), Executive will not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret of the Company or its affiliates that (a) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to Executive's attorney and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made in a complaint or other document that is filed under seal in a lawsuit or other proceeding. If Executive files a lawsuit for retaliation by the Company for reporting a suspected violation of law, Executive may disclose the trade secret to Executive's attorney and use the trade secret information in the court proceeding, if Executive (x) files any document containing the trade secret under seal, and (y) does not disclose the trade secret, except pursuant to court order. Nothing in this Agreement is intended to conflict with 18 U.S.C. § 1833(b) or create liability for disclosures of trade secrets that are expressly allowed by such section.

23. ***Section Headings***. The article, section and paragraph headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

24. ***No Third Party Beneficiary***. The Related Entities are intended third party beneficiaries of this Agreement. Otherwise, nothing expressed or implied in this Agreement is intended, or shall be construed, to confer upon or give any person other than the Company, the parties hereto and their respective heirs, personal representatives, legal representatives, successors and permitted assigns, any rights or remedies under or by reason of this Agreement.

25. ***Counterparts***. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original but all of which together shall constitute one and the same instrument and agreement.

IN WITNESS WHEREOF, the undersigned have executed this Agreement on the date first above written.

COMPANY:

LEAP THERAPEUTICS, INC.

By: /s/ Douglas E. Onsi
Name: Douglas E. Onsi
Title: President & Chief Executive Officer

EXECUTIVE:

/s/ Christine Granfield
Name: Christine Granfield

Exhibit A

General Release of Claims

1. [_____] ("***Executive***"), for herself and her family, heirs, executors, administrators, legal representatives and their respective successors and assigns, in exchange for the consideration (other than the Accrued Obligations) received pursuant to Article 6 of the Employment Agreement (the "***Severance Benefits***") to which this release is attached as Exhibit A (the "***Employment Agreement***"), does hereby release and forever discharge Leap Therapeutics, Inc. (the "***Company***"), its subsidiaries, affiliated companies, successors and assigns, and its current or former directors, officers, employees, stockholders or agents in such capacities (collectively with the Company, the "***Released Parties***") from any and all actions, causes of action, suits, controversies, claims and demands whatsoever, whether known or unknown, from the beginning of time through the date upon which Executive signs this General Release of Claims, including, without limitation, claims under any applicable laws, in each case in connection with Executive's employment or termination thereof, whether for tort, breach of express or implied employment contract, wrongful discharge, intentional infliction of emotional distress, or defamation or injuries incurred on the job or incurred as a result of loss of employment. Without limiting the generality of the release provided above, Executive expressly waives any and all claims under Age Discrimination in Employment Act ("***ADEA***") that she may have as of the date hereof. Executive further understands that, by signing this General Release of Claims, she is in fact waiving, releasing and forever giving up any claim under the ADEA as well as all other laws within the scope of this paragraph 1 that may have existed on or prior to the date hereof, including, but not limited to, [*additional citations to be added prior to execution at the time of separation*]. Notwithstanding anything in this paragraph 1 to the contrary, this General Release of Claims shall not apply to (i) any rights to receive any payments or benefits to which the Executive is entitled under the Employment Agreement or COBRA, (ii) any rights or claims that may arise as a result of events occurring after the date this General Release of Claims is executed, (iii) any indemnification and advancement rights Executive may have as a former employee, officer or director of the Company or its subsidiaries or affiliated companies (including any rights under any directors' and officers' indemnification agreement or under the Company's charter or bylaws), (iv) any claims for benefits under any directors' and officers' liability policy maintained by the Company or its subsidiaries or affiliated companies in accordance with the terms of such policy, (v) rights to vested benefits under the Company's 401(k) plan or other employee benefits plans, (vi) any rights as a holder of equity securities or debt securities/notes of the Company and (vii) any rights that Executive may have under any contracts or agreements with the Company or any of its subsidiaries or affiliated companies (other than the Employment Agreement) to the extent that such rights do not pertain to compensation or remuneration in connection with Executive's employment with the Company or any of its subsidiaries or affiliated companies or the termination of such employment.

2. Executive represents that she has not filed against the Released Parties any complaints, charges, or lawsuits arising out of her employment, or any other matter arising on or prior to the date of this General Release of Claims, and covenants and agrees that he will never individually or with any person file, or commence the filing of any lawsuits, complaints or proceedings with any governmental agency, or against the Released Parties with respect to any of the matters released by Executive pursuant to paragraph 1 hereof; provided, that nothing herein shall prevent Executive from filing a charge or complaint with the Equal Employment Opportunity Commission ("***EEOC***") or similar federal or state agency or Executive's ability to participate in any investigation or proceeding conducted by such agency. Executive does agree, however, that she is waiving her right to recover any money in connection with such an investigation or charge filed by her or by any other individual, or a charge filed by the Equal Employment Opportunity Commission or any other federal, state or local agency.

3. Executive acknowledges that, in the absence of her execution of this General Release of Claims, the Severance Benefits would not otherwise be due to her.

4. Executive acknowledges and agrees that she received adequate consideration in exchange for agreeing to the covenants contained in the Confidentiality Agreement and incorporated into the Employment Agreement by virtue of Section 7 of the Employment Agreement, that such covenants remain reasonable and necessary to protect the legitimate business interests of the Company and its affiliates and that he will continue to comply with those covenants.

5. Executive hereby acknowledges that the Company has informed her that she has up to twenty-one (21) days to sign this General Release of Claims and she may knowingly and voluntarily waive that twenty-one (21)-day period by signing this General Release of Claims earlier. Executive is advised to consult with an attorney before signing this General Release of Claims. Executive also understands that she shall have seven (7) days following the date on which she signs this General Release of Claims within which to revoke it by providing a written notice of her revocation to the Company in the manner described in Section 14 of the Employment Agreement.

6. Executive expressly acknowledges and agrees that Executive will not make any statements that are professionally or personally disparaging about, or adverse to, the Company or its business (including its officers, directors, employees and consultants) including, but not limited to, any statements that disparage any person, product, service, finances, financial condition, capability or any other aspect of the business of the Company, and that Executive shall not engage in any conduct which could reasonably be expected to harm professionally or personally the reputation of the Company (including its officers, directors, employees and consultants). Notwithstanding the foregoing, Executive shall not be (i) required to make any statement Executive believes to be false or inaccurate or (ii) restricted in connection with any litigation, arbitration or similar proceeding or with respect to Executive’s response to any legal process.

7. Executive acknowledges and agrees that this General Release of Claims will be governed by and construed and enforced in accordance with the internal laws of the Commonwealth of Massachusetts applicable to contracts made and to be performed entirely within such state.

8. Executive acknowledges that she has read this General Release of Claims, that she has been advised that she should consult with an attorney before he executes this general release of claims, and that she understands all of its terms and executes it voluntarily and with full knowledge of its significance and the consequences thereof.

9. This General Release of Claims shall become irrevocable on the eighth day following Executive's execution of this General Release of Claims, unless previously revoked in accordance with paragraph 5, above.

Intending to be legally bound hereby, Executive has executed this General Release of Claims on _____ ____, _____.

EXECUTIVE:

_____

Name:

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.

November 12, 2020	/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 September 30, 2020, 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: November 12, 2020

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.