Dicerna Pharmaceuticals Inc
Form 10-Q
November 05, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number: 001-36281

DICERNA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	20-5993609
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

87 Cambridgepark Drive

Cambridge, MA 02140

(Address of principal executive offices and zip code)

(617) 621-8097

(Registrant's telephone number, including area code)

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, 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. (Check one):

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 2, 2018, there were 62,731,942 shares of the registrant's common stock, par value $0.0001 per share, outstanding.

DICERNA PHARMACEUTICALS, INC.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q includes “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). All statements other than statements of historical fact are “forward-looking statements” for purposes of this Quarterly Report on Form 10-Q. In some cases, you can identify forward-looking statements by terminology such as “may,” “could,” “will,” “would,” “should,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “intend,” “contemplate,” “project,” “continue,” “potential,” “ongoing,” “goal,” or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- how long we expect to maintain liquidity to fund our planned level of operations and our ability to obtain additional funds for our operations;
- the initiation, timing, progress, and results of our research and development programs, preclinical studies, any clinical trials, and Investigational New Drug application, Clinical Trial Application, New Drug Application, and other regulatory submissions;
- our ability to identify and develop product candidates for treatment of additional disease indications;
- our or a collaborator’s ability to obtain and maintain regulatory approval of any of our product candidates;
- the rate and degree of market acceptance of any approved product candidates;
- the commercialization of any approved product candidates;
- our ability to establish and maintain additional collaborations and retain commercial rights for our product candidates in the collaborations;
- the implementation of our business model and strategic plans for our business, technologies, and product candidates;
- our estimates of our expenses, ongoing losses, future revenue, and capital requirements;
- our ability to obtain and maintain intellectual property protection for our technologies and product candidates and our ability to operate our business without infringing the intellectual property rights of others;
- our reliance on third parties to conduct our preclinical studies or any clinical trials;
- our reliance on third-party suppliers and manufacturers to supply the materials and components for, manufacture, and research and develop our preclinical and clinical trial drug supplies;
- our ability to attract and retain qualified key management and technical personnel;
- our dependence on our existing collaborators, Boehringer Ingelheim International GmbH, Alexion Pharmaceuticals, Inc., and Eli Lilly and Company, for developing, obtaining regulatory approval for, and commercializing product candidates in the collaborations;
- our receipt and timing of any potential milestone payments or royalties under our existing research collaboration and license agreements or any future arrangements with our existing collaboration partners or any other collaborators;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act;
- our financial performance; and
- developments relating to our competitors or our industry.

These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those set forth in Part II, Item 1A – “Risk Factors” below and for the reasons described elsewhere in this Quarterly Report on Form 10-Q. Any forward-looking statement in this Quarterly Report on Form 10-Q reflects our current view with respect to future events and is subject to these and other risks, uncertainties, and assumptions relating to our operations, results of operations, industry, and future growth. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

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This Quarterly Report on Form 10-Q also contains estimates, projections, and other information concerning our industry, our business, and the markets for certain drugs, including data regarding the estimated size of those markets, their projected growth rates, and the incidence of certain medical conditions. Information that is based on estimates, forecasts, projections, or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained these industry, business, market, and other data from reports, research surveys, studies, and similar data prepared by third parties, industry, medical and general publications, government data, and similar sources. In some cases, we do not expressly refer to the sources from which these data are derived.

Except where the context otherwise requires, in this Quarterly Report on Form 10-Q, “we,” “us,” “our,” “Dicerna,” and the “Company” refer to Dicerna Pharmaceuticals, Inc. and, where appropriate, its consolidated subsidiaries.

Trademarks

This Quarterly Report on Form 10-Q includes trademarks, service marks, and trade names owned by us or other companies. All trademarks, service marks, and trade names included in this Quarterly Report on Form 10-Q are the property of their respective owners.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements
DICERNA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(in thousands, except share data)

	September 30, 2018	December 31, 2017
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 46,399	$ 68,789
Held-to-maturity investments	133,980	44,889
Withholding tax receivable	—	1,583
Prepaid expenses and other current assets	3,107	3,415
Total current assets	183,486	118,676
NONCURRENT ASSETS:		
Property and equipment, net	1,212	1,512
Restricted cash equivalents	744	744
Other noncurrent assets	66	70
Total noncurrent assets	2,022	2,326
TOTAL ASSETS	$ 185,508	$ 121,002
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 3,595	$ 4,920
Accrued expenses and other current liabilities	8,101	5,726
Litigation settlement payable	12,797	—
Current portion of deferred revenue	4,635	6,180
Total current liabilities	29,128	16,826
NONCURRENT LIABILITIES:		
Deferred revenue, net of current portion	—	3,090
Total noncurrent liabilities	—	3,090
TOTAL LIABILITIES	29,128	19,916
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Preferred stock, $0.0001 par value – 5,000,000 shares authorized; no shares issued or outstanding at September 30, 2018 or December 31, 2017	—	—
Common stock, $0.0001 par value – 150,000,000 shares authorized; 61,889,206 and 51,644,841 shares issued and outstanding at	6	5

September 30, 2018 and December 31, 2017, respectively		
Additional paid-in capital	542,572	417,037
Accumulated deficit	(386,198)	(315,956)
Total stockholders' equity	156,380	101,086
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 185,508	$ 121,002

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

DICERNA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue from collaborative arrangements	$1,545	$—	$4,635	$—
Operating expenses:				
Research and development	11,695	8,527	31,927	26,338
General and administrative	5,354	4,137	14,449	12,324
Litigation expense	3,694	2,548	29,122	6,157
Total operating expenses	20,743	15,212	75,498	44,819
Loss from operations	(19,198)	(15,212)	(70,863)	(44,819)
Other income (expense):				
Interest income	401	179	1,020	360
Interest expense	(223)	—	(399)	—
Total other income, net	178	179	621	360
Net loss	(19,020)	(15,033)	(70,242)	(44,459)
Dividends on redeemable convertible preferred stock	—	(4,111)	—	(6,733)
Deemed dividend related to beneficial conversion feature of redeemable convertible preferred stock	—	—	—	(6,144)
Net loss attributable to common stockholders	$(19,020)	$(19,144)	$(70,242)	$(57,336)
Net loss per share attributable to common stockholders – basic and diluted	$(0.35)	$(0.92)	$(1.32)	$(2.76)
Weighted average common shares outstanding – basic and diluted	54,799,644	20,841,728	53,037,516	20,809,372

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

DICERNA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(in thousands)

	Nine Months Ended September 30,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(70,242)	$(44,459)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash litigation expense	10,315	—
Stock-based compensation expense	5,673	6,003
Depreciation expense	580	571
Loss on disposal of property and equipment	9	51
Amortization of premium on investments	(390)	(106)
Changes in operating assets and liabilities:		
Litigation settlement payable	12,797	—
Deferred revenue	(4,635)	—
Prepaid expenses and other assets	312	(1,963)
Accounts payable	(1,389)	1,114
Withholding tax receivable	1,583	—
Accrued expenses and other liabilities	2,045	(584)
Net cash used in operating activities	(43,342)	(39,373)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(245)	(133)
Maturities of held-to-maturity investments	50,000	45,000
Purchases of held-to-maturity investments	(138,699)	(64,853)
Net cash used in investing activities	(88,944)	(19,986)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of underwriters' commissions	108,099	—
Proceeds from issuance of redeemable convertible preferred stock	—	70,000
Redeemable convertible preferred stock issuance costs	—	(750)
Proceeds from stock option exercises and issuances under Employee Stock Purchase Plan	1,832	215
Settlement of restricted stock for tax withholding	(35)	(11)
Net cash provided by financing activities	109,896	69,454
NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH EQUIVALENTS	(22,390)	10,095
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH EQUIVALENTS — Beginning of period	69,533	21,981
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH EQUIVALENTS — End of period	$47,143	$32,076

SUPPLEMENTAL CASH FLOW INFORMATION:		
NONCASH FINANCING ACTIVITIES:		
Dividends on redeemable convertible preferred stock	$—	$6,733
Deemed dividend related to beneficial conversion feature of redeemable preferred stock	$—	$6,144
Common stock issuance costs included in accounts payable and accrued expenses	$349	$—
NONCASH INVESTING ACTIVITIES:		
Property and equipment purchases included in accounts payable	$44	$—

Reconciliation of cash, cash equivalents and restricted cash equivalents within the Company's condensed consolidated balance sheets:

	Nine Months Ended September 30,	
	2018	2017
Cash and cash equivalents	46,399	30,960
Restricted cash equivalents	744	1,116
Cash, cash equivalents and restricted cash equivalents presented above	$47,143	$32,076

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

DICERNA PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

(tabular amounts in thousands, except share and per share data and where otherwise noted)

1. DESCRIPTION OF BUSINESS AND BASIS OF PRESENTATION

Business

Dicerna Pharmaceuticals, Inc. (“Dicerna” or the “Company”) is a biopharmaceutical company focused on the discovery and development of innovative subcutaneously delivered ribonucleic acid (“RNA”) interference (“RNAi”)-based pharmaceuticals using its GalXC™ RNAi platform for the treatment of diseases involving the liver, including rare diseases, viral infectious diseases, chronic liver diseases, and cardiovascular diseases. Within these therapeutic areas, the Company believes its GalXC RNAi platform will allow the Company to build a broad pipeline of therapeutics with commercially attractive pharmaceutical properties, including a subcutaneous route of administration, infrequent dosing (e.g., dosing that is monthly or quarterly, and potentially even less frequent), high therapeutic index, and specificity to a single target gene.

Basis of presentation

These condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) and in accordance with the rules and regulations of the Securities and Exchange Commission (“SEC”) for interim financial information. The year-end condensed balance sheet data was derived from audited financial statements, but does not include all disclosures required by GAAP to constitute a complete set of financial statements. These condensed consolidated financial statements have been prepared on the same basis as the Company’s annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company’s financial position at September 30, 2018 and results of operations and cash flows for the interim periods ended September 30, 2018 and 2017. These unaudited condensed consolidated interim financial statements should be read in conjunction with the Company’s audited consolidated financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2017. The results of the three and nine months ended September 30, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018 or for any other interim period or for any other future year.

Stockholders’ Equity

Changes in stockholders’ equity for the nine months ended September 30, 2018 are as follows:

	Common Stock				Total
Description	Number of shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Stockholders' Equity

BALANCE – December 31, 2017	51,644,841	$ 5	$ 417,037	$ (315,956)	$ 101,086
Proceeds from issuance of common stock from public offering, net of underwriting fees and issuance costs	8,832,565	1	107,749	—	