

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**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, 2019

OR

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

Commission File Number 001-38135

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**DOVA PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**81-3858961**

(I.R.S. Employer Identification No.)

**240 Leigh Farm Road, Suite 245  
Durham, North Carolina 27707**

(Address of principal executive offices and zip code)

**(919) 748-5975**

(Registrant's telephone number, including area code)

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

<u>Title of each class</u>	<u>Trading symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock	DOVA	The Nasdaq Stock Market, LLC

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 definition of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	<input type="checkbox"/>	Accelerated Filer	<input checked="" type="checkbox"/>
Non-accelerated Filer	<input type="checkbox"/>	Smaller Reporting Company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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

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

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date.

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<u>Class of Common Stock</u>	<u>Outstanding Shares as of November 8, 2019</u>
Common Stock, \$0.001 par value	28,845,811

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**Part I. Financial Information**  
**Item 1. Financial Statements (unaudited)**

**Dova Pharmaceuticals, Inc.**  
**Consolidated Balance Sheets**  
(in thousands, except share and per share amounts)

	September 30, 2019 (unaudited)	December 31, 2018
<b>ASSETS</b>		
Current assets		
Cash and equivalents	\$ 68,448	\$ 104,566
Accounts receivable, net	1,244	612
Inventory, net	4,683	4,390
Prepaid expenses and other current assets	2,850	2,239
Total current assets	77,225	111,807
Furniture and equipment, net	579	362
Operating lease asset	1,146	—
<b>Total assets</b>	<b>\$ 78,950</b>	<b>\$ 112,169</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 1,859	\$ 781
Accrued expenses	10,920	11,935
Accrued interest	182	79
Due to related party	—	35
Current portion of operating lease liability	338	—
Current portion of long-term debt	1,913	6,667
Total current liabilities	15,212	19,497
Deferred revenue	453	2,373
Long-term operating lease liability	1,123	—
Long-term debt	28,924	13,941
<b>Total liabilities</b>	<b>45,712</b>	<b>35,811</b>
<b>Commitments and contingencies</b>		
<b>Stockholders' equity</b>		
Undesignated preferred stock, \$0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 28,821,405 and 28,821,405 shares issued and outstanding as of September 30, 2019 and 28,204,098 and 28,204,098 shares issued and outstanding as of December 31, 2018.	29	28
Additional paid-in capital	217,364	205,757
Accumulated deficit	(184,155)	(129,427)
Total stockholders' equity	33,238	76,358
<b>Total liabilities and stockholders' equity</b>	<b>\$ 78,950</b>	<b>\$ 112,169</b>

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

**Dova Pharmaceuticals, Inc.**  
**Consolidated Statements of Operations**  
(in thousands, except share and per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
<b>Revenue</b>				
Product sales, net	\$ 1,453	\$ 2,929	\$ 8,970	\$ 4,886
Other revenue	1,920	—	1,920	2,627
Total revenue, net	3,373	2,929	10,890	7,513
<b>Operating expenses:</b>				
Cost of product sales	653	370	1,612	889
Research and development	4,188	4,847	12,777	12,771
Selling, general and administrative	19,197	17,031	50,447	45,856
Total operating expenses	24,038	22,248	64,836	59,516
<b>Loss from operations</b>	<b>(20,665)</b>	<b>(19,319)</b>	<b>(53,946)</b>	<b>(52,003)</b>
Interest income and other income (expense), net	235	342	1,211	369
Interest expense	(855)	(546)	(1,993)	(1,315)
Total other expenses, net	(620)	(204)	(782)	(946)
<b>Net loss</b>	<b>\$ (21,285)</b>	<b>\$ (19,523)</b>	<b>\$ (54,728)</b>	<b>\$ (52,949)</b>
Net loss per share, basic and diluted	\$ (0.74)	\$ (0.69)	\$ (1.92)	\$ (1.91)
Weighted average common shares outstanding, basic and diluted	28,799,655	28,203,222	28,439,704	27,668,066

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

**Dova Pharmaceuticals, Inc.**  
**Consolidated Statements of Stockholders' Equity**  
(in thousands, except share amounts)

	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount			
<b>Balance as of December 31, 2018</b>	<b>28,204,098</b>	<b>\$ 28</b>	<b>\$ 205,757</b>	<b>\$ (129,427)</b>	<b>\$ 76,358</b>
Exercise of stock options	22,454	—	100	—	100
Restricted stock units vested	6,178	—	—	—	—
Stock-based compensation	—	—	3,213	—	3,213
Net loss	—	—	—	(16,379)	(16,379)
<b>Balance as of March 31, 2019</b>	<b>28,232,730</b>	<b>28</b>	<b>209,070</b>	<b>(145,806)</b>	<b>63,292</b>
Exercise of stock options	488,057	1	1,849	—	1,850
Restricted stock units vested	17,030	—	—	—	—
Stock-based compensation	—	—	2,730	—	2,730
Net loss	—	—	—	(17,064)	(17,064)
<b>Balance as of June 30, 2019</b>	<b>28,737,817</b>	<b>29</b>	<b>213,649</b>	<b>(162,870)</b>	<b>50,808</b>
Exercise of stock options	6,483	—	25	—	25
Restricted stock units vested	77,105	—	—	—	—
Stock-based compensation	—	—	3,690	—	3,690
Net loss	—	—	—	(21,285)	(21,285)
<b>Balance as of September 30, 2019</b>	<b>28,821,405</b>	<b>\$ 29</b>	<b>\$ 217,364</b>	<b>\$ (184,155)</b>	<b>\$ 33,238</b>

	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount			
<b>December 31, 2017</b>	<b>25,652,457</b>	<b>\$ 26</b>	<b>\$ 118,301</b>	<b>\$ (57,145)</b>	<b>\$ 61,182</b>
Exercise of stock compensation awards	38,809	—	145	—	145
Issuance of common stock in connection with secondary offering, net of offering costs	2,500,000	2	74,727	—	74,729
Stock-based compensation	—	—	2,816	—	2,816
Net loss	—	—	—	(13,770)	(13,770)
<b>Balance as of March 31, 2018</b>	<b>28,191,266</b>	<b>28</b>	<b>195,989</b>	<b>(70,915)</b>	<b>125,102</b>
Exercise of stock compensation awards	11,000	—	80	—	80
Stock-based compensation	—	—	4,192	—	4,192
Net loss	—	—	—	(19,657)	(19,657)
<b>Balance as of June 30, 2018</b>	<b>28,202,266</b>	<b>28</b>	<b>200,261</b>	<b>(90,572)</b>	<b>109,717</b>
Exercise of stock compensation awards	2,000	—	13	—	13
Stock-based compensation	—	—	4,036	—	4,036
FINRA S-3 filing fee	—	—	(46)	—	(46)
Net loss	—	—	—	(19,523)	(19,523)
<b>September 30, 2018</b>	<b>28,204,266</b>	<b>\$ 28</b>	<b>\$ 204,264</b>	<b>\$ (110,094)</b>	<b>\$ 94,198</b>

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

**Dova Pharmaceuticals, Inc.**  
**Consolidated Statements of Cash Flows**  
(in thousands)

	Nine months ended September 30,	
	2019	2018
<b>Cash flows from operating activities</b>		
Net loss	\$ (54,728)	\$ (52,949)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	69	19
Loss on disposal of furniture and equipment	—	35
Amortization of debt discount and debt issuance costs	725	416
Stock-based compensation	9,633	11,043
Net change in operating lease assets and liabilities	50	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(632)	(2,962)
Inventory	(293)	(1,781)
Prepaid expenses	(441)	(1,570)
Accounts payable	1,078	(1,195)
Accrued expenses	(920)	11,341
Accrued interest	103	(930)
Due to related party	(35)	(97)
Deferred revenue	(1,920)	2,373
Net cash used in operating activities	(47,311)	(36,257)
<b>Cash flows from investing activities</b>		
Purchases of furniture and equipment	(286)	(269)
Net cash used in investing activities	(286)	(269)
<b>Cash flows from financing activities</b>		
Payment of note payable	—	(31,077)
Payment of term loan, including a \$0.6 million prepayment fee	(20,600)	—
Debt issuance costs	(1,495)	(38)
Proceeds from the issuance of debt	31,600	20,000
Proceeds from exercise of stock options	1,974	92
Proceeds from the issuance of common stock	—	80,000
Payment of offering cost in connection with issuance of common stock	—	(5,270)
Net cash provided by financing activities	11,479	63,707
Net change in cash and equivalents	(36,118)	27,181
Cash and equivalents at the beginning of the period	104,566	94,846
<b>Cash and equivalents at the end of the period</b>	<b>\$ 68,448</b>	<b>\$ 122,027</b>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	\$ 1,159	\$ 1,830
<b>Supplemental disclosure of noncash investing and financing activities:</b>		
Shares issued from the early exercise of options	\$ —	\$ 100

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

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

**Note 1—Organization and description of business operations**

Dova Pharmaceuticals, Inc. ("Dova" or the "Company") is a pharmaceutical company focused on acquiring, developing and commercializing drug candidates for diseases that are treated by specialist physicians, with an initial focus on addressing thrombocytopenia, a disorder characterized by a low blood platelet count. On May 21, 2018, the U.S. Food and Drug Administration ("FDA") approved DOPTOLET® (avatrombopag), which is an orally administered thrombopoietin receptor agonist for the treatment of thrombocytopenia in adult patients with chronic liver disease ("CLD") scheduled to undergo a procedure, which was commercially launched on June 4, 2018. On June 20, 2019, the Company was granted a marketing authorization by the European Commission for the treatment of severe thrombocytopenia in adult patients with CLD who are scheduled to undergo an invasive procedure; DOPTOLET has not yet been commercially launched in Europe. Furthermore, on June 26, 2019, the Company received FDA approval for DOPTOLET for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia ("ITP") who have had an insufficient response to a previous treatment. The Company commercially launched DOPTOLET for the treatment of ITP on July 16, 2019.

On September 30, 2019, the Company and Swedish Orphan Biovitrum AB (publ), a Swedish public limited liability company ("Sobi") announced the execution of an Agreement and Plan of Merger (the "Merger Agreement"). Under the terms of the Merger Agreement, Sobi commenced a tender offer for all outstanding shares of the Company, whereby the Company's stockholders were offered an upfront payment for \$27.50 per share in cash, along with one non-tradeable Contingent Value Right ("CVR") that entitles them to an additional \$1.50 per share in cash upon regulatory approval of DOPTOLET for the treatment of chemotherapy-induced thrombocytopenia ("CIT"), representing a total potential consideration of \$29.00 per share, or a total potential consideration of up to \$915 million on a fully diluted basis. The tender offer was completed on November 8, 2019 and the merger is expected to close on November 12, 2019. Upon the closing of the merger, the Company will become a wholly-owned indirect subsidiary of Sobi. In addition, all of the Company's outstanding options (whether vested or unvested) that have an exercise price of less than \$27.50 will be canceled and the holders thereof will receive the offer price in respect of each share covered by such option, less the applicable exercise price, and all outstanding restricted stock units (whether vested or unvested) will be canceled and the holders thereof will receive the offer price in respect of each share covered by such restricted stock unit. In addition, any options with an exercise price between \$27.50 and \$29.00 will be entitled to receive a payment in respect of each share covered by such option upon regulatory approval of DOPTOLET for the treatment of CIT in an amount equal to the excess of \$29.00 over the applicable exercise price.

The unaudited condensed consolidated financial statements of the Company include the results of operations for the three and nine months ended September 30, 2019 and September 30, 2018.

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

**Note 2—Significant accounting policies**

***Basis of presentation and principles of consolidation***

The Company's unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented. The results of operations for the three and nine months ended September 30, 2019 are not necessarily indicative of the results for the full year or the results for any future periods and should be read in conjunction with the audited consolidated financial statements and related notes for the year ended December 31, 2018 in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission (the "SEC") on March 5, 2019.

***Liquidity and capital resources***

The Company has incurred substantial operating losses since inception and expects to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of September 30, 2019, the Company had an accumulated deficit of \$184.2 million.

Since inception, the Company has financed its operations through the issuance of equity and debt with net aggregate proceeds of \$38.0 million. Although the Company began generating revenue from product sales of DOPTelet in June 2018, the Company does not expect product revenue to be sufficient to satisfy its operating needs for several years. As of September 30, 2019, the Company had \$68.4 million in cash and equivalents. Based on the Company's forecast of future cash flows, the Company believes that it has adequate cash and equivalents to continue to fund operations in the normal course of business for at least the next 12 months.

***Use of estimates***

The preparation of 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 expenses during the reporting period. The most significant estimates in the Company's condensed consolidated financial statements relate to the determination of variable consideration for product sales, revenue recognized upon the satisfaction of performance obligations under the Company's strategic agreements, share-based compensation and some of its research and development expenses. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results the Company's future results of operations will be affected.

***Segments***

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one reportable segment, i.e., the development and commercialization of DOPTelet. Substantially all of the Company's assets and revenue are in the United States.

For the three and nine months ended September 30, 2019 as well as for the year ended December 31, 2018, the Company relied primarily on three specialty pharmacies to purchase and supply the majority of DOPTelet to patients. These three specialty pharmacies accounted for greater than 75% of all DOPTelet net product sales in the three and nine months ended September 30, 2019 and 2018 and accounted for predominately all of the Company's outstanding accounts receivable from product sales as of September 30, 2019. The loss, or a significant change in the buying patterns, of either one of these specialty pharmacies as a customer could negatively impact the sales of DOPTelet.

***Cash and equivalents***

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

The Company considers all highly liquid investments purchased with original maturities of 90 days or less at acquisition to be cash equivalents. Cash and equivalents include cash held in banks and money market mutual funds and are classified as Level 1 investments.

### *Inventory*

Inventory acquired prior to receipt of the FDA approval for DOPTOLET was expensed as research and development expense as incurred. The Company began capitalizing inventory upon receipt of FDA approval on May 21, 2018. Inventory is stated at the lower of cost or estimated net realizable value with cost determined under the first in first out method. Inventory consists of work in process, and DOPTOLET finished goods. The Company currently purchases inventory from Eisai under a long-term supply agreement for work in process and finished drug product and the cost of inventory is the greater of a fixed payment per tablet or a payment calculated in the mid-single digit percentages of net sales of DOPTOLET. The Company reduces its inventory to net realizable value for potentially excess, dated or obsolete inventory based on an analysis of forecasted demand compared to quantities on hand and any firm purchase orders, as well as product shelf life. At September 30, 2019, the Company determined that no write downs to inventory for potentially excess, dated or obsolete inventory were required. The Company's inventory at September 30, 2019 and December 31, 2018 consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Work in process	\$ 814	\$ 1,728
Finished goods	3,869	2,662
<b>Total</b>	<b>\$ 4,683</b>	<b>\$ 4,390</b>

### *Research and development prepaid and accrued expenses*

As part of the process of preparing financial statements, the Company is required to estimate its expenses resulting from its obligations under contracts with vendors and consultants and clinical site agreements in connection with its research and development efforts. The financial terms of these contracts are subject to negotiations which vary contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to the Company under such contracts. The Company's objective is to reflect the appropriate clinical trial expenses in its financial statements by matching those expenses with the period in which services and efforts are expended. The Company accounts for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. The Company determines prepaid and accrual estimates through discussion with applicable personnel and outside service providers as to the progress or state of communication of clinical trials, or other services completed. During the course of a clinical trial, the Company adjusts its rate of clinical trial expense recognition if actual results differ from its estimates. The Company makes estimates of its prepaid and accrued expenses as of each balance sheet date in its financial statements based on facts and circumstances known at that time. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of status and timing of services performed relative to the actual status and timing of services performed may vary and may result in the Company reporting amounts that are too high or too low for any particular period. The Company's clinical trial prepaid and accrual expense is dependent upon the timely and accurate reporting of fee billings and pass-through expenses from contract research organizations and other third-party vendors, as well as the timely processing of any change orders from the contract research organizations.

### *Leases*

Effective January 1, 2019, the Company adopted ASU No. 2016-02, "Leases (Topic 842)," as amended, using the modified retrospective approach. In addition, the Company elected the package of practical expedients permitted under the transition guidance within the new standard which among other things, allowed the Company to carry forward the historical lease classification. In addition, the Company elected the hindsight practical expedient to determine the lease term for existing leases. Our election of the hindsight practical expedient resulted in the shortening of lease terms for certain existing leases and the useful lives of corresponding leasehold improvements. In our application of hindsight, the Company determined that renewal options would not be reasonably certain in determining the expected lease term.

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

Adoption of the new standard resulted in the recording of additional net lease assets and lease liabilities of approximately \$1.4 million and \$1.7 million respectively, as of January 1, 2019. The standard did not materially impact the Company's consolidated net earnings and had no impact on cash flows.

The Company has operating leases for real estate (primarily office space) and certain equipment. The Company's finance leases are not material. Leases with a term of 12 months or less are not recorded on the balance sheet. The Company recognizes lease expense for these leases on a straight-line basis over the lease term. For lease agreements entered into or reassessed after the adoption of Topic 842, the Company combines lease and non-lease components.

#### ***Furniture and equipment***

Furniture and equipment are generally recorded at cost, or in the case of acquired property and equipment, at fair value at the date of acquisition. Maintenance and repair expenditures are charged to expense as incurred.

Depreciation is computed on a straight-line basis over the estimated useful lives of the assets as follows:

<b>Classification</b>	<b>Estimated useful life</b>
Computers and equipment	3 years
Fixtures and furniture	7 years
Tooling and equipment	5 years - 10 years
Leasehold improvements	Shorter of length of lease or life of asset

#### ***Concentrations of credit risk and off-balance sheet risk***

Cash and equivalents are financial instruments that are potentially subject to concentrations of credit risk. The Company's cash and equivalents are deposited in accounts at large financial institutions, and amounts may exceed federally insured limits. The Company believes it is not exposed to significant credit risk due to the financial strength of the depository institutions in which the cash and equivalents are held. The Company has no financial instruments with off-balance sheet risk of loss.

#### ***Research and development costs***

Research and development ("R&D") expenses for both the three and nine months ended September 30, 2019 and September 30, 2018 include direct and indirect R&D costs. Direct R&D costs consist principally of external costs, such as fees paid to investigators, consultants, central laboratories, contract manufacturing organizations and contract research organizations, including costs incurred in connection with clinical trials, and related clinical trial fees and all employee-related expenses for those employees working in R&D functions, including stock-based compensation for R&D personnel. Indirect R&D costs include insurance or other indirect costs related to the Company's R&D function to specific product candidates. The Company expenses pre-approval inventory as R&D until regulatory approval is received.

#### ***Revenue recognition***

##### *Product sales*

The Company is currently approved to sell DOPTELET for certain indications in both the United States, all 28 European Union member states, Iceland, Norway, and Liechtenstein. The product is currently commercially available in the United States and is predominantly distributed to a limited number of specialty pharmacies and specialty distributors (collectively, "customers") who have agreements in place with the Company. Patients, healthcare providers, hospitals and clinics purchase the product from the Company's customers.

The Company recognizes revenue on product sales when the control of the Company's product passes to its customers, which occurs at a point in time, upon delivery to the customers, or over time depending on the nature of the contract. The Company has determined that the delivery of its product to its customers constitutes a single performance obligation as there are no other promises to deliver goods or services. Shipping and handling activities are considered to be fulfillment activities and are not considered to be a separate performance obligation. The Company has assessed the existence of a significant financing

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

component in the agreements with its customers. The trade payment terms with its customers do not exceed one year and therefore the Company has elected to apply the practical expedient and no amount of consideration has been allocated as a financing component.

Revenue from product sales is recorded at the net sales price, which includes estimates of variable consideration for which reserves are established. Components of variable consideration include trade discounts and allowances, product returns, government chargebacks, discounts and rebates, and other incentives, such as voluntary patient assistance, and other fee for service amounts that are detailed within contracts between the Company and its customers relating to the Company's sale of its products. These reserves, as detailed below, are based on the amounts earned, or to be claimed on the related sales, and are classified as reductions of accounts receivable or a current liability. These reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts.

Revenue from product sales is recorded after considering the impact of the following variable consideration amounts at the time of revenue recognition:

*Trade discounts and distribution fees:* Trade discounts relate to prompt settlement discounts provided to customers. In addition, the Company compensates its customers for data and other activities. The Company has determined that such services received to date are not distinct from its sale of products and may not reasonably represent fair value for these services. Therefore, estimates of these payments are recorded as a reduction of revenue based on contractual terms.

*Product returns:* Consistent with industry practice, the Company generally offers customers a limited right of return for product that has been purchased from the Company based on the product's expiration date. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized, as well as within accrued expenses on the condensed consolidated balance sheets. The Company currently estimates product return liabilities using available industry data and its own sales information, including its visibility into the inventory remaining in the distribution channel. The Company has not received any returns to date.

*Government rebates and chargebacks:* The Company contracts with Medicaid, Medicare, U.S. Department of Veterans Affairs, 340b entities and other government agencies ("Government Payors") so that DOPTelet will be eligible for purchase by, or partial or full reimbursement from, such Government Payors. The Company estimates the rebates, chargebacks and discounts it will provide to Government Payors and deducts these estimated amounts from its gross product revenue at the time the revenue is recognized. The Company estimates these reserves based upon a range of possible outcomes that are probability-weighted for the estimated payor mix. These reserves are recorded in the same period the revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability, which is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. The Company estimates the rebates, chargebacks and discounts that it will provide to Government Payors based upon (i) the government-mandated discounts applicable to government-funded programs, (ii) information obtained from its customers and (iii) information obtained from other third parties regarding the payor mix for DOPTelet. The Company's liability for these rebates consists of estimates of claims for the current quarter and estimated future claims that will be made for product shipments that have been recognized as revenue but remain in the distribution channel inventories at the end of each reporting period.

*Co-pay assistance:* Other incentives which the Company offers include voluntary patient assistance and assurance programs, such as a co-pay assistance program, which are intended to provide financial assistance to qualified commercially-insured patients with prescription drug co-payments required by payers. The calculation of the accrual for co-pay assistance is based on an estimate of claims using data provided by third-party administrators and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue but remains in the distribution channel inventories at the end of each reporting period. The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included as a component of accrued expenses and other current liabilities on the condensed consolidated balance sheets.

*Commercial Chargebacks:* Chargebacks for discounts represent the estimated obligations resulting from contractual commitments to sell products to certain group purchasing organizations, and government entities at prices lower than the list prices charged to the specialty distributors. These specialty distributors charge the Company for the difference between what was paid for the product and the contracted selling price to these group purchasing organizations and government entities.

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These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue. Actual chargeback amounts are generally determined at the time of resale to the group purchasing organizations and government entities by the specialty distributors. The estimated obligations arising from these chargebacks and discounts are included as part of Other Accrued Liabilities in the balance sheet.

*Strategic agreements*

The Company's other revenue consists of revenue from the Company's strategic agreements for the development and commercialization of DOPTelet. The terms of the agreements typically include non-refundable upfront fees, payments based upon achievement of milestones and eventually revenue from the commercialized product. These agreements usually have both fixed and variable consideration. Non-refundable upfront fees are considered fixed, while milestone payments and revenue from the commercialized product are identified as variable consideration.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under these agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in Accounting Standards Codification ("ASC") Topic 606. The Company's performance obligations include intellectual property rights, development services, and services associated with regulatory submission and approval processes. Significant management judgment is required to determine the level of effort required under an arrangement and the period over which the Company expects to complete its performance obligations under the arrangement. If the Company cannot reasonably estimate when its performance obligations either are completed or become inconsequential, then revenue recognition is deferred until the Company can reasonably make such estimates. Revenue is then recognized over the remaining estimated period of performance using the cumulative catch-up method.

As part of the accounting for these arrangements, the Company develops assumptions that require judgment to determine the estimated selling price of each performance obligation identified in the contract. The Company uses key assumptions to determine the selling price on a standalone basis, which may include forecasted revenue, development timelines, and probabilities of regulatory success.

The Company allocates the total transaction price to each performance obligation based on the estimated relative standalone selling prices of the promised goods or service underlying each performance obligation.

If the right to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, upfront fees allocated to the right when the right is transferred to the customer, and the customer can use and benefit from the right. For rights that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

At the inception of the arrangement, the Company evaluates whether the development milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. Milestone payments that are not within the control of the Company, such as approvals from regulators, are not considered probable of being achieved until those approvals are received.

*Stock-based compensation*

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company has limited experience as a public company and lacks company-specific historical and implied volatility information. Therefore, the most significant subjective assumptions are management's estimates of the expected volatility and the expected

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term of the award. The Company estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. Due to the lack of historical exercise history, the expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to nonemployees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

***Income taxes***

Income taxes are recorded in accordance with ASC 740, *Income Taxes* ("ASC 740"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit would more likely than not be realized assuming examination by the taxing authority. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances.

The FASB Staff Q&A, Topic 740, No. 5, *Accounting for Global Intangible Low-Tax Income*, states that an entity can make an accounting policy election to either recognize deferred taxes for temporary basis difference expected to reverse as global intangible low-taxed income ("GILTI") in future years or to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only. The Company has elected to account for GILTI as a period expense in the year the tax is incurred.

***Net loss per share***

Net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Since the Company had a net loss in each of the periods presented, basic and diluted net loss per common share are the same. The computations of diluted net loss per common share for the three and nine months ended September 30, 2019 excluded options to purchase 1,721,465 and 2,276,837 shares of common stock, respectively, and excluded unvested restricted stock units of 80,327 and 127,599 shares of common stock, respectively, as the inclusion of these securities would have been antidilutive. The computations of diluted net loss per common share for the three and nine months ended September 30, 2018 did not include options to purchase 2,689,828 shares and 2,514,503 shares, respectively, of common stock, as the inclusion of these securities would have been antidilutive. There were no restricted stock units issued during the three and nine months ended September 30, 2018.

***Recent accounting pronouncements***

In June 2016, the FASB issued ASU No. 2016-13, "Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments," which was subsequently amended in November 2018, through ASU No. 2018-19, "Codification Improvements to Topic 326, Financial Instruments - Credit Losses." ASU No. 2016-13 will require entities to estimate lifetime expected credit losses for trade and other receivables, net investments in leases, financing receivables, debt securities and other instruments, which will result in earlier recognition of credit losses. Further, the new credit loss model will affect how entities in all industries estimate their allowance for losses for receivables that are current with respect to their payment terms. ASU No. 2018-19 further clarifies that receivables arising from operating leases are not within the scope of Subtopic 326. Instead, impairment from receivables of operating leases should be accounted for in accordance with Topic 842, Leases. The new guidance on credit losses is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. The Company expects to adopt ASU No. 2016-03, and the related ASU No. 2018-19 amendments, beginning as of January 1, 2020 and expects that the adoption of this ASU will not have a material impact on the Company's consolidated financial statements.

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In June 2018, the FASB issued ASU 2018-7, "Improvements to Nonemployee Share-Based Payment Accounting", which simplifies the accounting for share-based payments granted to nonemployees for goods and services. Under the ASU, most of the guidance on such payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. The changes take effect for public companies for fiscal years starting after December 15, 2018, including interim periods within that fiscal year. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company adopted this ASU during the first quarter and 2019, which did not have a material impact on the Company's consolidated financial statements.

In August 2018, the FASB issued an accounting standards update within ASU 2018-15 which expands the scope of costs associated with cloud computing arrangements that must be capitalized. Under the new guidance, costs associated with implementing a cloud computing arrangement that is a service contract must be capitalized and expensed over the term of the hosting arrangement. The provisions of the update are effective beginning January 1, 2020 for interim and annual periods with early adoption permitted for any interim period after issuance of the update. The Company is currently assessing the timing of its adoption as well as the potential impact that the standard will have on the Company's consolidated financial statements.

**Note 3—The purchase agreement and related transactions**

***Purchase agreement with Eisai***

Dova entered into a purchase agreement dated March 29, 2016 (the "Eisai stock purchase agreement") with Eisai, Inc. ("Eisai") for all of the issued and outstanding shares of the capital stock of AkaRx Inc., which consisted of the worldwide rights to DOPTOLET. The terms of the Eisai stock purchase agreement included (i) an upfront payment of \$5.0 million that was paid at closing and funded by a capital contribution by the Company's then sole member, PBM Capital Investments, LLC, (ii) milestone payments up to \$135.0 million in the aggregate based on annual net sales of DOPTOLET, and (iii) a commitment to negotiate in good faith to secure a long-term supply agreement with Eisai to govern manufacturing support and the purchase of DOPTOLET from Eisai for a certain period not to exceed three years after the first commercial sale of DOPTOLET.

The transaction was accounted for as an asset acquisition pursuant to ASU 2017-1, *Business Combinations (Topic 805), Clarifying the Definition of a Business*, as the majority of the fair value of the assets acquired was concentrated in a group of similar assets, and the acquired assets did not have outputs or employees. The assets acquired under the Eisai stock purchase agreement included a license to DOPTOLET, other associated intellectual property, inventory, documentation and records, and related materials. The potential milestone payments based on annual net sales are not yet considered probable, and no additional milestone payments have been accrued at September 30, 2019.

***Supply agreement with Eisai***

In June 2017, the Company entered into a supply agreement with Eisai, pursuant to which the Company agreed to purchase finished drug product of DOPTOLET from Eisai and Eisai agreed to supply finished drug product of DOPTOLET. The initial term of the agreement will expire three years after the first commercial sale of DOPTOLET. After the initial term, the supply agreement may be renewed by mutual agreement of the parties. During the initial term, Eisai is the Company's exclusive supplier of finished drug product of DOPTOLET, except that the Company has the right to terminate the exclusivity early by payment to Eisai of a fee calculated based on the Company's forecasted purchases of DOPTOLET during the remainder of the initial term. In addition, in the event that Eisai fails to deliver substantially all of the finished drug product due to the Company under the agreement, the Company may elect to seek alternative supply arrangements so long as such failure remains uncured, subject to certain exceptions. The aggregate payments to Eisai under the supply agreement for finished drug product will be the greater of a fixed payment per tablet or a payment calculated in the mid-single digit percentages of net sales of DOPTOLET.

***Amended and Restated Transition Services Agreement with Eisai and an Additional Work Order***

Effective April 1, 2018, the Company and Eisai entered into an Amended and Restated Transition Services Agreement (the "Amended TSA") and an Additional Work Order ("Work Order"), pursuant to which Eisai agreed to provide services to the Company after the expiration of the original Transition Services Agreement by and between Eisai and the Company, dated March 30, 2016 (the "TSA"), which expired on March 31, 2018. Under the Work Order, Eisai provided certain regulatory,

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CMC, nonclinical, clinical pharmacology, and statistical services to the Company in order to support the Company's new drug application and marketing authorization application to the European Medicines Agency for the period from April 1, 2018 through June 30, 2019, at which time the Work Order expired. Through September 30, 2019, the Company incurred \$32.3 million under the TSA and the Amended TSA.

***Eisai note and security agreement***

On March 30, 2016, the Company issued a Note to Eisai, which had an interest rate of 5% per annum, and enabled the Company to finance payments due to Eisai under the TSA for all costs incurred through December 31, 2017. The principal amount of the Note was increased on a quarterly basis by the amount of unpaid service fees and out-of-pocket expenses due and owed to Eisai under the TSA. The total aggregate spend through this Note was \$31.1 million and on March 16, 2018, this principal balance along with accumulated interest of \$1.3 million was repaid in full.

***License agreement with Astellas Pharma Inc.***

The primary intellectual property related to DOPTOLET is licensed from Astellas Pharma Inc. ("Astellas") on an exclusive, worldwide basis under the terms of a license agreement that the Company acquired from Eisai under the Eisai stock purchase agreement. Under the terms of the license agreement, the Company is required to make payments upon the achievement of certain milestones. On September 21, 2017, upon the submission of the NDA, the Company recorded a milestone payment of \$1.0 million. On June 26, 2019, upon the FDA approval of DOPTOLET for ITP, the Company recorded, within research and development expenses, a milestone payment for another \$1.0 million. The Company will be required to make additional aggregate milestone payments of up to \$3.0 million to Astellas if certain other regulatory milestones are achieved. In addition, the Company is required to pay Astellas tiered royalties ranging from the mid to high single digits on net sales of DOPTOLET. No amounts have been accrued for any potential milestone payments as the payments were not deemed probable. Unless earlier terminated, this license agreement with Astellas will expire on a country-by-country and product-by-product basis upon the latest of (i) the expiration of the last-to-expire claim of the licensed patents, (ii) the expiration of any government-granted marketing exclusivity period for DOPTOLET, and (iii) 10 years after the last date of launch of DOPTOLET to have occurred in any country. Thereafter, the term of the license agreement may be extended for successive one-year terms if the Company notifies Astellas in writing of its desire to extend such term at least three months before it is otherwise set to expire.

**Note 4—Related party agreements**

***Dova and AkaRx management services agreements***

On April 1, 2016, Dova and AkaRx each entered into a services agreement (each, a "SA") with PBM Capital Group, LLC. Pursuant to the terms of each of the SAs, which have terms of twelve months each (and are automatically renewable for successive one-year periods), PBM Capital Group, LLC will render advisory and consulting services to Dova and AkaRx. Services provided under the SAs may include certain scientific and technical, accounting, operations and back office support services. In consideration for these services, Dova and AkaRx are each obligated to pay PBM Capital Group, LLC a monthly management fee of \$25,000. On March 30, 2018, the SA agreement between AkaRx and PBM Capital Group, LLC was terminated. Effective April 1, 2018, the monthly management fee for the SA between Dova and PBM Capital Group, LLC was reduced to \$17,400.

For the three and nine months ended September 30, 2019, the Company incurred expenses under the SAs of \$2,200 and \$156,600, respectively, which were included in selling, general and administrative expenses.

For the three and nine months ended September 30, 2018, the Company incurred expenses under the SAs of \$2,200 and \$254,400, respectively, which were included in selling, general and administrative expenses.

**Note 5—Stock-based compensation**

***Equity Awards***

The Company maintains the Amended and Restated 2017 Equity Incentive Plan ("2017 Equity Incentive Plan"). The 2017 Equity Incentive Plan provides for the grant of incentive stock options to employees, and for the grant of nonstatutory options,

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restricted stock awards, restricted stock unit awards, stock appreciation rights, performance-based stock awards and other forms of stock awards to employees, including officers, consultants and directors. The 2017 Equity Incentive Plan also provides for the grant of performance-based cash awards to employees, including officers, consultants and directors. The Company's stock options generally vest as follows: 25% after 12 months of continuous services and the remaining 75% on a ratable basis over a 36-month period from 12 months after the grant date. Stock options granted to date have a maximum contractual term of 10 years.

On December 19, 2018, the Company's Board of Directors (the "Board") amended the 2017 Equity Incentive Plan (as amended, the "Amended Plan"), pursuant to which the Company reserved 1,250,000 shares of the Company's common stock for issuance as inducement awards (the "Inducement Pool"). The only persons eligible to receive grants of Awards (as defined below) from the Inducement Pool are individuals who satisfy the standards for inducement grants under Nasdaq Marketplace Rule 5635(c)(4) and the related guidance under Nasdaq IM 5635-1, including individuals who were not previously an employee or director of the Company or are following a bona fide period of non-employment, in each case as an inducement material to such individual's agreement to enter into employment with the Company. An "Award" is any right to receive the Company's common stock from the Inducement Pool, consisting of nonstatutory stock options and restricted stock unit awards. Options granted from the Inducement Pool generally vest over four years and vest at a rate of 25% upon the first anniversary of the issuance date and 1/48th per month thereafter and have terms of up to ten years consistent with options granted to other employees under the Amended Plan. All shares from the Inducement Pool were issued by December 31, 2018.

The Company initially reserved 4,285,250 shares of common stock for issuance under the Amended Plan. The number of shares of common stock reserved for issuance under the Amended Plan automatically increases on January 1 each year, for a period of ten years, from January 1, 2018 through January 1, 2027, by 4% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares as may be determined by the Board. As of September 30, 2019, 2,199,325 shares were available for grant under the Amended Plan. As of September 30, 2019, options to purchase 4,761,584 shares of the Company's common stock were outstanding at a weighted average exercise price of \$2.54 per share.

**Option awards**

The fair value of the Company's option awards was estimated using the assumptions below:

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Exercise price	\$14.82-\$27.95	\$22.29	\$7.97-\$27.95	\$22.29-\$33.47
Risk-free rate of interest	1.42%-1.92%	2.84%-2.92%	1.42%-2.6%	2.41%-3.02%
Expected term (years)	5.56-6.87	5.4-6.9	5.24-7.0	5.0-7.0
Expected stock price volatility	70.42%-71.57%	64%-65%	69.43%-71.89%	64%-88%

The following table summarizes the Company's stock option activity for the nine months ended September 30, 2019:

	Total options outstanding	Weighted-average exercise price	Weighted-average contractual term	Aggregate intrinsic value
Outstanding as of December 31, 2018	3,526,433	\$ 13.25	9.2	\$ 5,200,000
Employee options granted	2,902,374	10.66	9.1	2,743,904
Employee options exercised	(516,995)	3.82		
Employee options forfeited	(1,150,228)	13.90		
Outstanding as of September 30, 2019	4,761,584	\$ 12.54	9.1	\$ 74,573,799
Options vested and exercisable as of September 30, 2019	740,843	\$ 16.95	8.1	\$ 8,697,668

The aggregate intrinsic value in the above table is calculated as the difference between fair value of the Company's closing common stock price on September 30, 2019, or \$27.95 per share, and the exercise price of the stock options that had strike prices below \$27.95 per share. The weighted average grant date fair value per share of options granted during the nine months ended September 30, 2019 was \$6.66. The weighted average remaining contractual term of exercisable options is approximately 8.1 years at September 30, 2019. The expense is recognized over the vesting period of the award.

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As of September 30, 2019, there was approximately \$19.8 million of total unrecognized compensation expense, related to the unvested stock options shown in the table above, which is expected to be recognized over a weighted average period of 1.8 years.

**Restricted Stock Units**

Certain employees and Board members have been awarded restricted stock units with time-based vesting. During the nine months ended September 30, 2019, the Company granted 53,955 restricted stock units, with a weighted average grant date fair value of \$8.39 per share. As of September 30, 2019, 120,906 restricted stock units have vested.

The following table summarizes restricted stock unit activities for the nine months ended September 30, 2019:

	Number of units		Weighted average grant date fair value
Balance as of December 31, 2018	107,083	\$	6.07
Restricted stock units granted	53,955		8.39
Restricted stock units vested	(120,906)		6.85
Balance as of September 30, 2019	40,132	\$	6.84

As of September 30, 2019, the Company had unrecognized stock-based compensation expense related to restricted stock units of approximately \$0.1 million with a weighted average vesting period of approximately 0.3 years.

Stock-based compensation expense has been reported in the Company's consolidated statements of operations for the three and nine months ended September 30, 2019 as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Cost of product sales	\$ 18	\$ —	\$ 105	\$ 292
Research and development	396	590	1,241	1,602
Selling, general and administrative	3,276	3,446	8,287	9,149
Total stock-based compensation	\$ 3,690	\$ 4,036	\$ 9,633	\$ 11,043

**Note 6 — Significant agreements and contracts**

***Distribution Agreement with Fosun***

On March 16, 2018, the Company, through its wholly-owned subsidiary, AkaRx entered into an agreement by which it granted Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd., a wholly owned subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd., (collectively, "Fosun") the exclusive development and distribution rights of DOPTLET in mainland China and Hong Kong ("territory"). Under the terms of the agreement, Fosun will have the right to exclusively commercialize and to assist the Company with the registration of DOPTLET in the territory. Fosun is solely responsible for commercialization activities in the territory and associated expenses. The Company is responsible for supplying product at a fixed price to Fosun for the distribution of product upon approval.

The agreement between Fosun and the Company is governed by a joint steering committee comprised of equal representation by the Company and Fosun and operated on a consensus basis. In the event that the parties do not agree, the Company will have deciding authority, except with respect to matters that solely affect the territory.

Under the agreement, the Company received a non-refundable upfront payment of \$4.5 million during the second quarter of 2018, which consisted of an upfront payment of \$5.0 million, less \$0.5 million that was withheld in accordance with tax withholding requirements in China and recorded as an expense in 2018. The Company is also eligible to receive additional future payments upon the achievement of certain regulatory milestones. The Company assessed this arrangement in accordance with ASC Topic 606 and concluded that the contract counterparty, Fosun, is a customer. The Company determined the distinct,

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material performance obligations within this agreement consist of (1) the exclusive right to develop and commercialize DOPTOLET for multiple indications in the territory, (2) the delivery of certain indication specific information, and (3) manufacture and supply of commercial product.

The transaction price includes the \$5.0 million up-front consideration. None of the regulatory milestones have been included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and Fosun's efforts.

In 2018, the Company recognized \$2.6 million related to the up-front payment as other revenue in connection with the Fosun agreement. During the three months ended September 30, 2019, the Company recognized a further \$1.9 million of the up-front payment as other revenue. The amount of revenue recognized in connection with this agreement is commensurate with the deliverables provided by the Company to Fosun in achieving the performance obligation. The remaining transaction price of \$0.5 million is recorded within long-term deferred revenue, as of September 30, 2019, on the condensed consolidated balance sheet and will be recognized upon the delivery of certain information packages for indications which are in development. The relative fair value of deliverables was calculated using a combination of discounted cash flow and cost avoidance models (Level 3 inputs), under which estimated cash flows were discounted using a risk-adjusted rate that aligns with publicly available information of Fosun's cost structure. Estimated cash flows were determined based on management's best estimate of the performance of DOPTOLET for each indication in the territory.

***Commercial Outsourcing Agreement with Integrated Commercial Solutions, LLC ("ICS")***

On March 1, 2018, the Company entered into a Commercial Outsourcing Master Services Agreement with ICS, a division of AmerisourceBergen Specialty Group, a subsidiary of AmerisourceBergen, pursuant to which ICS is the exclusive provider of various third-party logistics services to support the Company's distribution of DOPTOLET in the United States. The key services provided by ICS include logistics, warehousing, returns and inventory management, contract administration and chargebacks processing and accounts receivable management.

Effective March 1, 2018, the Company also entered into a first amendment to the Commercial Outsourcing Master Services Agreement in order for ICS to purchase and sell DOPTOLET to the Company's customers in the United States. Pursuant to the amendment, ICS will only make shipments to customers who have an executed contract with the Company. Under this arrangement, ICS places orders with the Company to maintain an appropriate level of inventory. ICS assumes all inventory risk and has sole responsibility for determining the prices at which it sells these products, subject to specified limitations in the amendment. Effective April 1, 2019, ICS and the Company agreed to end the arrangement for ICS to purchase and sell DOPTOLET to the Company's customers, and ICS reverted to be the Company's third-party logistics provider.

***Co-Promotion Agreement with Valeant Pharmaceuticals North America LLC***

On September 26, 2018, the Company entered into a Co-Promotion Agreement (the "Co-Promotion Agreement") with the Salix division of Valeant Pharmaceuticals North America LLC ("Salix"), a subsidiary of Bausch Health Companies Inc., pursuant to which the Company granted Salix the exclusive right to co-promote DOPTOLET to specified medical professionals in the Gastroenterology, Colorectal Surgery and Proctology field (the "Specialty") in the United States. On June 27, 2019, the Company entered in to a First Amendment to the Co-Promotion Agreement effective July 1, 2019 (the "Amendment") in which the Company expanded its partnership with Salix, whereby Salix has the exclusive right to also co-promote in Hepatology, and Interventional Radiology, in addition to the previously defined Specialty (collectively, the "Expanded Specialty") in the United States for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

Pursuant to the Co-Promotion Agreement, the Company has been paying Salix a fee based on the quarterly Net Sales (as defined in the Co-Promotion Agreement) of DOPTOLET to specified medical professionals in the Specialty in the United States at specified tiered percentages, ranging from Salix receiving a mid-twenties to mid-thirties percent of Net Sales in a calendar year, subject to specified adjustments. Under the Amendment, the Company will pay Salix a fee based on the quarterly Net Sales of DOPTOLET to specified medical professionals in the Expanded Specialty in the United States, which equals a mid-thirties percentage of those Net Sales in a calendar year. In addition, pursuant to the Co-Promotion Agreement, the Company has agreed to pay Salix a milestone payment of \$2.5 million upon the achievement of an aggregate Net Sales amount to the Specialty. The Co-Promotion Agreement specifies that the Company will grant Salix a royalty-free right to use trademarks and

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copyrights relating to DOPTOLET in connection with the promotion of DOPTOLET in the United States. The Co-Promotion Agreement also contains provisions regarding payment terms, confidentiality and indemnification, as well as other customary provisions.

The co-promotion of DOPTOLET in the United States pursuant to the terms of the Co-Promotion Agreement is supervised by a joint steering committee composed of an equal number of representatives from the Company and Salix. Under the terms of the Co-Promotion Agreement, the Company is responsible for the costs of maintaining regulatory approval of, manufacturing, supplying and distributing DOPTOLET. Salix has also agreed to maintain at least one hundred Salix sales representatives (subject to certain adjustments) that will have the responsibility to promote DOPTOLET in the Expanded Specialty in the United States. Pursuant to the Amendment, the Company agreed to extend the term of the Co-Promotion Agreement by an additional year until September 26, 2023.

**Note 7 — Debt**

On April 17, 2018, the Company and its wholly owned subsidiary, AkaRx (collectively "Co-Borrowers"), entered into a Loan and Security Agreement ("Term Loan") with Silicon Valley Bank ("SVB") pursuant to which the Co-Borrowers borrowed \$20.0 million. The Term Loan was originally scheduled to mature on April 17, 2021 unless the Company achieved a specified revenue milestone in which case the maturity date would be extended to April 17, 2022. The Co-Borrowers were only required to make monthly interest payments until April 30, 2019 unless the Company achieved the specified revenue milestone, in which case the interest-only period would have been extended until October 31, 2019. Following the interest-only period, the Co-Borrowers would be required to also make equal monthly payments of principal and interest for the remainder of the term. The Co-Borrowers would have also been required to pay an additional final payment at maturity equal to \$2.0 million if the Term Loan was repaid by or after May 16, 2019 or a final payment of \$0.6 million if the Term Loan was repaid during the interest-only period. The final payment amount of \$2.0 million was recorded as a debt discount and was being accreted to the carrying value of the debt using the effective interest method. In addition, at its option, the Co-Borrowers were permitted to prepay all amounts owed under the Term Loan (including all accrued and unpaid interest), subject to a prepayment charge if the loan has been outstanding for less than one year, which prepayment charge would be 4% of the outstanding principal amount on the date the loan is prepaid. All obligations under this agreement were guaranteed by all the assets of the Co-Borrowers, except for intellectual property and certain other assets. The Term Loan bore interest at the WSJ prime rate plus 1.25% per annum. In connection with the Term Loan, the Company incurred debt issuance costs totaling approximately \$38,000. These costs were being amortized over the estimated term of the debt using the effective interest method.

On May 6, 2019, the Co-Borrowers entered into an Amended and Restated Loan and Security Agreement ("Term Loan Facility") with SVB and WestRiver Innovation Lending Fund VIII, L.P. ("WestRiver" and, together with SVB, the "Lenders"), pursuant to which the Company may borrow up to \$50.6 million, issuable in four separate tranches, of which \$20.6 million ("Advance A") was issued upon execution of the Term Loan Facility and used to repay in full all of the Company's outstanding obligations and liabilities to SVB under the Term Loan, including a prepayment fee of \$0.6 million, \$10.0 million ("Advance B") was issued in July 2019 upon the occurrence of regulatory approval for the ITP indication which occurred on June 26, 2019, \$10.0 million ("Advance C") is available to be issued upon the achievement of a specified commercial revenue milestone until the earlier of April 15, 2020 or the day before Advance D is available, and \$10.0 million ("Advance D") is available to be issued upon the achievement of specified regulatory and commercial revenue milestones until July 15, 2020. In the event that the Company does not borrow Advance C, then \$20.0 million, rather than \$10.0 million, will be available to be issued under Advance D upon the achievement of specified regulatory and commercial revenue milestones until July 15, 2020.

The maturity date of the Term Loan Facility is April 3, 2023. Under the terms of the Term Loan Facility, the Co-Borrowers will be required to make monthly interest-only payments on the principal amount outstanding under each Advance at a floating rate equal to the Prime Rate plus 2.00%. Upon the Company's draw of Advance B, the interest-only period was extended to August 3, 2020 followed by an amortization period of 32 months of equal monthly payments of principal plus interest amounts until paid in full. If either Advance C or Advance D is made, the interest-only period will be extended to May 3, 2021, followed by an amortization period of 23 months of equal monthly payments of principal plus interest amounts until paid in full. In addition to and not in substitution for the regular monthly payments of principal plus accrued interest, the Co-Borrowers are required to make a final payment equal to 10% of the aggregate principal amount of the Advances on the maturity date.

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

The Term Loan Facility has substantially the same terms as the Term Loan. In accordance with ASC 405-20, *Extinguishment of Liabilities*, and ASC 470-50, *Debt Modifications and Extinguishments*, the Company accounted for the repayment of the Company's outstanding obligations and liabilities to SVB under the Term Loan as a debt modification.

The Company deducted the debt issuance costs from the carrying amount of the debt as of September 30, 2019. As of September 30, 2019, the carrying value of the Term Loan Facility was approximately \$30.8 million. The short-term portion of \$1.9 million is due within 12 months and the long-term portion of \$28.9 million is due in greater than 12 months. The debt balance has been categorized within Level 2 of the fair value hierarchy. The carrying amount of the debt approximates its fair value based on prevailing interest rates as of the balance sheet date. In connection with the merger with Sobi, the Term Loan Facility is expected to be repaid in full on November 12, 2019.

As of September 30, 2019, annual principal payments due under the Term Loan Facility were as follows:

Year	Aggregate Minimum Payments (in thousands)
2019 (last three months)	\$ —
2020	4,781
2021	11,475
2022	11,475
2023	5,929
Total	33,660
Less unamortized debt issuance costs and final payment	(2,824)
Total	\$ 30,836

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

**Note 8 — Leases**

The Company currently subleases 14,378 square feet of office space (the "Existing Office Space") for its corporate headquarters located at 240 Leigh Farm Road, Durham, North Carolina through April 30, 2020. Effective October 12, 2018, the Company leased an additional 1,961 square feet of office space adjacent to the Existing Office Space directly from the building's landlord. On May 22, 2018, the Company entered into an Office Lease Agreement (the "Lease") directly with the building's landlord under which the Company will lease an additional 7,367 square feet of space adjacent to the Existing Office Space. Additionally, pursuant to the Lease, effective May 1, 2020, the Company will effectively renew the lease of the Existing Office Space directly with the landlord. On May 13, 2019, the Lease was amended to include an additional 3,881 square feet of office space, bringing the aggregate square feet of rentable office space to 25,626 square feet.

Under the sublease and the Lease, the Company's aggregate annual rent commitments are \$91,421 for the last three months of 2019, \$532,647 for 2020, \$713,385 for 2021, \$733,160 for 2022, and \$562,363 for 2023.

The term of the Lease will continue until September 30, 2023. The Company has an option to renew the Lease for one additional term of five years. If exercised, rent during the renewal term will be at the fair market rental rate as defined in the Lease.

The Lease provides for total tenant improvement allowance of approximately \$322,305. As of September 30, 2019, none of the allowance was utilized.

The Company recorded operating lease expense of \$98,523 and \$295,569 for the three and nine months ended September 30, 2019, respectively, compared to operating lease expense of \$71,565 and \$248,567 for the three and nine months ended September 30, 2018, respectively. Operating lease expense is recorded and classified as selling, general and administrative expenses on the Company's consolidated statements of operations.

**Maturity of lease liabilities**

<b>(in thousands)</b>	<b>Operating leases</b>	
2019 (last three months)	\$	91
2020		385
2021		455
2022		467
2023		359
Total lease payments		1,757
Less: Interest		(300)
Present value of lease liabilities	\$	1,457

The weighted average remaining lease term is 4.0 years and the weighted average discount rate is 6.5%. The discount rate is the same as the Company's incremental borrowing rate as the rate implicit in the leases cannot be readily determined.

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

**Note 9—Commitments and contingencies**

***Purchase commitments***

As noted in Note 3, the Company has an agreement with Eisai for the commercial supply of DOPTLET. Under the terms of the agreement, the Company will supply Eisai with non-cancelable firm commitment purchase orders. Future minimum purchase obligations are \$11.0 million through the first quarter of 2020.

The Company has also entered into other agreements with certain vendors for the provision of services, including services related to data access and packaging, under which the Company is contractually obligated to make certain payments to the vendors. The Company enters into contracts in the normal course of business that include, among others, arrangements with clinical research organizations for clinical trials, vendors for preclinical research, and vendors for manufacturing. These contracts generally provide for termination upon notice, and therefore the Company believes that its obligations under these agreements are not material.

***Litigation***

Between October 14, 2019 and October 31, 2019, four stockholder actions were filed in federal court (captioned *Wang v. Dova Pharm., Inc. et al*, No. 19-cv-01944-UNA (D. Del. filed Oct. 14, 2019); *Wheby v. Dova Pharm., Inc. et al*, No. 19-cv-01981-UNA (D. Del. filed Oct. 18, 2019) (filed on behalf of putative class); *Hurd v. Dova Pharm., Inc., et al*, No. 19-cv-09708 (S.D.N.Y. filed Oct. 21, 2019); and *Katz v. Dova Pharm. Inc. et al*, No. 19-cv-10147 (S.D.N.Y. filed Oct. 31, 2019) (collectively, the “Complaints”)) against the Company and the Board related to the tender offer. The Complaints assert violations of Sections 14(e) & (d) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 14d-9 promulgated thereunder. The Complaints contend the Company’s Schedule 14D-9, filed on October 11, 2019, omitted or misrepresented material information regarding the tender offer. The Complaints seek, among other things, injunctive relief, rescission or rescissory damages, and an award of The Complaints’ respective costs, including attorneys’ fees and expenses. The Company believes the allegations and claims asserted in the lawsuits are without merit and that the disclosures in the Schedule 14D-9, filed on October 11, 2019, comply fully with applicable law.

**Note 10—Income taxes**

The Company estimates an annual effective tax rate of 0% for the year ending December 31, 2019 as the Company incurred losses for the three and nine months ended September 30, 2019 and is forecasting additional losses through the fourth quarter of 2019, resulting in an estimated net loss for both financial statement and tax purposes for the year ending December 31, 2019. Therefore, no federal or state income taxes are expected, and none have been recorded at this time. Income taxes have been accounted for using the liability method in accordance with ASC 740.

Due to the Company’s history of losses since inception, the Company has determined, based upon available evidence, that it is more likely than not that the net deferred tax asset will not be realized and, accordingly, has provided a full valuation allowance against its net deferred tax asset.

At September 30, 2019, the Company had no unrecognized tax benefits that would reduce the Company’s effective tax rate if recognized.

**Note 11—Employee benefit plan**

The Company maintains a defined contribution 401(k) plan available to full-time employees, under which employee contributions are voluntary and are determined on an individual basis, limited by the maximum amounts allowable under federal tax regulations. The Company provides an automatic matching contribution of \$1.00 per \$1.00 of employee contribution into the plan for the first 3% and \$0.50 per \$1.00 of employee contribution for the next 2%, for a maximum deferral per employee of 4% of the employee’s salary. The Company’s matching contributions totaled approximately \$181,386 and \$438,161 during the three and nine months ended September 30, 2019, respectively. The Company’s matching contributions totaled approximately \$70,163 and \$179,003 during the three and nine months ended September 30, 2018, respectively.

## Note 12—Subsequent Events

The Company has evaluated subsequent events through the issuance date of these financial statements to ensure that this filing includes appropriate disclosure of events both recognized in the financial statements as of September 30, 2019, and events which occurred subsequently but were not recognized in the financial statements.

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

*The following discussion and analysis of our financial condition, results of operations and cash flows should be read in conjunction with (1) the unaudited interim condensed consolidated financial statements and the related notes thereto included elsewhere in this Quarterly Report on Form 10-Q, and (2) the audited consolidated financial statements and notes thereto for the year ended December 31, 2017 and 2018 and the related management’s discussion and analysis of financial condition and results of operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the Securities and Exchange Commission (the “SEC”) on March 5, 2019.*

### Forward-looking statements

*This Quarterly Report on Form 10-Q contains “forward-looking statements” within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). These statements are often identified by the use of words such as “expect,” “anticipate,” “estimate,” “may,” “will,” “should,” “intend,” “believe,” and similar expressions, although not all forward-looking statements contain these identifying words. Although we believe the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to significant risks and uncertainties and we can give no assurances that our expectations will prove to be correct. Actual results could differ materially from those described in this report because of numerous factors, many of which are beyond our control. These factors include, without limitation, changes resulting from the completion of our pending acquisition by Sobi (as defined below), as well as those factors described in our Annual Report on Form 10-K for the year ended December 31, 2018 under Part I - Item 1A “Risk Factors” filed with the Securities and Exchange Commission on March 5, 2019, in this Quarterly Report under Part II - Item 1A “Risk Factors,” and in our other filings with the SEC. We undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes.*

### Overview

We are a pharmaceutical company focused on acquiring, developing and commercializing drug candidates for diseases that are treated by specialist physicians, with an initial focus on addressing thrombocytopenia, a disorder characterized by a low blood platelet count. On May 21, 2018, the U.S. Food and Drug Administration (“FDA”) approved DOPTelet (avatrombopag), which is an orally administered thrombopoietin receptor agonist for the treatment of thrombocytopenia in adult patients with chronic liver disease (“CLD”) scheduled to undergo a procedure, which we commercially launched on June 4, 2018. In addition, on June 20, 2019, we were granted a marketing authorization by the European Commission for the treatment of severe thrombocytopenia in adult patients with CLD who are scheduled to undergo an invasive procedure. DOPTelet has not yet been commercially launched in Europe. Furthermore, on June 26, 2019, we received FDA approval for DOPTelet for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (“ITP”) who have had an insufficient response to a previous treatment. We believe that DOPTelet, along with currently marketed TPO-RAs Promacta and Nplate for the treatment of patients with ITP alone, has an approximately \$1.0 billion addressable market in the United States and an approximately \$2.0 billion worldwide addressable market. We commercially launched DOPTelet for the treatment of thrombocytopenia in adult patients with chronic ITP on July 16, 2019. In conjunction with the launch of DOPTelet for chronic ITP, we reduced the wholesaler acquisition cost for DOPTelet by approximately two thirds compared to the previous wholesaler acquisition cost for DOPTelet. We also expanded our distribution network to include several specialty distributors that are associated with certain group purchasing organizations.

We initiated a Phase 3 trial in chemotherapy-induced thrombocytopenia (“CIT”) during the first quarter of 2018. Results for the primary and select secondary endpoints from this trial are expected in the first half of 2020. Currently, there are no approved treatments for CIT. Physicians are currently managing CIT through chemotherapy dose reductions, cycle delays, and in severe cases platelet transfusions. In the United States, there are approximately 765,000 patients annually that receive chemotherapy. Among those patients, roughly 93% have solid tumors, while the remaining 7% have non-solid tumors. The incidence of thrombocytopenia in solid tumors and non-solid tumors is reported to be approximately 10% and 50%, respectively. Accordingly, we believe the U.S. addressable CIT population related to solid tumors to include approximately 71,000 patients annually. The ongoing clinical trial in CIT utilizes a dosage regimen of 60 mg once daily for 5 days prior to chemotherapy and

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60 mg once daily for 5 days after chemotherapy. If approved, patients receiving chemotherapy that develop clinically meaningful thrombocytopenia are expected to utilize DOPTOLET for 2 to 3 cycles out of a 6-cycle chemotherapy regimen.

We have a limited operating history as we were formed on March 24, 2016. Since our inception, our operations have focused on acquiring rights to DOPTOLET, organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio, conducting clinical trials, preparing for and submitting a new drug application ("NDA") and sNDA for DOPTOLET, building a commercial organization, including a field sales team and launching DOPTOLET. We have funded our operations primarily through the sale of preferred and common stock and the issuance of debt. On July 5, 2017, we closed our IPO of common stock, which resulted in the issuance and sale of 5,077,250 shares of common stock at a public offering price of \$17.00 per share, resulting in net proceeds of approximately \$78.7 million after deducting underwriting discounts and commissions and other offering costs. Upon the closing of the IPO, all outstanding shares of our Series A convertible preferred stock were automatically converted into 3,242,950 shares of common stock. In addition, on February 27, 2018, we completed an underwritten public offering of 2,500,000 shares of our common stock. The shares were sold to the public at an offering price of \$32.00 per share. Net proceeds raised from the offering were approximately \$74.7 million, after deducting underwriting discounts and commissions and other offering expenses. On April 17, 2018, we, along with our wholly owned subsidiary, AkaRx, (collectively the "Co-Borrowers"), entered into a Loan and Security Agreement ("Term Loan") with Silicon Valley Bank ("SVB"), pursuant to which we borrowed \$20.0 million maturing up to 48 months from the closing. On May 6, 2019, the Co-Borrowers entered into an Amended and Restated Loan and Security Agreement ("Term Loan Facility") with SVB and WestRiver Innovation Lending Fund VIII, L.P. (collectively the "Lenders"), to extend the interest-only period of the existing \$20.0 million Term Loan by 12 months and to provide aggregate additional potential borrowings of \$30.0 million upon achieving specified regulatory and revenue milestones. On July 1, 2019, we borrowed an additional \$10.0 million under the Term Loan Facility. Refer to Note 7 "Debt" of our unaudited condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for further information on the Term Loan Facility.

On September 30, 2019, we announced the execution of an Agreement and Plan of Merger (the "Merger Agreement") with Swedish Orphan Biovitrum AB (publ), a Swedish public limited liability company ("Sobi"). Under the terms of the Merger Agreement, Sobi commenced a tender offer for all outstanding shares of Dova, whereby Dova stockholders were offered an upfront payment for \$27.50 per share in cash, along with one non-tradeable Contingent Value Right ("CVR") that entitles them to an additional \$1.50 per share in cash upon regulatory approval of DOPTOLET for the treatment of CIT, representing a total potential consideration of \$29.00 per share, or a total potential consideration of up to \$915 million on a fully diluted basis. We refer to the upfront payment of \$27.50 per share in cash plus the CVR herein as "offer price." The tender offer was completed on November 8, 2019 and the merger is expected to close on November 12, 2019. Upon the closing of the merger, the Company will become a wholly-owned indirect subsidiary of Sobi. In addition, all of our outstanding options (whether vested or unvested) that have an exercise price of less than \$27.50 will be canceled and the holders thereof will receive the offer price in respect of each share covered by such option, less the applicable exercise price, and all outstanding restricted stock units (whether vested or unvested) will be canceled and the holders thereof received the offer price in respect of each share covered by such restricted stock unit. In addition, any options with an exercise price between \$27.50 and \$29.00 will also be entitled to receive a payment in respect of each share covered by such option upon regulatory approval of DOPTOLET for the treatment of CIT in an amount equal to the excess of \$29.00 over the applicable exercise price. Upon the closing of the merger, the Term Loan Facility is expected to be repaid in full.

Since inception, we have incurred significant operating losses. For the nine months ended September 30, 2019 and for the year ended December 31, 2018, our net loss was \$54.7 million and \$72.3 million, respectively. As of September 30, 2019, we had an accumulated deficit of \$184.2 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- continue to invest in the clinical development of DOPTOLET for the treatment of CIT;
- continue the commercialization of DOPTOLET;
- fulfill post-marketing obligations in territories where DOPTOLET is approved;
- manufacture DOPTOLET under our supply agreement with Eisai;
- establish an additional manufacturer for DOPTOLET;
- maintain, expand and protect our intellectual property portfolio;
- evaluate opportunities for development of additional drug candidates; and
- incur additional costs associated with operating as a public company, if the merger with Sobi is not consummated.

## **Significant Agreements and Contracts**

### ***Stock purchase agreement with Eisai***

In March 2016, we entered into the stock purchase agreement with Eisai, (the “Eisai stock purchase agreement”), pursuant to which we acquired the worldwide rights to DOPTOLET. The terms of the Eisai stock purchase agreement included (i) an upfront payment of \$5.0 million, (ii) milestone payments up to \$135.0 million in the aggregate based on annual net sales of DOPTOLET and (iii) a commitment to negotiate in good faith to secure a long-term supply agreement with Eisai to purchase supplies of DOPTOLET from Eisai. See Note 3 “The purchase agreement and related transactions” in the accompanying notes to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for additional information.

***Amended and restated transition services agreement and an additional work order***

Effective April 1, 2018, we entered into an Amended and Restated Transition Services Agreement (the “Amended TSA”) and an Additional Work Order (“Work Order”) with Eisai, pursuant to which Eisai agreed to provide services to us after the expiration of the original Transition Services Agreement by and between Eisai and us, dated March 30, 2016 (the “TSA”), which expired on March 31, 2018. Under the Work Order, Eisai provided certain regulatory, CMC, nonclinical, clinical pharmacology, and statistical services in order to support our NDA and marketing authorization application to the European Medicines Agency for the period from April 1, 2018 through June 30, 2019, at which time the Work Order expired. The Company incurred \$32.3 million under the TSA and the Amended TSA.

***Supply agreement with Eisai***

In June 2017, we entered into a supply agreement with Eisai, pursuant to which we agreed to purchase finished drug product of DOPTOLET from Eisai and Eisai agreed to supply finished drug product of DOPTOLET to us. The initial term of the agreement will expire three years after the first commercial sale of DOPTOLET. After the initial term, the supply agreement may be renewed by mutual agreement of the parties. During the initial term, Eisai is our exclusive supplier of finished drug product of DOPTOLET, except that we have the right to terminate the exclusivity early by payment to Eisai of a fee calculated based on our forecasted purchases of DOPTOLET during the remainder of the initial term. In addition, in the event that Eisai fails to deliver substantially all of the finished drug product due to us under the agreement, we may elect to seek alternative supply arrangements so long as such failure remains uncured, subject to certain exceptions. The aggregate payments to Eisai under the supply agreement for finished drug product will be the greater of a fixed payment per tablet or a payment calculated in the mid-single digit percentages of net sales of DOPTOLET.

***Eisai note and security agreement***

On March 30, 2016, we issued a secured promissory note with Eisai (the “Note”), which had an interest rate of 5% per annum, and enabled us to finance payments due to Eisai under the TSA for all costs incurred through December 31, 2017. The principal amount of the Note was increased on a quarterly basis by the amount of unpaid service fees and out-of-pocket expenses due and owed to Eisai under the TSA. The total aggregate spend through this Note was \$31.1 million and on March 16, 2018, we repaid in full this principal balance along with accumulated interest of \$1.3 million.

***License agreement with Astellas Pharma Inc.***

The primary intellectual property related to DOPTOLET is licensed to us from Astellas Pharma Inc. (“Astellas”) on an exclusive, worldwide basis under the terms of a license agreement which we acquired under the Eisai stock purchase agreement. Under the terms of the license agreement, we are required to make payments upon the achievement of certain milestones. On September 21, 2017, upon the submission of the NDA, we recorded a milestone payment of \$1.0 million. On June 26, 2019, upon the FDA approval of DOPTOLET for ITP, we became obligated to pay another \$1.0 million within 30 days, which has been recorded within research and development expenses. We will be required to make additional aggregate milestone payments of up to \$3.0 million to Astellas if certain other regulatory milestones are achieved. In addition, we are required to pay Astellas tiered royalties ranging from the mid to high single-digit percentages on net sales of DOPTOLET. No amounts have been accrued for any potential future milestone payments as such payments have not been deemed probable. Unless earlier terminated, this license agreement with Astellas will expire on a country-by-country and product-by-product basis upon the latest of (i) the expiration of the last-to-expire claim of the licensed patents, (ii) the expiration of any government-granted marketing exclusivity period for DOPTOLET, and (iii) 10 years after the last date of launch of DOPTOLET to have occurred in any country. Thereafter, the term of the license agreement may be extended for successive one-year terms if the Company notifies Astellas in writing of its desire to extend such term at least three months before it is otherwise set to expire. See Note 3 “The purchase agreement and related transactions” in the accompanying notes to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for additional information.

***Services agreements with PBM Capital Group, LLC***

On April 1, 2016, we and AkaRx each entered into a services agreement (each, a “SA”) with PBM Capital Group, LLC. Pursuant to the terms of each of the SAs, which have terms of 12 months each (and are automatically renewable for successive one-year periods), PBM Capital Group, LLC has rendered advisory and consulting services to us and AkaRx. Services provided under the SAs include certain scientific and technical, accounting, operations and back office support services. In consideration for these services, we and AkaRx were each obligated to pay PBM Capital Group, LLC a monthly management fee of \$25,000. On March 30, 2018, the SA agreement between AkaRx and PBM Capital Group, LLC was terminated. Effective April 1, 2018, the monthly management fee for the SA between us and PBM Capital Group, LLC was reduced to \$17,400.

#### ***Distribution Agreement***

On March 16, 2018, we entered into a Manufacturing and Distribution Agreement (the “Distribution Agreement”) with Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd., a wholly owned subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd., (collectively, “Fosun”) whereby we granted Fosun the exclusive development and distribution rights of DOPTOLET in mainland China and Hong Kong (the “Territory”). Under the terms of the Distribution Agreement, Fosun will have the right to exclusively commercialize and to assist us with the registration of DOPTOLET in the Territory. Fosun is solely responsible for commercialization activities in the Territory and associated expenses. We are responsible for supplying finished drug product at a fixed price to Fosun for the distribution of product upon approval.

The Distribution Agreement is governed by a joint steering committee comprised of equal representation by us and Fosun and operated on a consensus basis. In the event that the parties do not agree, we will have deciding authority, except with respect to matters that solely affect the territory.

Under the Distribution Agreement, we received a non-refundable upfront payment of \$4.5 million during the second quarter of 2018, which consisted of an upfront payment of \$5.0 million, less \$0.5 million that was withheld in accordance with tax withholding requirements in China. We are also eligible to receive additional future payments upon the achievement of certain regulatory milestones. We expect to receive a milestone payment within the next 12 months upon the achievement of a regulatory milestone.

#### ***Commercial outsourcing agreement***

On March 1, 2018, we entered into a Commercial Outsourcing Master Services Agreement with Integrated Commercial Solutions, LLC (“ICS”), a division of AmerisourceBergen Specialty Group, a subsidiary of AmerisourceBergen, pursuant to which ICS is the exclusive provider of various third-party logistics services to support our distribution of DOPTOLET in the United States. The key services provided by ICS include logistics, warehousing, returns and inventory management, contract administration and chargebacks processing and accounts receivable management.

#### ***Co-Promotion agreement***

On September 26, 2018, we entered into a Co-Promotion Agreement (the “Co-Promotion Agreement”) with the Salix division of Valeant Pharmaceuticals North America LLC (“Salix”), a subsidiary of Bausch Health Companies Inc., pursuant to which we granted Salix the exclusive right to co-promote DOPTOLET to specified medical professionals in the Gastroenterology, Colorectal Surgery and Proctology fields (the “Specialty”) in the United States. On June 27, 2019, we entered in to a First Amendment to the Co-Promotion Agreement effective July 1, 2019 (the “Amendment”) in which we expanded our partnership with Salix, whereby Salix has the exclusive right to also co-promote in Hepatology, and Interventional Radiology, in addition to the previously defined Specialty (collectively, the “Expanded Specialty”) in the United States for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

Pursuant to the Co-Promotion Agreement, we have been paying Salix a fee based on the quarterly Net Sales (as defined in the Co-Promotion Agreement) of DOPTOLET to specified medical professionals in the Specialty in the United States at specified tiered percentages, ranging from Salix receiving a mid-twenties to mid-thirties percent of Net Sales in a calendar year, subject to specified adjustments. Under the Amendment, we will pay Salix a fee based on the quarterly Net Sales of DOPTOLET to specified medical professionals in the Expanded Specialty in the United States, which, commencing on July 1, 2019, will equal a mid-thirties percentage of those Net Sales in a calendar year. In addition, pursuant to the Co-Promotion Agreement, we have agreed to pay Salix a milestone payment of \$2.5 million upon the achievement of an aggregate Net Sales amount to the Specialty. The Co-Promotion Agreement specifies that we will grant Salix a royalty-free right to use trademarks and copyrights relating to DOPTOLET in connection with the promotion of DOPTOLET in the United States. The Co-Promotion Agreement also contains provisions regarding payment terms, confidentiality and indemnification, as well as other customary provisions.

The co-promotion of DOPTOLET in the United States pursuant to the terms of the Co-Promotion Agreement will be supervised by a joint steering committee composed of an equal number of representatives from us and Salix. Under the terms of the Co-Promotion Agreement, we are responsible for the costs of maintaining regulatory approval of, manufacturing, supplying and distributing DOPTOLET. Salix has also agreed to maintain at least one hundred Salix sales representatives (subject to certain adjustments) that will have the responsibility to promote DOPTOLET in the Specialty in the United States. Pursuant to the Amendment, we agreed to extend the term of the Co-Promotion Agreement by an additional year until September 26, 2023.

### **Critical accounting policies and significant judgments and estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, ("U.S. GAAP"). The preparation of these financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the dates of the balance sheets and the reported amounts of expenses during the reporting periods. In accordance with U.S. GAAP, we evaluate our estimates and judgments on an ongoing basis.

Significant estimates include assumptions used in the determination of net revenue generated from product sales, revenue recognized upon the satisfaction of performance obligations under our strategic agreements, of share-based compensation and some of our research and development expenses. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We discussed accounting policies and assumptions that involve a higher degree of judgment and complexity in Note 2 to our consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2018 filed with the SEC on March 5, 2019. There have been no material changes during the three and nine months ended September 30, 2019 to our critical accounting policies, significant judgments and estimates disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018, except for the addition of a lease accounting policy as discussed in Note 2 of our unaudited condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q.

### **Components of results of operations**

#### ***Revenue***

Product sales, net consist of sales of DOPTOLET, which was approved by the FDA for the treatment of thrombocytopenia in adult patients with CLD scheduled to undergo a procedure on May 21, 2018. On June 26, 2019, we received FDA approval for DOPTOLET for ITP who have had an insufficient response to a previous treatment. We launched DOPTOLET for ITP on July 16, 2019.

In addition, for the three and nine months ended September 30, 2019, we recognized \$1.9 million of the upfront payment received from our Distribution Agreement with Fosun.

#### ***Cost of product sales***

Cost of product sales consists primarily of direct and indirect costs related to the manufacturing of DOPTOLET sold, including third-party manufacturing costs, packaging services, freight, royalty payments to Astellas in addition to inventory adjustment charges. We expect cost of product sales as a percentage of net sales to increase in the short-term as we work through our existing inventories.

#### ***Research and development expense***

Research and development expense consists of costs incurred in connection with our research activities, most of which to-date have been incurred under the TSA and the Amended TSA and includes costs associated with clinical trials, consultants, clinical trial materials, regulatory filings, facilities, laboratory expenses and other supplies.

Research and development costs are expensed as incurred. Costs for certain activities, such as manufacturing and preclinical studies and clinical trials, are generally recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and collaborators.

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We expect our research and development expense will increase for the foreseeable future as we pursue additional indications for DOPTOLET and establish a second source manufacturer to ensure continuity of product supply. In addition, drug candidates in later stages of clinical development, such as DOPTOLET, generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials.

The duration, costs and timing of additional clinical trials for DOPTOLET and any other drug candidates will depend on a variety of factors that include the following:

- number of trials required for approval;
- delays in reaching, or failing to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites or prospective contract research organizations, the terms of which can be subject to extensive negotiation and may vary significantly among different contract research organizations and trial sites;
- clinical trials of our drug candidates producing negative or inconclusive results, including failure to demonstrate statistical significance;
- per patient trial costs, including based on number of doses that patients receive;
- the number of patients that participate in the trials and then drop-out or discontinuation rates of patients;
- the number of sites included in the trials;
- the countries in which the trial is conducted;
- the length of time required to enroll eligible patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials;
- the duration of patient follow-up;
- timing and receipt of regulatory approvals;
- the efficacy and safety profile of the drug candidate;
- third-party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- whether and how many post-approval trials are required;
- regulators or institutional review boards requiring that we or our investigators suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks; and
- the insufficiency or inadequacy of the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates.

At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of DOPTOLET for new indications. We are also unable to predict when, if ever, material net cash inflows will commence from sales of DOPTOLET. This is due to the numerous risks and uncertainties associated with developing and commercializing DOPTOLET, including the uncertainty of:

- achieving successful enrollment and completion of additional clinical trials and achieving regulatory approval of DOPTOLET for the treatment of thrombocytopenia beyond its currently approved indications;
- establishing an appropriate safety profile;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers that provide for commercial quantities of DOPTOLET manufactured at acceptable cost levels and quality standards;
- whether any indication approved by regulatory authorities is narrower than we expect;
- compliance with ongoing regulatory review by the FDA, EMA, or any comparable foreign regulatory authorities;
- the efficacy and safety of DOPTOLET and potential advantages compared to alternative treatments, notwithstanding success in meeting or exceeding clinical trial endpoints;
- the size of the markets for approved indications in territories in which we receive regulatory approval, if any;
- the ability to set an acceptable price for DOPTOLET and obtain coverage and adequate reimbursement from third-party payors and develop and implement viable patient assistance programs;
- the acceptance by the prescribing community of DOPTOLET;
- the degree of competition we face from competitive therapies;
- the ability to add operational, financial, management and information systems personnel, including personnel to support our clinical, manufacturing and planned future commercialization efforts and operations as a public company;
- retention of key research and development personnel;
- the ability to continue to build out and retain an experienced management and advisory team;
- the ability to maintain, expand and protect our intellectual property portfolio, including any licensing arrangements with respect to our intellectual property; and

- the ability to avoid and defend against third-party infringement and other intellectual property related claims.

A change in the outcome of any of these variables with respect to the development of our drug candidate would significantly change the costs, timing and viability associated with the development of that drug candidate.

#### *Selling, general and administrative expense*

Selling, general and administrative expense consists primarily of salaries and other related costs, stock compensation expense, recruiting fees, professional fees, as well as increasingly the costs associated with supporting the commercialization of DOPTelet.

We expect our selling, general and administrative expense will increase for the foreseeable future to support the commercialization of DOPTelet for its currently approved indications and other indications, if these other indications gain marketing approval. These increases will likely include increased costs related to the hiring of additional personnel and fees related to the Co-Promotion Agreement. In addition, we expect to incur, at an increased rate compared to prior periods, significantly higher expenses associated with building and maintaining a sales and marketing team in connection with the commercialization of DOPTelet. As a result, we expect significantly higher selling, general and administrative expenses over the next several fiscal quarters compared to prior periods.

#### **Results of operations for the three months ended September 30, 2019 and 2018**

The following table sets forth our selected statements of operations data for the three months ended September 30, 2019 and 2018 (in thousands):

	<b>Three months ended September 30,</b>	
	<b>2019</b>	<b>2018</b>
<b>Revenue</b>		
Product sales, net	\$ 1,453	\$ 2,929
Other revenue	1,920	—
Total revenue, net	3,373	2,929
<b>Operating expenses:</b>		
Cost of product sales	653	370
Research and development	4,188	4,847
Selling, general and administrative	19,197	17,031
Total operating expenses	24,038	22,248
<b>Loss from operations</b>	<b>(20,665)</b>	<b>(19,319)</b>
Interest income and other income (expense), net	235	342
Interest expense	(855)	(546)
Total other expenses, net	(620)	(204)
<b>Net loss</b>	<b>\$ (21,285)</b>	<b>\$ (19,523)</b>

#### *Revenue*

Product sales, net decreased by \$1.5 million to \$1.4 million for the three months ended September 30, 2019 from \$2.9 million for the three months ended September 30, 2018 due to the decrease in wholesaler acquisition cost for DOPTelet and the replacement of channel inventory with product with updated labels.

In addition, for the three months ended September 30, 2019, other revenue consisted of a \$1.9 million upfront payment received pursuant to our Distribution Agreement with Fosun.

#### *Cost of product sales*

Cost of product sales increased by \$0.3 million to \$0.7 million for the three months ended September 30, 2019 from \$0.4 million for the three months ended September 30, 2018 due to an increase in the cost of inventory, royalty payments to Astellas and an increase in certain distribution and overhead costs.

***Research and development expense***

Research and development expenses were \$4.2 million and \$4.8 million for the three months ended September 30, 2019 and September 30, 2018, respectively. Product development costs were lower for the three months ended September 30, 2019 compared to the three months ended September 30, 2018 primarily driven by the termination of two studies and partially offset by the progression of the CIT program.

For the three months ended September 30, 2019, research and development expenses included approximately \$3.1 million of product development expenses, \$0.6 million of payroll-related expenses, and \$0.5 million of stock-based compensation expense.

For the three months ended September 30, 2018, we recorded approximately \$3.2 million of product development expenses, \$1.0 million of payroll-related expenses, and \$0.6 million of stock-based compensation expense.

***Selling, general and administrative expense***

For the three months ended September 30, 2019, selling, general and administrative expenses increased by \$2.2 million compared to the three months ended September 30, 2018, which was primarily driven by the commercial launch of DOPTOLET for the treatment of ITP in July 2019 and the Salix promotion fee recorded during the three months ended September 30, 2019.

For the three months ended September 30, 2019, selling, general and administrative expenses consisted of \$3.8 million of commercial-related expenses, \$9.0 million of payroll-related expenses, \$3.2 million of stock-based compensation expenses, \$0.2 million of office operations-related expenses, \$2.3 million in professional and consulting fees, \$0.2 million related to pharmacovigilance and medical writing, and \$0.5 million in educational sponsorship and grants.

For the three months ended September 30, 2018, selling, general and administrative expenses consisted of \$3.0 million of commercial-related expenses, \$7.7 million of payroll-related expenses, \$3.4 million of stock-based compensation expenses, \$0.7 million of office operations-related expenses, \$1.7 million in professional and consulting fees, and \$0.5 million in educational sponsorship grants.

***Other expenses, net***

Other expenses, net for the three months ended September 30, 2019 consisted primarily of \$0.9 million of interest expense and amortization of debt issuance costs and accretion expense for the final payment related to our loan with SVB, partially offset by \$0.4 million of income on our money market accounts.

Other expense, net for the three months ended September 30, 2018 consisted primarily of \$0.5 million of interest expense and amortization of debt issuance costs and accretion expense for the final payment related to our loan with SVB, and \$0.2 million of charitable contributions, partially offset by \$0.5 million of income on our money market accounts.

**Results of operations for the nine months ended September 30, 2019 and 2018**

The following table sets forth our selected statements of operations data for the nine months ended September 30, 2019 and 2018 (in thousands):

	<b>Nine months ended September 30,</b>	
	<b>2019</b>	<b>2018</b>
<b>Revenue</b>		
Product sales, net	\$ 8,970	\$ 4,886
Other revenue	1,920	2,627
Total revenue, net	10,890	7,513
<b>Operating expenses:</b>		
Cost of product sales	1,612	889
Research and development	12,777	12,771
Selling, general and administrative	50,447	45,856
Total operating expenses	64,836	59,516
<b>Loss from operations</b>	<b>(53,946)</b>	<b>(52,003)</b>
Interest income and other income (expense), net	1,211	369
Interest expense	(1,993)	(1,315)
Total other expenses, net	(782)	(946)
<b>Net loss</b>	<b>\$ (54,728)</b>	<b>\$ (52,949)</b>

**Revenue**

Product sales increased by \$4.1 million to \$9.0 million for the nine months ended September 30, 2019 from \$4.9 million for the nine months ended September 30, 2018 due to growth in sales of DOPTelet since its launch in June 2018. In addition, for the nine months ended September 30, 2019 and 2018, we recognized \$1.9 million and \$2.6 million, respectively, of the upfront payment received pursuant to our Distribution Agreement with Fosun.

**Cost of product sales**

Cost of product sales of \$1.6 million, or 15% of revenue, for the nine months ended September 30, 2019 consisted of the cost of inventory, royalty payments to Astellas and certain distribution and overhead costs. Cost of product sales of \$0.9 million for the nine months ended September 30, 2018 consisted of the cost of inventory that was purchased from Eisai that was sold after FDA approval of DOPTelet, royalty payments to Astellas and certain distribution and overhead costs. In addition, for the nine months ended September 30, 2018, cost of product sales included \$0.3 million related to a one-time stock-based compensation charge.

**Research and development expense**

Research and development expenses were comparable for the nine months ended September 30, 2018 and September 30, 2019.

For the nine months ended September 30, 2019, research and development expenses included approximately \$8.4 million of product development expenses, \$1.0 million of the Astellas license milestone payment, \$2.0 million of payroll-related expenses, and \$1.3 million of stock-based compensation expense.

For the nine months ended September 30, 2018, research and development expenses included \$8.8 million of clinical development costs associated with the clinical trials initiated to evaluate DOPTelet for the treatment of PST and CIT, \$2.4 million of payroll-related expenses and \$1.6 million of stock-based compensation expense.

**Selling, general and administrative expense**

For the nine months ended September 30, 2019, selling, general and administrative expenses increased by \$4.6 million, which was primarily driven by sales and marketing activities to continue the commercialization activities of DOPTelet.

For the nine months ended September 30, 2019, selling, general and administrative expenses of \$50.4 million consisted of \$11.4 million of commercial-related expenses, \$22.5 million of payroll-related expenses, \$8.2 million of stock-based compensation expenses, \$0.8 million of office operations-related expenses, \$6.0 million in professional and consulting fees, \$0.7 million related to pharmacovigilance and medical writing, and \$0.8 million in educational sponsorship and grants.

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For the nine months ended September 30, 2018, selling, general and administrative expenses of \$45.9 million, consists primarily of \$17.6 million of payroll-related expenses, \$10.0 million of commercial-related expenses, \$9.1 million of stock-based compensation expenses, \$5.8 million of professional and consulting fees, \$2.3 million of office operations-related expenses and \$1.1 million in educational sponsorship and grants.

**Other expenses, net**

Other expenses, net for the nine months ended September 30, 2019 consisted primarily of \$2.0 million of interest expense and amortization of debt issuance costs and accretion expense for the final payment related to our loan with SVB and \$0.3 million of expense related to franchise tax, partially offset by \$1.5 million of income on our money market accounts.

Other expenses, net for the nine months ended September 30, 2018 consisted primarily of \$1.3 million of interest expense, amortization of debt issuance costs and accretion expense for the final payment related to our loan with SVB, \$0.5 million of withholding taxes related to the \$5.0 upfront payment received from Fosun, \$0.2 million of charitable contributions, and \$0.4 million of various state franchise taxes partially offset by \$1.4 million of income on our money market accounts. Other expenses, net for the nine months ended September 30, 2017 consisted primarily of \$0.9 million of interest expense related to the Eisai Note, partially offset by \$0.3 million of interest income on our money market mutual funds.

**Liquidity and capital resources**

We have funded our operations primarily through the sale of equity securities and debt financing. On July 5, 2017, we closed our IPO, which resulted in the issuance and sale of 5,077,250 shares of our common stock at a public offering price of \$17.00 per share, resulting in net proceeds of \$78.7 million after deducting underwriting discounts and commissions and other offering costs. On February 27, 2018, we completed an underwritten public offering of 2,500,000 shares of our common stock at an offering price of \$32.00 per share. Net proceeds raised from the offering were approximately \$74.7 million, after deducting underwriting discounts and commissions and other offering expenses. In addition, on April 17, 2018, we borrowed \$20.0 million from SVB pursuant to the Term Loan.

On May 6, 2019, we entered into a Term Loan Facility with the Lenders, pursuant to which we may borrow up to \$50.6 million, issuable in four separate tranches, of which \$20.6 million ("Advance A") was issued upon execution of the Term Loan Facility and used to repay in full all of our outstanding obligations and liabilities to SVB under the Term Loan, \$10.0 million ("Advance B") was issued in July 2019 upon the occurrence of regulatory approval for the ITP indication which was received on June 26, 2019, \$10.0 million ("Advance C") is available to be issued upon the achievement of a specified commercial revenue milestone until the earlier of April 15, 2020 or the day before Advance D is available, and \$10.0 million ("Advance D") is available to be issued upon the achievement of specified regulatory and commercial revenue milestones until July 15, 2020. In the event that we do not borrow Advance C, then \$20.0 million, rather than \$10.0 million, will be available to be issued under Advance D upon the achievement of specified regulatory and commercial revenue milestones until July 15, 2020. The maturity date of the Term Loan Facility is April 3, 2023. The Term Loan Facility is expected to be repaid in full on November 12, 2019 upon the completion of the merger with Sobi.

We commercially launched DOPTELET in June 2018. Prior to the generation of revenue from DOPTELET, we had not generated any commercial revenue from the sale of our products. We expect to incur substantial and increasing losses for the foreseeable future. Our principal sources of liquidity were our cash and equivalents, which totaled \$68.4 million and \$104.6 million at September 30, 2019 and December 31, 2018, respectively.

The following table shows a summary of our cash flows for each of the periods shown below (in thousands):

	Nine months ended September 30,	
	2019	2018
<b>Cash and equivalents at the beginning of the period</b>	\$ 104,566	\$ 94,846
Net cash used in operating activities	(47,311)	(36,257)
Net cash used in investing activities	(286)	(269)
Net cash provided by financing activities	11,479	63,707
<b>Cash and equivalents at the end of the period</b>	<b>\$ 68,448</b>	<b>\$ 122,027</b>

**Operating activities**

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Operating activities used \$47.3 million of cash during the nine months ended September 30, 2019, primarily for employee related expenses, commercialization activities for DOPTOLET and clinical development fees related to the CIT study, partially offset by cash receipts from our product sales.

Operating activities used \$36.3 million of cash during the nine months ended September 30, 2018, primarily for employee related expenses, consulting fees primarily related to our commercial readiness activities and clinical development fees related to the initiation of the PST program, partially offset by the receipt of a \$4.5 million upfront payment from our Distribution Agreement with Fosun and cash receipts from our product sales. Operating cash flows also included office operational expenses, recruiting and legal fees.

### *Investing activities*

Net cash used in investing activities related primarily to the purchases of equipment during the nine months ended September 30, 2019 and 2018.

### *Financing activities*

For the nine months ended September 30, 2019, financing activities provided \$11.5 million of cash, consisting of the payment of our term loan of \$20.6 million, debt issuance costs of \$1.5 million, proceeds from new debt of \$31.6 million and \$2.0 million of net proceeds from the issuance of common stock in connection with employee option exercises, partially offset by \$1.5 million of debt issuance costs incurred in relation to the Term Loan Facility. Advance A of the Term Loan Facility had a net zero cash impact on our financing activities for the nine months ended September 30, 2019 as the \$20.6 million issued under Advance A was used to repay in full all of our outstanding obligations to SVB under the Term Loan, including a prepayment fee of \$0.6 million.

For the nine months ended September 30, 2018, financing activities provided \$63.7 million of cash, consisting primarily of net proceeds of \$74.7 million from the issuance of common stock from our underwritten offering completed on February 27, 2018 and \$20.0 million that was borrowed from SVB under the Term Loan, partially offset by the payment in full of the Eisai Note of \$31.1 million and \$37,705 in debt issuance costs to secure the new loan.

### *Funding requirements*

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue to build out our commercial organization including the sales leadership, marketing and market access functions and expand our commercialization activities. As we seek to obtain marketing approval for DOPTOLET in other indications, we will incur additional costs around clinical trials and research and development. In addition, if we obtain FDA approval for DOPTOLET in other indication or any other drug candidates, we expect to incur significant commercialization expenses. Based on our current operating plans, we believe our existing cash and equivalents as of September 30, 2019 will be sufficient to fund our current planned operations for at least the next 12 months. We have based this estimate on assumptions that could prove to be wrong and we could use our capital resources sooner than planned. Our future funding requirements will depend on many factors, including:

- costs of continued commercial activities, including product sales, marketing, manufacturing and distribution, for DOPTOLET in CLD, ITP and other indications, if approved;
- the extent of DOPTOLET sales, which are significantly influenced by the buying patterns of our customers, which may be influenced by many factors beyond our control;
- establishing an alternative manufacturer for DOPTOLET;
- the scope, progress, results and costs of clinical trials;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our drug candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under collaboration agreements, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the costs of retaining key research and development, sales and marketing personnel;
- the timing and size of any milestone payments required under our existing or future arrangements;
- the extent to which we acquire or in-license other drug candidates and technologies; and

- the costs of establishing sales and marketing capabilities if we obtain regulatory approvals to market our drug candidates.

Clinical trial development is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval of and achieve sales of DOPTLET in other indications or other drug candidates. In addition, DOPTLET or any other drug candidates, if approved, may not achieve commercial success or may be limited in approved indications. Accordingly, once we become a wholly owned subsidiary of Sobi, may need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

If we are unable to raise capital or otherwise obtain funding when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

#### **Contractual Obligations and Commitments**

Our future non-cancelable contractual obligations were reported in our Annual Report on Form 10-K for the year ended December 31, 2018 that was filed with the SEC on March 5, 2019. Except for the extinguishment of the Term Loan in connection with the completion of the merger with Sobi, there were no material changes outside the ordinary course of our business to our future non-cancelable contractual obligations during the nine months ended September 30, 2019.

#### **Off-balance sheet arrangements**

We do not have any relationships with unconsolidated entities or financial partnerships, including entities sometimes referred to as structured finance or special purpose entities that were established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. We do not engage in off-balance sheet financing arrangements. In addition, we do not engage in trading activities involving non-exchange traded contracts. We therefore believe that we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

#### **Recent accounting pronouncements**

See Note 2 to our unaudited condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for a description of recent accounting pronouncements.

#### **JOBS Act transition period**

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

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

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our borrowings pursuant to the Term Loan Facility accrue interest at a variable rate and, our investments, including cash equivalents, are in the form of a money market fund. We do not believe a 100 basis point change in interest rates would have a material effect on our results of operations. We do not currently engage in hedging transactions to manage our exposure to interest rate risk.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations for the three and nine ended September 30, 2019.

We contract with clinical research organizations globally. We may be subject to fluctuations in foreign currency rates in connection with certain of these agreements. Transactions denominated in currencies other than the U.S. dollar are recorded based on exchange rates at the time such transactions arise. As of September 30, 2019, substantially all of our total receivables and liabilities were denominated in the U.S. dollar.

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

### *Disclosure Controls and Procedures*

We maintain “disclosure controls and procedures,” as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, to allow timely decisions regarding required disclosure.

The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

With respect to the quarter ended September 30, 2019, under the supervision and with the participation of our management, we conducted an evaluation of the effectiveness of the design and operations of our disclosure controls and procedures. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective.

Management does not expect that our disclosure controls and procedures will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control systems are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in a cost-effective control system, no evaluation of disclosure controls and procedures can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been or will be detected.

### *Changes in Internal Control over Financial Reporting:*

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended September 30, 2019 which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

Not applicable.

## **Part II. Other Information**

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

Between October 14, 2019 and October 31, 2019, four stockholder actions were filed in federal court (captioned *Wang v. Dova Pharm., Inc. et al.*, No. 19-cv-01944-UNA (D. Del. filed Oct. 14, 2019); *Wheby v. Dova Pharm., Inc. et al.*, No. 19-cv-01981-UNA (D. Del. filed Oct. 18, 2019) (filed on behalf of putative class); *Hurd v. Dova Pharm., Inc., et al.*, No. 19-cv-09708 (S.D.N.Y. filed Oct. 21, 2019); and *Katz v. Dova Pharm. Inc. et al.*, No. 19-cv-10147 (S.D.N.Y. filed Oct. 31, 2019) (collectively, the “Complaints”)) against us and our board of directors related to the tender offer. The Complaints assert violations of Sections 14(e) & (d) and 20(a) of the Exchange Act and Rule 14d-9 promulgated thereunder. The Complaints contend our Schedule 14D-9, filed on October 11, 2019, omitted or misrepresented material information regarding the tender offer. The Complaints seek, among other things, injunctive relief, rescission or rescissory damages, and an award of The Complaints’ respective costs, including attorneys’ fees and expenses. We believe the allegations and claims asserted in the lawsuits are without merit and that the disclosures in the Schedule 14D-9, filed on October 11, 2019, comply fully with applicable law.

In addition, from time to time, we are subject to litigation and claims arising in the ordinary course of business but, except as stated above, we are not currently a party to any material legal proceedings and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on our business, operating results, cash flows or financial condition.

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

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Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. Except for the risk factors set forth immediately below, our risk factors have not changed materially from those described in “Part I, Item 1A. Risk Factors” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on March 5, 2019.

**Item 2. Recent Sales of Unregistered Securities and Use of Proceeds.**

Not applicable.

**Item 6. Exhibits**

<b>Exhibit No.</b>	<b>Description</b>
2.1* <sup>^</sup>	<a href="#">Agreement and Plan of Merger, dated as of September 30, 2019, by and among Dova Pharmaceuticals, Inc., Swedish Orphan Biovitrum AB (publ) and Dragonfly Acquisition Corp. (previously filed as Exhibit 2.1 to the Registrant’s Current Report on Form 8-K (File No. 001-38135), filed with the Commission on October 3, 2019, and incorporated by reference herein)</a>
3.1*	<a href="#">Amended and Restated Certificate of Incorporation (previously filed as Exhibit 3.3 to Amendment No. 1 to the Registrant’s Registration Statement on Form S-1 (File No. 333-218479), filed with the Commission on June 9, 2017, and incorporated by reference herein)</a>
3.2*	<a href="#">Amended and Restated Bylaws (previously filed as Exhibit 3.4 to Amendment No. 1 to the Registrant’s Registration Statement on Form S-1 (File No. 333-218479), filed with the Commission on June 9, 2017, and incorporated by reference herein)</a>
31.1#	<a href="#">Certification of Principal Executive Officer of Dova Pharmaceuticals, Inc. pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
31.2#	<a href="#">Certification of Principal Financial Officer of Dova Pharmaceuticals, Inc. pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
32.1# <sup>++</sup>	<a href="#">Certifications of Principal Executive Officer and Principal Financial Officer of Dova Pharmaceuticals, Inc. pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
101#	The following financial information from the Registrant’s Quarterly Report on Form 10-Q for the three and nine months ended September 30, 2019, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) Notes to the Condensed Consolidated Financial Statements (filed herewith).

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# Filed herewith. <sup>^</sup> Schedules omitted pursuant to Item 601 of Regulation S-K. The Registrant agrees to furnish supplementally a copy of any omitted schedule to the SEC upon request.

\* Previously filed.

+ These certifications are being furnished solely to accompany this Quarterly Report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**SIGNATURES**

Pursuant to the requirements of the Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**Dova Pharmaceuticals, Inc.**

Date: November 12, 2019

By: /s/ David S. Zaccardelli

David Zaccardelli

President and Chief Executive Officer

(Principal Executive Officer)

Date: November 12, 2019

By: /s/ Mark W. Hahn

Mark W. Hahn

Chief Financial Officer

(Principal Financial Officer)

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, David S. Zaccardelli, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2019 of Dova Pharmaceuticals, Inc. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: November 12, 2019

/s/ David S. Zaccardelli  
\_\_\_\_\_  
David S. Zaccardelli  
President and Chief Executive Officer  
(principal executive officer)

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Mark W. Hahn, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2019 of Dova Pharmaceuticals, Inc. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: November 12, 2019

/s/ Mark W. Hahn

Mark W. Hahn

Chief Financial Officer

(principal financial officer)

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the “Exchange Act”) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), David S. Zaccardelli, President and Chief Executive Officer of Dova Pharmaceuticals, Inc. (the “Company”), and Mark W. Hahn, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company’s Quarterly Report on Form 10-Q for the period ended September 30, 2019, to which this Certification is attached as Exhibit 32.1 (the “Periodic Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

**IN WITNESS WHEREOF**, the undersigned have set their hands hereto as of the 12th of November 2019.

/s/ David S. Zaccardelli  
\_\_\_\_\_  
David S. Zaccardelli  
President and Chief Executive Officer  
(principal executive officer)

/s/ Mark W. Hahn  
\_\_\_\_\_  
Mark W. Hahn  
Chief Financial Officer  
(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 the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.