NANOVIRICIDES, INC. Form 10-Q May 15, 2009

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

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FORM 10 - Q

# QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the quarterly period ended March 31, 2009

Commission File Number: 333-148471

#### NANOVIRICIDES, INC.

(Exact name of registrant as specified in its charter)

NEVADA (State or other jurisdiction of incorporation or organization) 76-0674577 (IRS Employer Identification No.)

135 Wood Street, Suite 205
West Haven, Connecticut 06516
(Address of principal executive offices and zip code)
(203) 937-6137
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act 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 Yes S No £

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes S No £

Indicate by check mark whether the registrant is a larger accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one)

Large accelerated filer £

Accelerated filer £

Non-accelerated filer £	;	Smaller reporting company S
Indicate by check mark whether the registran	t is a shell com Yes £	npany (as defined in Rule 12b-2 of the Exchange Act). No S
The number of shares outstanding of the Reg	istrant's Comm	non Stock as of May 15, 2009 was 123,023,653 shares.
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# NANOVIRICIDES, INC.

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# NANOVIRICIDES, INC.

# (A DEVELOPMENT STAGE COMPANY) BALANCE SHEETS

ASSETS		March 31, 2009 Inaudited)		ne 30, 008
Current assets:				
Cash and cash equivalents	\$	1,228,056	\$	816,386
Prepaid expenses		413,512	Ċ	328,544
Other current assets		83,183		102,873
Total current assets		1,724,751		1,247,803
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Property and equipment, net		666,479		133,738
Other assets:				
Security deposit		_		80,000
Trademarks, net		179,536		6,709
Total other assets		179,536		86,709
		,		,
Total assets	\$	2,570,766	\$	1,468,250
LIABILITIES AND STOCKHOLDERS' EQUITY Current liabilities:				
	\$	292 100	\$	205 555
Accounts payable – trade Accounts payable – related parties	Ф	283,190 169,975	Ф	295,555 374,394
Accounts payable – related parties  Accrued expenses		194,759		96,130
Payroll tax payable		27,730		258,432
Total current liabilities		675,654		1,024,511
Total current naomities		075,054		1,024,311
Commitments and contingencies				
Stockholders' equity:				
Common stock, \$0.001 par value; 300,000,000 shares authorized;122,851,298 and				
119,270,677 issued and outstanding	\$	122,851	\$	119,271
Additional paid-in capital		13,142,976		9,532,205
Deficit accumulated during the development stage	(	(11,370,715)		(9,207,737)
Total stockholders' equity		1,895,112		443,739
Total liabilities and stockholders' equity	\$	2,570,766	\$	1,468,250
See accompanying notes to the financial statements.				
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# NANOVIRICIDES, INC. (A DEVELOPMENT STAGE COMPANY) STATEMENTS OF OPERATIONS

(Unaudited)

		ee Months I	End	ed arch 31,	March 31, March 3 2009 2008			arch 31,	For the Period From May 12, 2005 (Inception) through March 31, 2009	
Operating expenses:										
Research and development	\$	498,801	\$	358,793	\$	1,331,661	\$	809,140	\$	6,114,194
Refund for credit of research and										
development costs		-		-		-		(166,050)		(200,190)
General and administrative		293,225		446,525		861,701		1,150,065		4,816,164
Total operating expenses		792,026		805,318		2,193,362		1,793,155	1	10,730,168
Loss from operations		(792,026)		(805,318)		(2,193,362)		(1,793,155)	(1	10,730,168)
Other income (expense):										
Interest income		4,303		14,431		30,384		47,570		146,462
Non cash interest on convertible										
debentures		-		-		-		-		(73,930)
Non cash interest expense on										
beneficial conversion feature of										
convertible debentures		-		-		-		-		(713,079)
Total other income (expense)		4,303		14,431		30,383		47,570		(640,547)
Net loss	\$	(787,723)	\$	(790,887)	\$	(2,162,978)	\$	(1,745,585)	\$(1	1,370,715)
Net loss per share: basic and diluted	\$	(0.01)	\$	(0.01)	\$	(0.02)	\$	(0.02)		
Weighted average shares										
outstanding: basic and diluted	12	2,793,839		119,196,586		122,073,961		117,489,413		

See accompanying notes to the financial statements.

# NANOVIRICIDES, INC. (A DEVELOPMENT STAGE COMPANY) STATEMENTS OF CASH FLOWS (UNAUDITED)

(UNAUDITED)			
	Nine Mon	For the Period From May 12, 2005 (Inception)	
	March 31, 2009	March 31, 2008	through March 31, 2009
CASH FLOWS FROM OPERATING ACTIVITIES:	_000	2000	_00/
Net loss	\$ (2,162,978)	\$ (1,745,585)	\$ (11,370,715)
Adjustments to reconcile net loss to net cash used in operating activities:			
Shares issued for services rendered	129,800	84,022	763,757
Warrants granted to scientific advisory board	107,000	30,500	414,241
Options issued to officers as compensation	-	7,044	121,424
Depreciation and amortization	8,073	4,783	17,120
Amortization of deferred financing expenses	-	-	51,175
Non cash interest on convertible debentures	-	-	73,930
Non cash interest expense on beneficial conversion feature of			
convertible debentures	-	-	713,079
Changes in assets and liabilities:			
Prepaid expenses	(84,968)	(86,850)	(413,512)
Deferred expenses	-	-	(2,175)
Other assets	99,690	(162,383)	(83,183)
Accounts payable- trade	(12,365)	46,757	283,190
Accounts payable –related parties	(204,419)	(147,265)	169,975
Accrued expenses	98,629	(23,763)	194,759
Accrued payroll to officers and related payroll tax expense	(230,702)	(212,395)	27,730
Net cash used in operating activities	(2,252,240)	(2,205,135)	(9,039,205)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property and equipment	(537,417)	(51,846)	(679,324)
Purchase of trademarks	(176,226)	-	(183,813)
Net cash used in investing activities	(713,643)	(51,846)	(863,137)
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CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of convertible debentures	-	-	1,000,000
Proceeds from issuance of common stock and warrants in connection			
with private placements of common stock – net of offering costs	3,377,553	2,500,020	9,120,398
Proceeds from exercise of stock warrants attached to convertible			
debentures	-	-	920,000
Proceeds from exercise of stock options	-	-	90,000
Net cash provided by financing activities	3,377,553	2,500,020	11,130,398
NET INCREASE IN CASH AND CASH EQUIVALENTS	411,670	243,039	1,228,056

CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	816,386	967,797	_
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 1,228,056	\$ 1,210,836 \$	1,228,056
See accompanying notes to the financi	al statements.		
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# NANOVIRICIDES, INC. (A DEVELOPMENT STAGE COMPANY) STATEMENTS OF CASH FLOWS (CONTINUED) (UNAUDITED)

		Nine Months Ended		For the Period From May 12, 2005 (Inception) through		
		March 31,2009		March 31,2008	ľ	March 31, 2009
Supplemental disclosure of cash flows information:						
Interest paid	\$	-	\$	-	\$	-
Tax paid	\$	-	\$	-	\$	-
Non-cash investing and financing investing activities:						
Common stock issued for services rendered	\$	129,800	\$	84,022	\$	763,757
Stock options issued to the officers as compensation		-		7,044		121,424
Stock warrants granted to scientific advisory board		107,000		30,500		414,241
Stock warrants granted to brokers		9,849		-		9,849
Common stock issued for interest on debentures		-		-		73,930
Shares of common stock issued in connection with debenture offering		-		-		49,000
Common stock issued upon conversion of convertible debentures		-		-		1,000,000
Debt discount related to beneficial conversion feature of convertible debt		-		-		713,079
Stock warrants issued in connection with private placement		827,485		-	,	2,090,117
Common stock issued upon conversion of accounts payable		150,000				150,000
See accompanying notes to the financial	state	ements.				

# NANOVIRICIDES, INC (A DEVELOPMENT STAGE COMPANY) FOR THE PERIOD FROM MAY 12, 2005 (INCEPTION) TO MARCH 31, 2009 NOTES TO THE FINANCIAL STATEMENTS (Unaudited)

#### Note 1. Organization and Nature of Business

NanoViricides, Inc. was incorporated under the laws of the State of Colorado on July 25, 2000 as Edot-com.com, Inc., and was organized for the purpose of conducting internet retail sales. On April 1, 2005, Edot-com.com, Inc. was incorporated under the laws of the State of Nevada for the purpose of re-domiciling the Company as a Nevada corporation. On May 12, 2005, the Corporations were merged and Edot-com.com, Inc., a Nevada corporation, (the "Company"), became the surviving entity.

On June 1, 2005, Edot-com.com, Inc. ("ECMM") acquired NanoViricides, Inc., a privately owned Florida corporation ("NVI"), pursuant to an Agreement and Plan of Share Exchange (the "Exchange"). NanoViricides, Inc. was incorporated under the laws of the State of Florida on May 12, 2005.

Pursuant to the terms of the Exchange, ECMM acquired NVI in exchange for an aggregate of 80,000,000 newly issued shares of ECMM common stock resulting in an aggregate of 100,000,000 shares of ECMM common stock issued and outstanding representing 80% of the voting capital stock of ECMM immediately after the Exchange transaction. NVI then became a wholly-owned subsidiary of ECMM. The ECMM shares were issued to the NVI Shareholders on a pro rata basis, on the basis of 4,000 shares of ECMM's Common Stock for each share of NVI common stock held by such NVI Shareholder at the time of the Exchange.

As a result of the ownership interests of the former shareholders of NVI for financial accounting purposes, the merger between ECMM and NVI has been treated as a reverse acquisition with NVI deemed the accounting acquirer and ECMM deemed the accounting acquiree under the purchase method of accounting in accordance with Statement of Financial Accounting Standards No. 141 "Business Combinations" ("SFAS No. 141"). The reverse merger is deemed a capital transaction and the net assets of NVI (the accounting acquirer) are carried forward to ECMM (the legal acquirer and the reporting entity) at their carrying value before the combination. The acquisition process utilizes the capital structure of ECMM and the assets and liabilities of NVI which are recorded at historical cost. The equity of ECMM is the historical equity of NVI retroactively restated to reflect the number of shares issued by ECMM in the transaction. Accordingly, the financial statements have been prepared to give retroactive effect to May 12, 2005 (date of inception), of the reverse acquisition completed on June 1, 2005, and represent the operations of NVI.

On June 28, 2005, NVI was merged into its parent ECMM and the separate corporate existence of NVI ceased. Effective on the same date, ECMM changed its name to NanoViricides, Inc. and its stock symbol to "NNVC", respectively. The Company is considered a development stage company at this time.

NanoViricides, Inc. (the "Company"), is a nano-biopharmaceutical company whose business goals are to discover, develop and commercialize therapeutics to advance the care of patients suffering from life-threatening viral infections. We are a development stage company with several drugs in various stages of early development. The Company's drugs are based on several patents, patent applications, provisional patent applications, and other proprietary intellectual property held by TheraCour Pharma, Inc. ("TheraCour"), to which the Company has licenses in perpetuity for the treatment of the following human viral diseases: Human Immunodeficiency Virus (HIV/AIDS), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Herpes Simplex Virus (HSV), Influenza, Rabies, and Asian Bird Flu Virus. TheraCour has granted the Company the right to include Dengue viruses, Ebola/Marburg viruses, and viruses causing viral Conjunctivitis (a disease of the eye) among the viruses the Company is able to treat. However, no written agreement has been entered into with TheraCour and no assurance can be given that a written amendment to the licensing agreement with TheraCour will ever be reached or that, if reached, will be on terms favorable to the Company.

The Company focuses its research and clinical programs on specific anti-viral therapeutics and is seeking to add to its existing portfolio of products through its internal discovery and clinical development programs and through an in-licensing strategy. To date, the Company has not developed any commercial products.

#### Note 2. Basis of Presentation

The accompanying unaudited interim financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the Securities and Exchange Commission for Interim Reporting. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements.

In the opinion of Management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation for the interim periods have been included. Operating results for the nine month period ended March 31, 2009, are not necessarily indicative of the results that may be expected for the year ending June 30, 2009. The accompanying financial statements and the information included under the heading "Management's Discussion and Analysis or Plan of Operation" should be read in conjunction with our company's audited financial statements and related notes included in our company's form 10-K for the year ended June 30, 2008.

#### Note 3. Summary of Significant Accounting Policies

For a summary of significant accounting policies (which have not changed from June 30, 2008), see the Company's Annual Report on Form 10K for the year ended June 30, 2008.

#### **Recently Issued Accounting Pronouncements**

In March 2008, the FASB issued FASB Statement No. 161 Disclosures about Derivative Instruments and Hedging Activities an amendment of FASB Statement No. 133 ("SFAS No. 161"), which changes the disclosure requirements for derivative instruments and hedging activities. Pursuant to SFAS No. 161, Entities are required to provide enhanced disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under Statement 133 and its related interpretations, and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008 with early application encouraged. SFAS No. 161 encourages but does not require disclosures for earlier periods presented for comparative purposes at initial adoption. In years after initial adoption, this Statement requires comparative disclosures only for periods subsequent to initial adoption. The Company does not expect the adoption of SFAS No. 161 to have a material impact on the financial results of the Company.

In April 2008, the FASB issued FSP No. 142-3, Determination of the Useful Life of Intangible Assets. FSP 142-3 amends the factors an entity should consider in developing renewal or extension assumptions used in determining the useful life of recognized intangible assets under SFAS 142, Goodwill and Other Intangible Assets, and adds certain disclosures for an entity's accounting policy of the treatment of the costs, period of extension, and total costs incurred. FSP 143-3 must be applied prospectively to intangible assets acquired after January 1, 2009. The Company does not expect the adoption of FSP 142-3 to have a material impact on the financial results of the Company.

In May 2008, the FASB issued SFAS No. 162, "The Hierarchy of Generally Accepted Accounting Principles" ("SFAS 162"). SFAS 162 is intended to improve financial reporting by identifying a consistent framework, or hierarchy, for selecting accounting principles to be used in preparing financial statements that are presented in conformity with U.S. GAAP for nongovernmental entities. SFAS 162 is effective 60 days following the Securities and Exchange Commission's approval of the Public Company Accounting Oversight Board auditing amendments to AU Section 411, "The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles." The Company does not expect SFAS 162 to have a material effect on its financial statements.

Management does not believe that any other recently issued, but not yet effective accounting pronouncements, if adopted, would have a material effect on the accompanying financial statements.

#### Reclassification

Certain reclassifications have been made in prior year's financial statements to conform to classification used in the current year. The reclassifications from general and administrative expenses to research and development expenses does not change total operating expenses, operating loss or net loss for any period presented.

#### Note 4. Substantial Doubt Regarding Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Accordingly, they do not include any adjustments relating to the realization of the carrying value of assets or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company's significant operating losses and significant capital requirements, however, raise substantial doubt about the Company's ability to continue as a going concern.

Since May 2005, the Company has been engaged exclusively in research and development activities focused on developing targeted nano viral drugs. The Company has not yet commenced any product commercialization. The Company has incurred significant operating losses since its inception, resulting in a deficit accumulated during the development stage of \$11,370,715 at March 31, 2009. Such losses are expected to continue for the foreseeable future and until such time, if ever, as the Company is able to attain sales levels sufficient to support its operations. There can be no assurance that the Company will achieve or maintain profitability in the future. Despite the Company's financings in 2009 and 2008 and a cash and cash equivalent balance of \$1,228,056 at March 31, 2009, substantial additional financing will be required in future periods. The Company believes it will require in excess of \$3,000,000 to further advance the current drug development priorities during the next twelve months, and will also require up to an additional \$2,000,000 to finance planned capital costs, and additional staffing requirements during the next twelve months. The Company believes it can adjust its priorities of drug development, and it's Plan of Operations as necessary if it is unable to raise such funds. The Company has taken several steps to conserve resources and reduce expenditures.

Based on the results of in-vivo and in-vitro studies which were completed in the first calendar quarter of 2007 and the Company's April 9, 2007 Cooperative Research and Development Agreement, ("CRADA"), with the Walter Reed Army Institute of Research, we commenced a program to seek substantial additional financing to meet our planned cash requirements, through private placements of our common stock and/or incurring debt. (See also Note 5.) No assurances can be given that financing will be available or be sufficient to meet our capital needs. If we are unable to obtain financing to meet our working capital requirements, then we may be required to modify our operations, including curtailing our business significantly or ceasing operations altogether. On August 22, 2008, the Company raised \$3,286,000 from the sale of stock and "Warrants." This private placement of stock included 150,000 shares of Common Stock and 75,000 Warrants subscribed in consideration of \$150,000 worth of scientific testing performed for the Company. Also on August 22, 2008, the Company consummated subscriptions with its Warrants holders, thereby raising an additional \$106,250.

#### Note 5. Significant Alliances and Related Parties

#### TheraCour Pharma, Inc.

Pursuant to an Exclusive License Agreement we entered into with TheraCour Pharma, Inc., (TheraCour), the Company was granted exclusive licenses in perpetuity for technologies developed by TheraCour for the virus types: HIV, HCV, Herpes, Asian (bird) flu, Influenza and rabies. The Company and TheraCour have agreed, in principle, to a Licensing Agreement to include additional virus types among the virus types the Company is permitted to manufacture, use, and offer for sale, and for payment of a license fee to TheraCour. TheraCour has permitted the

Company to use its nanomaterials to develop treatments for Dengue viruses, Ebola/Marburg viruses, Japanese Encephalitis, viruses causing viral Conjunctivitis (a disease of the eye) and Ocular Herpes. Until such time as the Company and TheraCour can complete an additional Licensing Agreement to include these additional virus types we are permitted to manufacture, use, and offer for sale these nanomaterials.. In consideration for obtaining these exclusive licenses, we agreed: (1) that TheraCour can charge its costs (direct and indirect) plus no more than 30% of direct costs as a Development Fee and such development fees shall be due and payable in periodic installments as billed. (2) to pay \$25,000 per month for usage of lab supplies and chemicals from existing stock held by TheraCour (3) we will pay \$2,000 or actual costs, whichever is higher, for other general and administrative expenses incurred by TheraCour on our behalf (4) make royalty payments (calculated as a percentage of net sales of the licensed drugs) of 15% to TheraCour Pharma, Inc. (5) agreed that TheraCour Pharma, Inc. retains the exclusive right to develop and manufacture the licensed drugs. TheraCour Pharma, Inc. agreed that it will manufacture the licensed drugs exclusively for NanoViricides, and unless such license is terminated, will not manufacture such product for its own sake or for others, (6) TheraCour may request and NanoViricides, Inc. will pay an advance payment (refundable) equal to twice the amount of the previous months invoice to be applied as a prepayment towards expenses.

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As to the license fee, there can be no assurance that the license fee will be paid or that the amendment will become effective, in which case TheraCour may revoke our permissive use of its materials, which may adversely impact our operations and cause the termination of our Cooperative Research and Development Agreement (CRADA) with the United States Army Medical Research Institute of Infectious Diseases (USAMRIID), The Walter Reed Army Institute of Research (WRAIR), and the United States Armed Forces Institute of Pathology (USAFIP).

TheraCour may terminate the license upon a material breach by us as specified in the agreement. However, we may avoid such termination if within 90 days of receipt of such termination notice we cure the breach.

Development costs charged by TheraCour Pharma, Inc. for the nine months ended March 31, 2009 and 2008, were \$1,440,649 and \$891,791 respectively, and \$5,980,336 since inception. As of March 31, 2009, pursuant to its license agreement the Company has paid a security advance of \$321,164 to and held by TheraCour Pharma, Inc. which is reflected in prepaid expenses

No royalties are due TheraCour from the Company's inception through March 31, 2009.

On February 27, 2007, NanoViricides, Inc. entered into a sublease to occupy 5,000 square feet of space in Woodbridge, Connecticut. Performance of the Company's obligations was guaranteed by TheraCour Pharma, Inc., a principal shareholder of the Company and provider of the materials the Registrant uses in its operations. This lease expired on January 30, 2009, and we have relocated our operations to an expanded facility at 135 Wood Street, West Haven, CT.

TheraCour Pharma, Inc., is affiliated with the Company through the common control of it and our Company by Anil Diwan, President, who is a director of each corporation, and owns approximately 70% of the capital stock of TheraCour Pharma, Inc., which itself owns approximately 30% of the capital stock of the Company.

TheraCour Pharma, Inc. owns 35,085,000 shares of the Company's outstanding common stock as of March 31, 2009. The Company anticipates the need to procure large quantities of the nanoviricides drug candidates for the upcoming studies. In order to support this production scale, TheraCour Pharma, Inc., the Company's largest shareholder and licensor of the technology that the Company uses in its anti-viral drug development, has initiated a program to expand its laboratory facilities. TheraCour has entered into a Rule 10b5-1 trading plan to sell, over a one year period, up to 1.8 million shares of the Company's common stock that it owns, that will go into effect Feb 17, 2009. The proceeds are expected to be used to pay for the necessary improvements in laboratory facilities, the purchase of analytical equipment, and the costs of intellectual property (patent) protection.

The FASB has issued Interpretation No. 46 (FIN-46R) (Revised December 2003), Consolidation of Variable Interest Entities. FIN-46R clarifies the application of Accounting Research Bulletin No. 51, "Consolidated Financial Statements," to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. It separates entities into two groups: (1) those for which voting interests are used to determine consolidation and (2) those for which variable interests are used to determine consolidation (the subject of FIN-46R). FIN-46R clarifies how to identify a variable interest entity and how to determine when a business enterprise should include the assets, liabilities, non-controlling interests, and results of activities of a variable interest entity in its consolidated financial statements.

FIN-46R requires that a variable interest entity to be consolidated by its "Primary Beneficiary." The Primary Beneficiary is the entity, if any, that stands to absorb a majority of the variable interest entity's expected losses, or in the event that no entity stands to absorb a majority of the expected losses, then the entity that stands to receive a majority of the variable interest entity's expected residual returns. If it is reasonably possible that an enterprise will consolidate or disclose information about a variable interest entity when FIN- 46R becomes effective, the enterprise is required to disclose in all financial statements initially issued after December 31, 2003, the nature, purpose, size, and activities of the variable interest entity and the enterprise's maximum exposure to loss as a result of its involvement with the variable interest entity. For all periods presented in the financial statements, the Company evaluated its relationship with TheraCour Pharma, Inc. for purposes of FIN-46R, and concluded that it is not a variable interest entity that is subject to consolidation in the Company's financial statements under FIN-46R.

#### KARD Scientific, Inc.

In June 2005, the Company engaged KARD Scientific to conduct pre clinical animal studies and provide the Company with a full history of the study and final report with the data collected. Dr. Krishna Menon, the Company's Chief Regulatory Officer, is also an officer and principal owner of KARD Scientific. Since inception, lab fees charged by KARD Scientific for services to the Company total \$554,235. The Company has paid KARD a \$50,000 advance payment (refundable) towards future fees.

#### Note 6. Prepaid Expenses

Prepaid expenses at March 31, 2009 and June 30, 2008 consisted of the following:

	M	farch 31, 2009	•	June 30, 2008
TheraCour Pharma, Inc. *	\$	321,164	\$	236,186
Kard Scientific, Inc. *		50,000		50,000
Prepaid other **		42,348		42,358
	\$	413,512	\$	328,544

(\* See Note 4. Significant Alliances and Related Parties)

#### Note 7. Equity Transactions

In August 2008, the Scientific Advisory Board (SAB) was granted warrants to purchase 50,000 shares of common stock at \$1.56 per share. These warrants, if not exercised, will expire in August 2012. The fair value of these warrants in the amount of \$47,500 was recorded as consulting expense.

The fair value of the Company's option-based awards granted were estimated using the Black-Scholes option pricing model and the following assumptions.

	For the three months	For the nine months
	ended March 31,	ended March 31,
	2009	2009
Expected life in years	4 years	4 years
Risk free interest rate	1.93	1.93-2.90
Expected volatility	201%	104%-201%

<sup>(\*\*</sup> See Note 7, Commitments and Contingencies)

Dividend yield 0% 0%

On August 22, 2008, the Company consummated subscriptions with certain investors whereby the Company sold 3,286,000 shares (the "Shares") of its common stock, par value \$0.001 per share (the "Common Stock") and ("Warrants") to purchase 1,643,000 shares of Common Stock at an exercise price of \$2.00 per share for an aggregate purchase price of \$3,286,000. The 3,286,000 share private placement of stock included 150,000 shares of Common Stock and 75,000 warrants subscribed in consideration of \$150,000 of scientific testing and other laboratory work performed for the Company. The Warrants may be exercised at any time and expire on September 17, 2011. The Company allocated a relative fair value of \$827,485 to these warrants, by using the Black-Scholes option pricing model.

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Also on August 22, 2008, the Company consummated subscriptions with certain of its Warrant holders whereby the Company offered all the holders of its \$2.50warrants the option of exercising the Warrants at \$1.00 per share of Common Stock, of which warrants to purchase 50,000 shares of Common Stock for an aggregate price of \$50,000 were exercised. Concurrently, the Company consummated subscriptions with certain other of its Warrant holders whereby the Company offered all the holders of its \$1.00 warrants the option of exercising the Warrants at \$0.75 per share of Common Stock, of which warrants to purchase 75,000 shares of Common Stock for an aggregate price of \$56,250 were exercised.

In November 2008, the Scientific Advisory Board (SAB) was granted warrants to purchase 50,000 shares of common stock at \$0.70 per share. These warrants, if not exercised, will expire in November 2012. The fair value of these warrants in the amount of \$30,500 was recorded as consulting expense.

In February 2009, the Scientific Advisory Board (SAB) was granted warrants to purchase 50,000 shares of common stock at \$0.58 per share. These warrants, if not exercised, will expire in November 2012. The fair value of these warrants in the amount of \$29,000 was recorded as consulting expense.

For the nine months ended March 31, 2009, the Company issued 169,476 shares of its common stock in aggregate with a restrictive legend, for consulting services valued at \$129,800, the fair value at the date of issuance.

#### Note 8. Commitments and Contingencies

#### **Operating Leases**

The Company's principal executive offices are located at 135 Wood Street, West Haven, Connecticut, and include approximately 5,000 square feet of office and laboratory space at a base monthly rent of \$4,692. Commencing September 1, 2008 the Company rented additional space and the base monthly rent increased to \$7,192. The lease expires February 28, 2011, and may be extended, at the option of the Company, for an additional two years. The lease can be cancelled by the Company upon providing six months written notice.

Total rent expense amounts to \$148,812 and \$149,230 for the nine months ended March 31, 2009 and 2008 respectively, and \$393,988 for the period from inception.

#### Note 9. Subsequent Events

On April 23, 2009, the Company filed a Definitive Information Statement disclosing that on March 18, 2009 a majority of the Company's shareholders consented to an, amendment of the Company's Articles of Incorporation to authorize the creation of a class of 10,000,000 shares of blank check preferred stock (the "Amendment"). The Amendment became effective on May 13, 2009.

On April 15, 2009, the Company issued 172,500 shares of its common stock as payment for equipment purchased.

#### ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

The following discussion and analysis should be read in conjunction with our unaudited financial statements and related notes included in this report. This report contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. The statements contained in this report that are not historic in nature, particularly those that utilize terminology such as "may," "will," "should," "expects," "anticipates," "estimates," "believes," or "plans" or comparable terminology are forward-looking statements based on current expectations and assumptions.

Various risks and uncertainties could cause actual results to differ materially from those expressed in forward-looking statements. All forward-looking statements in this document are based on information currently available to us as of the date of this report, and we assume no obligation to update any forward-looking statements. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results to differ materially from any future results, performance or achievements expressed or implied by such forward-looking statements.

#### **OUR CORPORATE HISTORY**

NanoViricides, Inc. was incorporated under the laws of the State of Colorado on July 25, 2000 as Edot-com.com, Inc. and was organized for the purpose of conducting internet retail sales. On April 1, 2005, Edot-com.com, Inc. was incorporated under the laws of the State of Nevada for the purpose of re-domiciling the Company as a Nevada corporation, Edot-com.com (Nevada). On April 15, 2005, Edot-com.com (Colorado) and Edot-com.com (Nevada) were merged and Edot-com.com, Inc., (ECMM) a Nevada corporation (the "Company"), became the surviving entity. On April 15, 2005, the authorized shares of common stock was increased to 300,000,000 shares at \$.001 par value and the Company effected a 3.2 - 1 forward stock split effective May 12, 2005.

On June 1, 2005, Edot-com.com, Inc. acquired NanoViricides, Inc., a privately owned Florida corporation ("NVI"), pursuant to an Agreement and Plan of Share Exchange (the "Exchange"). NVI was incorporated under the laws of the State of Florida on May 12, 2005 and its sole asset was comprised of a licensing agreement with TheraCour Pharma, Inc. ("TheraCour," an approximately 30% shareholder of NVI) for rights to develop and commercialize novel and specifically targeted drugs based on TheraCour's targeting technologies, against a number of human viral diseases. (For financial accounting purposes, the acquisition was a reverse acquisition of the Company by NVI, under the purchase method of accounting, and was treated as a recapitalization with NVI as the acquirer). Upon consummation of the Exchange, ECMM adopted the business plan of NVI.

Pursuant to the terms of the Exchange, ECMM acquired NVI in exchange for an aggregate of 80,000,000 newly issued shares of ECMM common stock, resulting in an aggregate of 100,000,000 shares of ECMM common stock issued and outstanding. As a result of the Exchange, NVI became a wholly-owned subsidiary of ECMM. The ECMM shares were issued to the NVI Shareholders on a pro rata basis, on the basis of 4,000 shares of the Company's Common Stock for each share of NVI common stock held by such NVI Shareholder at the time of the Exchange.

On June 28, 2005, NVI was merged into its parent ECMM and the separate corporate existence of NVI ceased. Effective on the same date, Edot-com.com, Inc., changed its name to NanoViricides, Inc. and its stock symbol on the Pink Sheets to "NNVC", respectively. The Company submitted a Form-10SB to the SEC to become a reporting company on November 14, 2006. The Company's filing status became effective in March, 2007. On June 28, 2007, the company became quotable on The OTC Bulletin Board under the symbol NNVC.OB.

The Company is considered a development stage company at this time.

#### Management's Plan of Operation

NanoViricides, Inc. (the "Company"), is an early developmental stage nano-biopharmaceutical company engaged in the discovery, development and commercialization of anti-viral therapeutics. The Company has no customers, products or revenues to date, and may never achieve revenues or profitable operations. Our drugs are based on several patents, patent applications, provisional patent applications, and other proprietary intellectual property held by TheraCour Pharma, Inc., one of the Company's principal shareholders, from which we have licensed, in perpetuity, the right to develop drug candidates for the treatment of the following human viral diseases: Human Immunodeficiency Virus (HIV/AIDS), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Herpes Simplex Virus (HSV), Rabies, Influenza and Asian Bird Flu Virus. Additionally, TheraCour has permitted the Company to use its nanomaterials to develop a treatment against Dengue Fever viruses, Ebola/Marburg viruses, and viruses causing certain eye diseases. The Company anticipates negotiating with TheraCour an amendment to the Licensing Agreement to include additional viruses. We are seeking to add to our existing portfolio of products through our internal discovery pre-clinical development programs and through an in-licensing strategy. We focus our laboratory research and pre-clinical programs on specific anti-viral solutions.

The Company has incurred significant operating losses since its inception resulting in an accumulated deficit of \$11,370,715 at March 31, 2009. For the nine months ended March 31, 2009 the Company had a net loss of \$2,162,978. Such losses are expected to continue for the foreseeable future and until such time, if ever, as the Company is able to attain sales levels sufficient to support its operations.

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To date, we have engaged in organizational activities; sourcing compounds and materials; developing novel compounds and nanomaterials, and experimentation with studies on cell cultures and animals. We have generated funding through the issuances of debt and private placement of common stock. We have not generated any revenues and we do not expect to generate revenues in the near future. We may not be successful in developing our drugs and start selling our products when planned, or that we will become profitable in the future. We have incurred net losses in each fiscal period since inception of our operations. The Company currently has no long term debt.

NanoViricides Technologies, Products in Development, and Collaborations

Pharmaceutical drug development is an expensive and long duration proposition. The Management's plan is to develop each of our nanoviricides to the necessary stage(s) and then engage into co-development relationships with other pharmaceutical companies. Such co-development relationships usually may entail upfront payments, milestones payments, cost-sharing, and eventual revenue-sharing, including royalty on sales. There is no guarantee that we will be able to negotiate agreements that are financially beneficial to the Company at the present stage. The Management plans to continue to raise additional funds as needed for our continuing drug development efforts on public markets.

The Company currently has several drug development programs. Our development model is to employ collaborations with academic labs, government labs, as well as external service providers in order to minimize our capital requirements. We currently have collaborations with the Center for Disease Control and Prevention (CDC) and the National (Central) Institute of Hygiene and Epidemiology (NIHE) (Vietnam) for Rabies, with the Armed Forces Institute of Pathology (AFIP) and NIHE for High-Path or Highly Pathogenic Avian Influenzas (in addition to H5N1, several H9N as well as H7N influenza virus subtypes are highly pathogenic and have caused or have the potential to cause severe influenza epidemics), and the Walter Reed Army Institute of Research (WRAIR) for Dengue family viruses, United States Army Medical Institute of Infectious Diseases (USAMRIID) for Ebola/Marburg family of hemorrhagic viruses, and the Long Island Jewish Medical System, Feinstein Institute of Medical Research (LIJMS) for viral EKC. In addition, our HIV and common influenza studies were subcontracted to KARD Scientific, Inc., USA. We have additional collaborations in formalization process for work on Dengue viruses, HIV, Viral Conjunctivitis, and other viruses.

We have developed lead drug candidates against a number of viral diseases. Proof-of-principle efficacy studies in animals have been conducted successfully in many of these.

Nanoviricides are designed to work by binding to and eliminating virus particles from the blood-stream, just as antibodies do, only potentially much better. This results in reduction in viremia. A nanoviricide is constructed by chemically attaching a ligand designed to bind to virus particle, to a polymeric material that forms a flexible nanomicelle by self-assembly. If antibodies are known to affect a viral disease, it is possible to construct a nanoviricide against it, and there can be a general expectation of some success, depending upon the ligand chosen.

#### Common Influenza, High Path Avian Influenzas, Bird Flu, Swine Flu

Our FluCide<sup>TM</sup> program has a lead drug candidate that has shown efficacies in animals that far exceed that of known drugs such as oseltamivir (Tamiflu®, Roche) against common influenza in an animal model. Our FluCide-HP<sup>TM</sup>, has demonstrated efficacies superior to FluCide against both Clade 1 and Clade 2 H5N1 strains, and is expected to be effective against all High Path influenzas, based on theoretical expectations. With its high efficacies and spectrum of all potentially epidemic influenza causing viruses, we have been able to stop the development of H5N1-specific AviFluCide in laboratory models. Recently, with additional SAR (structure-activity-relationship) studies, we have been able to develop influenza virus binding ligands that are expected to be superior to the previously used ligands in FluCide-HP. The new ligands are designed to be stronger mimics of the sialic acid receptors, capable of binding to influenza virus hemagglutinin proteins that use either the "avian" or the "human" types of sialic acid receptors. Pigs are known to be a "mixing vessel" species, exhibiting both avian and human types of sialic acid receptors, and thereby

re-assortment (mixing) of genetic material from different influenza strains, subtypes, or types, can occur readily in pigs. The new FluCide is expected to be highly active against all influenzas, including highly pathogenic strains such as H5N1, the 2009 H1N1 Mexico epidemic strain, H3N2, H7N, and H9N among others. We plan on stopping development of FluCide-HP as a separate drug for highly pathogenic influenzas, thus establishing a single drug for all influenzas, whether epidemic, or seasonal. We anticipate significant cost savings as well as simplification in regulatory and eventual marketing efforts by consolidating these drug programs.

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We are actively seeking partnerships, collaborations and government funding for our anti-influenza drug program.

#### Ebola, Marburg, Dengue

We have obtained significant positive results against Ebola, although additional development was expected to be required even as we engaged into this program, because Ebola virus produces a soluble glycoprotein decoy that may be capable of fooling certain of our virus-binding ligands. We have also submitted a grant application to the New England Regional Center of Excellence (NERCE) American Recovery and Reinvestment Act Supplement funding opportunity.

We are currently working on developing anti-Dengue therapeutics.

We have recently submitted a grant application to the Department of Defense for the development of broad-spectrum nanoviricides that may be useful in treating Ebola, Marburg, and Dengue viruses.

#### Rabies

Our RabiCide<sup>TM</sup> program has resulted in candidates that have enabled survival of 20% to 30% of infected animals after disease has set in, using a particular animal model. Further testing is in progress in a different experimental model. We believe that if this testing succeeds, it may be the first ever therapeutic against rabies. Currently, rabies is a uniformly lethal disease with only prophylactic medications available, which comprise of human antibodies, monoclonal antibody mixtures, and rabies vaccine virus strains. The potential market size for a rabies drug worldwide has been estimated at \$300M to \$500M.

#### Viral Diseases of the Eye: Viral Conjunctivitis, Viral Keratitis – Eye Drops

We recently developed a nanoviricide against adenoviral Epidemic Kerato-Conjunctivits (EKC). EKC is a severe disease of the eye which in some people causes long term or permanent blurred vision. In an animal study, our EKCCide<sup>TM</sup> lead candidate was shown to rapidly resolve the clinical signs of the disease, when treatment was started after infection had set in. The clinical success included demonstration that no SEI's (immunoprecipitates) were formed in treated animals, as opposed to control group. SEI's are known to be the cause of blurred vision. There are currently no approved drugs available against EKC, and it is an active field of drug development research. The Company is not aware of any other animal studies of anti-EKC drug candidates that have demonstrated resolution of clinical disease. There are about 2.5 million cases of EKC annually in the USA alone. The EKC market size worldwide is estimated variously between \$300M and \$1,000M.

Based on these successful results, we have since expanded this program to develop a single broad-spectrum nanoviricide treatment useful against a majority of viruses causing external eye diseases such as viral conjunctivitis and viral keratitis. HSV and some adenoviruses cause most of the cases of keratitis, a serious infection of the cornea. Importantly, HSV infection can lead to corneal scarring that may necessitate corneal transplantation. In addition, some adenoviruses cause a majority of conjunctivitis cases ("Pink eye"). The remaining cases of conjunctivitis are caused y bacteria and are treatable with topical antibiotics. Currently there are no effective treatments for viral diseases of the exterior portion of the eye.

The eye drugs are formulated as simple eye drops.

The total market for viral conjunctivitis and keratitis is estimated to be in the billions of dollars. The incidence of severe herpes keratitis is estimated to be 250,000 cases per year in the USA. In Japan, where EKC is a reportable disease, it is estimated that there are at least one million cases per year. The number of cases of non-specific conjunctivitis (pink eye) is considered to be far greater, possibly into the tens of millions in the US and hundreds of millions worldwide.

The Company reported on February 27, 2009 that it entered into a Material Transfer Agreement with a major pharmaceutical company. Pursuant to the terms of the agreement, the Company is not authorized to disclose the identity or the terms of the Agreement, except for securities reporting purposes. The pharmaceutical company will evaluate one of the Company's compounds as a drug candidate for certain viral infections of the external eye. The Agreement also provides that following evaluation, should the pharmaceutical company so elect, the parties may enter into good faith negotiations for an exclusive, worldwide license for drug development and commercialization of the eye drug candidate.

On May 6, 2009, the Company entered into a Clinical Study Agreement with THEVAC, LLC, a company affiliated with the Emerging Technology Center of the Louisiana State University. The Company will provide THEVAC with drug compounds that will be initially tested for their ability to inhibit replication of the HSV-1 virus, utilizing plaque reduction assays and inhibition of cytopathic effects (CPE)) assays. In addition, the drug compounds will be tested for their ability to inactivate free virus and inhibit penetration and virus spread to adjacent cells.

#### HIV

Our very first animal studies in SCID-hu mice against HIV-I have resulted in a demonstration that our primary nanoviricide drug candidate as well as several other nanoviricide drug candidates in the HIVCide<sup>TM</sup> program were found to be superior to the three-drug oral cocktail (HAART) given according to standard protocol. Resistance to HAART eventually leads to AIDS. It is possible that HIVCide can be used in addition to HAART to obtain even stronger beneficial effects, which may result in a "functional cure" of HIV as defined by scientists. (We believe that the term Functional Cure of HIV may be defined as: The HIV genome integrates into certain human cells that go into hiding or dormancy for several years. While in hiding, they do not produce HIV virus particles or HIV proteins to any significant extent and are thought to remain unaffected by current anti-HIV drugs. The current standard treatment results in very low levels of HIV viremia, but the immune cells (CD4+ T cells and CD8+T cells) count eventually begins decreasing at a slow rate. The HAART therapy must be continued for the life of the patient and the drug mix is altered as failure occurs. A more effective therapy could result in complete loss of HIV from the blood stream, allowing immune system function to return to normal, and thereby allowing the patient to enjoy normal life without further daily treatment, until an episode occurs which mobilizes the "sleeping" cells containing HIV genome. Such a therapy would be called a "functional cure" against HIV. A total cure of HIV would require elimination of the dormant cell pool containing the HIV genome. Nanoviricides act by a different mechanism than standard anti-HIV therapy. The Company believes, therefore, that by combining a nanoviricide with current therapy, a functional cure of HIV may be achieved. However, there is no way to predict whether such a treatment would be successful at providing a functional cure of HIV at present). Nevertheless, we believe that HIVCide is a significant anti-HIV candidate, acting by a novel mechanism of action and a first-in-class therapeutic, based on current preliminary data. We intend to develop it further.

## ADIF<sup>TM</sup> Technologies

We believe that our technologies and capabilities at attacking different viruses are fairly well demonstrated. Our nanoviricides against specific viruses are discussed earlier. In addition, we have developed "Accurate-Drug-In-Field<sup>TM</sup>" or ADIF<sup>TM</sup> technologies that may show efficacy in treating epidemics like H5N1, SARS or Ebola at source by preventing their spread using a therapeutic developed directly in the field. ADIF technologies are applicable to novel, or engineered viruses, or emerging infections whether natural or man-made. This technology may have significant applications in Biodefense area. Between these two spectrums of specific antiviral developed during peace-time effort, and specific antivirals developed as a "war-like" effort (ADIF), we have demonstrated the capability of developing broad-spectrum nanoviricides. Broad-spectrum nanoviricides are based on the notion that a large number of virus families employ the same cell surface receptor. Thus, if we constructed a nanoviricide that "looks like" a cell to the virus, by carrying the portion of such broad-spectrum receptor on the nanomicelle surface, the virus would "try to infect" such a cell biomimetic, and could in the process get entrapped or dismantled. A nanoviricide is designed as a cell biomimetic, and this has made our broad-spectrum nanoviricides approach possible. Such broad-spectrum

nanoviricides could be stockpiled to enable treatment of many infectious agents with very few drugs, and thus would be valuable to worldwide disease programs, and Strategic National Stockpiling efforts.

We believe therefore that the Company has a strong, wide and deep pipeline of drugs several years into the future. However, with relatively meager financial resources, the Company continues to juggle prioritization of the various programs, and program achievements. We are also working on bolstering our infrastructure with the objective of enabling us to file pre-IND applications or some of our drug candidates to the FDA. The Company has received significant interest from major pharmaceutical companies in its Viral Eye Diseases drug candidate, and HIVCide and FluCide programs to date, and we expect interest to pick up in other programs as well. There is no guarantee that this interest would result in any financially lucrative co-development agreements.

All of our programs are currently at the pre-clinical stage. We have established preliminary proof of efficacy in cell culture and animal models, and have conducted preliminary safety studies that have indicated that all of our nanoviricides are safe in the animal models as tested. We continue to work on further experiments necessary for development of our various drug candidates as FDA approvable drugs.

All of these drugs candidates are being developed as injectables, except EKCCide which is an ophthalmic formulation or eye drops solution.

#### Plan of Operations

The Company's drug development business model was formed in May 2005 with a license to the patents and intellectual property held by TheraCour Pharma, Inc. that enabled creation of drugs engineered specifically to combat viral diseases in humans. This exclusive license from TheraCour Pharma Inc. serves as a foundation for our intellectual property. The Company was granted a worldwide exclusive perpetual license to this technology for several drugs with specific targeting mechanisms in perpetuity for the treatment of the following human viral diseases: Human Immunodeficiency Virus (HIV/AIDS), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Rabies, Herpes Simplex Virus (HSV), Influenza and Asian Bird Flu Virus. Additionally, TheraCour has permitted the Company to use its nanomaterials to develop a treatment against Dengue Fever viruses, Ebola/Marburg viruses, and viruses causing certain eye diseases. The Company anticipates negotiating with TheraCour an amendment to the Licensing Agreement to include additional viruses. We are seeking to add to our existing portfolio of products through our internal discovery pre-clinical development programs and through an in-licensing strategy.

The Company intends to perform the regulatory filings and own all the regulatory licenses for the drugs it is currently developing. The Company will develop these drugs in part via subcontracts to TheraCour Pharma, Inc., the exclusive source for these nanomaterials. The Company may manufacture these drugs itself, or under subcontract arrangements with external manufacturers that carry the appropriate regulatory licenses and have appropriate capabilities. The Company intends to distribute these drugs via subcontracts with distributor companies or in partnership arrangements. The Company plans to market these drugs either on its own or in conjunction with marketing partners. The Company also plans to actively pursue co-development, as well as other licensing agreements with other Pharmaceutical companies. Such agreements may entail up-front payments, milestone payments, royalties, and/or cost sharing, profit sharing and many other instruments that may bring early revenues to the Company. Such licensing and/or co-development agreements may shape the manufacturing and development options that the company may pursue. The Company has received significant interest from certain major Pharmaceutical companies for potential licensing or co-development of some of our drug candidates. However, none of these distributor or co-development agreements is in place at the current time.

To date, we have engaged in organizational activities; developing and sourcing compounds, and preparing nano-materials; and experimentation involving preclinical studies using cell cultures and animals. We have generated funding through the issuances of debt and private placement of common stock (see Item 5 Recent Sales of Unregistered Securities). We have not generated any revenues and we do not expect to generate revenues in the near future. We may not be successful in developing our drugs and start selling our products when planned, or we may not become profitable in the future. We have incurred net losses in each fiscal period since inception of our operations.

Liquidity and Capital Resources

Requirement for Additional Capital

We currently do not have sufficient cash reserves to achieve all of our budgeted plans for the next twelve months and we may not be able to obtain the necessary financing.

The Company has taken several steps to reduce its operating expenses. We have not renewed certain consulting contracts, which is expected to result in annual savings of \$150,000 to \$300,000. We have not renewed our lease for laboratory facilities at 4 Research Drive and have constructed and consolidated our laboratory facilities at 135 Wood Street, West Haven, Connecticut, for an anticipated annual savings of approximately \$50,000. We have also made several changes which should result in a reduction in our professional fees of approximately \$100,000 annually.

As of March 31, 2009 we had a cash and cash equivalent balance of \$1,228,056 which can support operations through, approximately, September 30, 2009, at our current projected rate of spending.

However, in addition to current funds allocated to capital costs and staffing, and in accordance with our business plan, we have also budgeted for additional capital costs and staffing costs of approximately \$2 million dollars for the upcoming twelve months. If we are unable to obtain this additional financing, our business plan will be delayed.

Assuming that we are successful in raising this additional financing, we anticipate that we will incur the following expenses over the next twelve months:

- Research and Development of \$1,500,000: Includes planned costs of \$1,200,000 for in-vivo and in-vitro studies for pan-influenza FluCide, RabiCide, EKCCide, HIVCide, and Dengue and Ebola/Marburg programs, planned for the next twelve months ending March 31, 2010. The Company has allocated the planned costs of \$1,200,000 evenly over the seven drug candidates.
- 2 Corporate overhead of \$750,000: This amount includes budgeted office salaries, legal, accounting and other costs expected to be incurred by being a public reporting company.
- 3 Capital costs of \$1,250,000: This is the estimated cost for equipment and laboratory improvements expected during the next twelve months ending March 31, 2010.
- Staffing costs of \$1,500,000: This is the estimated cost of hiring additional scientific staff and consulting firms to assist with FDA compliance, material characterization, pharmaco-kinetic, pharmaco-dynamic and toxicology studies, and other items related to FDA compliance, as required for development of necessary data for filing an Investigational New Drug Application (IND) with the United States Food and Drug Administration.

The Company projects that it will be unable to proceed with its planned drug development progress, meet its administrative expense requirements, capital costs, and staffing costs beyond September 30, 2009 without obtaining additional financing of approximately \$3,000,000 to \$5,000,000. If we are unable to obtain additional financing, our business plan will be significantly delayed or curtailed. The Company continues to re-prioritize its objectives and delay certain drug development programs until we can raise sufficient funding that enables further development of the drugs with the goal of filing an Investigational New Drug application (IND) to the FDA.

The Company does not have any arrangements, at this time, for equity or other financing for these further needs of \$3-5 million beyond minimum operations. If we are unable to obtain additional financing, our business plan will be significantly delayed.

The Company has limited experience with pharmaceutical drug development. As such our budget estimates may vary significantly from actual expenses incurred. In addition, the actual work to be performed is not known at this time, other than a broad outline, as is normal with any scientific work. As further work is performed, additional work may become necessary or change in plans or workload may occur. Such changes may have an adverse impact on our estimated budget. Such changes may also have an adverse impact on our projected timeline of drug development.

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We believe that this coming year's work-plan will lead us to obtain certain information about the safety and efficacy of some of the drugs under development in animal models. If our studies are not successful, we will have to develop additional drug candidates and perform further studies. If our studies are successful, then we expect to be able to undertake further studies in animal models to obtain necessary data regarding the pharmaco-kinetic and pharmaco-dynamic profiles of our drug candidates. We believe these data will then enable us to file an Investigational New Drug (IND) application, towards the goal of obtaining FDA approval for testing the drugs in human patients.

Most pharmaceutical companies expect 4 to 10 years of study to be required before a drug candidate reaches the IND stage. We believe that because we are working in the infectious agents area, our studies will have objective response end points, and will be of relatively short durations. Our business plan is based on these assumptions. If we find that we have underestimated the time duration of our studies, or we have to undertake additional studies, due to various reasons within or outside of our control, this will grossly and adversely impact both our timelines and our financing requirements.

Management intends to use capital and debt financing, as required, to fund the Company's operations. There can be no assurance that the Company will be able to obtain the additional capital resources necessary to fund its anticipated obligations for the next twelve months.

The Company is considered to be a development stage company and will continue in the development stage until it generates revenues from the sales of its products or services.

#### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

The Company is not exposed to market risk related to interest rates or foreign currencies.

#### ITEM 4. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures.

Based upon an evaluation of the effectiveness of disclosure controls and procedures, our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO") have concluded that as of the end of the period covered by this Quarterly Report on Form 10-Q our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Exchange Act) were effective to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified by the rules and forms of the SEC and is accumulated and communicated to management, including the CEO and CFO, as appropriate to allow timely decisions regarding required disclosure.

b) Changes in internal control over financial reporting.

In our Annual Report on Form 10-K for the year ended June 30, 2008, Management reported that it was aware that there were the following material weaknesses in our internal control over financial reporting

1. Timeliness of Financial Reporting: Our Chief Executive Officer and Interim Chief Financial Officer concluded that the Company's controls were not effective as of March 31, 2009 due to inherent weaknesses present in the preparation of financial statements as a result of the departure of its Chief Financial Officer on May 16, 2007.

2. Segregation of Duties: We did not maintain adequate segregation of duties related to job responsibilities for initiating, authorizing, and recording of certain transactions. Due to this material weakness, there is a reasonable possibility that a material misstatement in the financial statements would not be prevented or detected on a timely basis.

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The Company believes that it has taken significant steps to remediate these weaknesses including implementing additional segregation of responsibilities and authorizations for initiating, authorizing and recording transactions. In addition, the Company has outsourced certain financial functions, including reviewing significant transactions and quarterly financial statements to independent contractors.

Other than as described above, there were no material changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that occurred as of March 31, 2009, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

None.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

In August 2008, the Scientific Advisory Board (SAB) was granted warrants to purchase 50,000 shares of common stock at \$1.56 per share. These warrants, if not exercised, will expire in August, 2012.

On August 22, 2008, the Company consummated subscriptions with certain investors whereby the Company sold 3,286,000 shares (the "Shares") of its common stock, par value \$0.001 per share (the "Common Stock") and ("Warrants") to purchase 1,643,000 shares of Common Stock at an exercise price of \$2.00 per share for an aggregate purchase price of \$3,286,000. The 3,286,000 share private placement of stock included 150,000 shares of Common Stock and 75,000 warrants subscribed in consideration of \$150,000 of scientific testing and other laboratory work performed for the Company. The Warrants may be exercised at any time and expire on September 17, 2011.

Also on August 22, 2008, the Company consummated subscriptions with certain of its Warrant holders whereby the Company offered all the holders of its \$2.50 warrants the option of exercising the Warrants at \$1.00 per share of Common Stock, of which warrants to purchase 50,000 shares of Common Stock for an aggregate price of \$50,000 were exercised. Concurrently, the Company consummated subscriptions with certain other of its Warrant holders whereby the Company offered all the holders of its \$1.00 warrants the option of exercising the Warrants at \$0.75 per share of Common Stock, of which warrants to purchase 75,000 shares of Common Stock for an aggregate price of \$56,250 were exercised.

In November 2008, the Scientific Advisory Board (SAB) was granted warrants to purchase 50,000 shares of common stock at \$0.70 per share. These warrants, if not exercised, will expire in November 2012. The fair value of these warrants in the amount of \$30,500 was recorded as consulting expense.

In February 2009, the Scientific Advisory Board (SAB) was granted warrants to purchase 50,000 shares of common stock at \$0.58 per share. These warrants, if not exercised, will expire in November 2012. The fair value of these warrants in the amount of \$29,000 was recorded as consulting expense.

For the nine months ended March 31, 2009, the Company's Board of Directors authorized the issuance of 106,628 shares of its common stock with a restrictive legend, for consulting services. The Company recorded an expense of \$79,800.

#### **Index**

For the nine months ended March 31, 2009, the Company's Board of Directors authorized the issuance of additional 29,248 shares of its common stock with a restrictive legend, for legal services. The Company recorded an expense of \$50,000.

All of the securities set forth above were issued by the Company pursuant to Section 4(2) of the Securities Act of 1933, as amended, or the provisions of Rule 504 of Regulation D promulgated under the Securities Act. All such shares issued contained a restrictive legend and the holders confirmed that they were acquiring the shares for investment and without intent to distribute the shares. All of the purchasers were friends or business associates of the Company's Management and all were experienced in making speculative investments, understood the risks associated with investments, and could afford a loss of the entire investment. The Company has never utilized an underwriter for an offering of its securities.

#### ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

#### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

On March 18, 2009 a majority of the Company's shareholders consented to an, amendment of the Company's Articles of Incorporation to authorize the creation of a class of 10,000,000 shares of blank check preferred stock (the "Amendment"). The Company filed a Definitive Information Statement with the Securities and Exchange Commission disclosing the action taken by its shareholders. The Amendment became effective May 13, 2009.

#### ITEM 5. OTHER INFORMATION

#### Subsequent Events

On May 6, 2009, the Company entered into a Clinical Study Agreement with THEVAC, LLC, a company affiliated with the Emerging Technology Center of the Louisiana State University. The Company will provide THEVAC with drug compounds that will be tested for their ability to inhibit replication of the HSV-1 virus, utilizing plaque reduction assays and inhibition of cytopathic effects (CPE) assays.

#### ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

#### (a) Exhibit index

Exhibit	
<u>31.1</u>	Certification of Chief Executive and Interim Chief Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
	Rule 13d-14(a) under the Securities Exchange Act of 1934, as afficiated.
<u>32.1</u>	Certification of Chief Executive Officer and Interim Chief Financial Officer required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C.

Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(b) Reports on Form 8-K. During the fiscal quarter ended March 31, 2009, the Company filed the following Current Reports on Form 8-K:

#### **Index**

On January 13, 2009, the Company filed a Current Report disclosing that it had dismissed Holtz Rubenstein Reminick LLP as its independent accountant and had engaged Li & Company, PC as its new independent accountant.

On February 10, 2009, the Company filed a Current Report disclosing that TheraCour Pharma, Inc., the largest single shareholder of the Company, had adopted a written trading plan pursuant to Securities and Exchange Commission Rule 10b5-1, under which it would sell up to 1,800,000 shares of the Company's common stock over a one year period.

On March 2, 2009, the Company filed a Current Report disclosing that on February 25, 2009, it had entered into a Material Transfer Agreement with a pharmaceutical company to evaluate one of the Company's compounds as a drug candidate for certain viral infections of the external eye.

#### **SIGNATURES**

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

Dated: May 15, 2009

NANOVIRICIDES, INC.

/s/ Eugene Seymour, MD
Eugene Seymour, M.D.
Chief Executive Officer and Interim Chief
Financial Officer and Director
(Principal Executive and Financial Officer)

/s/ Anil Diwan Anil Diwan, President and Chairman of the Board of Directors

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**Table of Contents** 

Pacira Pharmaceuticals, Inc.

Consolidated Statements of Stockholders' Equity (Deficit)

Years Ended December 31, 2012, 2011 and 2010

(In thousands)

	Prefer		•	G. 1	Additional		Ac	ccumulated Other	i
	Sto	CK	Commo	n Stock		AccumulatedI	reasi <b>Co</b> i		ve
	Shares	Amount	Shares	Amount	Capital	Deficit		Income	Total
Balances at December 31, 2009	6,322	6	574	1	86,806	(109,762)			\$ (22,949)
Exercise of stock options			1		2				2
Share-based compensation					23				23
Purchase of treasury stock							(2)		(2)
Debt discount from beneficial conversion features and									
issuance of warrants with convertible notes					1,692				1,692
Net loss						(27,149)			(27,149)
Balances at December 31, 2010	6,322	6	575	1	88,523	(136,911)	(2)		(48,383)
Exercise of stock options			67		135	, , , ,			135
Share-based compensation					2,493				2,493
Initial public offering, net of issuance costs			6,000	6	37,103				37,109
Follow-on public offering, net of issuance costs			8,050	8	48,998				49,006
Conversion of preferred stock	(6,322)	(6)	6,322	6					ĺ
Conversion of 2009 Convertible									
Notes and accrued interest			872	1	11,717				11,718
Conversion of 2009 Secured									ĺ
Notes and accrued interest			928	1	12,473				12,474
Conversion of 2010 Secured									
Notes and accrued interest			1,157	1	15,548				15,549
Conversion of 2010 Convertible									
Notes and accrued interest			1,071	1	7,499				7,500
Conversion of HBM Secured									
Notes and accrued interest									
and early prepayment penalty			297		3,981				3,981
Unrealized gain on short-term investments								15	15
Net loss						(43,328)			(43,328)
Balances at December 31, 2011			25,339	25	228,470	(180,239)	(2)	15	48,269
Exercise of stock options			279	1	769	( 11, 11,			770
Exercise of warrants			105		100				100
Share-based compensation					4,776				4,776
Unrealized gain on short-term investments					,			12	12
Follow-on public offering, net of issuance costs			6,900	7	62,848				62,855
Debt discount on issuance of warrants			- /		1,354				1,354
Net loss					,	(52,281)			(52,281)
									. , ,
Balances at December 31, 2012		\$	32,623	\$ 33	\$ 298,317	\$ (232,520)	\$ (2)	\$ 27	\$ 65,855

See accompanying notes to consolidated financial statements

# Pacira Pharmaceuticals, Inc.

# **Consolidated Statements of Cash Flows**

# $(In\ thousands)$

	Year Ended December 31,			
	2012	2011	2010	
Operating activities:				
Net loss	\$ (52,281)	\$ (43,328)	\$ (27,149)	
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	5,648	4,314	4,071	
Amortization of unfavorable lease obligation and deferred financing costs	(239)	(85)	(149)	
Amortization of end of term fee and warrants	831	1,644	146	
Loss on disposal of fixed assets	1	273	11	
Loss on early extinguishment of debt	1,062		184	
Impairment of long-lived assets	,,,,,	3,019		
Stock-based compensation	4,776	2,493	23	
Changes in operating assets and liabilities:	.,,	_, ., .		
Restricted cash	(224)	14	(98)	
Accounts receivable, net	(2,239)	(922)	264	
Inventories	(10,832)	360	124	
Prepaid expenses and other assets	(59)	(608)	32	
Accounts payable and accrued expenses	1,386	2,549	(1,118)	
Royalty interest obligation	(1,076)	(1,815)	(675)	
Other liabilities	(106)	27	1,782	
Deferred revenue	(16,778)	1,065	(2,328)	
Deferred revenue	(10,770)	1,005	(2,320)	
Net cash used in operating activities	(70,130)	(31,000)	(24,880)	
Investing activities:				
Purchase of fixed assets	(18,257)	(6,167)	(6,770)	
Proceeds from sales of fixed assets	1	14	1	
Purchases of short-term investments	(54,047)	(52,619)		
Sale of short-term investments	53,120	22,649		
Payment of contingent consideration	(10,339)			
Net cash used in investing activities	(29,522)	(36,123)	(6,769)	
Financing activities:				
Proceeds from exercise of stock options and warrants	870	136	2	
Proceeds from borrowings on long-term debt	27,500			
Proceeds from initial public offering, net		38,016		
Proceeds from public offering, net	62,855	49,006		
Purchase of treasury stock			(2)	
Proceeds from convertible notes			7,500	
Proceeds from secured promissory notes and credit facility			56,250	
Repayment of debt	(26,250)		(11,250)	
Payment of debt issuance and financing costs	(1,365)		(1,795)	
	( ) /		( ,)	
Net cash provided by financing activities	63,610	87,158	50,705	
Net (decrease) increase in cash and cash equivalents	(36,042)	20,035	19,056	
Cash and cash equivalents, beginning of year	46,168	26,133	7,077	

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Cash and cash equivalents, end of year	\$ 10,126	\$ 46,168	\$ 26,133
Supplemental cash flow information			
Cash paid for interest, including royalty interest obligation	\$ 4,229	\$ 4,739	\$ 2,371
Initial public offering costs paid in 2010	\$	\$ 907	\$
Non cash investing and financing activities:			
Value of warrants issued with debt	\$ 1,354	\$	\$
Value of warrants issued with debt and beneficial conversion feature	\$	\$	\$ 1,692
Accrued financing cost	\$	\$	\$ 500
Conversion of notes to common stock	\$	\$ 51,222	\$
Conversion of preferred stock to common stock	\$	\$ 6	\$

See accompanying notes to consolidated financial statements

#### Pacira Pharmaceuticals, Inc.

#### **Notes to Consolidated Financial Statements**

# NOTE 1 BUSINESS

Pacira Pharmaceuticals, Inc. and its subsidiaries (collectively, the "Company" or "Pacira") is an emerging specialty pharmaceutical company focused on the development, commercialization and manufacture of proprietary pharmaceutical products, based on its proprietary DepoFoam extended release drug delivery technology, for use in hospitals and ambulatory surgery centers. The Company's lead product EXPAREL, which consists of bupivacaine encapsulated in DepoFoam, was approved by the FDA on October 28, 2011 and launched commercially in April 2012. DepoFoam is also the basis for the Company's other FDA-approved product, DepoCyt(e), which the Company manufactures for commercial partners, and DepoDur, which the Company is no longer marketing.

Pacira Pharmaceuticals, Inc. is the holding company for its California operating subsidiary of the same name, also referred to as PPI-California, which was acquired from SkyePharma Holding, Inc., or SkyePharma, in March 2007, or the Acquisition.

#### Risks and Uncertainties

The Company is subject to risks common to companies in similar industries and stages of development, including, but not limited to, competition from larger companies, reliance on revenue from few customers and products, reliance on single manufacturing sites, new technological innovations, dependence on key personnel, reliance on third-party service providers and sole source suppliers, protection of proprietary technology and compliance with government regulations.

#### NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

# Basis of Presentation and Principles of Consolidation

The consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America, or GAAP, and in accordance with the rules and regulations of the Securities and Exchange Commission, or SEC. The accounts of wholly owned subsidiaries are included in the consolidated financial statements. All intercompany balances and transactions have been eliminated in consolidation. Certain reclassifications were made to conform to the current presentation. Specifically, the Company reclassified DepoCyt(e) and DepoDur supply sales for the years ended December 31, 2011 and 2010 to net product sales to conform to the current presentation. This reclassification had no impact on net loss or stockholders' equity as previously reported.

# Use of Estimates

The preparation of financial statements in conformity with GAAP requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, including disclosure of contingent assets and contingent liabilities, at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates are used for, among other things, the valuation of assets acquired, impairment of long-lived assets, goodwill, stock-based compensation and valuation of deferred tax assets. The Company's critical accounting policies are those that are both most important to the Company's consolidated financial condition and results of operations and require the most difficult, subjective or complex judgments on the part of management in their application, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Because of the uncertainty of factors surrounding the estimates or judgments used

# Pacira Pharmaceuticals, Inc.

#### **Notes to Consolidated Financial Statements (Continued)**

#### NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

in the preparation of the consolidated financial statements, actual results could differ from these estimates.

#### Liquidity

Management believes that the Company's existing cash and cash equivalents, short-term investments, including the proceeds from its private offering of \$120.0 million in convertible senior notes completed in January 2013, and revenue from product sales will be sufficient to enable the Company to meet its planned operating expenses, capital expenditure requirements and service its indebtedness at least through December 31, 2013. However, changing circumstances may cause the Company to expend cash significantly faster than currently anticipated, and the Company may need to spend more cash than currently expected because of circumstances beyond its control. The Company expects to continue to incur substantial additional operating losses as it commercializes EXPAREL and develops and seeks regulatory approval for its product candidates.

### Revenue Recognition

#### **Product Sales**

The Company sells EXPAREL primarily to wholesalers based on orders of the product from hospitals and other end user customers such as ambulatory surgery centers and doctors. The Company recognizes revenue when there is persuasive evidence that an arrangement exists, title has passed, collection is reasonably assured and the price is fixed or determinable. Sales to wholesalers provide for selling prices that are fixed on the date of sale. EXPAREL is delivered directly to the end user with the wholesaler never taking physical possession of the product. The Company records revenue at the time the product is delivered to the end user. The Company also recognizes revenue from products manufactured and supplied to commercial partners. Prior to the shipment of the manufactured products such as DepoCyt(e), the Company conducts initial product release and stability testing in accordance with current Good Manufacturing Practices, or cGMP.

At the time the Company recognizes revenue, it also records certain sales reserves and allowances as a reduction of revenue. These reserves and allowances include a prompt payment reserve, return reserves, volume rebates, chargeback reserve and wholesaler service fee. Due to estimates and assumptions inherent in determining some of the sales reserves, the actual amount of volume rebates, chargebacks and returns may be different from estimates, at which time the Company would adjust the reserves accordingly.

# Prompt Pay Reserve

The prompt payment reserve is based upon discounts offered to wholesalers as an incentive to meet certain payment terms. The Company accounts for these discounts at the time the sale is made and reduces accounts receivable accordingly.

# Return Reserves

The Company allows customers to return product that is damaged or received in error. In addition, the Company allows for EXPAREL product to be returned beginning six months prior to, and twelve months following product expiration. As EXPAREL is a new commercially available product, the

#### Pacira Pharmaceuticals, Inc.

### **Notes to Consolidated Financial Statements (Continued)**

#### NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Company is estimating its sales return reserve based on return history from other hospital-based products with similar distribution models, which management believes is the best estimate of the anticipated product to be returned. The returns reserve is recorded at the time of sale as a reduction to sales and an increase in returns liability.

Commercial partners can return the products within contracted specified timeframes if the products do not meet the applicable inspection tests. Historically, returns from commercial partners have not been material.

# Volume Rebates and Chargeback Reserve

Volume rebates and chargeback reserve are based upon contracted discounts and promotional offers the Company provides to certain end users, including hospitals and ambulatory surgery centers such as members of group purchasing organizations. The volume rebates and chargeback reserve are recorded as a reduction to sales and a customer payable and reduction to receivables, respectively.

#### Wholesaler Service Fee

The Company's customers include major and regional wholesalers with whom the Company has contracted a fee for service based on a percentage of sales. This fee for service is recorded as a reduction to gross sales and a liability is established at the time the sale is recorded based on the contracted percentage.

#### Allowance for Doubtful Accounts

The Company evaluates its accounts receivable to determine if a provision for an allowance for doubtful accounts is appropriate. The Company's sales to date are primarily to established customers. As of December 31, 2012 and 2011, the accounts receivable was considered collectible and no allowance for doubtful accounts was recorded.

# Royalty Revenue

The Company recognizes revenue from royalties based on sales of its products by commercial partners. Royalties are recognized as earned in accordance with contract terms when they can be estimated based on historical product sales, royalty receipts and other relevant information and collectability is reasonably assured.

#### Collaborative Licensing and Development Revenue

The Company recognizes revenue from reimbursements received in connection with feasibility studies and development work for third parties who desire to utilize its DepoFoam extended release drug delivery technology for their products when the Company's contractual services are performed, provided collectability is reasonably assured. The Company's principal costs under these agreements include its personnel conducting research and development and allocated overhead, as well as research and development performed by outside contractors or consultants.

The Company recognizes revenues from non-refundable up-front license fees received ratably over the performance period using the estimated development period in development agreements and the contract period or longest patent life in supply and distribution agreements. If the estimated

#### **Notes to Consolidated Financial Statements (Continued)**

#### NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

performance period is subsequently modified, the Company will modify the period over which the up-front license fee is recognized accordingly on a prospective basis. Upon notification of a termination of a collaboration agreement, any remaining non-refundable license fees received by the Company, which had been deferred, are recognized over the remaining contractual term. If the termination is immediate and no additional services are to be performed, the deferred revenue is generally recognized in full. All such recognized revenues are included in collaborative licensing and development revenue in the Company's consolidated statements of operations.

The Company recognizes revenue from milestone payments received under collaboration agreements when earned, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, the Company has no further performance obligations relating to the event, and collectability is reasonably assured. If these criteria are not met, the Company recognizes milestone payments ratably over the remaining period of the Company's performance obligations under the collaboration agreement. All such recognized revenues are included in collaborative licensing and development revenue in the Company's consolidated statements of operations.

#### Concentration of Major Customers

The Company's customers are its major and regional wholesalers and commercial and collaborative and licensing partners. The Company is dependent on its commercial partners to market and sell DepoCyt(e). The table below includes the percentage of revenue comprised by the three largest customers in each year presented.

		Year Ended	
	December 31,	December 31,	December 31,
	2012	2011	2010
Largest customer	30%	43%	49%
Second largest customer	14%	23%	21%
Third largest customer	11%	19%	13%
	55%	85%	83%

Sales to customers outside the U.S. accounted for 23%, 64% and 52% of the Company's revenue for the years ended December 31, 2012, 2011 and 2010, respectively.

# Research and Development Expenses

Research and development expenses consist of costs associated with products being developed internally, and include related personnel expenses, laboratory supplies, active pharmaceutical ingredients, manufacturing supplies, facilities costs, preclinical and clinical trial costs, and other outside service fees. The Company expenses research and development costs as incurred. A significant portion of the Company's development activities are outsourced to third parties, including contract research organizations. In such cases, the Company may be required to estimate related service fees to be accrued.

#### Pacira Pharmaceuticals, Inc.

#### **Notes to Consolidated Financial Statements (Continued)**

#### NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

# Cash and Cash Equivalents

All highly-liquid investments with maturities of 90 days or less when purchased are considered cash equivalents.

#### Restricted Cash

As further discussed in Note 9, *Debt*, the Company has entered into a financing agreement with Royalty Securitization Trust I ("RST") for the sale of a royalty interest in its DepoCyt(e) and DepoDur product revenue and royalties. As part of this financing agreement, the Company and RST maintain a lockbox, where all DepoCyt(e) and DepoDur product revenue and royalties are received. The Company has no minimum payment obligations under this agreement. Commencing on April 1 of every year, the first \$2.5 million received in the lockbox is restricted and is used to make quarterly payments due to RST, if any, under the agreement during the subsequent 12 month period. On March 31 of the subsequent year, the balance of cash in the lockbox, if any, is remitted to the Company. The RST agreement terminates on December 31, 2014. The royalty interest agreement pertains only to DepoCyt(e) and DepoDur, and does not include revenue related to EXPAREL or any other product candidates.

#### Short-Term Investments

The Company determines the appropriate classification of its investments at the time of purchase and reevaluates such determination at each balance sheet date. The Company's investment policy sets minimum credit quality criteria and maximum maturity limits on its investments to provide for preservation of capital, liquidity and a reasonable rate of return. Available-for-sale securities are recorded at fair value, based on current market valuations. Unrealized holding gains and losses on available-for-sale securities are excluded from net loss and are reported as a separate component of other comprehensive income (loss) until realized. Realized gains and losses are included in non-operating other income (expense) on the consolidated statement of operations and are derived using the specific identification method for determining the cost of the securities sold.

# **Inventories**

Inventories consist of finished goods held for sale and distribution, raw materials and work in process, and are stated at the lower of cost, which includes amounts related to material, labor and overhead, or market (net realizable) value and is determined using the first-in, first-out ("FIFO") method. The Company periodically reviews its inventory to identify obsolete, slow-moving or otherwise unsalable inventories, and establishes allowances for situations in which the cost of the inventory is not expected to be recovered. Overhead costs associated with excess manufacturing capacity are charged to cost of revenue, as incurred.

#### Fixed Assets

Fixed assets are recorded at cost, net of accumulated depreciation and amortization. The Company reviews its property, plant and equipment assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

#### **Notes to Consolidated Financial Statements (Continued)**

#### NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Depreciation of fixed assets is provided over their estimated useful lives on a straight-line basis. Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or the related lease terms. Useful lives by asset category are as follows:

Asset Category	Years
Manufacturing and laboratory equipment	5 to 10 years
Computer equipment and software	1 to 3 years
Office furniture and equipment	5 years

#### Goodwill and Intangible Assets

Intangible assets are recorded at cost, net of accumulated amortization. Amortization of intangible assets is provided over their estimated useful lives on a straight-line basis. The Company evaluates the recoverability of intangible assets periodically and takes into account events and circumstances which indicate that impairment exists. Goodwill represents the excess of purchase price over fair value acquired in a business combination and is not amortized, but subject to impairment at least annually or when a triggering event occurs that could indicate a potential impairment.

#### Impairment of Long-Lived Assets

Management reviews long-lived assets, including fixed assets, for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds the fair value of the assets.

# Foreign Currencies

The Company receives payment from certain of its commercial partners relating to royalties on DepoCyte in Euros. Realized gains and losses from foreign currency transactions are reflected in the consolidated statements of operations and were not significant in any period. All foreign currency receivables and payables are measured at the applicable exchange rate at the end of the reporting period.

# Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. As of December 31, 2012 and 2011, all deferred tax assets were fully offset by a valuation allowance.

#### Pacira Pharmaceuticals, Inc.

### **Notes to Consolidated Financial Statements (Continued)**

#### NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

The Company accrues interest and penalties, if any, on underpayment of income taxes related to unrecognized tax benefits as a component of income tax expense in its consolidated statements of operations.

#### Per Share Data

Basic net loss per share is computed by dividing net loss available (attributable) to common stockholders by the weighted average number of shares of common stock outstanding during the period. Because the holders of the Series A convertible preferred stock were not contractually required to share in the Company's losses, in applying the two-class method to compute basic net loss per common share no allocation to preferred stock was made for the years ended December 31, 2011 and 2010. At December 31, 2012, there were no Series A convertible preferred stock outstanding as a result of the initial public offering on February 8, 2011 when all convertible preferred stock was converted into common stock.

Diluted net income (loss) per share is calculated by dividing net income available (attributable) to common stockholders as adjusted for the effect of dilutive securities, if any, by the weighted average number of common stock and dilutive common stock outstanding during the period. Potential common shares include the shares of common stock issuable upon the exercise of outstanding stock options and warrants (using the treasury stock method). Potential common shares in the diluted net loss per share computation are excluded to the extent that they would be anti-dilutive. No potentially dilutive securities are included in the computation of any diluted per share amounts as the Company reported a net loss for all periods presented.

# Stock-Based Compensation

The Company's stock-based compensation programs include grants of stock options to employees, consultants and non-employee directors. The expense associated with these programs is recognized in the Company's consolidated statements of operations based on their fair values as they are earned under the applicable vesting terms.

The valuation of stock options is an inherently subjective process, since market values are generally not available for long-term, non-transferable stock options. Accordingly, the Company uses an option pricing model to derive an estimated fair value. In calculating the estimated fair value of stock options granted, the Company uses the Black-Scholes option pricing model which requires the consideration of the following variables for purposes of estimating fair value:

Expected term of the option	
Expected volatility	
Expected dividends	
Risk-free interest rate	
F	7-14

#### Pacira Pharmaceuticals, Inc.

### **Notes to Consolidated Financial Statements (Continued)**

# NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Because the Company's common stock was not publicly held prior to February 2011, the expected volatility was based on the historic volatility for publicly traded industry peers for shares granted prior to the initial public offering. Since its initial public offering, the Company utilizes its available historic volatility data combined with the publicly traded peer's historic volatility to determine expected volatility over the expected option term. The Company's limited historical stock option exercise experience does not provide a reasonable basis upon which to estimate expected term. Accordingly, the Company uses a term based on a simplified method, pursuant to SEC Staff Accounting Bulletin No. 107, Share-based Payment, for "plain vanilla" options. The risk-free interest rate is based on the implied yield on U.S. Department of the Treasury zero coupon bonds for periods commensurate with the expected term of the options. The dividend yield on the Company's common stock is estimated to be zero as the Company has not paid any dividends since inception. The Company estimates the level of award forfeitures expected to occur, and records compensation cost only for those awards that are ultimately expected to vest.

# Segment Reporting

The Company operates in one reportable segment and, accordingly, no segment disclosures have been presented.

# NOTE 3 RECENT ACCOUNTING PRONOUNCEMENTS

In February 2013, the Financial Accounting Standards Board, or FASB, issued amendments to the accounting guidance for presentation of comprehensive income to improve the reporting of reclassifications out of accumulated other comprehensive income. The amendments do not change the current requirements for reporting net income or other comprehensive income, but do require an entity to provide information about the amounts reclassified out of accumulated other comprehensive income by component. In addition, an entity is required to present, either on the face of the statement where the net income is presented or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income but only if the amount reclassified is required under GAAP to be reclassified to net income in its entirety in the same reporting period. For other amounts that are not required under GAAP to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures required under GAAP that provide additional detail about these amounts. These amendments are effective prospectively for reporting periods beginning after December 15, 2012. The Company does not believe the adoption of this guidance will have a material impact on the consolidated financial statements.

Other pronouncements issued by the FASB or other authoritative accounting standards groups with future effective dates are either not applicable or not significant to the consolidated financial statements of the Company.

#### NOTE 4 FINANCIAL INSTRUMENTS

Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in the principal or most advantageous market in an orderly transaction. To increase consistency and comparability in fair value measurements, FASB established a three-level hierarchy, which requires

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### **Notes to Consolidated Financial Statements (Continued)**

# NOTE 4 FINANCIAL INSTRUMENTS (Continued)

an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The three levels are:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs that are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

The fair value of the long-term debt at December 31, 2012 is calculated using a discounted cash flow analysis factoring in current market borrowing rates for similar types of borrowing arrangements under a similar credit profile. The carrying amount and fair value of the Company's long-term debt is for disclosure purposes only (in thousands):

	Carrying	Fair Va	lue Measuremei	nts Using
Financial Liabilities Carried at Historical Cost	Value	Level 1	Level 2	Level 3
December 31, 2012				
Long term debt_current and long-term	\$ 27,500	\$	\$ 28 497	\$

Short-term investments consist of U.S. Treasury securities, investment grade commercial paper, asset-backed securities collateralized by credit card receivables and corporate bonds with initial maturities of greater than three months at the date of purchase but less than one year. The net unrealized gains (losses) from the Company's short-term investments are captured in other comprehensive income (loss). At December 31, 2012, all of the Company's short-term investments are classified as available for sale investments and determined to be Level 2 instruments, which are measured at fair value using standard industry models with observable inputs. At December 31, 2012, the Company had \$30.9 million invested in short-term investments which were rated A or better by Standard & Poor's and had maturities ranging from 210 to 356 days from date of purchase.

The following summarizes the Company's short-term investments at December 31, 2012 and 2011 (in thousands):

December 31, 2012	Cost	Unr	Fross Pealized Fains	Gros Unreali Losso	ized	 ir Value Level 2)
Debt securities:						
Commercial Paper	\$ 15,974	\$	23	\$		\$ 15,997
Corporate Bonds	8,874		1		(1)	8,874
Asset-backed Securities	6,049		4			6,053
Total	\$ 30,897	\$	28	\$	(1)	\$ 30,924

#### Pacira Pharmaceuticals, Inc.

#### **Notes to Consolidated Financial Statements (Continued)**

# NOTE 4 FINANCIAL INSTRUMENTS (Continued)

December 31, 2011	Cost	Gross Unrealiz Gains	zed	Gross Unrealiz Losse	zed	 ir Value evel 2)
Debt securities:						
US Treasury Securities	\$ 1,000	\$		\$		\$ 1,000
Commercial Paper	11,476		23			11,499
Corporate Bonds	17,494		2		(10)	17,486
•						
Total	\$ 29,970	\$	25	\$	(10)	\$ 29,985

Certain assets and liabilities are measured at fair value on a nonrecurring basis including assets and liabilities acquired in a business combination, equity-method investments and long-lived assets, which would be recognized at fair value if deemed to be impaired or if reclassified as assets held for sale. The fair value in these instances would be determined using Level 3 inputs.

#### Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, short-term investments and accounts receivable. The Company maintains its cash and cash equivalents and short-term investments with high-credit quality financial institutions. At times, such amounts may exceed Federally insured limits. The Company performs ongoing credit evaluations of its customers, as warranted, and generally does not require collateral. As of December 31, 2012, four customers accounted for over 10% of the Company's accounts receivable; 31%, 27%, 16% and 15%. At December 31, 2011, two customers accounted for 56% and 41% of the Company's accounts receivable. Revenues are primarily derived from major wholesalers and pharmaceutical companies that generally have significant cash resources. Allowances for doubtful accounts receivable are maintained based on historical payment patterns, aging of accounts receivable and actual write-off history. As of December 31, 2012 and 2011, no allowances for doubtful accounts were deemed necessary by the Company on its accounts receivable.

#### **NOTE 5 INVENTORIES**

The components of inventories were as follows (in thousands):

	December 31,					
		2012	2	2011		
Raw materials	\$	4,081	\$	862		
Work-in-process		5,979		96		
Finished goods		2,017		287		
Total	\$	12,077	\$	1,245		

For the year ended December 31, 2012, the Company recorded a \$0.3 million write down of DepoCyt(e) finished inventory related to the amount of excess product that may not be marketable under the remediation plan committed to the Medicines and Healthcare products Regulatory Agency, or MHRA. See Note 18, *Commitments and Contingencies*, for further discussion. For the year ended December 31, 2011, the Company recorded a \$0.2 million write down of DepoDur inventory.

#### **Notes to Consolidated Financial Statements (Continued)**

#### NOTE 6 FIXED ASSETS

Fixed assets, at cost, summarized by major category, consist of the following (in thousands):

	December 31,					
		2012		2011		
Machinery and laboratory equipment	\$	12,414	\$	12,188		
Computer equipment and software		1,579		1,133		
Office furniture and equipment		437		352		
Leasehold improvements		6,217		6,056		
Construction in progress		30,072		13,656		
Total		50,719		33,385		
Less accumulated depreciation		(11,603)		(8,282)		
Fixed assets, net	\$	39,116	\$	25,103		

Depreciation expense for the years ended December 31, 2012, 2011 and 2010 was \$3.6 million, \$2.0 million and \$1.8 million, respectively. During the years ended December 31, 2012 and 2011, the Company capitalized interest of \$2.0 million and \$0.8 million, respectively, on the construction of its manufacturing site. Capitalized interest was not material and, therefore, not capitalized for the year ended December 31, 2010, due to non-routine delays in the construction of the manufacturing site.

During the year ended December 31, 2011, an impairment loss of \$1.3 million was recognized due to a decision made during the fourth quarter of 2011 to change the automation technology process in the Company's production line to expand EXPAREL capacity resulting in certain software and equipment previously capitalized as construction in progress that were no longer utilizable. Also during 2011, the Company impaired \$0.3 million of DepoDur-related equipment. Refer to Note 7, *Goodwill and Intangible Assets*, for discussion on the impairment. These impairment losses are reflected in impairment of long-lived assets in the Company's consolidated statements of operations.

# NOTE 7 GOODWILL AND INTANGIBLE ASSETS

The Company's goodwill arose from the triggering in April 2012 of a contingent milestone payment to Skyepharma in connection with the Acquisition. The Acquisition was accounted for under Statement of Financial Accounting Standards 141, *Accounting for Business Combinations*, which was the effective GAAP at the Acquisition date. In connection with the Acquisition, the Company agreed to certain earn-out payments based on a percentage of net sales of EXPAREL collected and certain other yet-to-be-developed products, as well as milestone payments for EXPAREL as follows:

- (a) \$10.0 million upon first commercial sale in the United States;
- (b) \$4.0 million upon first commercial sale in a major EU country (United Kingdom, France, Germany, Italy and Spain);
- (c) \$8.0 million when annual net sales collected reach \$100.0 million;
- (d) \$8.0 million when annual net sales collected reach \$250.0 million; and
- (e) \$32.0 million when annual net sales collected reach \$500.0 million.

# Notes to Consolidated Financial Statements (Continued)

# NOTE 7 GOODWILL AND INTANGIBLE ASSETS (Continued)

The first contingency was resolved in April 2012 resulting in a \$10.0 million payment to Skyepharma. The Company recorded this payment net of the \$2.0 million contingent consideration liability recognized at the time of the Acquisition resulting in \$8.0 million recorded as goodwill. Additionally, as of December 31, 2012, the Company also recorded \$0.3 million as goodwill for the percentage payments on net sales of EXPAREL collected. Any remaining earn-out payments will also be treated as additional cost of the Acquisition and, therefore, recorded as goodwill if and when each contingency is resolved.

Intangible assets, net consist of core technology, developed technology and trademarks and trade names acquired in the Acquisition as follows (in thousands):

Vear	Ended
1 Cai	Enucu

		Decemb	Estimated		
		2012		2011	<b>Useful Life</b>
Core Technology					
Gross amount	\$	2,900	\$	2,900	9 years
Accumulated amortization		(1,853)		(1,530)	
Net		1,047		1,370	
Developed Technology					
Gross amount		11,700		11,700	7 years
Accumulated amortization		(9,610)		(7,939)	·
Net		2,090		3,761	
		_,~~		-,	
Trademarks and trade names					
Gross amount		400		400	7 years
Accumulated amortization		(329)		(272)	Ĭ
				, ,	
Net		71		128	
2.00		, 1		120	
Intangible assets, net	\$	3,208	\$	5,259	
	~	-,-00	+	-,	

Annual amortization expense for intangibles for the years ended December 31, 2012, 2011 and 2010 was \$2.1 million, \$2.3 million and \$2.3 million, respectively.

In December 2011, the Company was notified of the intent of its commercial partner, EKR Therapeutics, Inc., or EKR, to exit the DepoDur market. As a result, the Company recorded an impairment loss of \$1.4 million representing the entire net intangible value of the DepoDur rights. In making the determination to impair the intangible asset, the Company also considered its inability to re-sublicense the product due to minimal supply revenue for the product both in the U.S. and in Europe as well as DepoDur's complex manufacturing process. Such impairment losses are reflected in impairment of long-lived assets in the Company's consolidated statements of operations.

# Notes to Consolidated Financial Statements (Continued)

# NOTE 7 GOODWILL AND INTANGIBLE ASSETS (Continued)

The approximate amortization expense for intangibles subject to amortization is as follows (in thousands):

					Trade	marks	
	C	ore	De	veloped	aı	nd	
	Tech	nology	Tec	hnology	Trade	names	 <b>Fotal</b>
2013	\$	322	\$	1,671	\$	57	\$ 2,050
2014		322		419		14	755
2015		322					322
2016		81					81
Total	\$	1,047	\$	2,090	\$	71	\$ 3,208

# NOTE 8 ACCRUED EXPENSES

Accrued expenses consist of the following (in thousands):

	December 31,				
		2012		2011	
Compensation and benefits	\$	1,635	\$	2,824	
Accrued operating expenses		5,924		3,090	
Accrued royalties		360		345	
Accrued interest and end of term fee		1,873		900	
Total	\$	9,792	\$	7,159	

# NOTE 9 DEBT

The composition of the Company's debt and financing obligations is as follows (in thousands):

	December 31,			
		2012		2011
Debt:				
Current portion of long-term debt	\$		\$	7,039
Long-term debt		27,500		19,211
Discount on debt		(2,309)		(674)
Total debt, net of discount		25,191		25,576
Royalty interest obligation:				
Current portion of royalty interest obligation		823		1,219
Long-term portion of royalty interest obligation		857		1,537
Total royalty interest obligation		1,680		2,756
Total debt and financing obligations	\$	26,871	\$	28,332
		F-2	0	

#### Pacira Pharmaceuticals, Inc.

# **Notes to Consolidated Financial Statements (Continued)**

#### NOTE 9 DEBT (Continued)

Oxford Loan Facility

On May 2, 2012, the Company entered into a definitive loan and security agreement, or the Loan Agreement, with Oxford Finance LLC, or the Lender, and borrowed the principal amount of \$27.5 million, or the Loan Facility, at a fixed rate of 9.75%, with the first principal payment due December 1, 2013. Payments under the Loan Agreement were interest-only in arrears through November 30, 2013, followed by 30 equal monthly payments of principal and interest. In addition, a payment equal to 6% of the Loan Facility was due on the final payment date, or such earlier date as specified in the Loan Agreement. The \$1.65 million end of term fee was recorded as a debt discount and amortized to interest expense over the term of the loan. The proceeds from the Loan Agreement were used by the Company to repay the entire \$24.2 million outstanding balance plus accrued interest, \$0.6 million end of term fee and \$0.3 million early prepayment penalty on its credit facility with Hercules Technology Growth Capital, Inc. and Hercules Technology II, L.P., as lenders, or Hercules Credit Facility. The Company recorded a loss on extinguishment of debt of \$1.1 million comprised of the remaining unamortized debt issuance costs, warrants and end of term fee, as well as the early prepayment penalty on the note issued under the Hercules Credit Facility.

The Company's obligations under the Loan Agreement were secured by a first priority security interest in substantially all of its assets, other than its intellectual property. The Company agreed not to pledge or otherwise encumber its intellectual property assets, except for permitted liens or to the extent the intellectual property constitutes royalty collateral, as such terms are defined in the Loan Agreement and except as otherwise provided in the Loan Agreement.

If the Company repaid all or a portion of the Loan Facility prior to maturity, it would pay the Lender a prepayment fee based on a percentage of the then outstanding principal balance equal to: 3.00% if the prepayment occurred prior to or on the first anniversary of the funding date, 2.00% if the prepayment occurs after the first anniversary of the funding date but prior to or on the second anniversary of the funding date, or 1.00% if the prepayment occurs after the second anniversary of the funding date.

The Loan Agreement includes customary affirmative and restrictive covenants for transactions of this type and customary events of default, including the following events of default: payment defaults, breaches of covenants, judgment defaults, cross defaults to certain other contracts, the occurrence of certain events under the Company's royalty agreements, certain events with respect to governmental approvals if such events could cause a material adverse change, a material impairment in the perfection or priority of the Lender's security interest or in the value of the collateral, a material adverse change in the business, operations or condition of the Company or any of its subsidiaries and a material impairment of the prospect of repayment of the loans. Upon the occurrence of an event of default, a default increase in the interest rate of an additional 5.00% could be applied to the outstanding loan balance and the Lender could declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement.

#### Pacira Pharmaceuticals, Inc.

### **Notes to Consolidated Financial Statements (Continued)**

# NOTE 9 DEBT (Continued)

In connection with the Loan Agreement, the Company issued to the Lender warrants that are exercisable for an aggregate of 162,885 shares of its common stock at a per share exercise price of \$10.97. Each warrant may be exercised on a cashless basis in whole or in part. The value of the warrants was recorded as a debt discount and amortized over the term of the loan to interest expense. The fair value of the warrants was determined using Black-Scholes option model (using a discount rate of 1.96%, volatility of 69.69%, a dividend yield of 0%, and a contractual term of 10 years). The relative fair value of the warrants totaled \$1.4 million.

The Company's principal payments were due under the Loan Agreement as follows: \$0.8 million in 2013, \$10.3 million in 2014, \$11.3 million in 2015 and \$5.1 million in 2016. See Note 19, *Subsequent Events*, for further discussion.

#### Hercules Credit Facility

On November 24, 2010, the Company entered into the \$26.3 million Hercules Credit Facility. At the closing of the Hercules Credit Facility, the Company entered into a term loan in the aggregate principal amount of \$26.3 million, which was the full amount available under the facility. The term loan under the Hercules Credit Facility was comprised of two tranches, Tranche A and Tranche B. The Tranche A portion of the term loan was comprised of \$11.3 million in principal and carried a floating per annum interest rate equal to 10.25% plus the amount, if any, by which the prime rate exceeds 4.00%. Upon the release of the investors' guaranty in November 2011, the interest rate on the Tranche A portion of the term loan was increased to a floating per annum interest rate equal to 11.00% plus the amount, if any, by which the prime rate exceeds 4.00%. The Tranche B portion of the term loan was comprised of \$15.0 million in principal and carried a floating per annum interest rate equal to 12.65% plus the amount, if any, by which the prime rate exceeds 4.00%. As of December 31, 2011, the blended interest rate was 11.94%.

As further consideration to the lenders to provide the term loan to the Company under the Hercules Credit Facility, the Company issued a warrant to purchase 178,986 shares of the Company's stock.

The term loan under the Hercules Credit Facility was terminated in May 2012.

# Sale of Royalty Interests

In 2000, PPI-California and SkyePharma PLC entered into a Royalty Interests Assignment Agreement ("PLC Royalty Agreement") with an affiliate of Paul Capital Advisors, LLC ("Paul Capital") to raise \$30.0 million. Under the PLC Royalty Agreement, Paul Capital had the right to receive a royalty interest in four of SkyePharma's product sales including product sales of, and other payments related to DepoCyt(e) and DepoDur. Payments began for product sales realized on or after January 1, 2003 and continue through December 31, 2014.

In connection with the Acquisition, the PLC Royalty Agreement was amended ("Amended and Restated Royalty Interests Assignment Agreement"). As part of this amendment the responsibility to pay the royalty interest in product sales of DepoCyt(e) and DepoDur were transferred to the Company and the payment to Paul Capital in a "Purchase Option Event" of the Company, as described below, was defined. The net present value of royalties expected to be repaid to Paul Capital (the "royalty interest obligation") was valued at \$13.0 million.

#### Pacira Pharmaceuticals, Inc.

### **Notes to Consolidated Financial Statements (Continued)**

#### NOTE 9 DEBT (Continued)

The Company recorded the royalty interest obligation as a liability in the Company's consolidated balance sheets in accordance with ASC 470-10-25, Sales of Future Revenues. The Company imputes interest expense associated with this liability using the effective interest rate method. The effective interest rate may vary during the term of the agreement depending on a number of factors including the actual sales of DepoCyt(e) and DepoDur and a significant estimation, performed quarterly, of certain of the Company's future cash flows related to these products during the remaining term of the Royalty Interests Assignment Agreement which terminates on December 31, 2014. Any adjustment to the estimates is reflected in the Company's consolidated statements of operations as interest income (expense). In addition, such cash flows are subject to foreign exchange movements related to sales of DepoCyt(e) and DepoDur denominated in currencies other than U.S. dollars.

The PLC Royalty Agreement also includes a provision for a "Purchase Option Event." The events include: (1) any change of control, a direct or indirect consequence of which is a material abatement of efforts to develop, market or sell any of the products or reformulated products; or (2) the transfer by the parent of all or substantially all of the parent's consolidated assets; or (3) the transfer by the Company of all or any part of their respective interests in the products or reformulated products, or (4) bankruptcy or other breach or default under the agreement. In the event a Purchase Option Event occurs, Paul Capital shall have the right, but not the obligation, exercisable within 90 days, to require the Company to repurchase from Paul Capital the Royalty Interests Assignment, for a repurchase price equal to 50% of the cumulative amount of all payments made during the preceding 24 months (calculated from the date of the Purchaser's receipt of the notice from the Company of the Purchase Option Event) multiplied by the number of days from the date of Paul Capital's exercise of such option until December 31, 2014, divided by 365.

The Company has no minimum payment obligations under the PLC Royalty Agreement. However, the repayment of the Paul Capital liability is supported through a jointly controlled lockbox, where all DepoCyt(e) and DepoDur supply revenue and royalties are received as discussed in Note 2, *Summary of Significant Accounting Policies*.

# NOTE 10 STOCKHOLDERS' EQUITY

Common Stock

On February 8, 2011, the Company completed an initial public offering of common stock for an aggregate of 6,000,000 shares and raised \$37.1 million in net proceeds after deducting underwriting discounts and offering expenses. In November 2011, the Company raised an additional \$49.0 million in net proceeds after deducting underwriting discounts and offering expenses in a registered public offering of common stock for an aggregate of 8,050,000 shares.

In April 2012, the Company sold 6,900,000 shares of common stock at a price of \$9.75 per share in a registered public offering, which includes the underwriter's exercise of the overallotment option. The Company raised approximately \$62.9 million in net proceeds after deducting discounts and offering expenses.

Convertible Preferred Stock

Upon the closing of the initial public offering in February 2011, all outstanding shares of Series A convertible preferred stock and the principal and accrued interest balance totaling \$51.2 million on the

# Pacira Pharmaceuticals, Inc.

### **Notes to Consolidated Financial Statements (Continued)**

# NOTE 10 STOCKHOLDERS' EQUITY (Continued)

convertible promissory notes sold in January 2009, the secured notes sold in June 2009, the secured notes sold in March 2010, the convertible promissory notes sold in December 2010, and the secured notes sold in April 2010 were converted into an aggregate of 10,647,549 shares of common stock, as shown in the table below.

	Conversion Shares
Series A Convertible Preferred Stock	6,322,640
2009 Convertible Notes	871,635
2009 Secured Notes	927,881
2010 Secured Notes	1,156,606
HBM Secured Notes	297,359
2010 Convertible Notes	1,071,428
Warrants	

On May 2, 2012, the Company issued warrants to the Lender in connection with the Loan Agreement that are exercisable for an aggregate of 162,885 shares of its common stock at a per share exercise price of \$10.97. On October 5, 2012, the Lender exercised the warrants on a cashless basis and received 67,279 shares of common stock. At December 31, 2012 and 2011, the Company had 490,464 and 527,656 warrants outstanding at a weighted average exercise price of \$10.79 and \$10.22, respectively.

Accumulated Other Comprehensive Income

	Net Unrealized Gains (Losses) From Marketable Securities	Total Accumulated Other Comprehesive Income (Loss)
Balances at December 31, 2010	\$	\$
Datances at December 31, 2010	φ	φ
Period Change	15	15
Balances at December 31, 2011	\$15	\$15
Period Change	12	12
Balances at December 31, 2012	\$27	\$27

### NOTE 11 STOCK PLANS

The Company's 2007 stock incentive plan, or 2007 Plan, provides 1,729,498 shares for issuance. The Company's 2011 stock incentive plan, or 2011 Plan, which became effective immediately prior to the completion of the Company's initial public offering in February 2011, was adopted by its board of directors and approved by its stockholders in December 2010. The 2011 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards and other stock-based awards. The remaining shares available for issuance under the 2007 Plan at the time of the completion of the Company's initial public offering were reallocated to the 2011 Plan. The 2011 Plan also increased the shares reserved for issuance from 1,729,498 to 2,546,657 shares. The 2011 Plan contained an "evergreen" provision, which allowed for an annual increase of up to 557,880 shares available for issuance under the 2011 Plan on the first day of each calendar year from 2012 through 2015. On

# Pacira Pharmaceuticals, Inc.

# **Notes to Consolidated Financial Statements (Continued)**

# NOTE 11 STOCK PLANS (Continued)

January 1, 2012, the evergreen provision increased the number of shares of common stock authorized for issuance under the 2011 stock plan by 557,880 shares. On June 5, 2012, the 2011 Plan was amended, to, among other things: (i) increase the number of shares of common stock authorized for issuance under the 2011 Plan by 2,100,000, (ii) remove the evergreen provision and (iii) require stockholder approval prior to any repricing of awards granted under the 2011 Plan.

The following table contains information about the Company's plans at December 31, 2012:

Plan	Awards Reserved for Issuance	Awards Issued	Awards Available for Grant
2011 Plan	3,138,519	2,393,214	745,305
2007 Plan	2,066,018	2,066,018	
	5,204,537	4,459,232	745,305

# Stock-Based Compensation

The Company recognized stock-based compensation in its consolidated statements of operations for the years ended December 31, 2012, 2011 and 2010 as follows (in thousands):

Year Ended December 31,						
		2012		2011	2	010
Cost of revenues	\$	563	\$	218	\$	12
Research and development		1,155		804		10
Selling, general and administrative		3,058		1,471		1
Total	\$	4,776	\$	2,493	\$	23
					F-2	25

# Pacira Pharmaceuticals, Inc.

# **Notes to Consolidated Financial Statements (Continued)**

# NOTE 11 STOCK PLANS (Continued)

The following table summarizes the Company's stock option activity and related information for the period from January 1, 2010 to December 31, 2012 (in thousands except share and per share amounts):

	Number of shares	Weighted average exercise price	Weighted Average remaining contractual term (years)	intri	ggregate insic value housands)
Outstanding at January 1, 2010	52,430	1.79	8.06	\$	47
Granted	2,028,158	2.71			
Exercised	(1,177)	1.89		\$	1
Forfeited	(3,337)	1.89			
Expired	(2,374)	1.75			
Outstanding at December 31, 2010	2,073,700	2.69	9.70	\$	6
Granted	395,234	10.21			
Exercised	(67,456)	2.01		\$	420
Forfeited	(62,776)	5.05			
Expired	(1,685)	2.69			
Outstanding at December 31, 2011	2,337,017	3.92	8.80	\$	11,829
Granted	2,120,250	11.55			
Exercised	(279,476)	2.75		\$	3,005
Forfeited	(174,610)	7.94			
Expired	(15)	7.07			
•					
Outstanding at December 31, 2012	4,003,166	\$ 7.86	8.66	\$	38,485
	.,,	, ,,,,,		-	,
Exercisable at December 31, 2012	1,269,921	\$ 3.76	7.80	\$	17,415
Excressible at December 51, 2012	1,207,721	φ 5.70	7.00	Ψ	17,413
Westerd and asserted to seek at December 21					
Vested and expected to vest at December 31,	2 000 202	¢ 7.70	9.64	¢	27.696
2012	3,889,392	\$ 7.78	8.64	\$	37,686

As of December 31, 2012, \$17.7 million of total unrecognized compensation cost related to non-vested stock options is expected to be recognized over the respective vesting terms of each award. The weighted average contractual term of the unrecognized stock-based compensation is approximately 3 years.

The weighted average fair value of stock options granted for the years ended December 31, 2012, 2011 and 2010 was \$8.52, \$7.06 and \$5.61 per share, respectively. The fair values of stock options granted were estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

Vear	Ended	December	31.
1 cai	Linucu	December	JI,

	2012	2011	2010	
Expected dividend yield	None	None	None	
Risk free interest rate	0.84 - 1.70%	1.1 - 2.7%	1.6 - 3.4%	
Expected volatility	74.0%	76.8%	80.8%	
Expected life of options	6.76 years	6.73 years	6.25 years	
-	•	F-26		

# **Notes to Consolidated Financial Statements (Continued)**

# NOTE 12 EARNINGS PER SHARE

Basic earnings per share is calculated by dividing the net loss attributable by the weighted average number of shares outstanding during the period, without consideration for common stock equivalents. Diluted earnings per share is calculated by dividing the net loss attributable by the weighted average number of shares outstanding plus common stock equivalents computed using the treasury stock method. For purposes of this calculation, convertible preferred stock, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive. The following table sets forth the computation of basic and diluted loss per share for the years ended December 31, 2012, 2011 and 2010 (in thousands except per share amounts):

	Year Ended					
	Dece	ember 31,	De	ecember 31,	De	ecember 31,
	2012		2011			2010
Numerator:						
Net loss	\$	(52,281)	\$	(43,328)	\$	(27,149)
Denominator:						
Weighted average shares of common stock outstanding		30,332		16,437		574
Net loss per share						
Basic and diluted net loss per share of common stock	\$	(1.72)	\$	(2.64)	\$	(47.29)

The preferred stock, convertible debt, stock options and warrants are excluded from the calculation of diluted loss per share because the net loss for the years ended December 31, 2012, 2011 and 2010, causes such securities to be anti-dilutive. The potential dilutive effect of these securities is shown in the chart below (in thousands):

		Year Ended	
	December 31, 2012	December 31, 2011	December 31, 2010
Convertible series A preferred stock			6,323
Stock options	1,276	1,177	1,058
Convertible debt			1,425
Warrants	161	110	80
Total	1,437	1,287	8,886

#### NOTE 13 COST OF REVENUES

Cost of revenues consists of the following (in thousands):

	Year Ended December 31,				
		2012		2011	2010
Cost of goods sold	\$	31,744	\$	15,310	\$ 11,374
Cost of collaborative licensing and development		395		1,429	902
Total cost of revenues	\$	32,139	\$	16,739	\$ 12,276
		]	F-27	1	

#### Pacira Pharmaceuticals, Inc.

# **Notes to Consolidated Financial Statements (Continued)**

# NOTE 13 COST OF REVENUES (Continued)

Cost of goods sold consists of the manufacturing and allocated overhead costs related to the Company's products. Cost of collaborative licensing and development consists of the Company's expenses related to feasibility studies and development work for third parties who desire to utilize the Company's DepoFoam extended release drug delivery technology for their products. Cost of goods sold and cost of collaborative licensing and development both include royalties due to Research Development Foundation ("RDF") for the use of DepoFoam technology.

#### NOTE 14 INCOME TAXES

A reconciliation of income taxes at the U.S. Federal statutory rate to the provision for income taxes is as follows:

	Year Ended December 31,			
	2012	2011	2010	
Benefit at U.S. Federal statutory rate	35.00%	35.00%	35.00%	
State taxes deferred	6.73%	3.98%	7.75%	
Increase in valuation allowance	(39.62)%	(38.27)%	(44.77)%	
Tax credits	0.00%	0.13%	0.18%	
Other	(2.11)%	(0.84)%	1.84%	
Provision for income taxes	0.00%	0.00%	0.00%	

Significant components of the Company's deferred tax assets are as follows (in thousands):

	December 31,			
		2012 2011		2011
Deferred tax assets:				
Federal and state net operating loss carry-forwards	\$	89,150	\$	62,231
Federal and state research credits		3,631		3,395
Depreciation and amortization		3,891		4,867
Accruals and reserves		3,388		2,685
Deferred revenue		1,897		8,745
Other		1,997		1,325
Total gross deferred tax assets		103,954		83,248
Less valuation allowance for deferred tax assets		(103,954)		(83,248)
Net deferred tax assets	\$		\$	

The Company has significant federal and state net operating loss carryforwards and federal and state research and development tax credit carryforwards. As of December 31, 2012, federal and state net operating losses totaled \$219.2 million and \$216.1 million, respectively. The Company also had federal and state research and development tax credit carry-forwards of approximately \$2.6 million and \$1.6 million, respectively. The net operating loss carryforwards will begin expiring in 2026 for federal purposes and 2015 for state purposes if the Company has not used them prior to that time, and the federal tax credits will begin expiring in 2028 unless previously used. The state tax credits carry forward indefinitely. There is significant doubt regarding the Company's ability to utilize its net deferred tax

### **Notes to Consolidated Financial Statements (Continued)**

#### **NOTE 14 INCOME TAXES (Continued)**

assets and, therefore, the Company has recorded a full valuation allowance. The valuation allowance for deferred tax assets increased by approximately \$20.7 million, \$16.6 million and \$12.2 million during the years ended December 31, 2012, 2011 and 2010, respectively.

Additionally, the Company's ability to use any net operating loss and credit carryforwards to offset taxable income or tax, respectively, in the future will be limited under Internal Revenue Code Sections 382 and 383 since the Company had a cumulative change in ownership of more than 50% within the three-year period. Such an ownership change was triggered by the cumulative ownership changes arising as a result of the completion of the initial public offering and other financing transactions. Because of the ownership change, the Company will be limited regarding the amount of net operating loss carryforwards and research tax credits that it can utilize annually in the future to offset taxable income or tax, respectively. The annual limitation may significantly reduce the utilization of the net operating loss carryforwards and research tax credits before they expire. In addition, California and certain states have suspended use of net operating loss carryforwards for certain taxable years, and other states are considering similar measures. As a result, the Company may incur higher state income tax expense in the future.

The Acquisition was treated as a stock acquisition for tax purposes and, therefore, the acquired intangibles for book purposes are not deductible for income tax purposes. The Company also recorded goodwill relating to contingent payments due under the Acquisition during the year ended December 31, 2012, which is not deductible for income tax purposes.

In connection with the adoption of stock-based compensation guidance in 2006, the Company elected to follow the with-and-without approach to determine the sequence in which deductions and net operating loss carryforwards are utilized. Accordingly, no tax benefit related to stock options was recognized in the current year. At December 31, 2012, the Company has approximately \$2.2 million of net operating loss carryforwards that relate to stock-based compensation for which future tax benefits will be credited to equity.

The Company evaluates its uncertain tax positions in a two-step process. The Company first determines whether it is more-likely-than-not that a tax position will be sustained upon examination. If a tax position meets the more-likely-than-not recognition threshold it is then measured to determine the amount of benefit to be recognized in the financial statements. The tax position is measured as the largest amount of benefit that has a greater than 50% likelihood of being realized upon ultimate settlement.

The Company did not have a liability related to unrecognized tax benefits as of December 31, 2012 and 2011 due to operating losses but has reduced its deferred tax assets by \$0.4 million at December 31, 2012 and 2011. Further, because the Company has recorded a full valuation allowance on its net deferred assets, the effect of implementing ASC 740 has been a reduction of the allowance

#### Pacira Pharmaceuticals, Inc.

#### **Notes to Consolidated Financial Statements (Continued)**

#### **NOTE 14 INCOME TAXES (Continued)**

by the amount above. A reconciliation of the beginning and ending amount of gross unrecognized tax benefit is as follows:

	Year Ended December 31,			
	2	012	2	011
Balance at beginning of year	\$	420	\$	420
Increases related to tax positions taken during the current year				
Increases related to tax positions taken during a prior period				
Balance at end of year	\$	420	\$	420

No interest or penalties were accrued for 2012, 2011 or 2010. The Company is currently open for audit by the United States Internal Revenue Service and state tax jurisdictions for 2006 through 2012. The American Tax Relief Act of 2012, enacted on January 2, 2013, retroactively reinstated the research and development tax credit for 2012. The Company will report credits of approximately \$0.2 million for federal income tax purposes in the first quarter of 2013.

### NOTE 15 OTHER EMPLOYEE BENEFITS

The Company sponsors a 401(k) savings plan. Under the plan, employees may make contributions to the plan, which are eligible for a discretionary percentage match as defined in the plan and determined by the board of directors. The Company recognized \$0.3 million, \$0.2 million and \$0.0 million of related compensation expense for the years ended December 31, 2012, 2011 and 2010, respectively.

### NOTE 16 COMMERCIAL PARTNERS AND OTHER AGREEMENTS

#### **Commercial Partners**

Aratana Therapeutics, Inc.

On December 5, 2012, the Company entered into a worldwide license, development and commercialization agreement with Aratana Therapeutics, Inc., or Aratana. Under the agreement, the Company granted Aratana an exclusive royalty-bearing license, including the limited right to grant sublicenses, for the development and commercialization of the Company's bupivacaine liposome injectable suspension product for animal health indications. Under the agreement, Aratana will develop and seek approval for the use of the product in veterinary surgery to manage postsurgical pain, focusing initially on developing the product for cats, dogs and other companion animals. In connection with its entry into the license agreement, the Company received a one-time payment of \$1.0 million and is eligible to receive up to an additional aggregate \$42.5 million upon the achievement of development and commercial milestones. Once the product has been approved by the Food and Drug Administration for sale in the United States, Aratana will pay the Company a tiered double digit royalty on net sales made in the United States. If the product is approved by foreign regulatory agencies for sale outside of the United States, Aratana will pay the Company a tiered double digit royalty on such net sales. Royalty rates will be reduced by a certain percentage upon the entry of a generic competitor for animal health indications into a jurisdiction or if Aratana must pay royalties to third parties under certain circumstances.

# Pacira Pharmaceuticals, Inc.

#### **Notes to Consolidated Financial Statements (Continued)**

# NOTE 16 COMMERCIAL PARTNERS AND OTHER AGREEMENTS (Continued)

Mundipharma International Holdings Limited

In June 2003, the Company entered into an agreement granting Mundipharma International Holdings Limited, or Mundipharma, exclusive marketing and distribution rights to DepoCyte in the European Union and certain other European countries. Under the agreement, as amended, and a separate supply agreement, the Company receives a fixed payment for manufacturing the vials of DepoCyte and a double-digit royalty, net of supply price, on sales in the applicable territories.

Sigma -Tau

In December 2002, the Company entered into a supply and distribution agreement with Enzon Pharmaceuticals Inc., subsequently acquired by Sigma-Tau Pharmaceuticals, Inc., or Sigma-Tau, regarding the sale of DepoCyt. Pursuant to the agreement, Sigma-Tau was appointed the exclusive distributor of DepoCyt in the United States and Canada. Under the supply and distribution agreement, the Company supplies unlabeled DepoCyt vials to Sigma-Tau for finished packaging by Sigma-Tau. Under these agreements, the Company receives a fixed payment for manufacturing the vials of DepoCyt and a double-digit royalty on sales, net of supply price, in the United States and Canada.

#### EKR Therapeutics, Inc.

On January 3, 2012, EKR Therapeutics, Inc., or EKR, delivered a notice to the Company to terminate the licensing, distribution and marketing agreement relating to DepoDur. Pursuant to the terms of the agreement, the termination of the agreement was effective on July 1, 2012. The associated supply agreement also terminated concurrently with the termination of the licensing, distribution and marketing agreement. Both parties agreed to terminate the agreements effective June 8, 2012. As a result of the termination, the Company recognized any unamortized deferred revenue relating to the agreement on a straight-line basis through the termination date in June 2012.

#### Flynn Pharmaceuticals Limited

On October 29, 2012, the Company terminated the marketing agreement with Flynn Pharma Limited, or Flynn, which had granted exclusive distribution rights to DepoDur in the European Union, certain other European countries, South Africa and the Middle East. The supply agreement terminated concurrently with the marketing agreement. The termination was effective immediately. As a result of the termination, the Company recognized any unamortized deferred revenue relating to the agreement upon termination.

#### Other Agreements

In the ordinary course of its business activities, the Company enters into agreements with third parties who desire access to its proprietary DepoFoam extended release drug delivery technology to conduct research, feasibility and formulation work. Under these agreements, the Company is compensated to perform feasibility testing on a third party product to determine the likelihood of developing a successful formulation of that product using its proprietary DepoFoam extended release drug delivery technology. If successful in the feasibility stage, these programs can advance to a full development contract.

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### **Notes to Consolidated Financial Statements (Continued)**

#### NOTE 16 COMMERCIAL PARTNERS AND OTHER AGREEMENTS (Continued)

Novo Nordisk

On June 29, 2012, the Company received a notice of termination from Novo Nordisk AS, or Novo, of the Development and License Agreement, dated January 14, 2011, which had granted non-exclusive rights to Novo under certain of its patents and know-how to develop, manufacture and commercialize formulations of a Novo proprietary drug using the Company's DepoFoam drug delivery technology. The Company received a one-time upfront payment of \$1.5 million in January 2011 and a milestone payment of \$2.0 million in November 2011, both of which had been deferred and was being recognized on a straight-line basis over the estimated contract period to collobrative licensing and development revenue in the consolidated statements of operations. Pursuant to the terms of the agreement, the termination of the agreement was effective on August 28, 2012. The agreement was terminated due to Novo's decision to discontinue development of the proprietary drug subject to the agreement. As a result of the termination, the Company recognized any unamortized deferred revenue relating to the agreement on a straight-line basis through the termination date in August 2012.

Amylin Pharmaceuticals, Inc.

In March 2008, the Company entered into a development and licensing agreement with Amylin Pharmaceuticals, Inc., or Amylin. Under the development and licensing agreement, the Company provides Amylin with access to its proprietary DepoFoam drug delivery technology to conduct research, feasibility and formulation work, and for the manufacturing of pre-clinical and clinical material for various Amylin products. The Company is entitled to payments from Amylin for its work on the formulation and development of compounds with the DepoFoam technology, its achievement of certain clinical development milestones, its achievement of certain worldwide sales and a tiered royalty based upon sales. The development and licensing agreement with Amylin remains effective, however, neither party is currently performing any activities under the agreement.

### NOTE 17 RELATED PARTY TRANSACTIONS

MPM Asset Management, or MPM, an investor in the Company, holds a seat on the Company's board of directors. MPM provides clinical management consulting services to the Company through Gary Patou, or Consultant, the Company's Chief Medical Officer. In October 2010, the Company entered into an agreement with MPM to provide services at a monthly rate of approximately \$26,000 in 2010 and 2011 in exchange for 80% of Consultant's business time devoted to the Company, \$16,000 in 2012 in exchange for 50% of Consultant's business time and \$6,000 in 2013 and 2014 in exchange for 20% of Consultant's business time. The original services agreement has been amended twice. The first amendment to this agreement was entered into in December 2011 and declared that Consultant will continue to earn a monthly consulting fee of approximately \$26,000 in exchange for 80% of its business time through September 30, 2012. In November 2012, the Company entered into a second amendment to the services agreement with MPM. Pursuant to the terms of the amended services agreement, the monthly services fee will remain at approximately \$16,000, through December 31, 2013, in exchange for 50% of Consultant's business time. The Company incurred expenses of \$0.4 million, \$0.5 million and \$0.7 million for the years ended December 31, 2012, 2011 and 2010, respectively. As of December 31, 2012 and 2011, \$0.1 million and \$0.2 million, respectively, was payable to MPM.

### **Notes to Consolidated Financial Statements (Continued)**

# NOTE 17 RELATED PARTY TRANSACTIONS (Continued)

In December 2012, the Company entered into a worldwide license, development and commercialization agreement with Aratana as discussed in Note 16, *Commercial Partners and Other Agreements*. MPM and its affiliates are holders of capital stock of Aratana.

In April 2010, the Company signed a statement of work for a feasibility study with Rhythm Pharmaceuticals, Inc., or Rhythm. During the year ended December 31, 2010, the Company earned \$0.3 million contract revenue from this statement of work. MPM and its affiliates are holders of capital stock of Rhythm and a managing director of MPM is a member of the board of directors of Rhythm.

In June 2011, the Company entered into an agreement with Gary Pace, a member of its board of directors, to provide consulting services for manufacturing-related activities at a monthly fee of \$5,000, not to exceed \$60,000 annually. In connection with these services, Dr. Pace received an option to purchase 10,000 shares of common stock at an exercise price of \$11.02 per share. In April 2012, the Company entered into an amended and restated consulting agreement with Gary Pace, whereby Dr. Pace will provide consulting services at the rate of \$10,000 per month and received an option to purchase 20,000 shares of common stock at an exercise price of \$11.02 per share pursuant to the amended and restated consulting agreement. The amendment also removed the stipulation that Dr. Pace's total yearly consulting fees could not exceed \$60,000. In August 2012, the Company further amended and restated the consulting agreement with Gary Pace, whereby Dr. Pace will provide consulting services at the rate of \$15,000 per month and received an option to purchase 70,000 shares of common stock at an exercise price of \$16.67 per share pursuant to the amended and restated consulting agreement. Under this amendment, Dr. Pace will be eligible to receive a bonus up to \$0.2 million, contingent upon the date of FDA approval of the Company's Suite C manufacturing facility for EXPAREL. The Company recorded expenses under the consulting arrangement for the years ended December 31, 2012 and 2011 of \$0.2 million and less than \$0.1 million, respectively.

In November 2011, the Company terminated its services agreement with Stack Pharmaceuticals Inc., or SPI, an entity controlled by David Stack, the Company's chief executive officer. SPI had provided the Company with the use of SPI's office facilities and certain consulting services. In November 2011, the Company also purchased \$0.02 million of office furniture and equipment from SPI. The Company incurred expenses under the SPI agreement of \$0.2 million and \$0.3 million for the years ended December 31, 2011 and 2010, respectively. As of December 31, 2012 and 2011, the Company had no outstanding balance payable to SPI.

# NOTE 18 COMMITMENTS AND CONTINGENCIES

Leases

In August 2011, the Company entered into a new lease contract for its corporate headquarters in Parsippany, New Jersey. The lease, which occupies approximately 13,000 square feet, expires in June 2017. Under the lease, the Company is required to pay certain maintenance expenses in addition to rent.

In addition, the Company leases research and development and manufacturing facilities in San Diego, California, in two facilities occupying approximately 106,000 square feet, referred to as the Science Center campus. The leases expire in July 2015. Under these leases, the Company is required to pay certain maintenance expenses in addition to the monthly rent. In connection with the Acquisition, the Company determined that its lease rates associated with the Science Center campus were in excess

#### **Notes to Consolidated Financial Statements (Continued)**

# NOTE 18 COMMITMENTS AND CONTINGENCIES (Continued)

of market rates resulting in a \$3.3 million unfavorable lease accrual as of the Acquisition date. The unfavorable lease accrual, which is recorded in other long-term liabilities in the Company's consolidated balance sheets, is amortized over the remaining terms of the leases. The annual amortization of the unfavorable lease accrual for each of the years ended December 31, 2012, 2011 and 2010 was \$0.4 million. In December 2012, the Company signed a letter of intent to negotiate an extension of the leases for the Science Center campus through August 31, 2020.

As of December 31, 2012, annual minimum payments due under the Company's lease obligations are as follows (in thousands):

Year	
2013	\$ 5,284
2014	5,463
2015	3,464
2016	405
2017	201
Total	\$ 14,817

Total rent expense, net of unfavorable lease obligation amortization, under all operating leases for years ended December 31, 2012, 2011 and 2010 was \$4.8 million, \$4.7 million and \$4.5 million, respectively. Deferred rent at December 31, 2012 and 2011 was \$1.3 million and \$1.4 million, respectively.

# Litigation

The Company periodically becomes subject to legal proceedings and claims arising in connection with its business. The ultimate legal and financial liability of the Company in respect to all claims, lawsuits and proceedings cannot be estimated with any certainty. Any outcome, either individually or in the aggregate, is not expected to be material to the Company's consolidated financial position, results of operations, or cash flows.

# Other Contingencies and Commitments

In July 2012, the Company received an inspection letter from the MHRA noting certain critical and major failures to comply with the Principles and Guidelines of Good Manufacturing Practices in the DepoCyt(e) manufacturing line, which is located in a separate building from the EXPAREL manufacturing site. As a result of the findings, the European Medicines Agency issued an assessment report which recommended that, until corrective actions are taken allowing new supply to enter the market, alternative medicines be used in European Union member countries where there are suitable alternatives. The assessment report also recommended a selective recall of DepoCyt(e) in European Union member countries where DepoCyt(e) is not considered to be an "essential medicinal product." In European Union member countries where the product is classified as an "essential medicinal product," DepoCyte can be used with specific recommendations to monitor patients' safety. No regulatory action has been taken by the FDA in the United States as a result of these inspection findings.

#### **Notes to Consolidated Financial Statements (Continued)**

# NOTE 18 COMMITMENTS AND CONTINGENCIES (Continued)

During the year ended December 31, 2012, the Company recorded a charge of \$1.3 million, in cost of revenues associated with the implementation of a remediation plan and estimated costs to replace the product once new product is available in Europe, which is expected in mid-2013. While the corrective actions and upgrades to the facilities were taking place, the Company stopped manufacturing DepoCyt(e). In December 2012, the MHRA re-inspected the DepoCyt(e) manufacturing facility to review progress in the implementation of the remediation commitments arising from the July 2012 inspection. The Company received notice in January 2013 from the MHRA that the Company's remediation efforts were successful and it plans to resume production of DepoCyt(e) for the European market in the first quarter of 2013. The temporary cessation of the manufacturing of DepoCyt(e) could result in additional costs or delays in production and sale of DepoCyt(e).

In May 2012, the Company entered into a construction management agreement with DPR Construction, a general partnership, or DPR. Under the terms of the agreement, DPR is responsible for the management of the renovation of the Company's existing manufacturing facility in San Diego, California. The manufacturing facility is being renovated to allow the Company to expand the current manufacturing capacity and meet anticipated future market demand for EXPAREL. Pursuant to the agreement, the contract sum (the cost of the work plus the contractor fee) will not exceed approximately \$7.7 million, provided that such amount is subject to change based on agreed-upon changes to the scope of work.

The FDA, as a condition of the EXPAREL approval, has required the Company to study EXPAREL in pediatric patients. The Company has agreed to a trial timeline where, over several years, it will study pediatric patient populations in descending order starting with 12 - 18 year olds and ending with children under two years of age. The cost to complete the trial may be significant.

In addition to the initial \$19.6 million purchase price for the Acquisition, the Company entered into an earn-out agreement with SkyePharma which was based on the Company reaching certain revenue milestones following the Acquisition. According to this agreement, the Company would pay SkyePharma percentage payments based on the net revenues of EXPAREL and certain other products from the future yet-to-be-developed biologics product line and milestone payments of up to an aggregate of \$62.0 million upon the occurrence of the following events: (a) first commercial sale in the United States; (b) first commercial sale in a major EU country (UK, France, Germany, Italy, or Spain); (c) annual net sales reaching \$100 million; (d) annual net sales reaching \$250 million and (e) annual net sales reaching \$500 million. Additionally, the Company agreed to pay to SkyePharma a 3% percentage payment on collections of EXPAREL sales in the United States, Japan, the United Kingdom, France, Germany, Italy and Spain. Refer to Note 7, *Goodwill and Intangible Assets*, for further discussion.

#### NOTE 19 SUBSEQUENT EVENTS

On January 23, 2013, the Company completed a private offering of \$120.0 million in aggregate principal amount of 3.25% convertible senior notes due 2019 ("Notes") and entered into an indenture with Wells Fargo Bank, National Association, a national banking association, as trustee, governing the Notes. The net proceeds from the offering are approximately \$115.3 million, after deducting the initial purchasers' discounts and commissions and the estimated offering expenses payable by the Company. The Notes accrue interest at 3.25% per year, payable semiannually in arrears on February 1 and August 1 of each year, beginning on August 1, 2013. The Notes will mature on February 1, 2019.

# Pacira Pharmaceuticals, Inc.

# **Notes to Consolidated Financial Statements (Continued)**

# NOTE 19 SUBSEQUENT EVENTS (Continued)

The Company used \$30.1 million of the net proceeds from the offering of the Notes to repay in full the \$27.5 million credit facility with Oxford Finance LLC. In connection with such termination, the Company paid the remaining principal amount of \$27.5 million as well as accrued interest, certain prepayment fees and an end of term charge in the aggregate amount of \$2.6 million.

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# **EXHIBIT INDEX**

Exhibit number 3.1	Description  Amended and Restated Certificate of Incorporation of the Registrant.(1)
3.3	Amended and Restated Bylaws of the Registrant.(1)
4.1	Specimen Certificate evidencing shares of common stock.(2)
10.1	Second Amended and Restated 2007 Stock Option/Stock Issuance Plan.(2)
10.2	Form of Stock Option Agreement under the Second Amended and Restated 2007 Stock Option/Stock Issuance Plan.(2)
10.3	Investors' Rights Agreement, dated March 23, 2007, among the Registrant and the parties named therein.(2)
10.4	Assignment Agreement, dated February 9, 1994, amended April 15, 2004, between the Registrant and Research Development Foundation.(2)
10.5	Stock Purchase Agreement, dated January 8, 2007, between SkyePharma, Inc. and the Registrant.(2)
10.6	Amended and Restated Royalty Interests Assignment Agreement, dated March 23, 2007, as amended, between SkyePharma, Inc. and Royalty Securitization Trust I.(2)
10.7	Amended and Restated Security Agreement (SKPI), dated March 23, 2007, between SkyePharma, Inc. and Royalty Securitization Trust I.(2)
10.8	Supply Agreement, dated June 30, 2003, between SkyePharma, Inc. and Mundipharma Medical Company.(2)
10.9	Distribution Agreement, dated June 30, 2003, between SkyePharma, Inc. and Mundipharma International Holdings Limited.(2)
10.10	Distribution Agreement, dated July 27, 2005, between SkyePharma, Inc. and Mundipharma International Holdings Limited.(2)
10.11	Co-development, Collaboration and License Agreement, dated January 2, 2003, among Enzon Pharmaceuticals, Inc., Jagotec, AG, SkyePharma, Inc. and SkyePharma PLC.(2)
10.12	DepoCyt Supply and Distribution Agreement, dated December 31, 2002, between SkyePharma, Inc. and Enzon Pharmaceuticals, Inc.(2)
10.13	Amended and Restated Strategic Licensing, Distribution and Marketing Agreement, dated October 15, 2009, between the Registrant and EKR Therapeutics, Inc.(2)
10.14	Amended and Restated Supply Agreement, dated October 15, 2009, between the Registrant and EKR Therapeutics, Inc.(2)
10.15	Strategic Marketing Agreement, dated September 25, 2007, between the Registrant and Flynn Pharma Limited.(2)
10.16	Supply Agreement, dated December 5, 2007, between the Registrant and Flynn Pharma Limited.(2)
10.17	Lease Agreement, dated August 17, 1993, amended July 2, 2009, between Pacira Pharmaceuticals, Inc. and HCP TPSP, LLC.(2)
10.18	Lease Agreement, dated December 8, 1994, amended July 2, 2009, between Pacira Pharmaceuticals, Inc. and LASDK Limited Partnership.(2)
10.19	Services Agreement, dated October 28, 2010, between the Registrant, MPM Asset Management LLC and Gary Patou.(2)

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Exhibit number 10.20	Description  Amendment to Services Agreement, dated October 28, 2010, between the Registrant, MPM Asset Management LLC and Gary Patou.(4)
10.21	Services Agreement, dated September 15, 2010, between Pacira Pharmaceuticals, Inc. and Stack Pharmaceuticals, Inc.(2)
10.22	Employment Agreement between the Registrant and David Stack.(2)
10.23	Employment Agreement between the Registrant and James Scibetta.(2)
10.24	Employment Agreement between the Registrant and Mark Walters.(2)
10.25	Employment Agreement between the Registrant and William Lambert.(2)
10.26	Loan and Security Agreement, dated November 24, 2010, among the Registrant, Pacira Pharmaceuticals, Inc. (California), Hercules Technology Growth Capital, Inc. and Hercules Technology II, L.P.(2)
10.27	Guaranty Agreement, dated November 24, 2010, between the Registrant, Hercules Technology Growth Capital, Inc., Hercules Technology II, L.P. and the parties named therein.(2)
10.28	Warrant to purchase preferred stock of the Registrant, dated November 24, 2010.(2)
10.29	Form of Warrant to purchase Series A convertible preferred stock of the Registrant, dated July 2, 2009.(2)
10.30	Form of Warrant to purchase common stock of the Registrant, dated January 22, 2009.(2)
10.31	Form of Warrant to purchase common stock of the Registrant, dated December 29, 2010.(2)
10.32	2011 Stock Incentive Plan.(2)
10.33	Form of Indemnification Agreement between the Registrant and its directors and officers.(2)
10.34	Development and License Agreement, dated January 14, 2011, between the Registrant and Novo Nordisk A/S.(2)
10.35	Commercial Outsourcing Services Agreement entered into as of August 25, 2011 by the Registrant and Integrated Commercialization Solutions, Inc.(3)
10.36	Master Services Agreement effective as of August 30, 2011, between the Registrant and Quintiles Commercial US, Inc.(3)
10.37	Amended and Restated Consulting Agreement, dated April 3, 2012, between the Registrant and Gary Pace(5)
10.38	Executive employment Agreement, dated November 1, 2010, between the Registrant and Taunia Markvicka(5)
10.39	Executive employment Agreement, dated November 18, 2011, between the Registrant and John Pratt(5)
10.40	Employment Agreement, dated April 19, 2012, between the Registrant and Lauren Riker(5)
10.41	Amended and Restated 2011 Stock Option Plan(6)
10.42	Construction Managenet Agreement between the Registant and DPR, dated May 17, 2012(7)
10.43	Loan and Security Agreement between the Registrant and Oxford Finance LLC, dated May 2, 1012(7)

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Exhibit number 10.44	Description  Warrant to Purchase Stock No 1, 2, 3 and 4, issued by the Registrant to Oxford Finance LLC, dated May 2, 2012(7)
10.45	Second Amended and Restated Consulting Agreement, dated August 17, 2012, between the Registrant and Gary Pace(8)
10.46	Amendment #2 to Services Agreement, between Registrant and MPM, dated November 29, 2012(9)
10.47	License, Development and Commercialization Agreement, dated December 5, 2012 between the Registrant and Aratana Therapeutics, Inc.*
10.48	Supply Agreement, dated December 5, 2012 between the Registrant and Aratana Therapeutics, Inc.*
21.1	Subsidiaries of Registrant.*
23.1	Consent of CohnReznick LLP.*
31.1	Certification of President and Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a)*
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a)*
32.1	Certification of President and Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**
101.INS <sup>*</sup>	XBRL Instance Document.
101.CAL*	XBRL Taxonomy Calculation Linkbase Document.
101.LAB*	XBRL Taxonomy Label Linkbase Document.
101.PRE <sup>*</sup>	XBRL Taxonomy Presentation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
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(1) Inco	orporated by reference to the registrant's Current Report on Form 8-K, filed on February 11, 2011.
(2) Inco	orporated by reference to the exhibits to the registrant's Registration Statement on Form S-1 (SEC File 333-170245).
(3) Inco	orporated by reference to the exhibits to the registrant's Quarterly Report on Form 10-Q, filed on October 31, 2011.
(4) Inco	orporated by reference to the exhibits to the registrant's Current Report on Form 8-K, filed on December 9, 2011.
(5) Inco	orporated by reference to the exhibits to the registrant's Quarterly Report on Form 10-Q, filed on May 9, 2012.
(6) Inco	orporated by reference to the exhibits to the registrant's Current Report on Form 8-K, filed on June 7, 2012.

- (7) Incorporated by reference to the exhibits to the registrant's Quarterly Report on Form 10-Q, filed on August 9, 2012.
- (8) Incorporated by reference to the exhibits to the registrant's Quarterly Report on Form 10-Q, filed on November 1, 2012

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- (9) Incorporated by reference to the exhibits to the registrant's Current Report on Form 8-K, filed on December 4, 2012.
- Filed herewith.

Furnished herewith.

Confidential treatment requested as to certain portions, which portions were omitted and filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Request.

Attached as Exhibit 101 to this report are the following formatted in XBRL (Extensible Business Reporting Language): (i) Consolidated Balance Sheets at December 31, 2012 and 2011, (ii) Consolidated Statements of Operations for the years ended December 31, 2012, 2011 and 2010, (iii) Consolidated Statements of Comprehensive Loss for the years ended December 31, 2012, 2011 and 2010, (iv) Consolidated Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2012, 2011 and 2010, (v) Consolidated Statements of Cash Flows for the years ended December 31, 2012, 2011 and 2010 and (vi) Notes to Consolidated Financial Statements.

In accordance with Rule 406T of Regulation S-T, the XBRL related information in Exhibit 101 to this Annual Report on Form 10-K is deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act, is deemed not filed for purposes of section 18 of the Exchange Act, and otherwise is not subject to liability under these sections.