

SUPERNUS PHARMACEUTICALS INC

Form S-1

December 23, 2010

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As filed with the Securities and Exchange Commission on December 23, 2010

Registration No. 333-

## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

## SUPERNUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**2834**  
(Primary Standard Industrial  
Classification Code Number)  
**1550 East Gude Drive**  
**Rockville, MD 20850**  
**(301) 838-2500**

**20-2590184**  
(I.R.S. Employer  
Identification Number)

(Address, including zip code, and telephone number, including  
area code, of registrant's principal executive offices)

**Jack A. Khattar**  
**President and Chief Executive Officer**  
**1550 East Gude Drive**  
**Rockville, MD 20850**  
**(301) 838-2500**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

#### *Copies to:*

**Paul M. Kinsella**  
**Ropes & Gray LLP**  
**Prudential Tower**  
**800 Boylston Street**  
**Boston, MA 02199-3600**  
**Telephone: (617) 951-7921**  
**Facsimile: (617) 235-0822**

**Russell P. Wilson**  
**Supernus Pharmaceuticals, Inc.**  
**Vice President, Chief Financial Officer**  
**1550 East Gude Drive**  
**Rockville, MD 20850**  
**Telephone: (301) 838-2500**  
**Facsimile: (301) 424-1364**

**Mitchell S. Bloom**  
**Edward A. King**  
**Goodwin Procter LLP**  
**Exchange Place**  
**Boston, MA 02109**  
**Telephone: (617) 570-1000**  
**Facsimile: (617) 523-1231**

#### **Approximate date of commencement of proposed sale to public:**

As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended (the "Securities Act"), check the following box. o

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If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

Large accelerated filer       Accelerated filer       Non-accelerated filer       Smaller reporting company

(Do not check if a  
smaller reporting company)

### CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee
Common stock, \$0.001 par value per share	\$100,000,000	\$7,130.00

- (1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act. The proposed maximum aggregate offering price includes amounts attributed to shares of common stock that the underwriters may purchase if they exercise their option to purchase additional shares.

**The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.**

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

**SUBJECT TO COMPLETION, DATED DECEMBER 23, 2010**

**PRELIMINARY PROSPECTUS**

**Shares**

**Supernus Pharmaceuticals, Inc.**

**Common Stock**  
**\$ \_\_\_\_\_ per share**

This is the initial public offering of our common stock. We are selling \_\_\_\_\_ shares of our common stock. We currently expect the initial public offering price to be between \$ \_\_\_\_\_ and \$ \_\_\_\_\_ per share of common stock.

We have granted the underwriters an option to purchase up to \_\_\_\_\_ additional shares of common stock to cover over-allotments.

We intend to apply to list our common stock on the Nasdaq Global Market under the symbol "SUPN."

**Investing in our common stock involves risks. See "Risk Factors" on page 9.**

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	<b>Per Share</b>	<b>Total</b>
Public Offering Price	\$ _____	\$ _____
Underwriting Discount	\$ _____	\$ _____
Proceeds to Supernus (before expenses)	\$ _____	\$ _____

The underwriters expect to deliver the shares to purchasers on or about \_\_\_\_\_, 2011 through the book-entry facilities of The Depository Trust Company.

*Joint Book-Running Managers*

**Citi**

**Barclays Capital**

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*Co-Managers*

**Cowen and Company**

**Stifel Nicolaus Weisel**

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, 2011.

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You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the front of this prospectus.

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Table of Contents**SUMMARY**

*This summary highlights selected information appearing elsewhere in this prospectus. While this summary highlights what we consider to be the most important information about us, you should carefully read this prospectus and the registration statement of which this prospectus is a part in their entirety before investing in our common stock, especially the risks of investing in our common stock which we discuss under "Risk Factors," the information set forth in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes beginning on page F-1.*

*Unless the context requires otherwise, the words "Supernus," "we," "us" and "our" refer to Supernus Pharmaceuticals, Inc. and its subsidiaries.*

**Supernus Pharmaceuticals, Inc.**

We are a specialty pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system, or CNS, diseases. Our extensive expertise in product development has been built over the past 20 years: initially as a stand alone development organization, then as a U.S. subsidiary of Shire plc and, upon our acquisition of substantially all the assets of Shire Laboratories Inc. in late 2005, as Supernus Pharmaceuticals. We are developing several product candidates in neurology and psychiatry to address large market opportunities in epilepsy and attention deficit hyperactivity disorder, or ADHD. We intend to market our product candidates in the United States through our own focused sales force targeting specialty physicians, including neurologists and psychiatrists.

We use our proprietary technologies to enhance the therapeutic benefits of approved antiepileptic drugs, or AEDs, through advanced extended release formulations. Our two epilepsy product candidates are SPN-538 (extended release topiramate), for which we expect to file a new drug application, or NDA, in the first quarter of 2011, and Epliga (extended release oxcarbazepine), which is in Phase III clinical trials. Our ADHD product candidates include SPN-810 (molindone hydrochloride), a novel treatment for impulsive aggression in patients with ADHD, and SPN-812, a novel non-stimulant treatment for ADHD. Both of these programs are in Phase II. In addition to these four lead product candidates, we have several additional product candidates in various stages of development, including SPN-809, which would represent a novel mechanism of action for the U.S. antidepressant market. We believe our broad and diversified portfolio of product candidates provides us with multiple opportunities to achieve our goal of becoming a leading specialty pharmaceutical company focused on CNS diseases.

The table below summarizes our current pipeline of novel product candidates.

<b>Product</b>	<b>Indication</b>	<b>Status</b>
<b>SPN-538</b>	Epilepsy	NDA to be filed Q1 2011
<b>Epliga</b>	Epilepsy	Phase III
<b>SPN-810</b>	Impulsive Aggression in ADHD	Phase II
<b>SPN-812</b>	ADHD	Phase II
<b>SPN-809</b>	Depression	IND filed

***Our Late-Stage Neurology Portfolio***

Epilepsy is a chronic neurological disorder characterized by recurrent convulsive seizures resulting from hyperactivity in the brain cells. It is estimated to affect 50 million people worldwide. Achieving reliable seizure control for patients, and avoiding the serious health and life dangers that can be associated with sudden unexpected, or breakthrough, seizures depends on patients being compliant and

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diligent in taking their medications. We believe there are a number of benefits associated with extended release products in epilepsy that create a significant market opportunity for us.

Extended release products have been shown to improve compliance and reduce breakthrough seizures.

Extended release products have been shown to reduce side effects and improve tolerability.

Managed care plans have not limited the success of extended release products.

Extended release products have performed well in the market.

*SPN-538 (extended release topiramate)*

Our most advanced product candidate, SPN-538, is a novel oral once-daily extended release topiramate product for the treatment of epilepsy. Topiramate is marketed by Johnson & Johnson under the brand name Topamax and is available in a generic form. Topiramate is currently available only in immediate release form and is indicated for monotherapy and adjunctive therapy of epilepsy and for the treatment of migraine. It works by enhancing the inhibitory effect of the GABA (Gamma-Aminobutyric Acid) neurotransmitter that regulates neuronal excitability throughout the nervous system, blocking the excitatory effect of the glutamate neurotransmitter, blocking the sodium channel and inhibiting the carbonic anhydrase enzyme. The side effects associated with taking topiramate, which have tended to limit its use, include, among others, dizziness, fatigue, somnolence and slowing of certain cognitive functions.

SPN-538 is designed to improve patient compliance and to have a better tolerability profile compared to the current immediate release products that are taken multiple times per day. SPN-538's pharmacokinetic profile delivers lower peak plasma concentrations and lower input rate over an extended time period, resulting in smoother and more consistent blood levels of topiramate during the day compared to immediate release Topamax. We have completed ten clinical trials in support of our NDA, which we expect to file in the first quarter of 2011. We are pursuing a regulatory strategy under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, which would allow us to rely in our filing on the existing data and knowledge the U.S. Food and Drug Administration, or FDA, has from the NDA of Topamax.

*Epliga (extended release oxcarbazepine)*

Our second late-stage product candidate, Epliga, is a novel oral once-daily extended release formulation of oxcarbazepine and is currently in Phase III trials. Oxcarbazepine is marketed by Novartis under the brand name Trileptal and is available in a generic form. Trileptal is indicated for monotherapy and adjunctive therapy of epilepsy. Oxcarbazepine is an active voltage-dependent sodium channel blocker that, despite its effectiveness in treating epilepsy, is associated with many side effects that tend to limit its use. The side effects associated with taking oxcarbazepine include, among others, dizziness, double vision, somnolence, nausea and vomiting.

With a novel pharmacokinetic profile that delivers lower peak plasma concentrations, a slower rate of input, smoother and more consistent blood levels compared to immediate release products such as Trileptal, we believe Epliga has the potential of improving the tolerability of oxcarbazepine by reducing the side effects experienced by patients. We have completed eight clinical trials to support filing the NDA in the second half of 2011. We are pursuing a Section 505(b)(2) regulatory strategy, which would allow us to rely in our filing on the existing data and knowledge the FDA has from the NDA of Trileptal.

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***Our Psychiatry Portfolio***

ADHD is a common CNS disorder characterized by developmentally inappropriate levels of inattention, hyperactivity, and impulsivity. ADHD affects an estimated 6.9% of all school-age children and 4.4% of adults in the United States. An estimated 60% to 80% of children with ADHD continue to meet the criteria for ADHD into adolescence. As many as 67% of children who have ADHD may have coexisting conditions such as oppositional defiant disorder, conduct disorder, anxiety disorder and depression. Approximately 25% of children with ADHD also exhibit persistent conduct problems, such as impulsive aggression.

*SPN-810 (molindone hydrochloride)*

We are developing SPN-810, which is currently in Phase II, as a novel treatment for impulsive aggression in patients with ADHD. If approved by the FDA, SPN-810 could be the first product available to address this serious, unmet medical need. SPN-810 is based on molindone hydrochloride, which was previously marketed in the United States as an anti-psychotic to treat schizophrenia under the trade name Moban. Molindone hydrochloride is unusual among anti-psychotics in that it is not associated with weight gain.

We have completed four clinical trials for SPN-810, including a Phase IIa trial in which we tested the safety and tolerability of immediate release molindone hydrochloride in children with ADHD who suffer from serious persistent conduct problems. This open-label, dose-ranging trial randomized 78 children, 6-12 years of age, into one of four treatment groups, which were given four different doses of immediate release molindone hydrochloride, between 10 mg and 40 mg per day, depending on weight, three times a day over a six-week treatment period, after 2-5 weeks of titration. SPN-810 was well tolerated in the trial with no clinically meaningful changes in standard hematology, clinical chemistry values, vital signs or electrocardiogram results. SPN-810 also showed improvements on the primary and secondary outcome measures, such as conduct problem and ADHD scales, across all four treatment groups.

*SPN-812*

We are developing SPN-812, which is currently in Phase II, as a novel non-stimulant treatment for ADHD. SPN-812 is a selective norepinephrine reuptake inhibitor that we believe could be more effective and have a better side effect profile than other non-stimulant treatments for ADHD. We initiated a proof-of-concept Phase IIa trial in mid-2010, and expect the results of this trial in the first quarter of 2011. The trial is a randomized, double-blind, placebo-controlled trial in approximately 50 adults with a current diagnosis of ADHD, with approximately 25 subjects per treatment group. SPN-812 has not been developed and marketed in the United States and, therefore, it would be considered and reviewed by the FDA as a new chemical entity.

***Our Proprietary Technology Platforms***

We have a long track record of developing novel products by applying proprietary technologies to known drugs to improve existing therapies and to enable the treatment of new indications. Our key proprietary technology platforms include: Microtrol (multiparticulate delivery platform), Solutrol (matrix delivery platform) and EnSoTrol (osmotic delivery system). These technologies create customized product profiles designed to meet efficacy needs, permit more convenient and less frequent dosing, enhance patient compliance and improve tolerability in certain specific applications. Our proprietary technologies have been used in the following approved and marketed products: Carbatrol (carbamazepine), Equetro (carbamazepine), Adderall XR (mixed amphetamine salts), Sanctura XR (trospium chloride), Oracea (doxycycline) and Intuniv (guanfacine). We do not expect these products to contribute to our future cash position as we have either monetized the future revenues associated with

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them or we developed them when we were formerly Shire Laboratories. In addition, we have used our proprietary technologies to develop an oral formulation of tadalafil diethanolamine which is currently in Phase III trials for pulmonary arterial hypertension.

***Our Strategy***

Our goal is to be a leading specialty pharmaceutical company developing and commercializing new medicines in neurology and psychiatry. Key elements of our strategy to achieve this goal are to:

*Build in-house sales and marketing capabilities, focused on specialty markets in the United States, to promote SPN-538 and Epliga.* We are currently focused on attaining regulatory approval for, and bringing our two late-stage epilepsy product candidates, SPN-538 and Epliga, to market. As SPN-538 and Epliga progress towards U.S. regulatory approval, we intend to build our own targeted, specialty sales force to promote, if approved, SPN-538 and Epliga in the United States. We intend to direct our marketing efforts to high potential prescribers of both product candidates.

*Continue to advance our product candidates in our psychiatry portfolio, including SPN-810 and SPN-812.* As part of our longer term strategy, we intend to further develop our product candidates in our psychiatry portfolio to enable further diversification of our pipeline and future growth. For example, we are currently preparing to initiate a Phase IIb trial of SPN-810.

*Develop differentiated products by applying our technologies to known drug compounds.* We intend to continue to focus our development activities on known drug compounds and compounds with established mechanisms of action and thereby reduce the risks, costs and time typically associated with pharmaceutical product development. We intend to leverage our proprietary and in-licensed technologies and expand our patent portfolio to further develop and protect our diverse pipeline of product candidates.

*Establish strategic partnerships to accelerate and maximize the potential of our product candidates worldwide.* We intend to continue to seek strategic collaborations with other pharmaceutical companies to commercialize our product candidates outside the United States. We believe that we are an attractive collaborator for pharmaceutical companies due to our broad portfolio of proprietary technologies and our product development track record.

*Leverage our management team's expertise to develop and commercialize our broad portfolio of product candidates.* We intend to leverage the expertise of our executive management team in developing and commercializing innovative therapeutic products. We plan to continue to evaluate and develop additional CNS product candidates that we believe have significant commercial potential through our internal research and development efforts or, if appropriate, external collaborations.

***Risks Associated With Our Business***

Our ability to implement our business strategy is subject to numerous risks and uncertainties. As an early stage pharmaceutical company, we face many risks inherent in our business and our industry, as more fully described in the section entitled "Risk Factors" immediately following this summary, including the following:

We are dependent on the success of our product candidates, which may never receive regulatory approval or be successfully commercialized.

Final marketing approval of SPN-538, Epliga or any of our other product candidates by the FDA or other regulatory authorities may be delayed, limited, or denied, any of which would adversely affect our ability to generate operating revenues.



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We have never generated any revenues from the sales of our own products, and we may never achieve or maintain profitability.

If other versions of extended or controlled release topiramate or oxcarbazepine are approved and successfully commercialized, especially if approved before SPN-538 or Epliga, our business would be materially harmed.

If the FDA or other applicable regulatory authorities approve generic products that compete with any of our product candidates, the sales of those product candidates may be adversely affected.

You should carefully consider all of the information set forth in this prospectus and, in particular, the information under the heading "Risk Factors," prior to making an investment in our common stock.

***Corporate Information***

We were incorporated in Delaware in 2005. Our principal executive office is located at 1550 East Gude Drive, Rockville, Maryland 20850. Our telephone number is (301) 838-2500.

We are the owner of various U.S. federal trademark registrations (®) and registration applications (TM), including the following marks referred to in this prospectus pursuant to applicable U.S. intellectual property laws: "Supernus®," "Epliga®," "Microtrol®," "Solutrol®," "ProScreen®," "OptiScreen®," "ProPhile®," and the registered Supernus Pharmaceuticals logo. All other trademarks or trade names referred to in this prospectus are the property of their respective owners.

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**THE OFFERING**

Common stock we are offering	shares
Common stock to be outstanding after this offering	shares
Over-allotment option	We have granted the underwriters an option for a period of up to 30 days to purchase up to additional shares of common stock at the initial public offering price.
Use of proceeds after expenses	We estimate that the net proceeds from this offering will be approximately \$ million, or approximately \$ million if the underwriters exercise their over-allotment option in full. We expect to use the net proceeds from this offering to fund our clinical trials and for other general corporate purposes.
Risk factors	You should read the "Risk Factors" section of this prospectus beginning on page 9 for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.

Proposed NASDAQ Global Market symbol SUPN

The number of shares of our common stock to be outstanding after this offering is based on 55,371,061 shares of common stock outstanding as of September 30, 2010 after giving effect to the conversion of 49,000,000 shares of our preferred stock outstanding as of September 30, 2010 into 49,000,000 shares of our common stock at the closing of this offering.

The number of shares of our common stock outstanding immediately after this offering excludes:

1,729,458 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2010, with exercise prices ranging from \$0.10 to \$1.76 per share and a weighted average exercise price of \$0.48 per share (of which options to acquire 940,324 shares of common stock were vested as of September 30, 2010);

411,765 shares of common stock remaining to vest under a restricted stock award; and

2,487,716 additional shares of common stock reserved for future grants under our 2005 Stock Plan as of September 30, 2010.

Unless otherwise indicated, all information in this prospectus:

assumes the issuance and sale of shares of our common stock in the offering at the initial public offering price of \$ per share;

assumes our planned -for- reverse stock split of our common stock to be effected in connection with this offering;

gives effect to the automatic conversion of all outstanding shares of our preferred stock into 49,000,000 shares of common stock upon the closing of this offering; and

assumes no exercise by the underwriters of their option to purchase up to shares of our common stock in this offering to cover over-allotments.



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We have derived our statement of operations data for the years ended December 31, 2007, 2008 and 2009 from our audited consolidated financial statements included in this prospectus. We have derived our balance sheet data as of September 30, 2010 and statement of operations data for each of the nine months ended September 30, 2009 and 2010 from our unaudited consolidated financial statements included in this prospectus. The unaudited consolidated financial statement data include, in our opinion, all adjustments (consisting only of normal recurring adjustments) that are necessary for a fair presentation of our consolidated financial position and consolidated results of operations for these periods.

Our historical results are not necessarily indicative of future operating results, and the results for the first nine months of 2010 are not necessarily indicative of results expected for the full year or for any other period. You should read this summary consolidated financial data in conjunction with the sections entitled "Risk Factors," "Capitalization," "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes, all included elsewhere in this prospectus.

	Year Ended December 31,			Nine Months Ended September 30,	
	2007	2008	2009	2009	2010
	(unaudited)				
	(in thousands of dollars, except share and per share data)				
<b>Consolidated Statement of Operations Data:</b>					
Revenues					
Development and milestone revenues	\$ 1,405	\$ 2,697	\$ 1,550	\$ 1,181	\$ 97
Royalty revenues	2,828	6,192	44,963	41,884	8,635
<b>Total revenues</b>	<b>4,233</b>	<b>8,889</b>	<b>46,513</b>	<b>43,065</b>	<b>8,732</b>
Costs and expenses					
Research and development	19,269	30,463	29,260	21,804	26,080
General and administrative	4,011	4,287	4,649	3,503	3,388
<b>Total costs and expenses</b>	<b>23,280</b>	<b>34,750</b>	<b>33,909</b>	<b>25,307</b>	<b>29,468</b>
Income (loss) from operations	(19,047)	(25,861)	12,604	17,758	(20,736)
Other income (expense):					
Interest income	1,773	1,057	514	101	623
Interest expense		(8,678)	(12,658)	(9,210)	(9,831)
Other					54
<b>Total other income (expense)</b>	<b>1,773</b>	<b>(7,621)</b>	<b>(12,144)</b>	<b>(9,109)</b>	<b>(9,154)</b>
<b>Net income (loss)</b>	<b>\$ (17,274)</b>	<b>\$ (33,482)</b>	<b>\$ 460</b>	<b>\$ 8,649</b>	<b>\$ (29,890)</b>
Cumulative dividends on Series A convertible preferred stock					
	\$ (3,430)	\$ (3,430)	\$ (3,430)	\$ (2,573)	\$ (2,573)
<b>Net income (loss) attributable to common stockholders</b>	<b>\$ (20,704)</b>	<b>\$ (36,912)</b>	<b>\$ (2,970)</b>	<b>\$ 6,076</b>	<b>\$ (32,463)</b>
Net income (loss) per common share					
Basic	\$ (4.21)	\$ (6.61)	\$ (0.53)	\$ 1.08	\$ (5.12)
<b>Diluted</b>	<b>\$ (4.21)</b>	<b>\$ (6.61)</b>	<b>\$ 0.01</b>	<b>\$ 0.15</b>	<b>\$ (5.12)</b>

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Weighted average number of  
common shares

Basic	4,921,376	5,587,467	5,653,506	5,610,047	6,345,420
Diluted	4,921,376	5,587,467	56,324,761	56,282,411	6,345,420

Net income (loss) used to  
compute pro forma net income  
(loss) per common share basic  
and diluted (unaudited)(1)

\$ 460 \$ (29,890)

Weighted-average number of  
shares used in calculating pro  
forma net income (loss) per  
share basic and diluted  
(unaudited)(1)

56,324,761 55,345,420

Pro forma net income (loss) per  
share basic and diluted(1)

\$