CAPRICOR THERAPEUTICS, INC.
Form S-1/A
May 23, 2014

As filed with the Securities and Exchange Commission on May 23, 2014 Registration No. 333-195385

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 1

TO

FORM S-1
REGISTRATION STATEMENT

UNDER
THE SECURITIES ACT OF 1933

Capricor Therapeutics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**2834**	**88-0363465**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

Capricor Therapeutics, Inc.
8840 Wilshire Blvd., 2nd Floor
Beverly Hills, CA 90211
(310) 358-3200

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

Karen G. Krasney, Esq.

General Counsel

Capricor Therapeutics, Inc.

8840 Wilshire Blvd., 2nd Floor

Beverly Hills, CA 90211

(310) 358-3200

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

Robert R. Carlson, Esq.

Paul Hastings LLP

1117 S. California Avenue

Palo Alto, California 94304

Telephone: (650) 320-1800

Approximate date of commencement of proposed sale to the 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, check the following box: x

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	¨ (Do not check if a smaller reporting company)	Smaller reporting company	x

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount of Shares to be Registered	Proposed Maximum Offering Price Per Share		Proposed Maximum Aggregate Offering Price	Amount of Registration Fee[4]
Common Stock, $0.001 par value per share	6,792,532	$ 5.06	(1)	$ 34,370,211.92	$ 4,426.88
Shares of Common Stock, $0.001 par value per share, Issuable Upon Exercise of Warrants[2]	251,044	$ 5.06	(1)	$ 1,270,282.64	$ 163.61
Total[3]	7,043,576	-		$ 35,640,494.56	$ 4,590.49

(1) Estimated pursuant to Rule 457(c) under the Securities Act of 1933, as amended, for the purpose of calculating the registration fee based on the average of the high and low prices per share of the registrant’s common stock as reported on the OTC Bulletin Board on May 21, 2014.

(2) Represents shares of common stock issuable upon the exercise of warrants issued in a private placement on November 20, 2013.

(3) Pursuant to Rule 416, there are also being registered such indeterminable additional securities as may be issued to prevent dilution as a result of stock splits, stock dividends or similar transactions.

(4) A filing fee of $5,470.50 was previously paid in connection with the initial filing of this Registration Statement on April 18, 2014.

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 of 1933, as amended,

or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities, nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion, dated May 23, 2014

OFFERING PROSPECTUS

6,792,532 Shares of Common Stock
251,044 Shares of Common Stock Issuable upon Exercise of Outstanding Warrants

This prospectus relates to the resale by the selling stockholders identified in this prospectus of up to 7,043,576 shares of common stock, $0.001 par value per share, of Capricor Therapeutics, Inc., a Delaware corporation. The shares of common stock offered by the selling stockholders identified herein consist of 6,792,532 shares of common stock and 251,044 shares of common stock issuable upon the exercise of warrants with an exercise price of $2.2725 per share, which expire 5 years after the date of grant. All of the shares of common stock and warrants held by the selling stockholders were issued by us in private placement transactions. We are not offering any shares of our common stock for sale under this prospectus and we will not receive any part of the proceeds from sales of the shares of common stock by the selling stockholders; however, we will receive proceeds upon any exercise of the warrants by the selling stockholders. The selling stockholders will bear all commissions and discounts, if any, attributable to the sale or other disposition of the shares. We will bear all costs, expenses and fees in connection with the registration of the shares.

The selling stockholders may, from time to time, sell, transfer or otherwise dispose of any or all of the shares of common stock offered by this prospectus on terms to be determined at the time of sale through ordinary brokerage transactions or through any other means described in this prospectus under the section entitled “Plan of Distribution”. The prices at which the selling stockholders may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions.

Our common stock trades on the OTCQB tier of the OTC Markets under the symbol “CAPR”. On May 21, 2014 the closing price of our common stock as reported on the OTCQB was $4.95.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 12.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

_____, 2014

We have not, and the selling stockholders have not, authorized anyone to provide any information or make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We do not, and the selling stockholders do not, take responsibility for, and can provide no assurance as to the reliability of, any information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in the jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of the time of delivery of this prospectus or of any sale of shares of our common stock. Our business, financial condition and results of operations may have changed since that date.

No action is being taken in any jurisdiction outside the United States to permit a public offering of the common stock or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to the offering and the distribution of this prospectus applicable to that jurisdiction.

Prospectus Summary

This summary highlights information contained elsewhere in this prospectus. Because it is a summary, it may not contain all of the information that is important to you. Accordingly, you are urged to carefully review this prospectus in its entirety, including the risks of investing in our securities discussed under the section entitled "Risk Factors" and the consolidated financial statements and other information that is contained in or incorporated by reference into this prospectus or the registration statement of which this prospectus is a part before making an investment decision. References to the "Company," "Capricor Therapeutics," "we," "us" or "our" in this prospectus refer to Capricor Therapeut Inc., a Delaware corporation, and its subsidiaries, unless the context indicates otherwise.

Company Overview

Capricor Therapeutics, Inc. is a development stage, biopharmaceutical company whose mission is to develop and commercialize regenerative medicine and large molecule products for the treatment of disease. Our initial pipeline products were developed to treat heart disease and its complications. The proprietary methods of Capricor, Inc., our wholly-owned subsidiary, center on producing therapeutic doses of cardiosphere-derived cells to boost the regenerative capacity of the heart and, with that, to perhaps improve cardiac function.

We currently have six drug candidates in various stages of development.

- **CAP-1002**: CAP-1002, Capricor's lead product candidate, consists of allogeneic cardiosphere-derived cells, or CDCs. CAP-1002 is currently being tested in Capricor's ALLSTAR Phase I/II clinical trial which will determine if the cells can lead to reduction in scar size in patients who have had a heart attack.

- **CAP-1001**: CAP-1001 consists of autologous CDCs. This product was used in the Phase I CADUCEUS clinical trial which was sponsored and conducted by Cedars-Sinai Medical Center in collaboration with The Johns Hopkins University. The data from CADUCEUS, using autologous CDCs, suggests that the cells are effective in reducing scar within several months of a heart attack. At present there is no plan for another clinical trial for CAP-1001.

- **CSps**: CSps are multicellular clusters called cardiospheres, a 3D micro-tissue from which CDCs are derived and have shown significant healing effects in pre-clinical models of heart failure. While Capricor considers the CSps an important product, at present there is no plan for a clinical trial for CSps.

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Exosomes: Exosomes are nano-sized, membrane-enclosed vesicles, or “bubbles”, that are filled with select molecules, including proteins and microRNAs, which, when released, send messages to neighboring cells to regulate cellular functions Capricor is currently in pre-clinical testing to explore the possible future therapeutic benefits that exosomes may possess.

- **Cenderitide (CD-NP)**: Cenderitide is a chimeric natriuretic peptide that is being considered for the treatment of heart failure. We are currently evaluating whether we will proceed with further clinical development of this product.

- **CU-NP**: CU-NP is a pre-clinical rationally-designed natriuretic peptide that consists of amino acid chains identical to those produced by the human body, specifically the ring structure of C-type natriuretic peptide, or CNP, and the N- and C-termini of Urodilatin, or URO. We are currently evaluating whether we will proceed with further clinical development of this product.

Corporate Information

Our executive offices are located at 8840 Wilshire Blvd., 2nd Floor, Beverly Hills, California 90211. Our telephone number is (310) 358-3200 and our Internet address is *www.capricor.com.* We do not incorporate the information on, or accessible through, our website into this prospectus, and you should not consider any information on, or accessible through, our website as part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

Risk Factors

Our business is subject to numerous risks and uncertainties, including those highlighted in the section of this prospectus entitled “Risk Factors,” which you should read carefully before making a decision to invest in our common stock. Some of these risks include:

- We need substantial additional funding before we can complete the development of our product candidates;
- Our success depends upon the viability of our product candidates and we cannot be certain any of them will receive regulatory approval to be commercialized;
- As the results of earlier clinical trials are not necessarily predictive of future results, any product candidate we advance into clinical trials may not have favorable results in later clinical trials or receive regulatory approval;
- Our business faces significant government regulation, and there is no guarantee that our products will receive regulatory approval;
- We have limited manufacturing capability, and may not be able to maintain our manufacturing licenses;
- We may face uncertainty and difficulty in obtaining and enforcing our patents and other proprietary rights;
- We are largely dependent on our relationships with our licensors and collaborators and there is no guarantee that such relationships will be maintained or continued; and
- Because our common stock will be primarily traded on the OTCQB tier of the OTC Markets, the volume of shares traded and the prices at which such shares trade may result in lower prices than might otherwise exist if our common stock was traded on a national securities exchange.

Description of Private Placements

On March 15, 2013, we entered into a convertible note purchase agreement with certain accredited investors pursuant to which we sold an aggregate principal amount of $450,000 of secured convertible promissory notes, or the 2013

Notes, for an aggregate original issue price of $382,500, representing a 15% original issue discount. On September 27, 2013, we and the holders of the 2013 Notes entered into an amendment to the 2013 Notes, which provided, among other things, that upon a Change of Control (as defined in the 2013 Notes), the conversion price applicable to the 2013 Notes and the exercise price applicable to the warrants issuable upon a Change of Control would be equal to the average dollar volume weighted average price, or VWAP, of our common stock for each trading day during the period from July 8, 2013 to September 30, 2013. The average VWAP during such period was approximately $0.045 per share.

On October 21, 2013, we and the holders of the 2013 Notes entered into an amendment to the Convertible Note Purchase Agreement pursuant to which we sold to such holders additional notes having an aggregate principal amount of $120,510, or the "Additional Notes." The Additional Notes have identical terms and conditions as the 2013 Notes described above and were allocated among the holders on a pro rata basis based on their initial purchase of the 2013 Notes. In exchange for the issuance of the Additional Notes, we received aggregate gross proceeds of $102,433. The 2013 Notes and the Additional Notes are collectively referred to herein as the 2013 Notes.

The 2013 Notes and the Additional Notes converted at the close of the merger between Nile Therapeutics, Inc., or Nile, and Capricor, Inc., or Capricor, on November 20, 2013 into 251,044 shares of our common stock. Additionally, 251,044 warrants to purchase shares of our common stock at a strike price of $2.2725 were issued to the holders of the 2013 Notes and the Additional Notes. No additional proceeds were received by us as a result of the issuance of such shares. The offer and sale of the 2013 Notes and the Additional Notes described above constituted a private placement under Section 4(2) of the Securities Act in accordance with Regulation D promulgated thereunder.

Immediately prior to the effective time of the merger between Nile and Capricor all shares of Capricor preferred stock were converted into shares of Capricor common stock pursuant to the terms of the merger agreement. On November 20, 2013, the shares of Capricor common stock which were exchanged for the shares of Capricor preferred stock, as a result of the merger and in accordance with the terms of the merger agreement, were exchanged according to the applicable multiplier for 6,591,494 shares of common stock of Capricor Therapeutics. Additionally, as a result of the merger between Nile and Capricor and in accordance with the terms of the merger agreement, each outstanding share of Capricor common stock was converted into the right to receive approximately 2.07 shares of Capricor Therapeutics common stock on November 20, 2013. No proceeds were received by us from the issuance of common stock to the former Capricor stockholders. For the issuance of shares of Capricor Therapeutics common stock to the former Capricor stockholders, we relied upon the exemption from federal registration under Section 4(2) of the Securities Act and Rule 506 promulgated thereunder.

The offering

Common stock offered by selling stockholders	6,792,532 shares of common stock 251,044 shares of common stock issuable upon exercise of warrants
Common stock to be outstanding after the offering	11,941,903 shares
Use of proceeds	We will not receive any proceeds from the sale of common stock by the selling stockholders. We will, however, receive proceeds upon the exercise of any warrants held by the selling stockholders. If such warrants are exercised in full, we would receive gross cash proceeds of approximately $570,497. We intend to use the net proceeds received upon exercise of the warrants to further develop our product candidates and for other general working capital purposes. See the section of this prospectus entitled “Use of Proceeds” on page 36 for a more complete description of the intended use of proceeds from the offering.
Risk Factors	You should read the section of this prospectus entitled “Risk Factors” beginning on page 12 for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Dividends Policy	Currently, we do not anticipate paying cash dividends.
OTCQB Symbol	“CAPR.” There is no established trading market for the warrants, and we do not expect one to develop.

The number of shares of common stock that will be outstanding after the offering is based on 11,690,859 shares of our common stock outstanding as of May 15, 2014, plus 251,044 shares of common stock issuable upon the exercise of warrants, and excludes:

- 4,876,322 shares of our common stock issuable upon the exercise of outstanding stock options with a weighted average exercise price of approximately $0.72 per share as of May 15, 2014;
- 81,237 shares of our common stock issuable upon the exercise of outstanding warrants with a weighted average exercise price of approximately $63.33 per share as of May 15, 2014 (excluding the shares underlying the warrants being registered hereby); and
- 2,010,892 shares of our common stock reserved for issuance as of May 15, 2014 under our: (1) Amended and Restated 2005 Stock Option Plan; (2) 2006 Stock Option Plan; (3) 2012 Restated Equity Incentive Plan; and (4) 2012

Non-Employee Director Stock Option Plan ((1) through (4), collectively, the “Plans”).

Except as otherwise indicated, all information in this prospectus assumes the sale of all shares of common stock covered by this prospectus.

Summary Financial Data

The following tables set forth our summary financial data as of the dates and for the periods indicated. We have derived the summary consolidated statement of operations data and comprehensive loss data for the years ended December 31, 2012 and 2013 and the consolidated balance sheet data as of December 31, 2013 from our audited consolidated financial statements included elsewhere in this prospectus. The summary consolidated financial data as of March 31, 2014, and for the three months ended March 31, 2014 and March 31, 2013, have been derived from our unaudited condensed consolidated financial statements appearing elsewhere in this prospectus.

The historical results presented below are not necessarily indicative of the results to be expected for any future period. The following summaries of our financial data for the periods presented should be read in conjunction with the sections of this prospectus entitled "Risk Factors," "Capitalization," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements, condensed consolidated financial statements, the related consolidated notes, and the related condensed consolidated notes included elsewhere in this prospectus.

CAPRICOR THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED BALANCE SHEETS

DECEMBER 31, 2013 AND 2012

ASSETS

	2013	2012
CURRENT ASSETS		
Cash and cash equivalents	$1,729,537	$170,106
Marketable securities	326,494	4,192,726
Restricted Cash	1,401,859	-
Grants receivable	-	767,163
Interest receivable	187	25,215
Prepaid expenses and other current assets	222,763	38,042
TOTAL CURRENT ASSETS	3,680,840	5,193,252
PROPERTY AND EQUIPMENT, at cost		
Furniture and equipment	38,850	29,623
Laboratory equipment	115,766	68,878
	154,616	98,501
Less accumulated depreciation	(80,429)	(64,558)
NET PROPERTY AND EQUIPMENT	74,187	33,943
OTHER ASSETS		
Patents, net of accumulated amortization of $32,475 and $28,145 respectively	227,207	178,307
Loan fees, net of accumulated amortization of $6,722 and $0, respectively	29,945	-
In-process research and development, net of accumulated amortization of $0	1,500,000	-
Deposits	25,728	18,088
TOTAL ASSETS	$5,537,907	$5,423,590
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$1,506,509	$264,707
Accounts payable and accrued expenses, related party	382,142	164,484
Sub-award payable, related party	41,855	75,072
Accrued royalties	122,416	24,904
TOTAL CURRENT LIABILITIES	2,052,922	529,167

LONG-TERM LIABILITIES		
Loan payable	3,961,733	-
Accrued interest	58,134	-
TOTAL LONG-TERM LIABILITIES	4,019,867	-
TOTAL LIABILITIES	6,072,789	529,167
SHAREHOLDERS' EQUITY		
Common stock, $0.001 par, 50,000,000 and 100,000,000 shares authorized, respectively, 11,687,747 and 10,351,294 shares issued and outstanding, respectively	11,687	10,351
Additional paid-in capital	15,552,946	12,114,689
Subscription receivable	-	(2,211)
Accumulated other comprehensive loss	(980)	(21,795)
Deficit accumulated during the development stage	(16,098,535)	(7,206,611)
TOTAL SHAREHOLDERS' EQUITY	(534,882)	4,894,423
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$5,537,907	$5,423,590

CAPRICOR THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Years Ended December 31,		July 5, 2005 (inception) through December 31,
	2013	2012	2013
GRANT INCOME	$503,233	$1,898,764	$4,180,970
OPERATING EXPENSES			
Research and development	5,197,178	2,634,222	11,499,595
General and administrative	2,208,955	1,364,582	6,953,667
TOTAL OPERATING EXPENSES	7,406,133	3,998,804	18,453,262
LOSS FROM OPERATIONS	(6,902,900)	(2,100,040)	(14,272,292)
OTHER INCOME (EXPENSES)			
Investment income (loss)	(11,890)	28,785	150,891
Interest expense	(58,134)	-	(58,134)
Impairment of goodwill	(1,919,000)	-	(1,919,000)
TOTAL OTHER INCOME (EXPENSES)	(1,989,024)	28,785	(1,826,243)
NET LOSS	(8,891,924)	(2,071,255)	(16,098,535)
OTHER COMPREHENSIVE GAIN (LOSS)			
Net unrealized gain (loss) on marketable securities	20,815	(21,795)	(980)
COMPREHENSIVE LOSS	$(8,871,109)	$(2,093,050)	$(16,099,515)
Net loss per share, basic and diluted	$(0.85)	$(0.21)	
Weighted average number of shares, basic and diluted	10,501,416	9,945,251	

CAPRICOR THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2014 (unaudited)	December 31, 2013
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 12,979,150	$ 1,729,537
Marketable securities	326,226	326,494
Restricted Cash	555,232	1,401,859
Interest receivable	757	187
Prepaid expenses and other current assets	169,579	222,763
TOTAL CURRENT ASSETS	14,030,944	3,680,840
PROPERTY AND EQUIPMENT, at cost		
Furniture and equipment	38,850	38,850
Laboratory equipment	208,667	115,766
	247,517	154,616
Less accumulated depreciation	(83,978)	(80,429)
NET PROPERTY AND EQUIPMENT	163,539	74,187
OTHER ASSETS		
Patents, net of accumulated amortization of $33,557 and $32,475 respectively	228,382	227,207
Loan fees, net of accumulated amortization of $8,556 and $6,722, respectively	28,111	29,945
In-process research and development, net of accumulated amortization of $0	1,500,000	1,500,000
Deposits	25,728	25,728
TOTAL ASSETS	$ 15,976,704	$ 5,537,907
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$ 1,518,595	$ 1,506,509
Accounts payable and accrued expenses, related party	481,643	382,142
Sub-award payable, related party	-	41,855
Accrued royalties	132,379	122,416
Deferred income, current	4,166,667	-
TOTAL CURRENT LIABILITIES	6,299,284	2,052,922

LONG-TERM LIABILITIES		
Deferred income, net of current portion	7,291,666	-
Loan payable	3,961,733	3,961,733
Accrued interest	83,461	58,134
TOTAL LONG-TERM LIABILITIES	11,336,860	4,019,867
TOTAL LIABILITIES	17,636,144	6,072,789
STOCKHOLDERS' EQUITY (DEFICIT)		
Preferred stock, $0.001 par value, 5,000,000 shares authorized, none issued and outstanding	-	-
Common stock, $0.001 par value, 50,000,000 shares authorized, 11,690,859 and 11,687,747 shares issued and outstanding respectively	11,690	11,687
Additional paid-in capital	15,638,420	15,552,946
Accumulated other comprehensive loss	(404)	(980)
Deficit accumulated during the development stage	(17,309,146)	(16,098,535)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(1,659,440)	(534,882)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 15,976,704	$ 5,537,907

CAPRICOR THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

	Three months ended March 31,		July 5, 2005 (inception) through
	2014	2013	March 31, 2014
INCOME			
Collaboration income	1,041,667	-	1,041,667
Grant income	-	233,291	4,180,970
TOTAL INCOME	1,041,667	233,291	5,222,637
OPERATING EXPENSES			
Research and development	1,374,757	1,191,154	12,874,352
General and administrative	852,347	474,429	7,806,014
TOTAL OPERATING EXPENSES	2,227,104	1,665,583	20,680,366
LOSS FROM OPERATIONS	(1,185,437)	(1,432,292)	(15,457,729)
OTHER INCOME (EXPENSE)			
Investment income (loss)	153	18,889	151,044
Interest expense	(25,327)	(3,711)	(83,461)
Impairment of goodwill	-	-	(1,919,000)
TOTAL OTHER INCOME (EXPENSE)	(25,174)	15,178	(1,851,417)
NET LOSS	(1,210,611)	(1,417,114)	(17,309,146)
OTHER COMPREHENSIVE GAIN (LOSS)			
Net unrealized gain (loss) on marketable securities	576	(8,763)	(404)
COMPREHENSIVE LOSS	$ (1,210,035)	$ (1,425,877)	$ (17,309,550)
Net loss per share, basic and diluted	$ (0.10)	$ (0.14)	
Weighted average number of shares, basic and diluted	11,689,441	10,351,294	

Risk Factors

Investment in our common stock involves significant risk. You should carefully consider the information described in the following risk factors, together with the other information appearing elsewhere in this prospectus, before making an investment decision regarding our common stock. If any of the events or circumstances described in these risks actually occur, our business, financial conditions, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or a part of your investment in our common stock. Moreover, the risks described below are not the only ones that we face.

Risks Relating to Our Business

We need substantial additional funding before we can complete the development of our product candidates. If we are unable to obtain such additional capital, we will be forced to delay, reduce or eliminate our product development programs and may not have the capital required to otherwise operate our business.

Developing biopharmaceutical products, including conducting pre-clinical studies and clinical trials and establishing manufacturing capabilities, is expensive. As of March 31, 2014, we had cash, cash resources, and marketable securities totaling approximately $13.3 million, plus approximately $0.6 million restricted cash in loans for our ALLSTAR clinical trial. We have not generated any product revenues, and will not generate any product revenues until, and only if, we receive approval to sell our drug candidates from the FDA and other regulatory authorities for our product candidates.

From inception, we have financed our operations through public and private sales of our equity and debt securities, NIH grants, and a CIRM loan award. We also recently entered into a collaboration agreement with Janssen Biotech, Inc., or Janssen, which provides for funding for the collaboration of our cell therapy program for cardiovascular applications, including CAP-1002. As we have not generated any revenue from operations to date, and we do not expect to generate revenue for several years, if ever, we will need to raise substantial additional capital in order to fund our immediate general corporate activities and, thereafter, to fund our research and development, including our long-term plans for clinical trials and new product development.

We expect our research and development expenses to increase in connection with our ongoing activities, particularly if we continue to develop cenderitide and initiate clinical development of CU-NP or as we further the development of our exosome program. In addition, our expenses could increase beyond expectations if the FDA requires that we perform additional studies to those that we currently anticipate, and the timing of any potential product approval may be delayed. Other than our cash on hand, we currently have no commitments or arrangements for any additional

financing to fund the research and development of cenderitide, CU-NP or exosomes. Although we have commenced certain development activities in connection with our cenderitide product candidate, the commencement of further clinical work and other development activities for our cenderitide and CU-NP programs will be subject to additional evaluation by our Board of Directors before full-scale development will be commenced.

We may seek to raise additional funds through various potential sources, such as equity and debt financings, or through strategic collaborations and license agreements. We can give no assurances that we will be able to secure such additional sources of funds to support our operations or, if such funds are available to us, that such additional financing will be sufficient to meet our needs. Moreover, to the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates, or grant licenses on terms that may not be favorable to us.

Our forecasts regarding our beliefs of the sufficiency of our financial resources to support our current and planned operations are forward-looking statements and involve significant risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this “Risk Factors” section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

§ the scope, rate of progress, cost and results of our research and development activities, especially our Phase II clinical trial of CAP-1002;

§ the continued availability of funding from NIH and CIRM;

§ the costs and timing of regulatory approval;

§ the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

§ the effect of competing technological and market developments;

§ the terms and timing of any collaboration, licensing or other arrangements that we may establish;

§ the cost and timing of completion of clinical and commercial-scale outsourced manufacturing activities; and

§ the costs of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval.

We have a history of net losses, and we expect losses to continue for the foreseeable future. In addition, a number of factors may cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.

We have a history of net losses, expect to continue to incur substantial and increasing net losses for the foreseeable future, and may never achieve or maintain profitability. Our operations to date have been primarily limited to organizing and staffing our company, developing our technology, and undertaking pre-clinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history. Specifically, our financial condition and operating results have varied significantly in the past and will continue to fluctuate from quarter-to -quarter and year-to -year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following factors, as well as other factors described elsewhere in this prospectus:

§ our need for substantial additional capital to fund our development programs;

§ delays in the commencement, enrollment, and timing of clinical testing;

§ the success of the ALLSTAR clinical trial through all stages of clinical development;

§ if further clinical trials are conducted, the success of clinical trials of cenderitide and CU -NP product candidates or future product candidates;

§

the viability of exosomes as a potential product candidate and the success of all stages of its pre-clinical and clinical development;

§ any delays in regulatory review and approval of our product candidates in clinical development;

§ our ability to receive regulatory approval or commercialize our product candidates, within and outside the United States;

§ potential side effects of our current or future products and product candidates that could delay or prevent commercialization or cause an approved treatment drug to be taken off the market;

§ regulatory difficulties relating to products that have already received regulatory approval;

§ market acceptance of our product candidates;

§ our ability to establish an effective sales and marketing infrastructure once our products are commercialized;

§ our ability to establish or maintain collaborations, licensing or other arrangements;

§ our ability and third parties' abilities to protect intellectual property rights;

- competition from existing products or new products that may emerge;
- guidelines and recommendations of therapies published by various organizations;
- the ability of patients to obtain coverage of or sufficient reimbursement for our products;
- our ability to maintain adequate insurance policies;
- our dependency on third parties to formulate and manufacture our product candidates;
- our ability to maintain our current manufacturing facility and secure other facilities as determined to be necessary;
- costs related to and outcomes of potential intellectual property litigation;
- compliance with obligations under intellectual property licenses with third parties;
- our ability to seek regulatory approvals for our product candidates;
- our ability to implement additional internal systems and infrastructure;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively; and
- the ability of our senior management who have limited experience in managing a public company to manage our business and operations.

The Company's technology is not yet proven and each of our product candidates is in an early stage of development.

Each of the Company's six product candidates, CAP-1002, CAP-1001, cardiospheres, exosomes, cenderitide and CU –NP, is in an early stage of development and requires extensive clinical testing before it may be approved by the U.S. Food and Drug Administration, or FDA, or another regulatory authority in a jurisdiction outside the United States, which could take several years to complete, if ever. The effectiveness of the Company's technology has not been

definitively proven in completed human clinical trials or preclinical studies. The Company's failure to establish the efficacy of its technology would have a material adverse effect on the Company. We cannot predict with any certainty the results of such clinical testing, including the results of our planned ALLSTAR trial. We cannot predict with any certainty if, or when, we might commence any clinical trials of our product candidates other than the ALLSTAR trial or whether such trials will yield sufficient data to permit us to proceed with additional clinical development and ultimately submit an application for regulatory approval of our product candidates in the United States or abroad, or whether such applications will be accepted by the appropriate regulatory agency.

We may not be able to manage our growth.

Should we achieve our near-term milestones, of which no assurance can be given, our long-term viability will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources. To manage this growth, we may need to expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business would be harmed.

Risks Relating to Clinical and Commercialization Activities

Our product candidates will require substantial time and resources in order to be developed, and there is no guarantee that we will develop them successfully.

We have not completed the development of any products and may not have products to sell commercially for many years, if at all. Our potential products will require substantial additional research and development time and expense, as well as extensive clinical trials and perhaps additional preclinical testing, prior to commercialization, which may never occur. There can be no assurance that products will be developed successfully, perform in the manner anticipated, or be commercially viable.

Our success depends upon the viability of our product candidates and we cannot be certain any of them will receive regulatory approval to be commercialized.

We will need FDA approval to market and sell any of our product candidates in the United States and approvals from the FDA-equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any of our product candidates, we must submit to the FDA a new drug application, or NDA, or a biologics license application, or BLA, demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as pre-clinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity, and novelty of the product candidate, and requires substantial resources for research, development, and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional pre-clinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation, administrative action or changes in FDA policy that occur prior to or during our regulatory review.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our NDAs or BLAs, as applicable. We cannot be sure that we will ever obtain regulatory clearance for our product candidates. Failure to obtain FDA approval of any of our product candidates will reduce our number of salable products and, therefore, corresponding product revenues, and will have a material and adverse impact on our business.

The Company has limited experience in conducting clinical trials.

The Company has limited human clinical trial experience with respect to its product candidates. The clinical testing process is governed by stringent regulation and is highly complex, costly, time-consuming, and uncertain as to outcome (and pharmaceutical products and products used in the regeneration of tissue may invite particularly close scrutiny and requirements from the FDA and other regulatory bodies). Our failure or the failure of our collaborators to conduct human clinical trials successfully or our failure to capitalize on the results of human clinical trials for our product candidates would have a material adverse effect on the Company. If our clinical trials of our product candidates or future product candidates do not produce results necessary to support regulatory approval in the United States or elsewhere, or if they show undesirable side effects, we will be unable to commercialize these product candidates.

To receive regulatory approval for the commercial sale of our product candidates, we must conduct adequate and well-controlled clinical trials to demonstrate efficacy and safety in humans. Clinical failure can occur at any stage of the testing. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing. In addition, the results of our clinical trials may show that our product candidates are ineffective or may cause undesirable side effects, which could interrupt, delay or halt clinical trials, resulting in the denial of regulatory approval by the FDA and other regulatory authorities. In addition, negative or inconclusive results may result in:

§ the withdrawal of clinical trial participants;

§ the termination of clinical trial sites or entire trial programs;

§ costs of related litigation;

§ substantial monetary awards to patients or other claimants;

§ impairment of our business reputation;

§ loss of revenues; and

§ the inability to commercialize our product candidates.

Delays in the commencement, enrollment, and completion of clinical testing could result in increased costs to us and delay or limit our ability to obtain regulatory approval for our product candidates.

Delays in the commencement, enrollment or completion of clinical testing could significantly affect our product development costs. A clinical trial may be suspended or terminated by the Company, the FDA, or other regulatory authorities due to a number of factors. The commencement and completion of clinical trials requires us to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs for the same indication as our product candidates, may be required to withdraw from a clinical trial as a result of changing standards of care, or may become ineligible to participate in clinical studies. We do not know whether planned clinical trials will begin on time or be completed on schedule, if at all. The commencement, enrollment and completion of clinical trials can be delayed for a number of reasons, including, but not limited to, delays related to:

§ findings in preclinical studies;

§ reaching agreements on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; obtaining regulatory approval to commence a clinical trial;

§ complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial, or being required to conduct additional trials before moving on to the next phase of trials;

§ obtaining institutional review board, or IRB, approval to conduct a clinical trial at numerous prospective sites;

§ recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including size of patient population, nature of trial protocol, meeting the enrollment criteria for our studies, screening failures, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;

§ retaining patients who have initiated a clinical trial but may be prone to withdraw due to the treatment protocol, lack of efficacy, personal issues, or side effects from the therapy, or who are lost to further follow-up;

§ manufacturing sufficient quantities of a product candidate for use in clinical trials;

§ complying with design protocols of any applicable special protocol assessment we receive from the FDA;

- severe or unexpected drug-related side effects experienced by patients in a clinical trial;
- collecting, analyzing and reporting final data from the clinical trials;
- breaches in quality of manufacturing runs that compromise all or some of the doses made, or positive results in FDA-required viral testing; karyotypic abnormalities in our cell product; either event which would necessitate disposal of all cells made from that source;
- availability of adequate amounts of tissue for preparation of master cell banks for our products;
- our inability to find a tissue source with an HLA haplotype that is compatible with the recipient may lead to limited utility of the product in a broad population; and
- requirements to conduct additional trials and studies, and increased expenses associated with the services of the Company's CROs and other third parties.

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In addition, a clinical trial may be suspended or terminated by us, the FDA, or other regulatory authorities due to a number of factors. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, we or our development partners, if any, may be delayed in obtaining, or may not be able to obtain, marketing approval for these product candidates. We may not be able to obtain approval for indications that are as broad as intended, or we may be able to obtain approval only for indications that are entirely different than those indications for which we sought approval.

Changes in regulatory requirements and guidance may occur, and we may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us to resubmit our clinical trial protocols to institutional review boards, or IRBs, for re -examination, which may impact the costs, timing, or successful completion of a clinical trial. If we experience delays in the completion of, or if we terminate, our clinical trials, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Even if we are able to ultimately commercialize our product candidates, other therapies for the same or similar indications may have been introduced to the market and established a competitive advantage. Any delays in obtaining regulatory approvals may:

- § delay commercialization of, and our ability to derive product revenues from, our product candidates;
- § impose costly procedures on us; or
- § diminish any competitive advantages that we may otherwise enjoy.

As the results of earlier clinical trials are not necessarily predictive of future results, any product candidate we advance into clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Even if our clinical trials are completed as planned, including our ALLSTAR clinical trial of CAP-1002, we cannot be certain that their results will support the claims of our product candidates. Positive results in pre-clinical testing and early clinical trials does not ensure that results from later clinical trials will also be positive, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and pre-clinical testing. A number of companies in the pharmaceutical industry, including those with greater resources and experience, have suffered significant setbacks in Phase III clinical trials, even after seeing promising results in earlier clinical trials.

Our clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay the filing of our NDAs and/or BLAs

with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. In addition, our clinical trials to date involve a small patient population. Because of the small sample size, the results of these clinical trials may not be indicative of future results.

Despite the results reported in earlier clinical trials for our product candidates, we do not know whether any Phase II, Phase III or other clinical programs we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates.

Our products face a risk of failure due to adverse immunological reactions.

A potential risk of an allogeneic therapy such as that being tested by the Company is that patients might develop an immune response to the cells being infused. Such an immune response may induce adverse clinical effects which would impact the safety of the Company’s products and the success of our trials. Additionally, if research subjects have pre-existing antibodies or other immune sensitization to our cells, there is a potentiality that our cells and the therapy would be rendered ineffective.

Our business faces significant government regulation, and there is no guarantee that our product candidates will receive regulatory approval.

Our research and development activities, preclinical studies, anticipated human clinical trials, and anticipated manufacturing and marketing of our potential products are subject to extensive regulation by the FDA and other regulatory authorities in the United States, as well as by regulatory authorities in other countries. In the United States, our product candidates are subject to regulation as biological products under the Public Health Service Act or as combination biological products/medical devices. Different regulatory requirements may apply to its products depending on how they are categorized by the FDA under these laws. These regulations can be subject to substantial and significant interpretation, addition, amendment or revision by the FDA and by the legislative process. The FDA may determine that we will need to undertake clinical trials beyond those currently planned. Furthermore, the FDA may determine that results of clinical trials do not support approval for the product. Similar determinations may be encountered in foreign countries. The FDA will continue to monitor products in the market after approval, if any, and may determine to withdraw its approval or otherwise seriously affect the marketing efforts for any such product. The same possibilities exist for trials to be conducted outside of the United States that are subject to regulations established by local authorities and local law. Any such determinations would delay or deny the introduction of our product candidates to the market and have a material adverse effect on our business, financial condition, and results of operations.

Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Agency, and corresponding state agencies to ensure strict compliance with Good Manufacturing Practices or GMPs and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards. Other risks include:

§ regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication, or field alerts to physicians and pharmacies;

§ regulatory authorities may withdraw their approval of the product or require us to take our approved products off the market;

§ we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of our products;

§ we may have limitations on how we promote our products; and

§ we may be subject to litigation or product liability claims.

Even if our product candidates receive regulatory approval in the United States, we may never receive approval or commercialize our product candidates outside of the United States. In order to market and commercialize any product candidate outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. For example, European regulatory authorities generally require a trial comparing the efficacy of the new drug to an existing drug prior to granting approval. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the United States. Such effects include the risks that our product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and have an adverse effect on product sales and potential royalties, and that such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

Even if our product candidates receive regulatory approval, we may still face future development and regulatory difficulties.

Even if United States regulatory approval is obtained, the FDA may still impose significant restrictions on a product’s indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies. Given the number of recent high -profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk management programs which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, pre-approval of promotional materials, and restrictions on direct-to -consumer advertising. Furthermore, heightened Congressional scrutiny on the adequacy of the FDA’s drug approval process and the agency’s efforts to assure the safety of marketed drugs has resulted in the proposal of new legislation addressing drug safety issues. If enacted, any new legislation could result in delays or increased costs during the period of product development, clinical trials, and regulatory review and approval, as well as increased costs to assure compliance with any new post-approval regulatory requirements. Any of these restrictions or requirements could force us to conduct costly studies or increase the time for us to become profitable. For example, any labeling approved for any of our product candidates may include a restriction on the term of its use, or it may not include one or more of our intended indications.

Our product candidates will also be subject to ongoing FDA requirements for the labeling, packaging, storage, advertising, promotion, record-keeping, and submission of safety and other post-market information on the drug. In addition, approved products, manufacturers, and manufacturers' facilities are subject to continuous review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If our product candidates fail to comply with applicable regulatory requirements, such as current Good Manufacturing Practices or GMPs, a regulatory agency may:

- issue warning letters;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions, and penalties for noncompliance;
- impose other civil or criminal penalties;
- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require a product recall.

We have limited manufacturing capability, and may not be able to maintain our manufacturing licenses.

We presently maintain our lab and research facilities in leased premises at CSMC. We presently manufacture our cells in an accredited GMP facility which is owned by and located within CSMC. Our intention is to manufacture cells at this facility for our Phase II trial. We also intend to utilize our premises at CSMC to develop and manufacture exosomes. If the lease is terminated or if CSMC revokes its permission to allow us to utilize the GMP facility, we would have to secure alternative facilities in which to operate our research and development activities and/or manufacture our products, which would involve a significant monetary investment and would negatively impact the progress of our clinical trials and regulatory approvals. In addition, we will have to build out our own manufacturing facility for the Phase III trial or establish a collaboration agreement with a third party.

We are required to obtain and maintain certain licenses in connection with our manufacturing facilities and activities. We have been issued a Manufacturing License and a Tissue Bank License from the State of California. There is no guarantee that any licenses issued to us will not be revoked or forfeited by operation of law or otherwise. If we were denied any required license or if any of its licenses were to be revoked or forfeited, we would suffer significant harm. Additionally, in the event a serious adverse event in our clinical trial were to occur during the period in which any required license was not in place, we could be exposed to additional liability if it were determined that the event was due to our fault and we had not secured the required license.

We obtain the donor hearts from which our CDCs are manufactured from an organ procurement organization, or OPO. There is no guarantee that the OPO which currently provides donor hearts to us will be able to continue to supply us with donor hearts in the future or that an alternative OPO will be available to us. If that OPO or an alternative OPO is not able or willing to supply us with donor hearts, we would be unable to produce our CDCs and the development of our lead product candidate would be significantly impaired and possibly terminated. Additionally, OPO’s are subject to regulations of various government agencies. There is no guarantee that laws and regulations pursuant to which our OPO provides donor hearts will not change making it more difficult or even impossible for the OPO to continue to supply us with the hearts we need to produce our product.

We have no prior experience in manufacturing product for large clinical trials or commercial use.

Our manufacturing experience has been limited to manufacturing CAP-1002 for the current ALLSTAR trial. We have no prior history or experience in manufacturing our allogeneic product or any other product for any clinical use and no experience manufacturing any product for large clinical trials or commercial use. Our product candidates have not previously been tested in any large trials to show safety or efficacy, nor are they available for commercial use. We face risks of manufacturing failures and risks of making products that are not proven to be safe or effective.

If we continue with the development of Cenderitide or CU -NP, we will rely exclusively on third parties to formulate and manufacture these product candidates.

We have no experience in drug formulation or manufacturing and do not intend to establish our own manufacturing facilities for the production of Cenderitide or CU -NP. We lack the resources and expertise to formulate or manufacture our own product candidates. If we continue with the development of Cenderitide or CU -NP, we will have to contract with one or more manufacturers to manufacture, supply, store, and distribute drug supplies for our clinical trials. If either of these product candidates receives FDA approval, we will rely on one or more third-party contractors to manufacture supplies of our drug candidates. Our current and anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We may be unable to identify manufacturers needed to manufacture our product candidates on acceptable terms or at all, because the number of potential manufacturers is limited, and subsequent to approval of an NDA or BLA, the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer may have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.

- Some of the raw materials needed to manufacture our product candidates are available from a very limited number of suppliers. Although we believe we have good relationships with these suppliers, we may have difficulty identifying alternative suppliers if our arrangements with our current suppliers are disrupted or terminated.

- Our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical and commercial needs, if any.

- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products.

- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Agency, and corresponding state agencies to ensure strict compliance with good manufacturing practice and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA, or the commercialization of our product candidates, or result in higher costs or deprive us of potential product revenues.

Risks Related to Our Intellectual Property

We may face uncertainty and difficulty in obtaining and enforcing our patents and other proprietary rights.

Our success will depend in large part on our ability to obtain, maintain, and defend patents on our products, obtain licenses to use third party technologies, protect our trade secrets and operate without infringing the proprietary rights of others. Legal standards regarding the scope of claims and validity of biotechnology patents are uncertain and evolving. There can be no assurance that our pending, licensed-in or owned patent applications will be approved, or that challenges will not be instituted against the validity or enforceability of any patent licensed-in or owned by us. Additionally, we have entered into various confidentiality agreements with employees and third parties. There is no assurance that such agreements will be honored by such parties or enforced in whole or part by the courts. The cost of litigation to uphold the validity and prevent infringement of a patent is substantial. Furthermore, there can be no assurance that others will not independently develop substantially equivalent technologies not covered by patents to which we own rights or obtain access to our know-how. In addition, the laws of certain countries may not adequately protect our intellectual property. Our competitors may possess or obtain patents on products or processes that are necessary or useful to the development, use, or manufacture of our products. There can also be no assurance that our proposed technology will not infringe patents or proprietary rights owned by others, with the result that others may bring infringement claims against us and require us to license such proprietary rights, which may not be available on commercially reasonable terms, if at all. Any such litigation, if instituted, will have a material adverse effect, including monetary penalties, diversion of management resources, and injunction against continued manufacture, use, or sale of certain products or processes.

Some of our technology has resulted, and will result, from research funded by agencies of the United States government and the State of California. As a result of such funding, the United States government and the State of California have certain rights in the technology developed with the funding. These rights include a non-exclusive, paid-up, worldwide license under such inventions for any governmental purpose. In addition, under certain conditions, the government has the right to require us to grant third parties licenses to such technology. The licenses by which we have obtained some of our intellectual property are subject to the rights of the funding agencies. We also rely upon non-patented proprietary know-how. There can be no assurance that we can adequately protect our rights in such non-patented proprietary know-how, or that others will not independently develop substantially equivalent proprietary information or techniques or gain access to our proprietary know-how. Any of the foregoing events could have a material adverse effect on us. In addition, if any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

In September 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the U.S. transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO and may become involved in opposition, derivation, reexamination, inter-parties review or interference proceedings challenging our patent rights or the patent rights of our licensors. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our or our licensors' patent rights, which could adversely affect our competitive position.

The USPTO is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, did not become effective until March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents and those licensed to us.

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If we fail to protect or enforce our intellectual property rights adequately or secure rights to patents of others, the value of our intellectual property rights would diminish.

Our commercial viability will depend in part on obtaining and maintaining patent protection and trade secret protection of our product candidates, and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell, or importing our products is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

We have licensed certain patent and other intellectual property rights that cover our CAP-1002, CAP-1001, CSps, and exosomes product candidates from University of Rome, JHU and CSMC. Under the license agreements with University of Rome and JHU, those institutions prosecute and maintain their patents and patent applications in collaboration with us. We rely on these institutions to file, prosecute, and maintain patent applications, and otherwise protect the intellectual property to which we have a license, and we have not had and do not have primary control over these activities for certain of these patents or patent applications and other intellectual property rights. We cannot be certain that such activities by these institutions have been or will be conducted in compliance with applicable laws and regulations, or will result in valid and enforceable patents and other intellectual property rights. Under the Amended CSMC License Agreement and the Exosomes License Agreement, we have assumed, in coordination with CSMC, responsibility for the prosecution and maintenance of all patents and patent applications. Our enforcement of certain of these licensed patents or defense of any claims asserting the invalidity of these patents would also be subject to the cooperation of the third parties.

We license certain patent and other intellectual property rights that cover our cenderitide and CU-NP product candidates from Mayo. In the past, we have relied on the Mayo to file, prosecute, and maintain patent applications, and otherwise protect the intellectual property to which we have a license, prior to the Amended Mayo License Agreement, we did not have primary control over these activities for certain of these patents or patent applications and other intellectual property rights. With the execution of the Amended Mayo License Agreement, we have the responsibility for the prosecution and maintenance of the Mayo patents and patent applications at our expense. We cannot be certain that that the activities conducted by Mayo have been or will be conducted in compliance with applicable laws and regulations, or will result in valid and enforceable patents and other intellectual property rights. Our enforcement of certain of these licensed patents or defense of any claims asserting the invalidity of these patents would also be subject to the cooperation of the third parties. We are also responsible for paying any prosecution and maintenance fees of all Mayo patents and Mayo patent applications now existing and included in the Amended Mayo License Agreement.

The patent positions of pharmaceutical and biopharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biopharmaceutical patents has emerged to date in the United States. The biopharmaceutical patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents we own or to which we have a license or third-party patents. Further, if any of our patents are deemed invalid and unenforceable, it could impact our ability to commercialize or license our technology.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

§ others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of any of our patents;

§ we might not have been the first to make the inventions covered by any issued patents or patent applications we may have (or third parties from whom we license intellectual property may have);

§ we might not have been the first to file patent applications for these inventions;

§ it is possible that any pending patent applications we may have will not result in issued patents;

§ any issued patents may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;

- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators, and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how.

If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

Our viability also depends upon the skills, knowledge and experience of our scientific and technical personnel, our consultants and advisors as well as our licensors and contractors. To help protect our proprietary know-how and our inventions for which patents may be unobtainable or difficult to obtain, we rely on trade secret protection and confidentiality agreements. To this end, we require all of our employees, consultants, advisors and contractors to enter into agreements which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use of, our technology.

If we choose to go to court to stop someone else from using the inventions claimed in our patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to these patents. In addition, the United States Supreme Court has recently invalidated some tests used by the United States Patent and Trademark Office, or USPTO, in granting patents over the past 20 years. As a consequence, issued patents may be found to contain invalid claims according to the newly revised standards. Some of our own or in -licensed patents may be subject to challenge and subsequent invalidation in a re -examination proceeding before the USPTO or during litigation under the revised criteria which make it more difficult to obtain patents.

Furthermore, a third party may claim that we or our manufacturing or commercialization partners are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we or our commercialization partners are infringing the third party's patents and would order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court will order us or our partners to pay the other party damages for having violated the other party's patents. We have agreed to indemnify certain of our commercial partners against certain patent infringement claims brought by third parties. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents

cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a United States patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our United States patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Risks Related to Our Relationships with Third Parties

We are largely dependent on our relationships with our licensors and collaborators and there is no guarantee that such relationships will be maintained or continued.

We have entered into certain license agreements for certain intellectual property rights which are essential to enable us to develop and commercialize our products. Agreements have been entered into with the University of Rome, JHU and CSMC, which is also a shareholder of ours. Each of those agreements provides for an exclusive license to certain patents and other intellectual property and requires the payment of fees, milestone payments and/or royalties to the institutions that will reduce our net revenues, if and to the extent that we have future revenues. Each of those agreements also contains additional obligations that we are required to satisfy. There is no guarantee that we will be able to satisfy all of our obligations under our license agreements to each of the institutions and that such license agreements will not be terminated. Each of the institutions receives funding from independent sources such as the NIH and other private not-for-profit sources and are investigating scientific and clinical questions of interest to their own principal investigators as well as the scientific and clinical communities at large. These investigators (including Capricor's founder, Dr. Eduardo Marbán, who is the Director of the Heart Institute at CSMC) are under no obligation to conduct, continue, or conclude either current or future studies utilizing our stem cell or exosomes technology, and they are not compelled to license any further technologies or intellectual property rights to us except as may be stated in the applicable licensing agreements between those institutions and us. Changes in these collaborators' research interests or their funding sources away from our technology would have a material adverse effect on us. We are substantially dependent on our relationships with these institutions from which we license the rights to our technologies and know-how. If requirements under our license agreements are not met, we could suffer significant harm, including losing rights to our product candidates.

Our rights to our cenderitide and CU -NP drug candidates were both derived from separate license agreements between us and Mayo. On November 14, 2013, we entered into an Amended and Restated Exclusive License Agreement, which we refer to as the Amended Mayo Agreement, with Mayo pursuant to which the rights to both cenderitide and CU-NP were included in the Amended Mayo Agreement and many of the terms of the former agreements were revised on terms more favorable to us. We are substantially dependent on our relationship with Mayo with respect to the rights to these two drug candidates. If requirements under our license agreement are not met, we could suffer significant harm. In order to develop these products, we will need to maintain the intellectual property rights to these product candidates. The Amended Mayo Agreement requires us to perform certain obligations that affect our rights under the Amended Mayo Agreement, including making cash payments if we were to enter into certain types of business transactions. If we fail to comply with our obligations required under the Amended Mayo Agreement, we could lose important patent and other intellectual property rights which may be critical to our business.

In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under our license agreements in a timely manner, we could lose the rights to our proprietary technology.

Finally, we may be required to obtain licenses to patents or other proprietary rights of third parties in connection with the development and use of our product candidates and technologies. Licenses required under any such patents or proprietary rights might not be made available on terms acceptable to us, if at all.

We have received government grants and a loan award which impose certain conditions on our operations.

Commencing in 2009, we received several grants from the NIH to fund various projects, including Phase I of the ALLSTAR trial. These awards are subject to annual and quarterly reporting requirements. If we fail to meet these requirements, the NIH could cease further funding.

On February 5, 2013, we entered into a Loan Agreement with CIRM, pursuant to which CIRM has agreed to disburse $19,782,136 to us over a period of approximately three and one-half years to support Phase II of our ALLSTAR clinical trial. Under the Loan Agreement, we are required to repay the CIRM loan with interest at maturity. The loan also provides for the payment of a risk premium whereby we are required to pay CIRM a premium up to 500% of the loan amount upon the achievement of certain revenue thresholds. The loan has a term of five years and is extendable annually up to ten years from the original issuance at our option if certain conditions are met. CIRM has the right to cease disbursements if a no-go milestone occurs or certain other conditions are not satisfied. The timing of the distribution of funds pursuant to the Loan Agreement is contingent upon the availability of funds in the California Stem Cell Research and Cures Fund in the State Treasury, as determined by CIRM in its sole discretion. So long as we are not in default, the loan may be forgiven during the term of the project period if we abandon the trial due to the occurrence of a no-go milestone. After the end of the project period, the loan may be forgiven if we elect to abandon the project under certain circumstances. Under the Loan Agreement, we are also required to meet certain financial milestones by demonstrating to CIRM prior to each disbursement of loan proceeds that we have funds available sufficient to fund all costs and expenses anticipated to be required to continue Phase II of the ALLSTAR trial for at least the following 12-month period, less the costs budgeted to be covered by planned loan disbursements. There is no assurance that we will meet our milestones under the Loan Agreement or that CIRM will not discontinue the disbursement of funds.

If we enter into strategic partnerships, we may be required to relinquish important rights to and control over the development of our product candidates or otherwise be subject to terms unfavorable to us.

If we do not establish strategic partnerships, we will have to undertake development and commercialization efforts on our own, which would be costly and adversely impact our ability to commercialize any future products or product candidates. If we enter into any strategic partnerships with pharmaceutical, biotechnology or other life sciences companies, we will be subject to a number of risks, including:

- we may not be able to control the amount and timing of resources that our strategic partners devote to the development or commercialization of product candidates;
- strategic partners may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic partners may not pursue further development and commercialization of products resulting from the strategic partnering arrangement or may elect to discontinue research and development programs;
- strategic partners may not commit adequate resources to the marketing and distribution of any future products, limiting our potential revenues from these products;
- disputes may arise between us and our strategic partners that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic partners may experience financial difficulties;
- strategic partners may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a strategic partner's business strategy may also adversely affect a strategic partner's willingness or ability to complete its obligations under any arrangement; and
- strategic partners could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors.

Risks Related to Competitive Factors

Our products will likely face intense competition.

The Company is engaged in fields that are characterized by extensive worldwide research and competition by pharmaceutical companies, medical device companies, specialized biotechnology companies, hospitals, physicians and academic institutions, both in the United States and abroad. We will experience intense competition with respect to our existing and future product candidates. The pharmaceutical industry is highly competitive, with a number of established, large pharmaceutical companies, as well as many smaller companies. Many of these organizations competing with us have substantially greater financial resources, larger research and development staffs and facilities, greater clinical trial experience, longer drug development history in obtaining regulatory approvals, and greater manufacturing, distribution, sales and marketing capabilities than we do. There are many pharmaceutical companies, biotechnology companies, public and private universities, government agencies, and research organizations actively engaged in research and development of products which may target the same indications as our product candidates. We expect any future products and product candidates that we develop to compete on the basis of, among other things, product efficacy and safety, time to market, price, extent of adverse side effects, and convenience of treatment procedures. One or more of our competitors may develop products based upon the principles underlying our proprietary technologies earlier than we do, obtain approvals for such products from the FDA more rapidly than we do, or develop alternative products or therapies that are safer, more effective and/or more cost effective than any product developed by us. Our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, useful, and less costly than ours and may also be more successful than us in manufacturing and marketing their products.

Our future success will depend in part on our ability to maintain a competitive position with respect to evolving therapies as well as other novel technologies. There can be no assurance that existing or future therapies developed by others will not render our potential products obsolete or noncompetitive. The drugs that we are attempting to develop will have to compete with existing therapies. In addition, companies pursuing different but related fields represent substantial competition. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures, or other collaborations.

If we are unable to retain and recruit qualified scientists and advisors, or if any of our key executives, key employees or key consultants discontinues his or her employment or consulting relationship with us, it may delay our development efforts or otherwise harm our business. In addition, several of our employees and consultants render services on a part-time basis to us or to other companies.

All former employees of Nile were terminated upon consummation of the merger between Nile and Capricor. The loss of any of our key employees or key consultants could impede the achievement of our research and development objectives. Furthermore, recruiting and retaining qualified scientific personnel to perform research and development work in the future is critical to the Company's success. The Company may be unable to attract and retain personnel on acceptable terms given the competition among biotechnology, biopharmaceutical, and health care companies, universities, and non-profit research institutions for experienced scientists. Certain of the Company's officers, directors, scientific advisors, and/or consultants or certain of the officers, directors, scientific advisors, and/or consultants hereafter appointed may from time to time serve as officers, directors, scientific advisors, and/or consultants of other biopharmaceutical or biotechnology companies. The Company may not maintain "key man" insurance policies on any of its officers or employees. All of the Company's employees will be employed "at will" and, therefore, each employee may leave the employment of the Company at any time. If we are unable to retain our existing employees, including qualified scientific personnel, and attract additional qualified candidates, the Company's business and results of operations could be adversely affected.

Because of the specialized nature of our technology, we are dependent upon existing key personnel and on our ability to attract and retain qualified executive officers and scientific personnel for research, clinical studies, and development activities conducted or sponsored by us. There is intense competition for qualified personnel in our fields of research and development, and there can be no assurance that we will be able to continue to attract additional qualified personnel necessary for the development and commercialization of our product candidates or retain our current personnel. Dr. Linda Marbán, our Chief Executive Officer and employee, also provides services on a part-time basis to CSMC as do several other of our employees and Dr. Frank Litvack is only a part-time consultant to the Company and provides services to other non-competing enterprises. These individuals' multiple responsibilities on behalf of the Company and other entities could cause the Company harm in that such employees are unable to devote their full time and attention to the Company.

If we do not establish strategic partnerships, we will have to undertake development and commercialization efforts on our own, which would be costly and delay our ability to commercialize any future products or product candidates.

An element of our business strategy includes potentially partnering with pharmaceutical, biotechnology and other companies to obtain assistance for the development and potential commercialization of our product candidates, including the cash and other resources we need for such development and potentially commercialization. We may not be able to negotiate strategic partnerships on acceptable terms, or at all. If we are unable to negotiate strategic partnerships for our product candidates we may be forced to curtail the development of a particular candidate, reduce or delay its development program, delay its potential commercialization, reduce the scope of our sales or marketing activities or undertake development or commercialization activities at our own expense. In addition, we will bear all the risk related to the development of that product candidate. If we elect to increase our expenditures to fund development or commercialization activities on our own, we will need to obtain substantial additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue.

We have no experience selling, marketing, or distributing products and no internal capability to do so.

The Company currently has no sales, marketing, or distribution capabilities. We do not anticipate having resources in the foreseeable future to allocate to the sales and marketing of our proposed products. Our future success depends, in part, on our ability to enter into and maintain sales and marketing collaborative relationships, or on our ability to build sales and marketing capabilities internally. If we enter into a sales and marketing collaborative relationship, then we will be dependent upon the collaborator's strategic interest in the products under development, and such collaborator's ability to successfully market and sell any such products. We intend to pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our proposed products, significant capital expenditures, management resources, and time will be required to establish and develop an in-house marketing and sales force with technical expertise. There can also be no assurance that we will be able to establish or maintain relationships with third-party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

If any of our product candidates for which we receive regulatory approval do not achieve broad market acceptance, the revenues that we generate from their sales will be limited.

The commercial viability of our product candidates for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon their acceptance among physicians, the medical community, and patients, and coverage and reimbursement of them by third-party payors, including government payors. The degree of market acceptance of any of our approved products will depend on a number of factors, including:

§ limitations or warnings contained in a product's FDA -approved labeling;

§ changes in the standard of care for the targeted indications for any of our product candidates, which could reduce the marketing impact of any claims that we could make following FDA approval;

§ limitations inherent in the approved indication for any of our product candidates compared to more commonly understood or addressed conditions;

§ lower demonstrated clinical safety and efficacy compared to other products;

- prevalence and severity of adverse effects;
- ineffective marketing and distribution efforts;
- lack of availability of reimbursement from managed care plans and other third-party payors;
- lack of cost-effectiveness;
- timing of market introduction and perceived effectiveness of competitive products;
- availability of alternative therapies at similar costs; and
- potential product liability claims.

Our ability to effectively promote and sell our product candidates in the marketplace will also depend on pricing and cost effectiveness, including our ability to manufacture a product at a competitive price. We will also need to demonstrate acceptable evidence of safety and efficacy and may need to demonstrate relative convenience and ease of administration. Market acceptance could be further limited depending on the prevalence and severity of any expected or unexpected adverse side effects associated with our product candidates. If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, health care payors, and patients, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful. If our approved drugs fail to achieve market acceptance, we will not be able to generate significant revenue, if any.

Our ability to generate product revenues will be diminished if our drugs sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.

Our ability to generate significant sales of our products depends on the availability of adequate coverage and reimbursement from third-party payors. Healthcare providers that purchase medicine or medical products for treatment of their patients generally rely on third-party payors to reimburse all or part of the costs and fees associated with the products. Adequate coverage and reimbursement from governmental, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Patients are unlikely to use our products if they do not receive reimbursement adequate to cover the cost of our products.

In addition, the market for our future products will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. Industry competition to be included in such formularies results in downward pricing pressures on pharmaceutical companies. Third-party payors may refuse to include a particular branded drug in their formularies when a generic equivalent is available.

All third-party payors, whether governmental or commercial, whether inside the United States or outside, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for medical technology exists among all these payors. Therefore, coverage of and reimbursement for medical products can differ significantly from payor to payor.

Further, we believe that future coverage and reimbursement may be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for our products may not be available or adequate in either the United States or international markets, limiting our ability to sell our products on a profitable basis.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payors, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payors increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs. Even if our product candidates are approved by the FDA, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover our drugs. If government and other healthcare payors do not provide adequate coverage and reimbursement levels for any of our products, once approved, market acceptance of our products could be reduced.

Risks Related to Product and Environmental Liability

Our products may expose us to potential product liability, and there is no guarantee that we will be able to obtain and maintain adequate insurance to cover these liabilities.

The testing, marketing, and sale of human cell therapeutics, pharmaceuticals, and services entail an inherent risk of adverse effects or medical complications to patients and, as a result, product liability claims may be asserted against us. A future product liability claim or product recall could have a material adverse effect on the Company. There can be no assurance that product liability insurance will be available to us in the future on acceptable terms, if at all, or that coverage will be adequate to protect us against product liability claims. In the event of a successful claim against the Company, insufficient or lack of insurance or indemnification rights could result in liability to us, which could have a material adverse effect on the Company and its future viability. The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval, if at all, expose the Company to the risk of product liability claims. Product liability claims might be brought against the Company by consumers, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- decreased demand for our product candidates;
- impairment of our business reputation;
- loss of revenues; and
- the inability to commercialize our product candidates.

The Company has obtained clinical trial insurance coverage for its clinical trials. However, such insurance coverage may not reimburse the Company or may not be sufficient to reimburse it for any expenses or losses it may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect the Company against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against the Company could have a material adverse effect on us and, if judgments exceed our insurance coverage, could decrease our cash position and adversely affect our business.

Our business involves risk associated with handling hazardous and other dangerous materials.

Our research and development activities involve the controlled use of hazardous materials, chemicals, human blood and tissue, animal blood and blood products, and animal tissue, biological waste, and various radioactive compounds. The risk of accidental contamination or injury from these materials cannot be completely eliminated. The failure to comply with current or future regulations could result in the imposition of substantial fines against the Company, suspension of production, alteration of our manufacturing processes, or cessation of operations.

Our business depends on compliance with ever-changing environmental laws.

We cannot accurately predict the outcome or timing of future expenditures that may be required to comply with comprehensive federal, state and local environmental laws and regulations. We must comply with environmental laws that govern, among other things, all emissions, waste water discharge and solid and hazardous waste disposal, and the remediation of contamination associated with generation, handling and disposal activities. To date, the Company has not incurred significant costs and is not aware of any significant liabilities associated with its compliance with federal, state and local laws and regulations. However, environmental laws have changed in recent years and the Company may become subject to stricter environmental standards in the future and may face large capital expenditures to comply with environmental laws. We have limited capital and we are uncertain whether we will be able to pay for significantly large capital expenditures that may be required to comply with new laws. Also, future developments, administrative actions or liabilities relating to environmental matters may have a material adverse effect on our financial condition or results of operations.

Risks Related to Our Common Stock

We expect that our stock price will fluctuate significantly, and you may not be able to resell your shares at or above your investment price.

The stock market, particularly in recent years, has experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. Our operating results may fluctuate from period to period for a number of reasons, and as a result our stock price may be subject to significant fluctuations. Factors that could cause volatility in the market price of our common stock include, but are not limited to:

- our financial condition, including our need for additional capital;
- results from, delays in, or discontinuation of, any of the clinical trials for our drug candidates, including delays resulting from slower than expected or suspended patient enrollment or discontinuations resulting from a failure to meet pre-defined clinical endpoints;
- announcements concerning clinical trials;
- failure or delays in entering drug candidates into clinical trials;
- failure or discontinuation of any of our research programs;
- developments in establishing new strategic alliances or with existing alliances;
- market conditions in the pharmaceutical, biotechnology and other healthcare related sectors;
- actual or anticipated fluctuations in our quarterly financial and operating results;
- developments or disputes concerning our intellectual property or other proprietary rights;
- introduction of technological innovations or new commercial products by us or our competitors;

- issues in manufacturing our drug candidates or drugs;
- FDA or other United States or foreign regulatory actions affecting us or our industry;
- market acceptance of our drugs, when they enter the market;
- third-party healthcare coverage and reimbursement policies;
- litigation or public concern about the safety of our drug candidates or drugs;
- issuance of new or revised securities analysts' reports or recommendations;
- additions or departures of key personnel; or
- volatility in the stock prices of other companies in our industry.

These and other external factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert our management's time and attention.

Since we have broad discretion in how we use the proceeds received upon the exercise of the warrants, if any, we may use the proceeds in ways with which you disagree.

We intend to use the net proceeds that we may receive upon the exercise of the warrants to fund our general corporate expenses and working capital. However, our management will have significant flexibility in applying any net proceeds from the exercise of such warrants. You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for us. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flow.

Because the Company's common stock will be primarily traded on the OTCQB tier of the OTC Markets, the volume of shares traded and the prices at which such shares trade may result in lower prices than might otherwise exist if our common stock was traded on a national securities exchange.

The Company's shares are traded on the OTCQB tier of the OTC Markets. Stock traded on the OTCQB tier of the OTC Markets is often less liquid than stock traded on national securities exchanges, not only in terms of the number of shares that can be bought and sold at a given price, but also in terms of delays in the timing of transactions and reduced coverage of the Company by security analysts and media. This may result in lower prices for the Company's common stock than might otherwise be obtained if the common stock were traded on a national securities exchange, and could also result in a larger spread between the bid and asked prices for the Company's common stock. There is no guarantee that the Company will be able to re-list its common stock on the NASDAQ Capital Market or any other market. The Company's management will be required to devote substantial time to comply with public company regulations.

We have never paid dividends and we do not anticipate paying dividends in the future.

We have never paid dividends on our capital stock and do not anticipate paying any dividends for the foreseeable future. We anticipate that the Company will retain its earnings, if any, for future growth. Investors seeking cash dividends should not invest in the Company's common stock for that purpose.

There may be additional issuances of shares of blank check preferred stock in the future.

Our certificate of incorporation authorizes the issuance of up to 5,000,000 shares of preferred stock, none of which are issued or currently outstanding. Our Board of Directors will have the authority to fix and determine the relative rights and preferences of preferred shares, as well as the authority to issue such shares, without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that is senior to our common stock that would grant to holders preferred rights to our assets upon liquidation, the right to receive dividends, additional registration rights, anti-dilution protection, the right to the redemption of such shares, together with other rights, none of which will be afforded holders of our common stock.

Recent turmoil in the financial markets and the global recession has adversely affected and may continue to adversely affect our industry, business and ability to obtain financing.

Recent global market and economic conditions have been unprecedented and challenging with tighter credit conditions leading to decreased spending by businesses and consumers alike. Continued turbulence in the U.S. and international markets and economies and prolonged declines in business and consumer spending may adversely affect our liquidity and financial condition, including our ability to access the capital markets to meet our liquidity needs.

We may not be able to attract the attention of major brokerage firms.

Security analysts of major brokerage firms may not provide coverage of us since there is no incentive to brokerage firms to recommend the purchase of our common stock. No assurance can be given that brokerage firms will want to conduct any secondary offerings on behalf of our Company in the future. The lack of such analyst coverage may decrease the public demand for our common stock, making it more difficult for you to resell your shares when you deem appropriate.

The operational and other projections and forecasts that we may make from time to time are subject to inherent risks.

The projections and forecasts that our management may provide from time to time (including, but not limited to, those relating to timing, progress and anticipated results of clinical development, regulatory processes, clinical trial timelines and any anticipated benefits of our product candidates) reflect numerous assumptions made by management, including assumptions with respect to our specific as well as general business, economic, market and financial conditions and other matters, all of which are difficult to predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate. There will be differences between actual and projected results, and actual results may be materially different from than those contained in the projections. The inclusion of the projections in (or incorporated by reference in) this prospectus should not be regarded as an indication that we or our management or representatives considered or consider the projections to be a reliable prediction of future events, and the projections should not be relied upon as such.

Our certificate of incorporation and by-laws contain provisions that may discourage, delay or prevent a change in our management team that stockholders may consider favorable.

Our certificate of incorporation, our bylaws and Delaware law contain provisions that may have the effect of preserving our current management, such as:

- authorizing the issuance of "blank check" preferred stock without any need for action by stockholders;
- eliminating the ability of stockholders to call special meetings of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

These provisions could make it more difficult for our stockholders to affect our corporate policies, make changes in our Board of Directors and for a third party to acquire us, even if doing so would benefit our stockholders.

Ownership of the Company's common stock is highly concentrated, which may prevent you and other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause the Company's stock price to decline.

Capricor's former stockholders, many of whom are executive officers and directors continuing with the Company, together with their respective affiliates beneficially own or control approximately 90% of the outstanding shares of the Company. Accordingly, stockholders, executive officers, directors and their affiliates, acting individually or as a group, will have substantial influence over the outcome of a corporate action of the Company requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of the Company's assets or any other significant corporate transaction. These stockholders may also exert influence in delaying or preventing a change in control of the Company, even if such change in control would benefit the other stockholders of the Company. In addition, the significant concentration of stock ownership may adversely affect the market value of the Company's common stock due to investors' perception that conflicts of interest may exist or arise.

The Company's ability to utilize Nile's net operating loss and tax credit carryforwards in the future is subject to substantial limitations and may be further limited as a result of the recent merger with Capricor.

Federal and state income tax laws impose restrictions on the utilization of net operating loss, or NOL, and tax credit carryforwards in the event that an “ownership change” occurs for tax purposes, as defined by Section 382 of the Code. In general, an ownership change occurs when shareholders owning 5% or more of a “loss corporation” (a corporation entitled to use NOL or other loss carryforwards) have increased their aggregate ownership of stock in such corporation by more than 50 percentage points during any three-year period. If an “ownership change” occurs, Section 382 of the Code imposes an annual limitation on the amount of post-ownership change taxable income that may be offset with pre-ownership change NOLs of the loss corporation experiencing the ownership change. The annual limitation is calculated by multiplying the loss corporation’s value immediately before the ownership change by the greater of the long-term tax-exempt rate determined by the IRS in the month of the ownership change or the two preceding months. This annual limitation may be adjusted to reflect any unused annual limitation for prior years and certain recognized built-in gains and losses for the year. Section 383 of the Code also imposes a limitation on the amount of tax liability in any post-ownership change year that can be reduced by the loss corporation’s pre-ownership change tax credit carryforwards.

It is expected that the merger between Nile and Capricor resulted in another “ownership change” of Nile. Accordingly, the Company’s ability to utilize Nile’s NOL and tax credit carryforwards may be substantially limited. These limitations could, in turn, result in increased future tax payments for the Company, which could have a material adverse effect on the business, financial condition, or results of operations of the Company.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse effect on our business and stock price.

The Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley, as well as rules implemented by the SEC and any market on which the Company's shares may be listed in the future, impose various requirements on public companies, including those related to corporate governance practices. The Company's management and other personnel will need to devote a substantial amount of time to these requirements. Moreover, these rules and regulations will increase the Company's legal and financial compliance costs and will make some activities more time consuming and costly.

Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, requires that we establish and maintain an adequate internal control structure and procedures for financial reporting. Our annual reports on Form 10-K must contain an assessment by management of the effectiveness of our internal control over financial reporting and must include disclosure of any material weaknesses in internal control over financial reporting that we have identified. The requirements of Section 404 are ongoing and also apply to future years. We expect that our internal control over financial reporting will continue to evolve as our business develops. Although we are committed to continue to improve our internal control processes and we will continue to diligently and vigorously review our internal control over financial reporting in order to ensure compliance with Section 404 requirements, any control system, regardless of how well designed, operated and evaluated, can provide only reasonable, not absolute, assurance that its objectives will be met. Therefore, we cannot be certain that in the future material weaknesses or significant deficiencies will not exist or otherwise be discovered. If material weaknesses or other significant deficiencies occur, these weaknesses or deficiencies could result in misstatements of our results of operations, restatements of our consolidated financial statements, a decline in our stock price, or other material adverse effects on our business, reputation, results of operations, financial condition or liquidity.

Special Note Regarding Forward-Looking Statements

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which statements involve substantial risks and uncertainties. Forward-looking statements generally relate to future events or our future financial or operating performance. In some cases, you can identify forward-looking statements because they contain words such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “could,” “intends,” “target,” “projects,” “contemplates,” “be “estimates,” “predicts,” “potential” or “continue” or the negative of these words or other similar terms or expressions that concern our expectations, strategy, plans or intentions. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- the development of our drug candidates, including when we expect to undertake, initiate and complete clinical trials of our product candidates;
- the regulatory approval of our drug candidates;
- our use of clinical research centers, third party manufacturers and other contractors;
- our ability to find collaborative partners for research, development and commercialization of potential products;
- our ability to manufacture products for clinical and commercial use;
- our ability to protect our patents and other intellectual property;
- our ability to market any of our products;
- our history of operating losses;
- our ability to secure adequate protection for our intellectual property;
- our ability to compete against other companies and research institutions;
- the effect of potential strategic transactions on our business;

- acceptance of our products by doctors, patients or payors and the availability of reimbursement for our product candidates;
- our ability to attract and retain key personnel;
- the volatility of our stock price; and
- other risks and uncertainties detailed in the section of this prospectus entitled “Risk Factors”.

We caution you that the forward-looking statements highlighted above do not encompass all of the forward-looking statements made in this prospectus.

You should not rely upon forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this prospectus primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, results of operations and prospects. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in the section of this prospectus entitled “Risk Factors” and elsewhere in this prospectus. Moreover, we operate in a very competitive and challenging environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this prospectus. We cannot assure you that the results, events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements.

The forward-looking statements made in this prospectus relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this prospectus to reflect events or circumstances after the date of this prospectus or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

This prospectus also contains statistical data, estimates, and forecasts that are based on independent industry publications or other publicly available information, as well as other information based on our internal sources. Although we believe that the third-party sources referred to in this prospectus are reliable, we have not independently verified the information provided by these third parties. While we are not aware of any misstatements regarding any third-party information presented in this prospectus, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed under the section of this prospectus entitled “Risk Factors” and elsewhere in this prospectus.

USE OF PROCEEDS

We will not receive any proceeds from the sale of the common stock by the selling stockholders. However, we may receive up to approximately $570,497 in the aggregate upon the exercise of the warrants. We intend to use the proceeds received from any exercise of the warrants to further develop our product candidates and for other general corporate and working capital purposes.

Our management will have broad discretion regarding the use of proceeds from the exercise of any warrants, and investors will be relying on the judgment of our management regarding the application of the proceeds from the exercise of any warrants. We may change the use of these proceeds from those described above as a result of various factors such as competitive developments, the results of our early clinical development and commercialization efforts, acquisition and investment opportunities and other factors.

MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Prior to November 20, 2013, our common stock traded on the OTCQB tier of the OTC Markets under the symbol "NLTX.PK". On November 20, 2013, our symbol changed to "NLTXD". On December 20, 2013, we began trading under the symbol "CAPR". On November 20, 2013, we effected a 1:50 reverse stock split of all of our outstanding shares of common stock (the "Reverse Stock Split"). The following table lists the high and low prices of our common stock as quoted, in U.S. dollars, by the OTCQB during each quarter within the last two completed fiscal years, as well as the first quarter of 2014. The quotations reflect inter-dealer prices, without retail markup, markdown or commission, and may not represent actual transactions. Consequently, the information provided below may not be indicative of our common stock price under different conditions. All share and per share information set forth in this prospectus has been adjusted to reflect the Reverse Stock Split. The closing price of our common stock as reported on the OTCQB was $4.95 on May 21, 2014.

	High	Low
Year ended December 31, 2012		
First Quarter	$29.50	$22.00
Second Quarter	25.00	3.50
Third Quarter	7.50	4.50
Fourth Quarter	5.50	1.00
Year ended December 31, 2013		
First Quarter	10.00	2.00
Second Quarter	5.50	2.50
Third Quarter	3.50	1.50
Fourth Quarter	5.00	2.15
Year ended December 31, 2014		
First Quarter	17.15	2.50

Holders

According to the records of our transfer agent, American Stock Transfer & Trust Company, as of May 15, 2014, we had 107 holders of record of common stock, not including those held in "street name."

Dividends Policy

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our Board of Directors or any authorized committee thereof after considering our financial condition, results of operations, capital requirements, business prospects and other factors our Board of Directors or such committee deems relevant, and subject to applicable Delaware law and the restrictions contained in our current or future financing instruments.

Capitalization

The following table sets forth our cash, cash equivalents and marketable securities and capitalization as of March 31, 2014:

- on an actual basis; and
- on a pro forma basis after giving effect to the exercise of the outstanding warrants to purchase 251,044 shares of our common stock.

The information in this table should be read in conjunction with “Use of Proceeds” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our condensed consolidated financial statements and related condensed consolidated notes thereto included elsewhere in this prospectus.

As of March 31, 2014

	Actual (unaudited)	Pro Forma (unaudited)	Pro Forma As Adjusted (unaudited)
Cash, cash equivalents and marketable securities	$13,305,376	$ 570,497	$13,875,873
DEBT			
Loan payable	3,961,733	-	3,961,733
STOCKHOLDERS' EQUITY (DEFICIT)			
Preferred stock, $0.001 par, 5,000,000 shares authorized, none issued and outstanding	-	-	-
Common stock, $0.001 par, 50,000,000 shares authorized 11,690,859 shares issued and outstanding actual, 251,044 shares issued and outstanding Pro Forma, 11,941,903 shares issued and outstanding Pro Forma as adjusted	11,690	251	11,941
Additional paid-in capital	15,638,420	570,246	16,208,666
Subscription receivable	-	-	-
Accumulated other comprehensive loss	(404)	-	(404)
Deficit accumulated during the development stage	(17,309,146)	-	(17,309,146)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(1,659,440)	570,497	(1,088,943)
TOTAL CAPITALIZATION	$2,302,293	$ 570,497	$2,872,790

The table set forth above is based on 11,690,859, the number of shares of our common stock outstanding as of March 31, 2014. The table excludes:

- 4,709,000 shares of our common stock issuable upon the exercise of outstanding stock options with a weighted average exercise price of approximately $0.58 per share as of March 31, 2014;

- 81,237 shares of our common stock issuable upon the exercise of outstanding warrants with a weighted average exercise price of approximately $63.33 per share as of March 31, 2014 (excluding the shares underlying the warrants being registered hereby); and

- 2,178,214 shares of our common stock reserved for issuance as of March 31, 2014 under our: (1) Amended and Restated 2005 Stock Option Plan; (2) 2006 Stock Option Plan; (3) 2012 Restated Equity Incentive Plan; and (4) 2012 Non-Employee Director Stock Option Plan.

Management's Discussion and Analysis of Results of Operations and Financial Condition

The following discussion of our financial condition and results of operations should be read in conjunction with the consolidated financial statements, condensed consolidated financial statements, the consolidated notes, and condensed consolidated notes to those statements included elsewhere in this prospectus. This discussion includes forward-looking statements that involve risks and uncertainties. As a result of many factors, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

Our mission is to improve the treatment of diseases by commercializing innovative therapies, with a primary focus on heart disease. Our executive offices are located at 8840 Wilshire Blvd., 2nd Floor, Beverly Hills, California 90211. Our telephone number is (310) 358-3200 and our Internet address is *www.capricor.com*.

Consummation of the Merger

On November 20, 2013, pursuant to that certain Agreement and Plan of Merger and Reorganization dated as of July 7, 2013, as amended by that certain First Amendment to Agreement and Plan of Merger and Reorganization dated as of September 27, 2013, or, as so amended, the Merger Agreement, by and among Nile Therapeutics, Inc., a Delaware corporation, or Nile, Bovet Merger Corp., a Delaware corporation and a wholly-owned subsidiary of Nile, or Merger Sub, and Capricor, Merger Sub merged with and into Capricor and Capricor became a wholly-owned subsidiary of Nile. Immediately prior to the effective time of the merger, or the Effective Time, and in connection therewith, Nile filed certain amendments to its certificate of incorporation which, among other things (i) effected a 1-for-50 reverse split of its common stock, (ii) changed its corporate name from "Nile Therapeutics, Inc." to "Capricor Therapeutics, Inc.," and (iii) effected a reduction in the total number of authorized shares of common stock from 100,000,000 to 50,000,000, and a reduction in the total number of authorized shares of preferred stock from 10,000,000 to 5,000,000.

At the Effective Time and in connection with the merger between Capricor and Nile, each outstanding share of Capricor's Series A-1, Series A-2 and Series A-3 Preferred Stock was converted into one share of common stock, par value $0.001 per share, of Capricor.

As a result of the merger between Capricor and Nile and in accordance with the terms of the Merger Agreement, each outstanding share of Capricor common stock was converted into the right to receive approximately 2.07 shares of the common stock of Capricor Therapeutics, par value $0.001 per share, on a post 1-for-50 reverse stock split basis.

Immediately after the Effective Time and in accordance with the terms of the Merger Agreement, the former Capricor stockholders owned approximately 90% of the outstanding common stock of Capricor Therapeutics, and the Nile stockholders owned approximately 10% of the outstanding common stock of Capricor Therapeutics, in each case on a fully-diluted basis. For accounting purposes, the merger between Capricor and Nile is accounted for as a reverse merger with Capricor as the accounting acquiror (legal acquiree) and Nile as the accounting acquiree (legal acquiror).

After the Effective Time, each then outstanding Capricor stock option, whether vested or unvested, was assumed by Capricor Therapeutics in accordance with the terms of the (i) 2006 Stock Option Plan, (ii) 2012 Restated Equity Incentive Plan, or (iii) 2012 Non-Employee Director Stock Option Plan, as applicable, and the stock option agreement under which each such option was issued. All rights with respect to Capricor common stock under outstanding Capricor options were converted into rights with respect to Capricor Therapeutics common stock.

Since Capricor was deemed to be the accounting acquiror in the merger, the historical financial information for periods prior to the merger reflects the financial information and activities solely of Capricor and not of Nile. The historical equity of Capricor has been retroactively adjusted to reflect the equity structure of Capricor Therapeutics using the respective exchange ratio established in the merger between Capricor and Nile, which reflects the number of shares Capricor Therapeutics issued to equity holders of Capricor as a result of the merger. The retroactive adjustment of Capricor’s equity includes Capricor’s preferred stock as if such shares of preferred stock had been converted into Capricor common stock at the respective dates of issuance, which is consistent with the terms of the merger. Accordingly, all common and preferred shares and per share amounts for all periods presented in the condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q and condensed consolidated notes thereto have been adjusted retrospectively, where applicable, to reflect the respective exchange ratio established in the merger.

Capricor, our wholly-owned subsidiary, was founded in 2005 as a Delaware corporation based on the innovative work of its founder, Eduardo Marbán, M.D., Ph.D., and his collaborators. First located in Baltimore, Maryland, adjacent to The Johns Hopkins University, or JHU, where Dr. Marbán was chief of cardiology, Capricor moved to Los Angeles, California in 2007 when Dr. Marbán become Director of the Heart Institute at Cedars-Sinai Medical Center, or CSMC. Capricor's labs are located in space that Capricor leases from CSMC.

We currently have six drug candidates in various stages of development:

CAP-1002: Capricor's lead product candidate consists of allogeneic cardiosphere-derived cells, or CDCs. CAP-1002 is currently being tested in Capricor's ALLSTAR Phase I/II clinical trial which will determine if the cells can lead to reduction in scar size in patients who have had a heart attack. It is a dual cohort clinical trial that has two independently recruiting strata: the first are patients who have recently experienced a myocardial infarction, or MI (30-90 days post MI); the second are patients who have suffered an MI within one year (90 days to one-year post MI) to see if the cells can reduce the size of older, more established scar. In addition to measuring scar size, ALLSTAR will also look at a variety of clinical and quality of life endpoints. Phase I of the ALLSTAR trial was a 14 patient trial conducted at three sites to determine if allogeneic CDCs are safe for patients. Phase I of the trial was funded in large part by a grant received from the National Institutes of Health, or NIH. The primary endpoints focused on acute effects of cell delivery and potential immune consequences of allogeneic cell delivery. Patient enrollment was completed for the Phase I portion of the trial on October 11, 2013. On December 15, 2013, Capricor received notification from the National Heart Lung and Blood Institute, or the NHLBI, Gene and Cell Therapy Data Safety Monitoring Board that the 14-patient Phase I portion had met its safety endpoints and that Capricor was cleared to begin the Phase II portion of the trial. Capricor began enrollment of the Phase II portion of the ALLSTAR study in the first quarter of 2014. Phase II is an estimated 300 patient, double-blind, randomized, placebo-controlled trial which is powered to detect a reduction in infarct (scar) size as measured by MRI in both groups of patients, those with recent and chronic MI, at the one year follow-up. As infarct size was reduced significantly in the CADUCEUS patients at six months, Capricor intends to get a preliminary readout of ALLSTAR at six months post infusion. Phase II of ALLSTAR is being funded in large part through the support of the California Institute for Regenerative Medicine, or CIRM. Recently, Capricor entered into a Collaboration Agreement and Exclusive License Option with Janssen Biotech, Inc., or Janssen. Under the agreement, Janssen has an exclusive option to enter into an exclusive license agreement with Capricor, pursuant to which, if exercised, Janssen would receive a worldwide, exclusive license to exploit CAP-1002 as well as certain allogeneic cardiospheres and cardiosphere-derived cells in the field of cardiology.

Additionally, Capricor has been awarded a grant from the NIH to support further development of the CAP-1002 product. Dr. Eduardo Marbán of CSMC, and Capricor's founder, has received approval on an investigational new drug, or IND, for a trial named "DYNAMIC" (dilated cardiomyopathy intervention with allogeneic myocardially-regenerative cells). Presently, Capricor is in discussions with the NIH with respect to the possible use of the funds subject to the grant for other clinical purposes. If approved, it is possible that Capricor will deploy this grant to fund the Phase I portion of the DYNAMIC trial. The Phase I portion of the DYNAMIC trial would use CAP-1002 to treat patients with advanced heart failure and a recent hospitalization for such. Capricor's decision to become involved in the DYNAMIC trial will depend on multiple factors, including, but not limited to: approval by the NHLBI to utilize the grant monies to fund the DYNAMIC trial, the ability of Capricor to reach an agreement with CSMC regarding the clinical

operations aspect of the trial, and the assessment by Capricor of the appropriateness of DYNAMIC with respect to our pipeline development plan.

- **CAP-1001:** CAP-1001 consists of autologous CDCs. This product was used in the Phase I CADUCEUS clinical trial, which was sponsored and conducted by CSMC in collaboration with JHU. In that study, 25 patients were enrolled, of which 17 patients received autologous CDCs. 16 of the 17 treated patients showed a mean reduction of approximately 45% in scar mass and an increase in viable heart muscle one-year post heart attack. The eight patients in the control group had no significant change in infarct (scar) size. At present there is no plan for another clinical trial for CAP-1001. The data from CADUCEUS, using autologous CDCs, suggests that the cells are effective in reducing scar within several months of a heart attack. The ALLSTAR trial is designed to validate the results of CADUCEUS using an allogeneic product while also looking for potential efficacy in patients between 90 days and one year post MI with a more chronic scar, a patient population that CADUCEUS was not designed to study.

- **CSps:** CSps are multicellular clusters called cardiospheres, a 3D micro-tissue from which CDCs are derived, and have shown significant healing effects in pre-clinical models of heart failure. While Capricor considers the CSps an important product, at present there is no plan for a clinical trial for CSps.

- **Exosomes**: Exosomes are nano-sized, membrane-enclosed vesicles, or "bubbles", that are filled with select molecules, including proteins and microRNAs, which, when released, send messages to neighboring cells to regulate cellular functions. Exosomes act as a transport vehicle out of the cell for microRNA, other fragments of genetic material and proteins that act as messengers between cells, ultimately providing regulatory function for many cell processes, including inflammation, angiogenesis, programmed cell death (apoptosis) and scarring. Research has shown that exogenous exosomes can be used as therapeutic agents aimed to direct or, in some cases, re-direct cellular activities. Their size, ease of crossing cell membranes, and ability to communicate in native cellular language makes them a class of exciting and novel therapeutic agents. Capricor is currently in pre-clinical testing to explore the possible future therapeutic benefits that exosomes may possess.

- **Cenderitide (CD-NP)**: Cenderitide is a chimeric natriuretic peptide that is being considered for the treatment of heart failure. To date, we have explored the use of cenderitide in acute heart failure admissions as well as in the setting of patients in the vulnerable post-hospitalization phase. Any further development of cenderitide is subject to our ability to either raise additional capital or enter into a strategic transaction in which a strategic partner provides the capital necessary to continue development activities. We are currently evaluating whether we will proceed with further clinical development of this product.

- **CU-NP**: CU-NP is a pre-clinical rationally-designed natriuretic peptide that consists of amino acid chains identical to those produced by the human body, specifically the ring structure of C-type natriuretic peptide, or CNP, and the N- and C-termini of Urodilatin, or URO. Any further development of CU-NP is subject to our ability to either raise additional capital or enter into a strategic transaction in which a strategic partner provides the capital necessary to continue development activities. We are currently evaluating whether we will proceed with further clinical development of this product.

We have no product sales to date and will not have the ability to generate any product revenue until after we have received approval from the U.S. Food and Drug Administration, or the FDA, or equivalent foreign regulatory bodies to begin selling our pharmaceutical product candidates. Developing pharmaceutical products is a lengthy and very expensive process. Even if we obtain the capital necessary to continue the development of our product candidates, whether through a strategic transaction or otherwise, we do not expect to complete the development of a product candidate for many years, if ever. To date, most of our development expenses have related to our product candidates, CAP-1002 and cenderitide. As we proceed with the clinical development of CAP-1002 and other potential indications for CAP-1002, or if we further develop cenderitide or other additional products, our expenses will further increase. To the extent that we are successful in acquiring additional product candidates for our development pipeline, our need to finance further research and development activities will continue increasing. Accordingly, our success depends not only on the safety and efficacy of our product candidates, but also on our ability to finance the development of the products. Our major sources of working capital have been proceeds from private and public equity sales, grants received from the NIH, a payment from Janssen, and a loan award from CIRM.

Research and development, or R&D, expenses consist primarily of salaries and related personnel costs, clinical patient costs, consulting fees, costs of manufacturing personnel and supplies, costs of service providers for pre-clinical, clinical and certain legal expenses resulting from intellectual property prosecution, stock compensation expense and other expenses relating to the design, development, testing and enhancement of our product candidates. Except for certain capitalized patent expenses, R&D costs are expensed as incurred.

General and administrative, or G&A, expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, stock compensation expense, accounting, legal and other professional fees, consulting expenses, rent for corporate offices, business insurance and other corporate expenses.

Our results have included non-cash compensation expense as a result of the issuance of stock options and warrants, as applicable. We expense the fair value of stock options and warrants over their vesting period as applicable. When more precise pricing data is unavailable, we determine the fair value of stock options using the Black-Scholes option-pricing model. The terms and vesting schedules for share-based awards vary by type of grant and the employment status of the grantee. Generally, the awards vest based upon time-based or performance-based conditions. Performance-based conditions generally include the attainment of goals related to our financial performance and product development. Stock-based compensation expense is included in the condensed consolidated statements of operations under G&A or R&D expenses, as applicable. We expect to record additional non-cash compensation expense in the future, which may be significant.

Results of Operations for the three months ended March 31, 2014 and 2013; and the fiscal years ending 2013 and 2012

General and Administrative Expenses. G&A expenses for the three months ended March 31, 2014 and 2013 were approximately $0.9 million and $0.5 million, respectively. The increase in the first quarter of 2014 of approximately $0.4 million compared to the same period of 2013 is primarily attributable to an increase of approximately $0.2 million in professional fees related to legal, consulting and accounting work related to the merger between Capricor and Nile, as well as additional expenses related to relevant public company compliance. Additionally, there was an increase of approximately $0.1 million in compensation costs related to increased headcount.

G&A expenses for the years ended December 31, 2013 and 2012 were approximately $2.2 million and $1.4 million, respectively. The increase of approximately $0.8 million compared to the same period of 2012 is primarily attributable to an increase of approximately $0.2 million in compensation costs, primarily related to increased headcount. Additionally, there was an increase in rent expense of approximately $0.1 million due to us amending our then current lease arrangement to provide for additional office space at our corporate offices. Additionally, there was an increase in professional fees related to legal, consulting and accounting work primarily related to the merger between Nile and Capricor of approximately $0.3 million compared to the same period of 2012.

Research and Development Expenses. R&D expenses for three months ended March 31, 2014 and 2013 were approximately $1.4 million and $1.2 million, respectively. The increase of approximately $0.2 million over the same period of 2013 is primarily due to the timing of clinical development activities of CAP-1002 in our Phase I/II trial throughout 2013 and 2014. This resulted in an increase of approximately $0.2 million in clinical costs primarily related to patient costs, site costs and expenses for the operational team that supports our clinical trial.

R&D expenses for the years ended December 31, 2013 and 2012 were approximately $5.2 million and $2.6 million, respectively. The increase of approximately $2.6 million over the same period of 2012 is primarily due to the fact that Capricor was actively conducting clinical development activities of CAP-1002 in our Phase I/II trial throughout 2013. This resulted in an increase of approximately $2.1 million in clinical costs primarily related to contract research organizations for statistical programming and data management, as well as patient costs and expenses for the operational team that supports our clinical trial. Additionally, we had an increase of approximately $0.3 million in manufacturing costs, primarily related to the supplies and testing required to release our clinical product.

CAP-1002 – Although the development of CAP-1002 is in its early stages, we believe that it has the potential to treat heart disease. On December 15, 2013 the NHLBI Gene and Cell Therapy Data Safety Monitoring Board gave Capricor approval to move into the Phase II portion of the ALLSTAR trial. We expect to spend approximately $7.5 to $10.0 million during 2014 on the development of CAP-1002, which is primarily related to our Phase II ALLSTAR trial. The Phase I portion of the trial was funded in large part through a grant received from the NIH. We began enrollment of the Phase II portion of the ALLSTAR trial in the first quarter of 2014. Phase II is an estimated 300

patient, double blind, placebo controlled, multi-centered study in which CAP-1002 is administered to patients via intracoronary infusion within 30 days to one year following a heart attack. Phase II is substantially funded through the support of a loan award from CIRM for approximately $19.8 million. The trial will measure several endpoints, including infarct size. Additional endpoints include left ventricular end-systolic and diastolic volume and ejection fraction at six and twelve months. Our strategy for further development of CAP-1002 will depend to a large degree on the outcome of these planned studies.

CAP-1001 – In 2011, CSMC, in collaboration with JHU, completed a Phase I, 25 patient clinical trial called CADUCEUS. In this study, 25 patients were enrolled who had suffered a heart attack within a mean of 65 days. 17 of those patients received CAP-1001 and the remaining eight received standard of care. 12 months after the study was completed, no measurable safety effects occurred in the 17 patients who were treated with CAP-1001. 16 of the 17 treated patients showed a mean reduction of approximately 45% in scar mass and an increase in viable heart muscle one-year post heart attack. The eight patients in the control group had no significant change in infarct (scar) size. At present, there is no plan for another clinical trial for CAP-1001. Capricor's strategy for further development of CAP-1001 will depend to a large degree on the outcome of its trial involving its CAP-1002 product and its ability to obtain significant capital to conduct further studies to further develop this product.

CSps – This product candidate is multicellular clusters called cardiospheres. This product is in pre-clinical development and has yet to be studied in humans. At present, there is no plan for a clinical trial of CSps.

Exosomes – Exosomes are nano-sized, membrane-enclosed vesicles, or “bubbles”, that are filled with select molecules, including proteins and microRNAs, which, when released, send messages to neighboring cells to regulate cellular functions. Capricor is currently in pre-clinical testing to explore the possible future therapeutic benefits that exosomes may possess.

Cenderitide – The Company acquired the rights to cenderitide in 2006, and incurred substantial losses surrounding the development of the product. Prior to the merger between Capricor and Nile, Nile had incurred approximately $19.9 million in expenses directly relating to the cenderitide development program through September 30, 2013. We are currently evaluating whether to proceed with further clinical development of this product.

CU-NP – The Company acquired the rights to CU-NP in September 2008. Prior to the merger between Capricor and Nile, Nile had incurred approximately $0.7 million directly relating to the CU-NP development program through September 30, 2013.We are currently evaluating whether to proceed with further clinical development of this product.

Our expenditures on current and future clinical development programs, particularly our CAP-1002 and cenderitide programs, are expected to be substantial and to increase in relation to our available capital resources. However, these planned expenditures are subject to many uncertainties, including the results of clinical trials and whether we develop any of our drug candidates with a partner or independently. As a result, we cannot predict with any significant degree of certainty the amount of time which will be required to complete our clinical trials, the costs of completing research and development projects or whether, when and to what extent we will generate revenues from the commercialization and sale of any of our product candidates. The duration and cost of clinical trials may vary significantly over the life of a project as a result of unanticipated events arising during clinical development and a variety of other factors, including:

- the number of trials and studies in a clinical program;
- the number of patients who participate in the trials;
- the number of sites included in the trials;
- the rates of patient recruitment and enrollment;
- the duration of patient treatment and follow-up;
- the costs of manufacturing our drug candidates; and
- the costs, requirements and timing of, and the ability to secure, regulatory approvals.

Grant Income. Grant income for the three months ended March 31, 2014 and 2013 was approximately $0 and $0.2 million, respectively. This decrease in grant income in the first quarter of 2014 as compared to 2013 is due to the timing of activities under certain research and development projects that are covered under grant awards. These activities are not necessarily consistent from project to project and period to period. Additionally, in the last six months of 2013, Capricor’s active grants were approaching the ends of their respective project periods.

Grant income for the years ended December 31, 2013 and 2012 was approximately $0.5 million and $1.9 million, respectively. This decrease in grant income in 2013 as compared to 2012 is primarily due to the timing of activities under certain research and development projects that are covered under grant awards. These activities are not necessarily consistent from project to project and period to period. Additionally, in 2013 Capricor's primary grants were approaching the ends of their respective project periods.

Collaboration Income. As a result of the Collaboration Agreement and Exclusive License Option with Janssen, or the Janssen Agreement, income for the three months ended March 31, 2014 and 2013 was approximately $1.0 million and $0, respectively. The increase in the three months ended March 31, 2014 over the same period in 2013 is due to the fact that the Janssen Agreement was entered into with Janssen in late 2013, and a payment of $12.5 million was received by Capricor pursuant to the terms of the Janssen Agreement during the first quarter of 2014. A ratable portion of the payment to Capricor was recognized during the three months ended March 31, 2014.

Investment Income (Loss). Investment income (loss) for the three months ended March 31, 2014 and 2013 was $153 and $18,889, respectively. This decrease in investment income in the first quarter of 2014 as compared to the same period in 2013 is due to the timing of interest payments in the marketable securities account, as well as the principal balance in the marketable securities account being higher in the three month period ending March 31, 2013 as compared to March 31, 2014.

Investment income (loss) for the years ended December 31, 2013 and 2012 was $(11,890) and $28,785, respectively. This decrease in investment income over the same period in 2012 is primarily due to realized losses on the marketable securities account as securities held were sold in 2013 due to additional operational cash needs.

Interest Expense. Interest expense for the three months ended March 31, 2014 and 2013 was $25,327 and $3,711, respectively. This increase in interest expense in the first quarter of 2014 as compared to the same period in 2013 is due to the interest on the CIRM loan award, related to the principal balance being higher in the first quarter of 2014, as compared to the same period of 2013.

Interest expense for the years ended December 31, 2013 and 2012 was $58,134 and $0, respectively. This increase in interest expense over the same period in 2012 is due to the interest on the CIRM loan award, which was not disbursed until 2013.

Impairment of Goodwill. Goodwill impairment for each of the three months ended March 31, 2014 and 2013 was $0. There was impairment as a result of goodwill recorded at the consummation of the merger between Capricor and Nile of approximately $1.9 million which we deemed fully impaired as of December 31, 2013.

Goodwill impairment for the years ended December 31, 2013 and 2012 was approximately $1.9 million and $0, respectively. This impairment is a result of goodwill recorded at the consummation of the merger of approximately $1.9 million which the Company deemed fully impaired as of December 31, 2013.

Liquidity and Capital Resources for the three months ending March 31, 2014 and 2013; and the fiscal years ending 2013 and 2012

The following table summarizes our liquidity and capital resources as of March 31, 2014 and December 31, 2013 and our net increase (decrease) in cash and cash equivalents for the three months ended March 31, 2014 and 2013, and is intended to supplement the more detailed discussion that follows. The amounts stated are expressed in thousands.

Liquidity and capital resources	March 31, 2014	December 31, 2013
Cash and cash equivalents	$ 12,979	$ 1,730
Working capital	$ 7,732	$ 1,628
Stockholders' equity (deficit)	$ (1,659)	$ (535)

	Three months ended March 31,	
Cash flow data	2014	2013
Cash provided by (used in):		
Operating activities	$ 11,343	$ (1,176)
Investing activities	(94)	431
Financing activities	1	857
Net increase in cash and cash equivalents	$ 11,250	$ 112

Our total cash resources, not including restricted cash, as of March 31, 2014 were approximately $13.0 million compared to approximately $1.7 million as of December 31, 2013. Total marketable securities, consisting primarily of United States treasuries, were approximately $0.3 million as of each of March 31, 2014 and December 31, 2013. As of March 31, 2014, we had approximately $17.6 million in total liabilities, of which approximately $11.5 million is recorded as deferred income under the Janssen Agreement, and approximately $7.7 million in net working capital. We incurred a net loss of approximately $1.2 million and had positive cash flow from operating activities of approximately $11.3 million for the three months ended March 31, 2014. Since July 5, 2005 (inception) through March 31, 2014, we have incurred an aggregate net loss of approximately $17.3 million. To the extent we obtain sufficient capital and/or long-term debt funding and are able to continue developing our product candidates, we expect to continue to incur substantial and increasing losses, which will continue to generate negative net cash flow from operating activities as we expand our technology portfolio and engage in further research and development activities, particularly the conducting of pre-clinical studies and clinical trials.

We had cash flow from operating activities of approximately $11.3 million, $(1.2) million and $(1.8) million for the three months ended March 31, 2014 and 2013 and for the period from July 5, 2005 (inception) through March 31, 2014, respectively. The difference of approximately $12.5 million in cash from operating activities for the three months ended March 31, 2014 as compared to the same period of 2013 is primarily due to our receipt of the $12.5 million payment under the terms of the Janssen Agreement. To the extent we obtain sufficient capital and/or long-term debt funding and are able to continue developing our product candidates, we expect to continue incurring substantial and increasing losses, which will continue to generate negative net cash flows from operating activities as we expand our technology portfolio and engage in further research and development activities, particularly in conducting pre-clinical studies and clinical trials.

We had cash flow from investing activities of approximately $(0.1) million for the three months ended March 31, 2014, cash flow from investing activities of approximately $0.4 million for the three months ended March 31, 2013, and cash flow from investing activities of approximately $(0.9) million for the period from July 5, 2005 (inception) through March 31, 2014. The difference in cash used in investing activities for the three months ended March 31, 2014 as compared to the same period of 2013 is primarily due to the proceeds from sales of marketable securities.

We had positive cash flow from financing activities of approximately $0, $0.9 million and $15.6 million for the three months ended March 31, 2014 and 2013 and for the period from July 5, 2005 (inception) through March 31, 2014, respectively. The cash flow of approximately $0.9 million in the three months ended March 31, 2013 is a result of Capricor's CIRM loan financing, with no such funds received during the three months ended March 31, 2014.

The following table summarizes the Company's liquidity and capital resources as of and for each of the last two fiscal years, and is intended to supplement the more detailed discussion that follows. The amounts stated are expressed in thousands.

Liquidity and capital resources	December 31, 2013	December 31, 2012
Cash and cash equivalents	$ 1,730	$ 170
Working Capital	$ 1,628	$ 4,664
Stockholders' equity (deficit)	$ (535)	$ 4,894

	Years ending December 31,	
Cash flow data	2013	2012
Cash provided by (used in):		
Operating activities	$ (6,144)	$ (2,063)
Investing activities	3,778	(4,317)
Financing activities	3,925	5,000
Net increase (decrease) in cash and cash equivalents	$ 1,559	$ (1,380)

The Company's total cash resources as of December 31, 2013 were approximately $1.7 million compared to approximately $0.2 million as of December 31, 2012. Total marketable securities, consisting primarily of United States treasuries, were approximately $0.3 million as of December 31, 2013 and approximately $4.2 million as of December 31, 2012. As of December 31, 2013, the Company had approximately $6.1 million in liabilities, and approximately $1.6 million in net working capital. The Company incurred a net loss of approximately $8.9 million and had negative cash flow from operating activities of approximately $6.1 million for the year ended December 31, 2013. Since July 5, 2005 (inception) through December 31, 2013, the Company has incurred an aggregate net loss of approximately $16.1 million, while negative cash flow from operating activities has amounted to approximately $13.1 million. To the extent we obtain sufficient capital and/or long-term debt funding and are able to continue developing our product candidates, we expect to continue to incur substantial and increasing losses, which will continue to generate negative net cash flow from operating activities as we expand our technology portfolio and engage in further research and development activities, particularly the conducting of pre-clinical studies and clinical trials.

The Company had negative cash flow from operating activities of approximately $6.1 million, $2.1 million and $13.1 million for the years ended December 31, 2013 and 2012, and for the period from July 5, 2005 (inception) through December 31, 2013, respectively. The difference of approximately $4.0 million in cash used in operating activities for the year ended December 31, 2013 as compared to the same period of 2012 is primarily due to the fact that Capricor's net loss was substantially higher in 2013 as compared to 2012. Capricor was actively involved in clinical activities relating to the ALLSTAR Phase I/II trial throughout 2013, which increased overall operational losses. To the extent the Company obtains sufficient capital and/or long-term debt funding and is able to continue developing its product candidates, it expects to continue incurring substantial and increasing losses, which will continue to generate negative net cash flows from operating activities as the Company expands its technology portfolio and engages in further research and development activities, particularly in conducting pre-clinical studies and clinical trials.

The Company had positive cash flow from investing activities of approximately $3.8 million for the year ended December 31, 2013, negative cash flow from investing activities of approximately $4.3 million for the year ended December 31, 2012, and negative cash flow from investing activities of approximately $0.8 million for the period from July 5, 2005 (inception) through December 31, 2013. The difference in cash used in investing activities for the year ended December 31, 2013 as compared to the same period of 2012 is primarily due to the proceeds and payments from purchases and sales of marketable securities.

The Company had positive cash flow from financing activities of $3.9 million, $5.0 million and $15.6 million for the years ended December 31, 2013 and 2012, and for the period from July 5, 2005 (inception) through December 31, 2013, respectively. The cash flow of approximately $3.9 million in 2013 is a result of Capricor's CIRM loan financing, and the $5.0 million in 2012 is a result of a portion of the proceeds received from Capricor's A-3 financing.

Phase II of Capricor's ALLSTAR trial has been funded in large part through a loan award from CIRM. Following completion of the Phase II trial would be a Phase IIb and/or Phase III trial. If we continue with a Phase IIb or Phase III trial, we will need substantial additional capital in order to continue the development of CAP-1002. Pursuant to the Janssen Agreement, the CMC package will be developed by the joint efforts of Janssen and Capricor. Capricor will be required to reimburse Janssen for its costs of development up to an agreed-upon maximum amount. If Janssen exercises its exclusive option, Janssen will be responsible for any additional trials with respect to CAP-1002.

We need substantial additional capital in order to continue the development of cenderitide. We are currently evaluating whether to proceed with further clinical development of this product.

From inception through March 31, 2014, Capricor has financed its operations through private sales of its equity securities, NIH grants, a payment from Janssen, and a CIRM loan award. Prior to the merger between Capricor and Nile, Nile financed its operations through public sales of its equity. As we have not generated any revenue from the sale of our products to date, and we do not expect to generate revenue for several years, if ever, we will need to raise substantial additional capital in order to fund our immediate general corporate activities and, thereafter, to fund our

research and development, including our long-term plans for clinical trials and new product development. We may seek to raise additional funds through various potential sources, such as equity and debt financings, or through strategic collaborations and license agreements. We can give no assurances that we will be able to secure such additional sources of funds to support our operations, or if such funds are available to us, that such additional financing will be sufficient to meet our needs. Moreover, to the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates, or grant licenses on terms that may not be favorable to us.

Our estimates regarding the sufficiency of our financial resources are based on assumptions that may prove to be wrong. We may need to obtain additional funds sooner than planned or in greater amounts than we currently anticipate. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include the following:

· the progress of our research activities;

· the number and scope of our research programs;

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- the progress of our pre-clinical and clinical development activities;
- the progress of the development efforts of parties with whom we have entered into research and development agreements;
- our ability to maintain current research and development programs and to establish new research and development and licensing arrangements;
- the cost involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the cost and timing of regulatory approvals.

Financing Activities by the Company

March 2013 Financing. On March 15, 2013, we entered into a convertible note purchase agreement with certain accredited investors pursuant to which we agreed to sell an aggregate principal amount of up to $500,000 of secured convertible promissory notes, or the 2013 Notes, for an aggregate original issue price of $425,000, representing a 15% original issue discount. The closing of the private placement also occurred on March 15, 2013, and resulted in the sale of 2013 Notes in the aggregate principal amount of $450,000 for an aggregate original issue price of $382,500.

On September 27, 2013, we and the holders of the 2013 Notes entered into an amendment to the 2013 Notes, which provided, among other things, that upon a Change of Control (as defined in the 2013 Notes), the conversion price applicable to the 2013 Notes and the exercise price applicable to the warrants issuable upon a Change of Control will be equal to the average dollar volume weighted average price, or VWAP, of our common stock for each trading day during the period from July 8, 2013 to September 30, 2013. The average VWAP during such period was approximately $0.045 per share. Additionally, pursuant to the amendment, upon a conversion of the 2013 Notes in connection with a Change of Control, the holders confirmed that all obligations under the 2013 Notes would be deemed satisfied in full and released us from any claims relating to the 2013 Notes.

On October 21, 2013, we and the holders of the 2013 Notes entered into an amendment to the Convertible Note Purchase Agreement pursuant to which we sold to such holders additional notes having an aggregate principal amount of $120,510, or the Additional Notes. The Additional Notes have identical terms and conditions as the 2013 Notes described above and were allocated among the holders on a pro rata basis based on their initial purchase of the 2013 Notes. In exchange for the issuance of the Additional Notes, we received aggregate gross proceeds of $102,433. The 2013 Notes and the Additional Notes are collectively referred to herein as the 2013 Notes.

The 2013 Notes converted at the close of the merger between Capricor and Nile on November 20, 2013 into 251,044 shares of our common stock on a post-reverse stock split basis. Additionally, 251,044 warrants to purchase our common stock at a strike price of $2.2725, on a post-reverse stock split basis, were issued to the holders of the 2013 Notes. We have filed a Registration Statement on Form S-1 to register for resale the shares of common stock underlying the 2013 Notes.

April 2012 Financing. On March 30, 2012, the Company entered into subscription agreements with certain purchasers pursuant to which we agreed to sell an aggregate of 67,000 shares of our common stock to such purchasers for a purchase price of $20.00 per share (calculated using the post-reverse stock split factor of 1:50). In addition, for each share purchased, each purchaser also received three-fourths of a five-year warrant to purchase an additional share of common stock at an exercise price of $25.00 per share (calculated using the post-reverse stock split factor of 1:50), resulting in the issuance of warrants to purchase an aggregate of 50,250 shares of our common stock. The total gross proceeds from the offering were $1.3 million, before deducting anticipated selling commissions and expenses of approximately $0.2 million. The closing of the offering occurred on April 4, 2012. In connection with the offering, we engaged Roth Capital Partners, LLC, or Roth, to serve as placement agent. Pursuant to the terms of the placement agent agreement, we agreed to pay Roth a cash fee equal to seven percent of the gross proceeds received by us, or approximately $93,800, plus a non-accountable expense allowance of $35,000. Richard B. Brewer, our former Executive Chairman, Joshua A. Kazam, our former President and Chief Executive Officer and a current director of the Company, Daron Evans, our former Chief Financial Officer, and Hsiao Lieu, M.D., our former Executive VP of Clinical Development, participated in the offering on the same terms as the unaffiliated purchasers, and collectively purchased 5,500 shares of our common stock and warrants to purchase 4,125 shares of our common stock for an aggregate purchase price of $110,000.