FORM 10-Q

Quarterly report pursuant to sections 13 or 15(d)

Filing Date: **2008-05-08** | Period of Report: **2008-03-31**
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FILER

ANESIVA, INC.

CIK:**1131517**| IRS No.: **770503399** | State of Incorp.:**DE** | Fiscal Year End: **1231**
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2008

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

For the transition period from _____ to _____

COMMISSION FILE NO. 000-50573

Anesiva, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**77-0503399**
(State or Other Jurisdiction of Incorporation or Organization)	**(IRS Employer Identification Number)**

650 Gateway Boulevard
South San Francisco, California 94080
(650) 624-9600
(Address, including zip code, and telephone number, including area code, of registrant' s principal executive offices)

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

Large accelerated filer ☐	Accelerated filer ☒	Non-accelerated filer ☐	Smaller reporting company ☐
		(Do not check if a smaller reporting company)	

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The total number of shares outstanding of the Registrant' s common stock as of April 30, 2008 was 40,445,831.

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PART I - FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

Anesiva, Inc.
(a development stage company)
Condensed Consolidated Balance Sheets
(In thousands, except per share data)

	March 31, 2008 (Unaudited)	December 31, 2007 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$70,043	$90,840
Prepaid expenses and other current assets	1,609	1,666
Inventories	1,584	559
Total current assets	73,236	93,065
Property and equipment, net	15,602	15,276
Restricted cash	590	590
Other assets	791	805
Total assets	$90,219	$109,736
Liabilities and stockholders' equity		
Current liabilities:		

Accounts payable	$3,375	$3,370
Accrued clinical trial liabilities	1,538	1,219
Accrued compensation	1,791	2,301
Other accrued liabilities	3,173	2,929
Current portion of long term debt	3,053	2,356
Total current liabilities	12,930	12,175
Long-term debt, net of current portion	7,640	8,485
Other long-term liabilities	412	562
Minority interest of the CJV	537	–
Commitments		
Stockholders' equity:		
Common stock, $0.001 par value; 100,000 shares authorized at March 31, 2008 and December 31, 2007; 40,446 and 40,378 shares issued and outstanding at March 31, 2008 and December 31, 2007, respectively	40	40
Additional paid-in capital	298,999	297,239
Accumulated other comprehensive loss	9	–
Deficit accumulated during the development stage	(230,348)	(208,765)
Total stockholders' equity	68,700	88,514
Total liabilities and stockholders' equity	$90,219	$109,736

See accompanying notes to condensed consolidated financial statements.

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Anesiva, Inc.
(a development stage company)
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except per share data)

	For the three months ended March 31,		Period from March 6, 2001 (inception) to March 31,
	2008	2007	2008
Contract revenues	$1	$–	$390
Operating expenses:			
Research and development	13,384	6,962	145,067
General and administrative	8,457	5,754	89,112
Acquired in-process research and development	–	–	5,716
Total operating expenses	21,841	12,716	239,895
Loss from operations	(21,840)	(12,716)	(239,505)
Gain (loss) on sale of assets	–	16	(27)
Interest expense	(283)	–	(1,950)
Interest and other income	531	1,022	9,672
Loss before extraordinary gain	(21,592)	(11,678)	(231,810)
Extraordinary gain	–	–	1,725

Loss before minority interest	(21,592)	(11,678)	(230,085)
Minority interest in loss of the CJV	9	–	9
Net loss	$(21,583)	$(11,678)	$(230,076)
Basic and diluted net loss per common share	$(0.54)	$(0.43)	
Weighted average shares used to compute basic and diluted net loss per common share	40,269	27,315	

See accompanying notes to condensed consolidated financials statements.

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Anesiva, Inc.
(a development stage company)
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	For the three months ended March 31,		Period from March 6, 2001 (inception) to March 31,
	2008	2007	2008
Net loss	$(21,583)	$(11,678)	$(230,076)
Adjustments to reconcile net loss to net cash used in operating activities:			
Minority interest in loss of the CJV	(9)	–	(9)
Depreciation and amortization	290	65	4,674
Extraordinary gain	–	–	(1,725)
Stock-based compensation	1,562	2,047	26,314
Retention plan	–	–	4,828
Write down of and realized loss on sales of marketable securities	–	–	1,255
Interest expense	10	–	24
Non-cash interest expense	–	–	131
Issuance of common stock for licensing fee	–	–	1,536
Acquired in-process research and development	–	–	5,716

Amortization of intangible assets	–	–	448
Loss (gain) on disposal of equipment	–	(16)	27
Changes in assets and liabilities:			
Prepaid expenses and other current assets	57	80	(402)
Inventories	(1,025)	–	(1,584)
Other assets	14	9	(731)
Accounts payable	5	(880)	3,356
Accrued clinical trial liabilities	319	(75)	99
Accrued compensation	(510)	(1,073)	163
Other accrued liabilities	109	(9)	1,503
Net cash used in operating activities	(20,761)	(11,530)	(184,453)
Investing activities			
Cash from consolidation of the CJV	546	–	546
Purchases of property and equipment	(631)	(2,369)	(17,253)
Proceeds from disposal of equipment	–	36	475
Purchases of marketable securities	–	(6,000)	(141,343)
Sales of marketable securities	–	9,462	198,085

Acquisition of Powderject Technologies, Inc.	–	–	(1,442)
Other acquisition related expenditures	–	–	(97)
Net cash provided by (used in) investing activities	(85)	1,129	38,971
Financing activities			
Repayment of equipment loans and capital lease obligations	(158)	–	(351)
Cash acquired	–	–	22,575
Proceeds from issuance of convertible preferred stock, net of issuance costs	–	–	77,887
Proceeds from issuance of common stock	198	464	94,778
Proceeds from debt	–	–	20,627
Net cash provided by financing activities	40	464	215,516
Net increase (decrease) in cash and cash equivalents	(20,806)	(9,937)	70,034
Foreign currency translation adjustment	9	–	9
Cash and cash equivalents at beginning of period	90,840	46,454	–
Cash and cash equivalents at end of period	$70,043	$36,517	$70,043

See accompanying notes to condensed consolidated financial statements.

Anesiva, Inc.
(a development stage company)
Notes to Unaudited Condensed Consolidated Financial Statements
March 31, 2008

1. Basis of Presentation

Anesiva, Inc. ("we" or "Anesiva") was incorporated on January 19, 1999 in Delaware. We are a biopharmaceutical company focused on the development and commercialization of novel therapeutic treatments for pain management. Our portfolio of products includes:

Zingo™ (lidocaine hydrochloride monohydrate) powder intradermal injection system, which was approved by the Food and Drug Administration, the FDA, in August 2007 to reduce the pain associated with peripheral IV insertions or blood draws in children three to 18 years of age. In October 2007, we announced that our Phase 3 clinical trial in adults requested by the FDA met its primary endpoint. In March 2008, we submitted to the FDA a supplemental New Drug Application for the use of Zingo in adults.

Adlea™, a long-acting, site-specific, non-opioid analgesic, is being developed for moderate to severe pain, and has completed multiple Phase 2 trials in post-surgical, musculoskeletal and neuropathic pain. We are initially pursuing an indication for Adlea for the management of acute pain associated with orthopedic surgeries–and are executing on a registration-directed plan which involves multiple Phase 2 and Phase 3 studies. Adlea has also demonstrated activity in early stage trials in the treatment of pain associated with osteoarthritis of the knee.

Zingo and Adlea are different drugs, each with its own mechanisms of action. Zingo is comprised of microcrystals of lidocaine delivered into the skin by compressed gas. Zingo employs a proprietary needle-free dispenser. Adlea is a novel non-opioid drug candidate that is a vanilloid receptor 1 agonist, or TRPV1 agonist, based on the compound capsaicin which provides analgesia for between two and three months.

In October 2007, we entered into a joint venture agreement with Jiangsu Wanbang Biological Pharmaceutical Corporation Limited, or Wanbang, a Fosun company, of XuZhou, China to establish a collaborative venture (the "CJV") which will provide additional manufacturing capacity for worldwide supply utilizing materials sourced in the United States. The operation will provide a second source for Zingo commercial supply, assist with ongoing efforts to reduce manufacturing costs, and provide additional manufacturing capacity. We own a 49% interest in profit or loss of the CJV, which is named Wanbang Anesiva (Jiangsu) Pharmaceuticals Ltd. The production area will be located at an existing Wanbang facility in the city of XuZhou in Jiangsu province. Following completion of the assembly facility in XuZhou, the CJV will seek FDA certification of the facility.

We expect to continue to incur substantial losses over the next several years during our development and commercialization phase. To fully execute our business plan, we will need to complete certain research and development activities and clinical trials. Further, we must receive FDA approval for Adlea before we can commercialize or sell this product candidate in the United States. These activities may span many years and require substantial expenditures to complete and may ultimately be unsuccessful. Any delays in completing these activities could adversely impact us. We plan to meet our capital requirements primarily through issuances of equity and/or debt securities, research and development contract revenue, and in the longer term, revenue from product sales. Accordingly and because we have not generated revenue from the commercialization of Zingo, we are in the development stage as defined by Statement of Financial Accounting standards No.7, *Accounting and Reporting by Development Stage Enterprise*. We operate in one business segment.

The accompanying unaudited condensed consolidated financial statements of Anesiva and its subsidiaries have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions for Form 10-Q and Article 10 of Regulation S-X. In the opinion of management these unaudited condensed consolidated financial statements contain all adjustments, consisting only of normal recurring adjustments, necessary to present fairly Anesiva' s financial position at March 31, 2008 and Anesiva' s results of operations and cash flows for the three-month periods ended March 31, 2008 and 2007. Interim-period results are not necessarily indicative of results of operations and cash flows for a full-year period.

Balance sheet data as of December 31, 2007 were derived from audited financial statements, but do not include all disclosures required by U.S. generally accepted accounting principles.

These unaudited condensed consolidated financial statements and the notes accompanying them should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2007 filed with the Securities and Exchange Commission. Stockholders are encouraged to review the Form 10-K for a broader discussion of Anesiva' s business and the risks inherent therein.

Principles of Consolidation

The consolidated financial statements include the accounts of Anesiva, Inc., its wholly owned subsidiaries, AlgoRx Pharmaceuticals, Inc., located in Secaucus, New Jersey and its partially owned subsidiary, Wanbang Anesiva (Jiangsu) Pharmaceutical Co. Limited, or the CJV, located in Jiangsu, China, whose financial statements are consolidated with ours pursuant to FASB Interpretation No. 46R "*Consolidation of Variable Interest Entities*" ("FIN 46R"), an Interpretation of Accounting Research Bulletin No. 51. In February 2008, we contributed approximately $515,000 to the CJV, in accordance with the cooperative joint venture contract. We are committed to invest up to an additional $514,500 in the CJV. Jiangsu Wanbang Biological Pharmaceutical Corporation Limited, or Wanbang, and an individual investor contributed $546,000 to the CJV. We own a 49% interest in the CJV' s profit or loss. We have guaranteed Wanbang and the individual investor' s return on their investment for a period ending three years after the FDA approval of manufacturing at the CJV. We have determined that we are the primary beneficiary of this entity and have consolidated the results of the CJV (See Note 7). We recorded a minority interest in the condensed consolidated financial statements to account for the ownership interest of Wanbang. Intercompany accounts and transactions have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Cash and Cash Equivalents and Marketable Securities

We invest our excess cash in money market funds and in highly liquid debt instruments of the U.S. government, its agencies and municipalities and corporate notes. All highly liquid investments with stated maturities of 90 days or less from date of purchase are classified as cash equivalents; highly liquid investments with stated maturities of greater than 90 days are classified as marketable securities.

We determine the appropriate classification of investments in debt securities at the time of purchase. Cash equivalents and marketable securities are classified as available-for-sale securities as we do not intend to hold securities with stated maturities greater than twelve months until maturity. Available-for-sale securities are carried at fair value, with unrealized gains and losses reported as a component of accumulated other comprehensive income (loss). Any realized gains or losses on the sale of marketable securities are determined on a specific identification method, and such gains and losses are reflected as a component of interest income or expense.

In August 2007, $900,000 invested in a AAA-rated auction rate security failed to settle in auction. The failure resulted in the interest rate on this investment resetting at a higher rate. We concluded that the impairment for the security was other-than-temporary. At March 31, 2008, we continue to conclude that the impairment for this security is other-than-temporary and are maintaining the carrying amount for that investment at $0. Based on our ability to access our cash and other short-term investments, our expected operating cash flows, and our other sources of cash, we do not anticipate the lack of liquidity on this investment will affect our ability to operate our business as usual. At March 31, 2008, this investment continues being rated AAA and is current in paying interest. Should this auction rate security reset or trade again due to improvements in the corporate debt market, we would then be able to sell it. At March 31, 2008, we invest all of our cash equivalents in a money market fund that holds in United States treasury debt. We hold no marketable securities, except the illiquid security discussed above.

Fair Value of Financial Instruments

The carrying values of our financial instruments, which include cash and cash equivalents, accounts payable and accrued expenses, approximate their fair values.

Inventories

Inventories are stated at the lower of cost or market and consist primarily of material and certain contract manufacturing costs for the production of Zingo that were incurred subsequent to the approval for marketing by the FDA. Cost is determined using the first-in, first-out basis. The valuation of inventory requires us to estimate obsolete or excess inventory based on analysis of future demand for Zingo. If

inventory costs exceed expected market value due to obsolescence, impairment charges may be recorded as deemed necessary by management for the difference between the cost and the market value.

Inventories consist of the following (in thousands):

	March 31, 2008	December 31, 2007
Raw material	$ 556	$ 274
Work in process	1,028	285
Total	$ 1,584	$ 559

Other Assets

Other assets consist of nonmarketable equity investments in Lumen Therapeutics LLC, or Lumen, and Particle Therapeutics Ltd., or Particle Therapeutics, carried at the cost of approximately $89,000 and $50,000, respectively, which approximates their fair values.

Stock-Based Compensation Expense

On January 1, 2006, we adopted SFAS 123(R), which supersedes our previous accounting under APB 25. SFAS 123(R) requires the recognition of compensation expense, using a fair-value based method, for costs related to all share-based payments including stock options and stock issued under our employee stock purchase plan. Under SFAS 123(R), the value of the portion of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service periods in our condensed consolidated statements of operations.

Employee Stock Plans

The 1999 Equity Incentive Plan was adopted in July 1999 and provides for the issuance of stock options. The Anesiva Board of Directors adopted in December 2003 and the stockholders approved in January 2004 the reservation of an additional 250,000 shares of common stock for issuance under the 1999 Equity Incentive Plan and to rename it the 2003 Equity Incentive Plan (the "2003 Plan"). Shares reserved under the 2003 Plan are increased annually for the life of the 2003 Plan on January 1 beginning in 2006, by the lesser of (a) 5% of the number of shares of common stock outstanding on such date and (b) 2,500,000 shares of common stock. However, the board of directors has the authority to designate a smaller number of shares by which the authorized number of shares of common stock will be increased on such date.

Stock options granted under the 2003 Plan may be either incentive stock options, nonstatutory stock options, stock bonuses, or rights to acquire restricted stock. Incentive stock options may be granted to employees with exercise prices of no less than the fair value of the common stock on the grant date and nonstatutory options may be granted to employees, directors, or consultants at exercise prices of no less than 50% of the fair value of the common stock on the grant date, as determined by the board of directors. If, at the time we grant an option, the optionee directly or by attribution owns stock possessing more than 10% of the total combined voting power of all classes of our stock, the option price shall be at least 110% of the fair value and shall not be exercisable more than five years after the date of grant. Options may be granted with vesting terms as determined by the board of directors. Except as noted above, options expire no more than 10 years after the date of grant or earlier if employment is terminated. Stock options granted under the 2003 Plan have vesting terms as determined by the board of directors.

The Board of Directors adopted in December 2003 and the stockholders approved in January 2004 the 2003 Nonemployee Directors' Stock Option Plan (the "Directors' Plan"). The Directors' Plan provides for the automatic grant of nonstatutory stock options to purchase shares of common stock to non-employee directors. Shares reserved under the plan are increased annually on January 1, from 2006 until 2014, by the number of shares of common stock subject to options granted during the prior calendar year. However, the Board of Directors has the authority to designate a smaller number of shares by which the authorized number of shares of common stock will be increased. Stock options

granted under the Directors' Plan vest as follows: initial grants vest in 48 equal monthly installments from the date of grant; and annual grants vest in 12 equal monthly installments from the date of grant.

Stock compensation

We estimate the fair value of each option grant to employees on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	For the three months ended March 31,			
	Stock option plans		ESPP	
	2008	2007	2008	2007
Dividend yield	–	–	–	–
Risk-free interest rate	2.8 %	4.7 %	3.0 %	5.1 %
Volatility	73 %	79 %	74 %	79 %
Expected life (in years)	5.3	5.3	0.5	0.5

In the three months ended March 31, 2008 and 2007, the fair value of the options granted was $3.10 and $5.22, respectively.

Employee stock-based compensation expense recognized in the first quarters of 2008 and 2007 was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Employee stock-based compensation expense recognized under SFAS 123(R) for the three months ended March 31, 2008 and 2007 as follows (in thousands):

	Stock options		ESPP		Restricted Stock	
	2008	2007	2008	2007	2008	2007
Research and development	$383	$425	$26	$25	$ 9	$ 19
General and administrative	1,012	1,436	20	22	72	27
Total	$1,395	$1,861	$46	$47	$ 81	$ 46

At March 31, 2008, the unrecognized compensation expense related to unvested outstanding stock options is approximately $7.0 million which will be recognized through 2012, and the weighted-average remaining recognition period is 2.7 years.

We have also granted restricted stock awards and stock options to consultants. We account for stock awards issued to such non-employees in accordance with the provisions of Emerging Issues Task Force, or EITF, Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or* Services, or Issue No. 96-18. Under Issue No. 96-18, stock awards to non-employees are accounted for at their respective fair values using the Black-Scholes option-pricing model unless a more readily determinable fair value is available. The fair value of options granted to non-employees is remeasured during the performance period as the underlying options vest or as milestones are reached. During the three months ended March 31, 2008, we granted 10,000 shares of restricted stock to one non-employee. During the three months ended March 31, 2008 we recorded approximately $14,000 and $26,000 in stock-based compensation expense for the restricted stock and stock options granted to non-employees, respectively. During the three months ended March 31, 2007 we recorded approximately $57,000 and $36,000 in stock-based compensation expense for the restricted stock and stock options granted to non-employees, respectively.

2. Net Loss Per Share

Basic and diluted net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration of additional potential common shares.

The following table sets forth the computation of Anesiva' s basic and diluted net loss per share (in thousands, except share and per share amounts).

	For the three months ended March 31,	
	2008	2007
Numerator for basic and diluted net loss per share:		

Net loss	$(21,583)	$(11,678)
Denominator for basic and diluted net loss per share:		
Weighted-average shares of common stock outstanding	40,269,148	27,315,197
Less: weighted-average shares subject to repurchase	–	(395)
Weighted-average shares used in computing basic and diluted net loss per share	40,269,148	27,314,802
Basic and diluted net loss per share	$(0.54)	$(0.43)

The following table shows dilutive common share equivalents outstanding, which are not included in the above historical calculations, as the effect of their inclusion is anti-dilutive due to our net loss during each period. Restricted stock that is not yet vested is included as dilutive common share equivalents because we consider such securities equivalent to stock options.

	Three months ended March 31,	
	2008	2007
Restricted stock	117,711	185,383
Warrants	65,212	65,212
Options	4,257,148	3,283,022
Total	4,440,071	3,533,617

3. Comprehensive Loss

Comprehensive loss is comprised of net loss, unrealized gains on available-for-sale securities, and foreign currency translation adjustments in accordance with SFAS No. 130, *Reporting Comprehensive Income.* Comprehensive loss and its components for the three months ended March 31, 2008 and 2007 are as follows (in thousands):

	For the three months ended March 31,	
	2008	2007
Net loss	$(21,583)	$(11,678)
Change in unrealized gain on investments	–	11
Cumulative foreign currency translation adjustment	9	–
Comprehensive loss	$(21,574)	$(11,667)

4. Stockholders' Equity

In February 2005, we issued 19,684 shares of restricted common stock to employees and two directors, half of which will cliff vest on the anniversary dates of the grant date over a two to three year period. The weighted-average fair value of this stock at the time of issuance was $24.72 per share. In February 2007, we issued 127,650 shares of restricted common stock to employees, one-third of which will cliff vest on the anniversary dates of the grant date over a three-year period. The weighted-average fair value of this stock at the time of issuance was $7.60 per share. In February 2008, we issued 19,012 shares of restricted common stock to employees, one-third of which will cliff vest on the anniversary dates of the grant date over a three-year period. The weighted-average fair value of this stock at the time of issuance was $5.03 per

share. Restricted stock awards are grants that entitle the holder to shares of common stock as the award vests. As a result of these awards, during the three months ended March 31, 2008, we recognized approximately $81,000 in compensation expense. These stock awards offer employees the opportunity to earn shares of our stock over time, rather than options that give the employee the right to purchase stock at a set price. If all the remaining restricted stock awards that were granted in 2005, 2007 and 2008 continue to vest, we expect to recognize approximately $271,000, $378,000, $219,000, and $15,000 in compensation expense during the remainder of 2008 and the years ended December 31, 2009, 2010, and 2011, respectively. However, no compensation expense will be recognized for stock awards that do not vest.

In June 2006, we entered into a stock purchase agreement with Azimuth Opportunity, Ltd for a two-year commitment of up to $30.0 million. In March 2008, we entered into an amendment to the purchase agreement to extend the term of the agreement to March 2010. As of March 31, 2008, we had received a total of $4.1 million of cash proceeds from the sale of 617,898 shares of our common stock to Azimuth Opportunity, Ltd. and have approximately $25.9 million available for future draws.

5. Restructuring Activities

In December 2005, we announced a restructuring plan to reduce research costs, realign development efforts and realize operational efficiencies in general and administrative functions. We recorded a charge of $439,000 in severance salaries and other termination-related benefits related to the termination of 19 employees, which was included in accrued compensation on the balance sheet at December 31, 2005. During the year ended December 31, 2006, we recorded a charge of $881,000 to reflect the accrual of severance salaries and benefits for employees related to the termination of ten employees.

In October 2006, we announced the closure of a former AlgoRx office space in Secaucus, New Jersey to further reduce ongoing operational costs. As a result, we incurred a charge of approximately $176,000 primarily related to severance costs for five

employees. Also in October 2006, we recorded a charge of approximately $487,000 related to vacating our office space in Secaucus, New Jersey and discontinuing other office equipment operating leases. In September 2007, we recorded an additional charge of $579,000 due to the elimination of any future sublease income, as a result of a worsening of the office rental market in Secaucus, New Jersey. The lease related to this office space expires in July 2009 and the remaining leases related to the office equipment expire in January 2009. At March 31, 2008, the remaining accrued liability related to this sublease of the Secaucus office was approximately $548,000. The following table sets forth the activity in the accrued liability related to exiting the lease of our office space in Secaucus, New Jersey, which is included in other accrued liabilities and other long term liabilities at March 31, 2008 (in thousands):

	Exit Costs of Secaucus Office
Accrued liabilities at December 31, 2006	$ 443
Additional accrual for exit costs of Secaucus office recorded in September 2007	579
Payment against accrued liability	(365)
Accrued liabilities at December 31, 2007	$ 657
Payment against accrued liability	(109)
Accrued liabilities at March 31, 2008	$ 548

6. Debt

In August 2007, we entered into an equipment loan and security agreement with General Electric Capital Corporation, GECC, with respect to the financing of laboratory and manufacturing equipment in an amount up to $15.0 million. We borrowed approximately $6.6 million and $4.4 million under the agreement on August 30, 2007 and November 30, 2007, respectively. We may borrow against qualified purchases of eligible equipment expected through May 31, 2008. Each borrowing will be evidenced by a promissory note and will be solely secured by the financed equipment. The promissory notes for the two borrowings are repayable over 42 months and bear a fixed interest rate of 9.91% per annum. The first six payments under the promissory notes are interest payments and the next 36 payments are both interest and principal payments. The loan and security agreement contains certain restrictive covenants relating primarily to the financed equipment and additional indebtedness. The loan and security agreement also contains provisions permitting the lender to accelerate the loan if we are in default. A default includes a failure to pay any amount due under the debt documents which is not cured, a breach of any other obligations under the debt documents which is not cured, and an event or development which could reasonably be expected to have a material adverse effect on it. At March 31, 2008, we owed approximately $10.7 million in principal on this equipment loan.

7. Minority Interest in Variable Interest Entity

In February 2008, we contributed approximately $515,000 to our joint venture with Wanbang in accordance with the cooperative joint venture contract upon approval by the Chinese commerce government authorities in January 2008. We are committed to invest up to approximately $1.0 million in the CJV. Wanbang and an individual investor contributed $546,000 to the CJV.

The CJV has five directors on its board of directors; two are appointed by Anesiva, two are appointed by Wanbang, and one is appointed jointly. The chairman of the board is appointed by Wanbang and the vice-chairman is appointed by Anesiva. A quorum of the board of directors is two thirds of the directors, or four out of the five directors. The vote of two thirds of the directors, or four out of five directors, is required to change a supply agreement and a quality agreement between the CJV and Anesiva. The directors of the CJV serve without remuneration. Anesiva and Wanbang each appoint a supervisor to oversee the activities of the board of the directors and the CJV and to investigate any irregularities.

Under the terms of the joint venture agreement with Jiangsu Wanbang Biological Pharmaceutical Corporation Limited, if by the end of the third year of U.S. FDA approval of the Zingo manufacturing process at the CJV, the accumulated net profits obtained by Wanbang are less than the actual capital contributions made by Wanbang to the CJV by then, we will reimburse Wanbang for the difference between Wanbang actual capital contribution and Wanbang cumulative third anniversary profits from the U.S. FDA approval date. We have incurred a liability for the fair value of this guarantee, approximately $18,000 in accordance with FASB Interpretation No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* ("FIN 45"), as of March 31, 2008. We could potentially have to pay out a maximum of $546,000 under this guarantee if the CJV receives FDA approval but does not accumulate any profits within three years of that approval.

If we pay these amounts to Wanbang, we believe that this condition would be a special allocation of the CJV losses and consequently our obligations to absorb the expected losses or rights to receive the expected residual returns would not be proportionate to our equity in the CJV. We are the primary beneficiary of the CJV.

We have concluded that this variable interest, the reimbursement guarantee, not held proportionately by the other interest holders causes us to consolidate the financial results of the CJV in accordance with the provisions of FIN 46R.

As a result of consolidating the accounts of the CJV at March 31, 2008, we recognized minority interest of $537,000 in the consolidated balance sheet, representing the equity interests of the CJV' s other stockholders. This amount is less than the carrying cost of their collective investment by $9,000 at March 31, 2008 and is equal to their share of operating loss of the CJV for the three months ended March 31, 2008.

8. Subsequent Events

In April 2008, we entered into an amendment to the license agreement, dated as of February 4, 2008 with Sigma-Tau Industrie Farmaceutiche Riunite S.p.A. which, among other things, (i) extends the rights granted by Anesiva to Sigma-Tau under the license agreement to certain French-speaking African countries, Liechtenstein, Portugal, Spain and Switzerland and (ii) provides for additional upfront payments to Anesiva.

In April 2008, we entered into an exclusive license and distribution agreement with Green Vision Company. Under the terms of the agreement, Green Vision will be the exclusive distributor of Zingo in Bahrain, Jordan, Kuwait, Lebanon, Oman, Qatar, Saudi Arabia and United Arab Emirates. The agreement provides for an upfront payment, royalty payments, and payments for the achievement of certain sales milestones.

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

This Quarterly Report on Form 10-Q, including particularly the sections entitled "Business Risks" and "Management' s Discussion and Analysis of Financial Condition and Results of Operations," 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 are subject to the "safe harbor" created by those sections. These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "anticipates," "believes," "continue," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "should," "will," or the negative of these terms or other comparable terminology. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this Quarterly Report on Form 10-Q is filed with the Securities and Exchange Commission.

Overview

We are a biopharmaceutical company focused on the development and commercialization of novel therapeutic treatments for pain management. Our portfolio of products include:

Zingo™ (lidocaine hydrochloride monohydrate) powder intradermal injection system, which was approved by the FDA in August 2007 to reduce the pain associated with peripheral IV insertions or blood draws in children three to 18 years of age. In October 2007, we announced that our Phase 3 clinical trial in adults requested by the Food and Drug Administration (FDA) met its primary endpoint. In March 2008, we submitted to the FDA a supplemental New Drug Application for the use of Zingo in adults.

Adlea™, a long-acting, site-specific, non-opioid analgesic, is being developed for moderate to severe pain, and has completed multiple Phase 2 trials in post-surgical, musculoskeletal and neuropathic pain. We are initially pursuing an indication for Adlea for the management of acute pain associated with orthopedic surgeries–and are executing on a registration-directed plan which involves multiple Phase 2 and Phase 3 studies. Adlea has also demonstrated activity in early stage trials in the treatment of pain associated with osteoarthritis of the knee.

Zingo and Adlea are different drugs, each with its own mechanisms of action. Zingo is comprised of microcrystals of lidocaine delivered into the skin by compressed gas. Zingo employs a proprietary needle-free dispenser. Adlea is a novel non-opioid drug candidate that is a vanilloid receptor 1 agonist, or TRPV1 agonist, based on the compound capsaicin which provides analgesia for between two and three months.

In October 2007, we entered into a joint venture agreement with Jiangsu Wanbang Biological Pharmaceutical Corporation Limited, or Wanbang, a Fosun company, of XuZhou, China to establish a collaborative venture (the "CJV") which will provide

additional manufacturing capacity for worldwide supply utilizing materials sourced in the United States. The operation will provide a second source for Zingo commercial supply, assist with ongoing efforts to reduce manufacturing costs, and provide additional manufacturing capacity. We own a 49% interest in profit or loss of the CJV, which is named Wanbang Anesiva (Jiangsu) Pharmaceuticals Ltd. The production area will be located at an existing Wanbang facility in the city of XuZhou in Jiangsu province. Following completion of the assembly facility in XuZhou, the CJV will seek FDA certification of the facility.

Financial Operations Overview

Research and Development Expenses

The following table sets forth the allocation of research and development expenses among projects for the three months ended March 31, 2008 and 2007 (in thousands):

	For the three months ended March 31,	
	2008	**2007**
Zingo	$ 3,768	$ 2,391
Adlea	6,102	1,598
Avrina™	18	43
1207	–	209
Non-project	3,496	2,721
Total	$ 13,384	$ 6,962

General and Administrative Expenses

General and administrative expenses consist primarily of compensation, including stock-based compensation, for employees in executive and operational functions, including finance, business development and marketing. Other significant costs include facilities costs and professional fees for marketing, accounting and legal services, including legal services associated with obtaining and maintaining patents.

Critical Accounting Policies and Significant Judgments and Estimates

Our management' s discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an on-going basis, we evaluate our estimates and judgments. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe that the following accounting policies relating to stock compensation and clinical trial accounting are most critical to a full understanding and evaluation of our reported financial results.

Stock Compensation

On January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment,* or SFAS 123(R), using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006. Our condensed consolidated financial statements as of and for the three months ended March 31, 2008 and 2007 reflect the impact of SFAS 123(R). In accordance with the modified prospective transition method, our condensed consolidated financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R).

SFAS 123(R) requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. We value share-based awards using the Black-Scholes option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in our consolidated statement of operations. As stock-based compensation expense recognized in the consolidated statement of operations for the three months ended March 31, 2008 and 2007 are based on awards ultimately expected to vest, they have been reduced for estimated forfeitures. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Stock compensation is amortized on a straight-line basis over the vesting period of the underlying option, generally four years for stock options and two to three years for restricted stock.

Clinical Trial Accounting

Our expenses related to clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee or unit price. Payments under the contracts depend on factors such as the successful enrollment of patients or the completion of clinical trial milestones. Expenses related to clinical trials generally are accrued based on contracted amounts applied to the level of patient enrollment and activity according to the protocol. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

Marketable Securities Accounting

We invest our excess cash in money market funds and in highly liquid debt instruments of the U.S. government, its agencies and municipalities and corporate notes. All highly liquid investments with stated maturities of 90 days or less from date of purchase are classified as cash equivalents; highly liquid investments with stated maturities of greater than 90 days are classified as marketable securities.

We determine the appropriate classification of investments in debt securities at the time of purchase. Cash equivalents and marketable securities are classified as available-for-sale securities as we do not intend to hold securities with stated maturities greater than twelve months until maturity. Available-for-sale securities are carried at fair value, with unrealized gains and losses reported as a component of accumulated other comprehensive income (loss). Any realized gains or losses on the sale of marketable securities are determined on a specific identification method, and such gains and losses are reflected as a component of interest income or expense.

We periodically evaluate investments for impairment and write-down if we estimate that the impairment is other than temporary. We take into account general market conditions, changes in economic environment as well as specific investment attributes, such as credit downgrade or illiquidity for each investment, to estimate either the fair value of our investments and to determine whether impairment is other than temporary.

Inventories

Inventories are stated at the lower of cost or market and consist primarily of material and certain contract manufacturing costs for the production of Zingo that were incurred subsequent to the approval for marketing by the FDA. Cost is determined using the first-in, first-out basis. The valuation of inventory requires us to estimate obsolete or excess inventory based on analysis of future demand for Zingo. If inventory costs exceed expected market value due to obsolescence, impairment charge may be recorded as deemed necessary by management for the difference between the cost and the market value. There were no impairment charges at March 31, 2008.

Results of Operations

Three Months Ended March 31, 2008 Compared to Three Months Ended March 31, 2007

Research and Development Expenses

The following table summarizes the period over period changes in research and development expenses:

	Three Months Ended March 31,		2008 to 2007 Change	
	2008	2007	$	%
	(in thousands, except percentages)			
Research and development	$ 13,384	$ 6,962	$ 6,422	92 %

The increase of $6.4 million in research and development expenses for the three months ended March 31, 2008 compared to the same period in 2007 was primarily due to the following:

Increase in clinical trial costs of $2.9 million primarily due to expenses for Phase 2 and Phase 3 Adlea trials for post-surgical and osteoarthritis pain;

Increase in research and development expenses of $1.5 million reflecting $0.6 million supplemental New Drug Application filing fee for the use of Zingo in adults, $0.4 million in manufacturing development expenses for Zingo and Adlea, $0.2 million in pre-clinical study expenses for Adlea, and $0.3 million in other expenses of which $0.2 million was related to milestone royalty due upon initiation of Phase 3 Adlea trial;

Increase in compensation expense and employee related expenses of $1.4 million due to higher headcount primarily in clinical development and manufacturing;

Increase in professional services of $0.4 million reflecting higher expenses of $0.2 million in manufacturing, $0.1 million in clinical, and $0.1 million in quality assurance.

We anticipate that research and development expenses will remain relatively flat through the end of 2008 due to continuing clinical activities for Adlea Phase 2 and Phase 3 trials.

General and Administrative Expenses

The following table summarizes the period over period changes in general and administrative expenses:

	Three Months Ended March 31,		2008 to 2007 Change	
	2008	2007	$	%
	(in thousands, except percentages)			
General and administrative	$ 8,457	$ 5,754	$ 2,703	47 %

The increase of $2.7 million in general, and administrative expenses for the three months ended March 31, 2008 compared to the same period in 2007 was primarily due to the following:

Increase in compensation expense and employee related expenses of $1.3 million due to higher headcount primarily due to the addition of sales force personnel;

Increase in professional services of $0.9 million primarily due to pre-launch/launch marketing costs for Zingo;

Increase in other corporate expenses of $0.3 million reflecting Zingo FDA product and establishment fees and expenses in support of sales force automation system;

Increase in facilities and related expenses of $0.2 million.

We anticipate that general and administrative expenses will remain relatively flat through the end of 2008 due to costs in support of launch efforts for Zingo.

Interest and Other Income. Interest and other income decreased to $0.5 million for the three months ended March 31, 2008 from $1.0 million for the three months ended March 31, 2007, primarily due to lower cash and investment balances and lower interest rates in the three months ended March 31, 2008.

Interest Expense. Interest and other expense increased to $0.3 million for the three months ended March 31, 2008 from none for the three months ended March 31, 2007 due to interest paid on our equipment line of credit.

Liquidity and Capital Resources

Sources of Liquidity

To date, we have funded our operations primarily through the sale of equity securities. As of March 31, 2008, we had raised $182.5 million of cash proceeds from the sale of equity securities, including promissory notes that were converted into preferred stock, net of offering expenses.

As of March 31, 2008, we had $70.0 million in cash, cash equivalents and marketable securities as compared to $90.8 million as of December 31, 2007, a decrease of $20.8 million. This decrease was primarily the result of cash used in operations.

Cash Flows

The following table summarizes our statement of cash flows (in millions):

	Three months ended March 31,	
	2008	2007
Cash flows provided by (used in):		
Operating activities	$(20.8)	$(11.5)
Investing activities	(0.1)	1.1
Financing activities	0.1	0.5
Net increase (decrease) in cash and cash equivalents	**$(20.8)**	**$(9.9)**

Net cash used in operating activities was $20.8 million for the three months ended March 31, 2008 compared to $11.5 million for the three months ended March 31, 2007. The increase of cash used in operations of $9.3 million was primarily due to the increase in compensation expenses and employee related expenses of $3.2 million due to additional personnel including hiring a sales force, increase in clinical trial expenses of $2.9 million due to Phase 2 and Phase 3 Adlea trials, increase in research and development expenses of $1.5 million which included $0.6 million for supplemental New Drug Application filing fees for use of Zingo in adults, and increase in professional fees of $1.3 million due to cost in support of pre-launch/launch efforts for Zingo.

Net cash used in investing activities was $0.1 million for the three months ended March 31, 2008 compared to $1.1 million cash provided by investing activities for the three months ended March 31, 2007. The decrease in net cash from investing activities of $1.2 million was due to a net decrease in sales of marketable securities of $3.5 million offset by a decrease in purchase of equipment of $1.7 million and increase in cash from consolidation of interest entity of $546,000.

Net cash provided by financing activities was $40,000 for the three months ended March 31, 2008 compared to $464,000 for the three months ended March 31, 2007. The decrease in net cash provided by financing activities of $424,000 was primarily due to the decrease in sales of common stock of $266,000 and increase in repayment of equipment loans of $158,000.

Stock Purchase Agreement

In June 2006, we entered into a stock purchase agreement with Azimuth Opportunity, Ltd. for a two year commitment of $30.0 million. Through March 31, 2008, we had raised approximately $4.1 million from the sales of common stock under this arrangement. In March 2008, we entered into an amendment to the purchase agreement with Azimuth to extend the term of the agreement until March 2010.

Operating Capital and Capital Expenditure Requirements

We expect to devote substantial resources to continue our research and development efforts for our future products and to launch Zingo, and do not currently generate any revenue. We believe that the key factors that will affect our internal and external sources of cash are:

the progress of preclinical development and laboratory testing and clinical trials;

the time and costs involved in obtaining regulatory approvals;

delays that may be caused by evolving requirements of regulatory agencies;

the number of product candidates we pursue;

the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims;

our plans to establish sales, marketing and/or manufacturing capabilities;

our ability to establish, enforce and maintain selected strategic alliances and activities required for product commercialization;

the acquisition of technologies, products and other business opportunities that require financial commitments; and

our revenues, if any, from successful development and commercialization of our products.

We believe that our existing cash and cash equivalents and marketable securities will be sufficient to fund our activities into 2009. If we need to raise funds in the future, we may be required to raise those funds through public or private financings, strategic relationships or other arrangements. The sale of additional equity and debt securities may result in additional dilution to our stockholders. Additional financing may not be available in amounts or on terms acceptable to us or at all. If we are unable to obtain this additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned research, development and commercialization activities, which could harm our business.

Contractual Obligations

Our outstanding contractual obligations relate to facilities leases and obligations under our agreement with our third-party contract manufacturer. Our contractual obligations as of March 31, 2008 were as follows (in millions):

	Payments Due by Period				
Contractual Obligations	**Total**	**Less than One Year**	**One to Three Years**	**Four to Five Years**	**After Five Years**
Equipment Financing	$12.6	$ 4.0	$8.3	$ 0.3	$ –
Operating leases	5.5	2.3	3.2	–	–
Total contractual cash obligations	$18.1	$ 6.3	$11.5	$ 0.3	$ –

Under all of our license agreements, we could be required to pay up to a total of approximately $1.0 million in payments for milestones such as the initiation of clinical trials and the granting of patents. As of March 31, 2008, we incurred approximately $3.1 million of milestone charges, including approximately $1.6 million of cash payments and approximately $1.5 million of stock compensation, for the execution of agreements, patent approvals and the initiation of U.S. clinical trials. Milestone payments will also be due upon the first administration to a subject using licensed technology in a Phase 1 clinical trial, the first administration to a subject using licensed technology in a Phase 3 clinical trial and FDA approval of Adlea in addition to sales milestones and royalties payable on commercial sales if any occur. Dr. James N. Campbell, who has been a member of the Board of Anesiva since June 29, 2007, is one of the three licensors of Adlea.

We have also entered into letters of credit totaling $658,000 securing our operating lease obligations. We are required to set aside cash as collateral. At March 31, 2008, we had $658,000 in certificates of deposit designated as restricted cash, which is not available for use in current operations, of which $68,000 was included as prepaid expenses and other current assets.

In August 2006, we entered an agreement with GlaxoSmithKline to extend the term of the lease agreement for our headquarter office in South San Francisco, California from June 1, 2007 through November 13, 2010.

In March 2007, we amended our existing lease agreement with Eight Tower Bridge Development Associates to lease an additional 3,658 square feet for our marketing office in Pennsylvania and the lease will expire in November 2009.

Off-Balance Sheet Arrangements

At March 31, 2008 and 2007, we did not have any off-balance sheet arrangements or relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purposes entities, which are typically established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our exposure to market risk is principally limited to our cash equivalents and investments that have maturities of less than two years. We maintain an investment portfolio of investment grade, liquid debt securities that limit the amount of credit exposure to any one issue, issuer or type of instrument. At March 31, 2008, we had approximately $66.7 million in a money market fund that holds United States treasury debt. During the three months ended March 31, 2008, there were no material changes in the interest rate risk or foreign currency exchange risk disclosures set forth in Part II, Item 7A “Quantitative and Qualitative Disclosures About Market Risk” in our Annual Report on Form 10-K for the year ended December 31, 2007.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures.

Based on their evaluation as of March 31, 2008, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) were effective to ensure that the information required to be disclosed by us in reports we file with the Securities and Exchange Commission is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission' s rules and forms.

Changes in internal controls over financial reporting.

There were no changes in our internal controls over financial reporting during the quarter ended March 31, 2008 that have materially affected, or are reasonably likely to materially affect our internal controls over financial reporting.

Limitations on the effectiveness of controls.

Our management, including our chief executive officer and chief financial officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within Anesiva have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be involved in litigation relating to claims arising out of our operations. We are not currently involved in any material legal proceedings.

Item 1A. Risk Factors

We have marked with an asterisk (*) those risks described below that reflect substantive changes from the risks described under "Item 1A. Risk Factors" included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 14, 2008.

Risk Factors Relating to Our Business

We have no in-house manufacturing and a limited number of manufacturing personnel and expect to depend on third-party manufacturing.

We have limited manufacturing facilities, and we have a limited number of personnel with experience in manufacturing any clinical or commercial products or in designing drug manufacturing processes. We are in the process of acquiring manufacturing equipment and certain leasehold modifications that will be located at our contract manufacturer facilities. We have contracted with third-party manufacturers to produce, in collaboration with us, clinical and commercial supplies of our products. We intend to rely substantially on third-party contract manufacturers to manufacture, supply, warehouse and distribute any resulting products. Linde AG acts as the sole supplier for the cylinder of compressed helium gas, a key component in the dispenser for Zingo.

There are a small number of suppliers of the materials which are necessary to manufacture Zingo and, in the case of the cylinder used in Zingo, we rely on a sole supplier. The cylinder of compressed helium gas is a key component in the dispenser for Zingo. We acquire the cylinders for Zingo from PowderMed Limited, a wholly-owned subsidiary of Pfizer, Inc., under a long-term supply agreement. PowderMed Limited is currently our sole supplier and source of cylinders, which are manufactured for it by Linde AG, and to date we have not identified an alternative source. If we are required to seek an alternative source for the cylinders, we might not be successful in establishing an alternative commercial arrangement with a supplier, or if we were successful in finding an alternate supplier, it could be on terms which are less favorable than the current supply agreement with PowderMed Limited. In addition, we currently have no approved supplier of the sealing film for the drug cassette in the dispenser for Zingo. We may not be successful in establishing a commercial arrangement for a supplier for the sealing film.

The contract manufacturers for Zingo need to purchase the materials required for Zingo. Suppliers may not sell these materials to us at the time we need them or on commercially reasonable terms. If our manufacturers or we are unable to purchase these materials or manufacture Zingo on commercially reasonable terms the commercial launch of Zingo would be delayed or there would be a shortage in supply of Zingo, which would harm our ability to generate revenues from the sale of Zingo. If suppliers increase the price of these materials or we cannot otherwise produce Zingo with an acceptable cost of goods, the price for Zingo may increase which may make Zingo a less competitive product for the relief of venipuncture pain. If we change suppliers for any of these materials or any of our current suppliers experience a shutdown or disruption in the facilities used to produce these materials, due to technical, regulatory or other problems, it could harm our ability to manufacture products.

We may in the future elect to manufacture certain of our products in our own manufacturing facilities. We would need to invest additional funds and recruit qualified personnel in order to build or lease and operate any manufacturing facilities.

If our third-party manufacturers' facilities do not follow current good manufacturing practices, our product development and commercialization efforts may be harmed.

Our third-party manufacturers may encounter difficulties in achieving quality control and quality assurance and may experience shortages of qualified personnel. A failure of our third-party manufacturers to follow current good manufacturing practices or other regulatory requirements and to document their adherence to such practices may lead to significant delays in the availability of products for commercial

use or clinical study, the termination of a clinical study, or may delay or prevent filing or approval of marketing applications for our products. In addition we could be subject to sanctions being imposed on us, including fines, injunctions and civil penalties. Changing manufacturers may require revalidation of the manufacturing process and procedures in accordance with FDA mandated current good manufacturing practices and will require FDA approval. This revalidation may be costly and time consuming. If we are unable to arrange for third-party manufacturing of our products, or to do so on commercially reasonable terms, we may not be able to complete development of our products or market them.

We have no experience selling, marketing or distributing product.

In order to commence commercial sales of Zingo, or any other product for which we receive regulatory approval, we have established a sales and marketing organization with appropriate technical expertise and distribution capability. At present, we have 15 sales reps and a limited number of marketing employees. While our sales and marketing team is highly experienced, they have not worked together at Anesiva. Factors that may inhibit our efforts to commercialize our products without strategic partners or licensees include:

- difficulty in retaining adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to, or persuade adequate numbers of, physicians to prescribe our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage against companies with broader product lines; and
- unforeseen costs associated with creating an independent sales and marketing organization.

If our third-party promotional partner for Zingo does not perform in an acceptable and timely manner, our commercialization of Zingo could be delayed, less successful or unsuccessful.

We have entered into a promotion and distribution agreement with Sagent Pharmaceuticals, Inc. ("Sagent") for Zingo. Under this agreement, Sagent will undertake certain promotion activities with respect to Zingo in the United States for a period of time. These activities include facilitation of Zingo-related contract negotiations with hospitals and group purchasing organizations, and the management of the warehousing and distribution of Zingo. If Sagent fails to perform these services in an acceptable and timely manner, it could affect our ability to sell Zingo and our revenues may be reduced.

If we fail to obtain U.S. regulatory approvals for product candidates under development, we will not be able to generate revenue in the U.S. market.

We must receive FDA approval for each of our product candidates including Adlea before we can commercialize or sell these product candidates in the United States. Even if one of our product candidates is approved by the FDA, the approval may be significantly limited to specific disease indications, patient populations and dosages. The FDA can limit or deny its approval for many reasons, including:

- a product candidate may be found to be unsafe or ineffective;
- regulators may interpret data from preclinical testing and clinical trials differently and less favorably than we do;
- regulators may not approve the manufacturing processes or facilities that we use; and
- regulators may change their approval policies or adopt new regulations.

Failure to obtain FDA approval or any delay or setback in obtaining such approval would:

- adversely affect our ability to market any drugs that we develop and our ability to generate product revenues; and
- impose additional costs and diminish any competitive advantages that we may attain.

As to any product for which marketing approval is obtained, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping related to the product will be subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems with the product, such as an adverse side effect, may result in restrictions on the product, including withdrawal of the product from the market. We may be slow to adapt, or we may never adapt, to changes in existing requirements or adoption of new requirements or policies.

If we fail to comply with applicable U.S. regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

If our clinical trials with respect to our product candidates do not meet safety or efficacy endpoints in these evaluations, or if we experience significant delays in these tests or trials, our ability to commercialize products and our financial position will be impaired.

Clinical development is a long, expensive and uncertain process and is subject to delays. It may take us several years to complete our testing, and failure can occur at any stage of testing. Patient enrollment in future clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, and the eligibility criteria for the study and patient compliance. Delays in patient enrollment or failure of patients to continue to participate in a study may cause an increase in costs and delays, or result in the failure of the trial.

The results of preclinical or clinical studies do not necessarily predict future clinical trial results, and acceptable results in early studies might not be seen in later studies. Any preclinical or clinical test may fail to produce results satisfactory to the FDA or foreign regulatory authorities. Preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Drug-related adverse events during a clinical trial could cause us to repeat a trial, terminate a trial or cancel the program. In addition, we are required by the FDA to conduct additional preclinical studies, including toxicology, while our clinical studies are ongoing.

To obtain regulatory approval to market our product candidates, we will need to conduct nonclinical studies in animals, and the results of these nonclinical studies may not demonstrate adequate safety or efficacy and, even if they do, the results may not necessarily be predictive of results in human trials.

As part of the regulatory approval process, we must conduct, at our own expense, nonclinical studies in laboratory animals and clinical trials in humans. The number of nonclinical trials that the regulatory authorities will require varies depending on the product candidate, the disease or condition the product candidate is being developed to address and regulations applicable to the particular product candidate. We may need to perform multiple nonclinical studies using various doses and formulations of our product candidates before we can begin clinical trials, continue clinical trials or obtain approval of our drugs, which could result in delays in our ability to develop or obtain approval of our product candidates. Furthermore, nonclinical results in animal studies are not necessarily predictive of outcomes in human clinical trials. After we have conducted nonclinical studies in animals, we must demonstrate in clinical trials that our product candidates are safe and efficacious for use on humans in order to receive regulatory approval for commercial sale. Even if initial results of nonclinical studies for our product candidates are positive, we may obtain different results in later stages of drug development, including failure to show desired safety and efficacy.

There may be delays in developing a product candidate as a result of the necessary preclinical studies to assess the safety of the product candidate including its ability to cause cancer and interactions with other drugs.

We are required to conduct preclinical studies to evaluate the safety of our product candidates including its ability to cause cancer. For example, such studies may be required for Adlea for the treatment of certain indications. Such studies require about three years to complete and report.

Failure to enroll patients for clinical trials may cause delays in developing the product candidates, and delays in the commencement of clinical testing of the current product candidates could result in increased costs to us and delay our ability to generate revenues.

We will encounter delays or possibly regulatory rejections if we are unable to enroll enough patients to complete clinical trials. Patient enrollment depends on many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the trial. Any delays in planned patient enrollment in the future may result in increased costs and delays, which could harm our ability to develop the product candidate.

Delays in the commencement of clinical testing could significantly increase product development costs and delay product commercialization. The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;

reaching agreement on acceptable terms with prospective contract research organizations and trial sites;

manufacturing sufficient quantities of a product candidate; and

obtaining institutional review board approval to conduct a clinical trial at a prospective site.

It may require longer and larger clinical trials to study a product candidate for certain indications such as chronic conditions.

The time frame of our clinical studies for a product candidate for a chronic condition may also be affected by the International Conference on Harmonisation guidelines that state that at least 1,500 patients must be exposed to the drug prior to submission of a registration application and from 300 to 600 patients be exposed to a new drug for one year. If development of Adlea for pain resulting from musculoskeletal diseases is subject to these guidelines, development for these indications may be longer than a development program for an acute condition such as postsurgical pain. In addition to the time required to conduct these studies, the results of such studies may demonstrate harmful side effects of a product candidate which would impair or prevent our ability to develop such product candidate.

If third-party clinical research organizations do not perform in an acceptable and timely manner, our clinical trials could be delayed or unsuccessful.

We do not have the ability to conduct all of our clinical trials independently. We rely on clinical investigators, third-party clinical research organizations and consultants to perform substantially all of these functions. If we cannot locate acceptable contractors to run our clinical trials or enter into favorable agreements with them, or if these third parties do not successfully carry out their contractual duties, satisfy FDA requirements for the conduct of clinical trials or meet expected deadlines, we will be unable to obtain required approvals and will be unable to commercialize our products on a timely basis, if at all. Our agreements are generally cancelable by either party with 30 days notice, with or without cause.

Even if our products are approved by regulatory authorities, if we fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continual review and periodic inspections by the FDA and other regulatory bodies. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturer or manufacturing processes, or failure to comply with regulatory requirements, may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recall, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products abroad.

We intend to market our products in international markets. In order to market our products in the European Union and many other foreign jurisdictions, we or our foreign marketing partners must obtain separate regulatory approvals. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

If we do not find collaborators for our product candidates, we may have to reduce or delay our rate of product development and/or increase our expenditures.

Our strategy to develop, manufacture and commercialize our products may include entering into various relationships with pharmaceutical companies with respect to some programs to advance such programs and reduce our expenditures on such programs. Our product candidates will target highly competitive therapeutic markets in which we have limited experience and expertise. If we are unable to develop this expertise ourselves, we will need to enter into agreements with a biotechnology or pharmaceutical company to provide us with the necessary resources and experience for the development and commercialization of products in these markets. There are a limited number of companies with the resources necessary to develop our future products commercially, and we may be unable to attract any of these firms. A company that has entered into a collaboration agreement with one of our competitors may choose not to enter into a collaboration agreement

with us. We may not be able to negotiate any collaboration on acceptable terms or at all. If we are not able to establish collaborative arrangements, we may have to reduce or delay further development of some of our programs and/or increase our expenditures and undertake the development activities at our own expense. If we elect to increase our expenditures to fund our development programs, we will need to obtain additional capital, which may not be available on acceptable terms or at all.

In addition, there have been a significant number of recent business combinations among biotechnology and pharmaceutical companies that have reduced the number of potential future collaborators. If business combinations involving potential collaborators were to occur, the effect could be to diminish, terminate or cause delays in one or more of our product development programs.

If we fail to successfully commercialize our single approved product or fail to successfully clinically develop our single product candidate, our revenue will be adversely affected.

At this time, Zingo is our only approved product and Adlea is our only product candidate being actively developed. Our future revenues, if any, in the foreseeable future will be derived solely from these two products. If commercialization of Zingo or clinical development of Adlea is unsuccessful, our revenues will be adversely affected.

Our competitors currently offer and may develop therapies that reduce the size of our markets.

Our business has been characterized by extensive research and development efforts, rapid developments and intense competition. Our competitors may have or may develop superior technologies or approaches, which may provide them with competitive advantages. Our potential products may not compete successfully. If these competitors get to the marketplace before we do with better or less expensive drugs, our product candidates, if approved for commercialization, may not be profitable to sell or worthwhile to continue to develop. Technology in the pharmaceutical industry has undergone rapid and significant change, and we expect that it will continue to do so. Any compounds, products or processes that we develop may become obsolete or uneconomical before we recover any expenses incurred in connection with their development. The success of our product candidates will depend upon factors such as product efficacy, safety, reliability, availability, timing, scope of regulatory approval, acceptance and price, among other things. Other important factors to our success include speed in developing product candidates, completing clinical development and laboratory testing, obtaining regulatory approvals and manufacturing and selling commercial quantities of potential products to the market.

Our product candidates are intended to compete directly or indirectly with existing drugs. Even if approved and commercialized, our products may fail to achieve market acceptance with hospitals, physicians or patients. Hospitals, physicians or patients may conclude that our potential products are less safe or effective or otherwise less attractive than these existing drugs. If our product candidates do not receive market acceptance for any reason, our revenue potential would be diminished, which would materially adversely affect our ability to become profitable.

Zingo, if commercialized, will face significant competition. Two leading products for local anesthesia prior to venipuncture procedures were L.M.X.4®, a cream-based product (formerly ELA-MAX, Ferndale Labs), and EMLA®, a cream-based product sold by AstraZeneca. EMLA® has historically been the market leader, and several generic versions of EMLA® that are manufactured by Fougera, Atrix, Geneva, and Hi-Tech Pharmaceuticals were approved by the FDA. These products already have established distribution channels and are well known to physicians and hospitals. A third product, Synera™, a topical anesthetic patch, was launched by ZARS/Endo Pharmaceuticals Inc. during 2006. There are additional products including Numby Stuff® (Iomed) and LidoSite® (Braun-Vyteris) with more rapid onset than the cream-based products above.

Adlea, if approved and commercialized, will face significant competition. For postsurgical pain, morphine administered by infusion pump is a common treatment method. Several other oral, injectable and patch opioids are also used, including Vicodin® (Abbott Labs), OxyContin® (Purdue Pharma), Ionsys™ and Duragesic® (Johnson & Johnson) and generic versions of Duragesic that are manufactured by Mylan & Sandoz. For later-stage osteoarthritis, in addition to NSAIDs, and Celebrex® (Pfizer), hyaluronic acid products, including Synvisc® (Genzyme), are injected locally and there is some oral opioid use. For the treatment of tendonitis, glucocorticosteroids are used. TRPV1, which is involved in the transmission of pain signals to the brain and which is affected by Adlea, has become a popular target for the pharmaceutical industry. TRPV1 inhibitors that may also compete with Adlea are being developed by several companies, including Merck-Neurogen, Pfizer-Renovis (a subsidiary of Evotec AG), Amgen, Schwarz Pharma-Amore Pacific, Purdue Pharma, and PainCeptor. These TRPV1 inhibitors are expected to advance to clinical evaluation shortly. We believe there are other products that are in development that may compete with our current product candidates.

Most of our competitors, including many of those listed above, have substantially greater capital resources, research and development staffs, facilities and experience in conducting clinical trials and obtaining regulatory approvals, as well as in manufacturing and marketing pharmaceutical products. As a result, they may achieve product commercialization or patent protection earlier than we can.

If we fail to obtain an adequate level of reimbursement for our products by third-party payors, there may be no commercially viable markets for our products or the markets may be much smaller than expected.

The availability and levels of reimbursement by governmental and other third party payors affect the market for our products. The efficacy, safety and cost-effectiveness of our products as well as the efficacy, safety and cost-effectiveness of any competing products will determine the availability and level of reimbursement. These third-party payors continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services. In certain countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take nine to 12 months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products to other available therapies. If reimbursement for our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, our revenues would be reduced.

We have a limited operating history and if we do not generate significant revenues, we will not be able to achieve profitability.*

We have a limited history of operations and we have incurred net losses since our inception. As of March 31, 2008, we had deficit accumulated during the development stage of approximately $230.3 million. We expect to incur substantial net losses to further develop and commercialize our products and do not know whether or when we will become profitable and may not be able to sustain our operations.

We will need additional financing, which may be difficult to obtain. If we fail to obtain necessary financing or do so on unattractive terms, our development programs and other operations could be harmed.

We will require substantial funds to further develop and commercialize our products. We expect to incur significant spending as we expand our development programs and commercialization activities and our future capital requirements will depend on many factors, including:

- the scope and results of our clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for Adlea, and other future product candidates;
- the cost of manufacturing activities;
- the cost of Zingo commercialization activities; and
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including any litigation costs and the results of such litigation.

Additional financing may not be available when we need it or may not be available on favorable terms. If we are unable to obtain adequate funding on a timely basis, we may be required to significantly curtail one or more of our research, development or commercial programs. We could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates or products which we would otherwise pursue on our own. If we raise additional funds by issuing equity securities, our then-existing stockholders will experience dilution and the terms of any new equity securities may have preference over our common stock.

We depend on our officers and key employees, and if we are not able to retain them or recruit additional qualified personnel, our business will suffer.

We are highly dependent on our chief executive officer, John P. McLaughlin and other officers and key employees. Due to the specialized knowledge each of our officers and key employees possesses with respect to our product candidates and our operations, the loss of service of any of our officers or key employees could delay or prevent the successful enrollment and completion of our clinical trials or the commercialization of Zingo. We do not carry key man life insurance on our officers or key employees.

We have employment agreements with Messrs. McLaughlin, our chief executive officer and Patrick A. Broderick, our vice president and general counsel. Each of our officers and key employees may terminate their employment without notice and without cause or good reason.

In addition, our growth will require hiring a significant number of qualified executive, scientific, regulatory, manufacturing, commercial and administrative personnel. Accordingly, recruiting and retaining such personnel in the future will be critical to our success. There is intense

competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. Our offices are located in the San Francisco Bay Area, where competition for personnel with biopharmaceutical skills is intense. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our development and commercialization activities.

Risks Related to Our Industry

We face the risk of product liability claims and may not be able to obtain insurance.

Our business exposes us to the risk of product liability claims that is inherent in the testing, manufacturing, and marketing of drugs and related devices. Although we have product liability and clinical trial liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. We may not be able to obtain or maintain adequate protection against potential liabilities.

In addition, as our product candidates other than Zingo are approved for marketing, we may seek additional insurance coverage. If we are unable to obtain insurance at acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may harm our business. These liabilities could prevent or interfere with our product commercialization efforts. Defending a suit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity or reduced acceptance of our products in the market.

Our operations involve hazardous materials and we must comply with environmental laws and regulations, which can be expensive.

Our research and development activities involve the controlled use of hazardous materials, including chemicals and radioactive and biological materials. Our operations also produce hazardous waste products. We are subject to a variety of federal, state and local regulations relating to the use, handling, storage and disposal of these materials. We generally contract with third parties for the disposal of such substances and store certain low-level radioactive waste at our facility until the materials are no longer considered radioactive. We cannot eliminate the risk of accidental contamination or injury from these materials. We may be required to incur substantial costs to comply with current or future environmental and safety regulations. If an accident or contamination occurred, we would likely incur significant costs associated with civil penalties or criminal fines and in complying with environmental laws and regulations. We do not have any insurance for liabilities arising from hazardous materials. Compliance with environmental laws and regulations is expensive, and current or future environmental regulation may impair our research, development or production efforts.

The life sciences industry is highly competitive and subject to rapid technological change.

The life sciences industry is highly competitive and subject to rapid and profound technological change. Our present and potential competitors include major pharmaceutical companies, as well as specialized biotechnology and life sciences firms in the United States and in other countries. Most of these companies have considerably greater financial, technical and marketing resources than we do. Additional mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated in our competitors. Our existing or prospective competitors may develop processes or products that are more effective than ours or be more effective at implementing their technologies to develop commercial products faster. Our competitors may succeed in obtaining patent protection and/or receiving regulatory approval for commercializing products before us. Developments by our competitors may render our product candidates obsolete or non-competitive.

We also experience competition from universities and other research institutions, and we frequently compete with others in acquiring technology from those sources. These industries have undergone, and are expected to continue to undergo, rapid and significant technological change, and we expect competition to intensify as technical advances in each field are made and become more widely known. There can be no assurance that others will not develop technologies with significant advantages over those that we are seeking to develop. Any such development could harm our business.

Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact upon our ability to sell our products profitably. In the United States in recent years, new legislation has been proposed at the federal and state levels that would effect major changes in the healthcare system, either nationally or at the state level. These proposals have included prescription drug benefit proposals for Medicare beneficiaries introduced in Congress. Legislation creating a prescription drug benefit and making certain changes in Medicare reimbursement has recently been enacted by Congress. Given this legislation's recent enactment, it is still too early to determine its impact on the pharmaceutical industry and our business. Further federal and state proposals are likely. More recently, administrative proposals are pending that would change the method for calculating the reimbursement of certain drugs. The potential for adoption of these proposals may affect our ability to raise capital, obtain additional collaborators or market our products. Such proposals, if enacted, may reduce our revenues, increase our expenses or limit the markets for our products. In particular, we expect to experience pricing pressures in connection with the sale of our products due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals.

Risk Factors Relating to Our Intellectual Property

If we are unable to obtain and maintain protection for the intellectual property incorporated into our products, the value of our technology and products will be adversely affected.

Our success will depend in large part on our ability or the ability of our licensors to obtain and maintain protection in the United States and other countries for the intellectual property incorporated into our products. The patent situation in the field of biotechnology and pharmaceuticals generally is highly uncertain and involves complex legal and scientific questions. Neither we nor our licensors may be able to obtain additional issued patents relating to our technology. Even if issued, patents may be challenged, narrowed, invalidated, or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of the term of patent protection we may have for our products. In addition, our patents and our licensors' patents may not afford us protection against competitors with similar technology. Because patent applications in the United States and many foreign

jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications.

We also rely on trade secret protection and confidentiality agreements to protect our interests in proprietary know-how that is not patentable and for processes for which patents are difficult to enforce. We cannot be certain that we will be able to protect our trade secrets adequately. Any leak of confidential data into the public domain or to third parties could allow our competitors to learn our trade secrets.

If we lose our licenses from PowderMed Limited for Zingo or certain licensees for Adlea, we will not be able to continue development or outlicensing of our current products.

We are a party to two significant license agreements relating to patents, patent applications and know-how covering the technology relating to Zingo and Adlea. These license agreements impose various diligence, commercialization, royalty and other obligations on us. If we fail to comply with the obligations in the license agreements, the licensor may have the right to terminate the license and we may not be able to market products that were covered by the license.

The license agreement with James N. Campbell, M.D., Richard A. Meyer, M.S. and Marco Pappagallo, M.D. relates to the steps of administering capsaicin for pain reduction utilized in Adlea, and our rights under this agreement can be terminated on 10 days' written notice if we fail to make a payment or fulfill any material obligation under the agreement and the failure is not cured by us within 180 days of receiving notice of such failure. The license agreement with PowderMed Limited, now a wholly-owned subsidiary of Pfizer, Inc., relates to technology underlying Zingo. The agreement with PowderMed Limited can be terminated immediately by either party if the other party ceases to do business in the ordinary course, or assigns all or substantially all of its assets for the benefit of creditors. Either party can also terminate for material breach if not cured within 60 days of notice or if not cured within 30 days of notice if the breach relates to payment provisions. To date, we believe we have met our obligations under all of these agreements.

We may incur substantial costs enforcing our patents, defending against third-party patents, invalidating third-party patents or licensing third-party intellectual property, as a result of litigation or other proceedings relating to patent and other intellectual property rights.

We may not have rights under some patents or patent applications that would be infringed by technologies that we use in our research, drug targets that we select, or product candidates that we seek to develop and commercialize. Third parties may own or control these patents and patent applications in the United States and abroad. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. We or our collaborators therefore may choose to seek, or be required to seek, a license from the third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or forced to cease some aspect of our business operations, as a result of patent infringement claims, which could harm our business.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. Although we are not currently a party to any patent litigation or any other adversarial proceeding, including any interference proceeding declared before the United States Patent and Trademark Office, regarding intellectual property rights with respect to our products and technology, we may become so in the future. We are not currently aware of any actual or potential infringement claim involving our intellectual property rights. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. The outcome of patent litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of the adverse party, especially in biotechnology related patent cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. If a patent or other proceeding is resolved against us, we may be enjoined from researching, developing, manufacturing or commercializing our products

without a license from the other party and we may be held liable for significant damages. We may not be able to obtain any required license on commercially acceptable terms or at all.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could harm our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

Other Risk Factors

Anti-takeover defenses that we have in place could prevent or frustrate attempts by stockholders to change the direction or management of the company.

Provisions of our certificate of incorporation and bylaws and applicable provisions of Delaware law may make it more difficult for or prevent a third-party from acquiring control of us without the approval of our board of directors. These provisions:

- establish a classified board of directors, so that not all members of our board may be elected at one time;
- set limitations on the removal of directors;
- limit who may call a special meeting of stockholders;
- establish advance agreement requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings;
- prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; and
- provide our board of directors the ability to designate the terms of and issue new series of preferred stock without stockholder approval.

These provisions may have the effect of entrenching our management team and may deprive you of the opportunity to sell your shares to potential acquirors at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock.

Our principal stockholders and management own a significant percentage of our stock and are able to exercise significant influence.*

Our executive officers, directors and principal stockholders, together with their affiliates, own approximately 54.8% of our voting stock, including shares subject to outstanding options based upon shares outstanding as of March 31, 2008. Our executive officers are not affiliated with any of our directors, principal stockholders or their affiliates. These stockholders will likely be able to determine the composition of our board of directors, possess the voting power to approve all matters requiring stockholder approval, including the approval of mergers and acquisitions or other changes in corporate control, and will continue to have significant influence over our operations. The interests of these stockholders may be different than the interests of other stockholders on these matters. This concentration of ownership could also have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could reduce the price of our common stock.

If our stock price is volatile, purchasers of our common stock could incur substantial losses.

Our stock price is likely to be volatile. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The price for our common stock may be influenced by many factors, including:

results of our clinical trials;

failure of any of our product candidates, if approved, to achieve commercial success;

regulatory developments in the United States and foreign countries;

developments or disputes concerning patents or other proprietary rights;

ability to manufacture our products to commercial standards;

public concern over our products;

litigation;

the departure of key personnel;

future sales of our common stock;

variations in our financial results or those of companies that are perceived to be similar to us;

changes in the structure of healthcare payment systems;

investors' perceptions of us; and

general economic, industry and market conditions.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults upon Senior Securities

Not applicable.

Item 4. Submission of Matters to a Vote of Security Holders

None.

Item 5. Other Information

None.

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Item 6. Exhibits

Exhibit Number	Description of Document
3.1(1)	Amended and Restated Certificate of Incorporation.
3.2(2)	Certificate of Amendment of Amended and Restated Certificate of Incorporation.
3.3(3)	Certificate of Amendment of Amended and Restated Certificate of Incorporation.
3.4(4)	Amended and Restated Bylaws.
4.1	Reference is made to Exhibits 3.1 through 3.4.
4.2(5)	Specimen stock certificate.
10.58(6)	Executive Change in Control and Severance Benefit Plan, as amended.
10.60(7)	Amendment No. 1 to the Common Stock Purchase Agreement entered into as of March 24, 2008, by and between Anesiva and Azimuth Opportunity Ltd.
10.61+	License Agreement entered into as of February 4, 2008, by and between Anesiva and Sigma-Tau Industrie Farmaceutiche Riunite S.p.A. (“Sigma-Tau”).
10.62+	Amendment to the License Agreement entered into as of February 4, 2008, by and between Anesiva and Sigma-Tau Industrie Farmaceutiche Riunite S.p.A. (“Sigma-Tau”).
10.63+	License and Distribution Agreement entered into as of April 24, 2008, by and between Anesiva and Green Vision Company
31.1	Certification of Chief Executive Officer, as required by Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Vice President and Chief Financial Officer, as required by Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
32.1*	Certification of Chief Executive Officer, as required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).
32.2*	Certification of Vice President and Chief Financial Officer, as required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).

+ Confidential treatment has been requested for portions of this exhibit. Omitted portions have been filed separately with the SEC pursuant to Rule 24b-2 of the Securities and Exchange Act o f1934, as amended.

(1) Filed as Exhibit 3.2 to our Registration Statement on Form S-1, as amended (File No. 333-110923), filed with the SEC on December 4, 2003, and incorporated herein by reference.

(2) Filed as the like-numbered exhibit to our Quarterly Report on Form 10-Q (File No. 000-50573) for the period ended June 30, 2006, as filed with the SEC on August 10, 2006, and incorporated by reference herein.

(3) Filed the like-numbered exhibit to our Annual Report on Form 10-K (File No. 000-50573) for the year ended December 31, 2007, as filed with the SEC on March 14, 2008, and incorporated herein by reference.

(4) Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 000-50573), filed with the SEC on February 11, 2008, and incorporated by reference herein.

(5) Filed as the like-numbered exhibit to our Registration Statement on Form S-1, as amended (File No, 333-110923), filed with the SEC on December 4, 2003, and incorporated by reference herein.

(6) Filed the like-numbered exhibit to our Current Report on Form 8-K (File No. 000-50573), filed on April 2, 2008, and incorporated by reference herein.

(7) Filed the like-numbered exhibit to our Current Report on Form 8-K (File No. 000-50573), filed on March 25, 2008, and incorporated by reference herein.

* The certifications attached as Exhibit 32.1 and Exhibit 32.2 accompany this Quarterly Report on Form 10-Q, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Anesiva, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

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SIGNATURES

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

Dated: May 8, 2008

Anesiva, Inc.

/s/ John P. McLaughlin

John P. McLaughlin
Chief Executive Officer
(Principal Executive Officer)

/s/ Jean-Frédéric Viret

Jean-Frédéric Viret
Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

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4.2(5)	Specimen stock certificate.
10.58(6)	Executive Change in Control and Severance Benefit Plan, as amended.
10.60(7)	Amendment No. 1 to the Common Stock Purchase Agreement entered into as of March 24, 2008, by and between Anesiva and Azimuth Opportunity Ltd.
10.61+	License Agreement entered into as of February 4, 2008, by and between Anesiva and Sigma-Tau Industrie Farmaceutiche Riunite S.p.A.
10.62+	Amendment to the License Agreement entered into as of February 4, 2008, by and between Anesiva and Sigma-Tau Industrie Farmaceutiche Riunite S.p.A.
10.63+	License and Distribution Agreement entered into as of April 24, 2008, by and between Anesiva and Green Vision Company
31.1	Certification of Chief Executive Officer, as required by Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Vice President and Chief Financial Officer, as required by Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
32.1*	Certification of Chief Executive Officer, as required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).
32.2*	Certification of Vice President and Chief Financial Officer, as required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).

+ Confidential treatment has been requested for portions of this exhibit. Omitted portions have been filed separately with the SEC pursuant to Rule 24b-2 of the Securities and Exchange Act o f1934, as amended.

(1) Filed as Exhibit 3.2 to our Registration Statement on Form S-1, as amended (File No. 333-110923), filed with the SEC on December 4, 2003, and incorporated herein by reference.

(2) Filed as the like-numbered exhibit to our Quarterly Report on Form 10-Q (File No. 000-50573) for the period ended June 30, 2006, as filed with the SEC on August 10, 2006, and incorporated by reference herein.

(3) Filed the like-numbered exhibit to our Annual Report on Form 10-K (File No. 000-50573) for the year ended December 31, 2007, as filed with the SEC on March 14, 2008, and incorporated herein by reference.

(4) Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 000-50573), filed with the SEC on February 11, 2008, and incorporated by reference herein.

(5) Filed as the like-numbered exhibit to our Registration Statement on Form S-1, as amended (File No, 333-110923), filed with the SEC on December 4, 2003, and incorporated by reference herein.

(6) Filed the like-numbered exhibit to our Current Report on Form 8-K (File No. 000-50573), filed on April 2, 2008, and incorporated by reference herein.

(7) Filed the like-numbered exhibit to our Current Report on Form 8-K (File No. 000-50573), filed on March 25, 2008, and incorporated by reference herein.

* The certifications attached as Exhibit 32.1 and Exhibit 32.2 accompany this Quarterly Report on Form 10-Q, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Anesiva, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Exhibit 10.61

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

LICENSE AGREEMENT

This Agreement is entered as of February 4, 2008 (hereinafter "Effective Date")

By and between

Anesiva Inc., a company organised and existing pursuant to the laws of Delaware, USA, and having its principal place of business at 650 Gateway Boulevard, South San Francisco, CA 94080, USA (hereinafter "ANESIVA")

on the one part

and

SIGMA-TAU Industrie Farmaceutiche Riunite S.p.A., a company organised and existing pursuant to the laws of Italy and having its registered offices in Rome, 47 Viale Shakespeare, 00144, Italy (hereinafter "SIGMA-TAU")

on the other part

PREMISES

WHEREAS, ANESIVA possesses certain rights relating to the Product, the Know-How and the Patents (as hereinafter respectively defined); and

WHEREAS, ANESIVA and SIGMA-TAU signed on August 29, 2007 a Letter of Intent (hereinafter "LOI") whereby the Parties (as hereinafter defined) have agreed to enter into a licence agreement in order to have SIGMA-TAU register, import, promote, distribute and sell, directly or indirectly, the Product in the Field in the Territory (as hereinafter respectively defined) under the Know-How and the Patents in accordance with certain terms and conditions;

WHEREAS, in accordance with the LOI, SIGMA-TAU is willing to obtain from ANESIVA an exclusive license under the Know-How and the Patents to register, import, promote, distribute and sell, directly or indirectly, the Product in the Field in the Territory; and

WHEREAS, in accordance with the LOI, ANESIVA is willing to grant to SIGMA-TAU such exclusive license in the Territory under the terms and conditions hereinafter set forth.

NOW THEREFORE, in consideration of the foregoing premises and of the mutual covenants and agreements hereinafter set forth, the Parties do hereby agree as follows:

1. PREMISES

1.1 The premises form an integral part of this Agreement and are binding for the Parties hereof.

2. DEFINITIONS

2.1 Definitions: The following terms as used in this Agreement shall, unless the context clearly indicates to the contrary, have the meanings set forth in this Article:

2.1.1 "Affiliated Company" shall mean:

(i) an organization more than fifty percent (50%) of the voting stock of which is owned and/or controlled directly or indirectly by either Party;

(ii) an organization which directly or indirectly owns and/or controls more than fifty percent (50%) of the voting stock of either Party;

(iii) an organization which is directly or indirectly under common control of either Party through common shareholding or which is directly or indirectly under common control of the respective shareholders of either Party;

2.1.2 "DCP" shall have the meaning set forth in **Clause 6.1.1**;

2.1.3 "Drug Release Testing" shall mean the final drug release testing conducted by the Release Site in Europe before releasing the Product for human use in the Territory under this Agreement. The testing should be conducted as per the specifications provided by ANESIVA being in line with the respective approved Registrations of the Product in the Territory and all the costs of drug release testing for the Product ordered by SIGMA-TAU to ANESIVA under this Agreement will be [*];

2.1.4 "Ex-Factory Price" shall mean the average selling price to independent buyers for each unit of Product in the Territory for a Marketing Year, less value added tax and other similar sales taxes related to the sale of the Products;

2.1.5 "Field" shall mean the [*] and all other similar indications for which the Product may be developed, registered, imported, promoted, distributed, sold or used;

2.1.6 "Know-How" shall mean all scientific, medical, marketing data and information relating to the Product and known, available to or in the possession of ANESIVA whether generally known to others or not, which are necessary or useful to SIGMA-TAU to carry out the Drug Release Testing, register, import, promote, distribute and sell the Product in the Field in the Territory under the terms of this Agreement;

2.1.7 "Other Anesiva Partners" shall have the meaning set forth in **Clause 6.1.3**;

2.1.8 "Manufacture" shall have the meaning set forth in **Clause 8.7**. The terms "Manufacturer", "Manufactured" and "Manufacturing" as used in this Agreement shall be interpreted accordingly;

2.1.9 "Marketing Year" shall mean the period starting from the date of the first distribution of the Product by SIGMA-TAU and/or its designated Sub-licensees to the first customer in the Territory ending after 12 (twelve) months from such first distribution date and each 12 (twelve) month period thereafter;

2.1.10 "Net Sales" shall mean the gross amount of sales made by SIGMA-TAU and/or its designated Sub-licensees of the Product in the Territory to the first independent buyer in bona fide arm' s length transactions, less: (i) quantity and/or cash discounts actually allowed or taken to the extent customary (ii) customs duties excise taxes, if any, directly related to the sale of the Product and actually paid (iii) amounts allowed by reason of rejections and return of goods, (iv) third party rebates related to the sale of the Product, to the extent allowed, and (v) value added tax and other similar sales taxes related to the sale of the Product;

2.1.11 "Parties" shall mean ANESIVA and SIGMA-TAU collectively, and Party means either of them;

2.1.12 "Patents" shall mean any and all patent/s and/or patent application/s disclosing and/or claiming the Product as listed in **Appendix A** attached hereto, owned by or licensed to ANESIVA during the term of this Agreement, as well as any extension, continuation and continuations-in-part applications, divisions, re-issues and re-examination thereof in the Territory;

2.1.13 "Product" shall mean ANESIVA' s powder intradermal injection system containing lidocaine in finished form ready for use, as described in **Appendix B** attached hereto, and [*], and/or [*] developed and realized by and/or on behalf of ANESIVA and/or made available to ANESIVA;

2.1.14 "Release Site" shall have the meaning set forth in **Clause 6.1.3**;

2.1.15 "Registrations" shall mean any and all government registrations, including the marketing authorizations and any other licenses and permits necessary to register, import, promote, distribute and sell the Product in the Field in the Territory;

2.1.16 "Registration Dossier" shall mean any pre-clinical, clinical, medical, scientific an technical information relating to the Product and contained in the registration dossier prepared or to be prepared by ANESIVA in order to file an application to obtain a Registration under the decentralized procedure in accordance with: ii) EU standards; and any and all EU regulations and directives currently in force;

2.1.17 "Specifications" shall have the meaning set forth in **Clause 8.7**;

2.1.18 "Sub-licensees" shall mean any entities, including but not limited to SIGMA-TAU' s Affiliated Companies, to whom any of the marketing rights with regard to the Product granted to SIGMA-TAU under this Agreement have been further licensed or sublicensed by SIGMA-TAU in accordance with the provisions of **Clause 3.5**;

2.1.19 "Territory" shall mean the territories set forth in **Appendix C**. Other countries may be added to the Territory from time to time upon mutual written agreement between the Parties;

2.1.20 "Trademark" shall mean the trademark set forth in **Appendix D**, registered or to be registered in the name of ANESIVA or, [*], any other trademark/s chosen at its sole discretion by [*] and registered in the name of [*] in the Territory, which shall be used to identify the Product sold by SIGMA-TAU in the Territory. Any such other trademark [*] shall hereafter be referred to as the "[*] Trademark".

2.2 **Sections and Headings**: The division of this Agreement into Articles, sections, subsections and Appendices and the insertion of headings are for convenience of reference only and shall not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Clause or Appendices refers to the specified Clause or Appendices to this Agreement. In this Agreement, the terms "this Agreement", "hereof' , "herein", "hereunder" and similar expressions refer to this Agreement and not to any particular part, Clause, Appendix or the provision hereof.

2.3 **Other Terms**: Words in this Agreement having the singular meaning shall include the plural meaning, words denoting any genera include all genders, words denoting persons include firms and corporation and in each case vice versa.

2.4 **Appendices**: The Appendices attached hereto are incorporated in and form part of this Agreement.

3. GRANT OF LICENCE

3.1 ANESIVA hereby grants to SIGMA-TAU and SIGMA-TAU hereby accepts: a) an exclusive license under the Patents and the Know-How to register, import, promote, sell and distribute the Product in the Territory; b) an exclusive license to use the Trademark, [*], to register, import, promote, sell and distribute the Product in the Territory. In such a case, SIGMA-TAU shall make use of the Trademark in all materials and activities related to the marketing, sale and distribution of the Product.

3.2 In accordance with **Clause 3.1 (b)**, [*] to the [*], to [*] the Product in the Territory; such [*] trademark to be chosen, owned and registered and maintained by [*] under this Agreement.

3.3 SIGMA-TAU shall have the right to use the SIGMA-TAU logo along on Product' s material packaging.

3.4 Furthermore, ANESIVA hereby grants to SIGMA-TAU, and SIGMA-TAU hereby accepts, the exclusive right to use the Patents, the Registration Dossier, the Know-How and the Trademark, if applicable, to carry out the Drug Release Testing in order to register, import, promote, sell and distribute the Product in the Territory.

3.5 SIGMA-TAU shall have the right to grant sub-licenses to any of its Affiliated Companies upon written notice to ANESIVA and to third parties upon prior written approval by ANESIVA; such approval not to be unreasonably withheld or delayed.

3.6 [*] shall be entitled to describe itself as [*] for the Product, but shall not be or be considered as [*] or as [*]. Neither SIGMA-TAU nor ANESIVA shall have any right to negotiate or to enter into any contracts or commitments in the name of, or on behalf of, either of the said Parties, to bind the other in any respect whatsoever.

4. EXCHANGE OF INFORMATION

4.1 ANESIVA shall disclose to SIGMA-TAU the Know-How available to ANESIVA which is necessary or helpful for SIGMA-TAU to carry out the Drug Release Testing, register, import, promote, sell and distribute the Product in the Territory and generally to fulfil the purpose of this Agreement. ANESIVA shall also promptly disclose to SIGMA-TAU from time to time additional Know-How which is available to ANESIVA and which may be developed or acquired by ANESIVA during the term of this Agreement and which ANESIVA is free to disclose.

4.2 SIGMA-TAU shall provide ANESIVA with access, and the right to reference, to any marketing, clinical and other data and information in its possession and control that are potentially useful in the sale and marketing of the Product in the Territory for ANESIVA' s potential use outside the Territory.

4.3 ANESIVA shall provide SIGMA-TAU with access, and the right to reference, to any marketing, clinical and other data and information in its possession and control, including the Know-How, which are potentially useful to register, import, promote, sell and distribute the Product in the Territory. In accordance with **Clause 4.2** above, SIGMA-TAU will do the same with such data and information in its possession for ANESIVA' s potential use outside the Territory.

4.4 Both Parties shall appoint a project leader within [*] of signing the Agreement, through which all communications regarding this Agreement will be initially directed. The project leaders will facilitate direct communication between functional experts as needed to manage activities under this Agreement.

5. OBLIGATION TO KEEP SECRET

5.1 SIGMA-TAU shall, during the term of this Agreement and thereafter, keep confidential any and all information received from ANESIVA, including the Know-How, except for:

(a) information which, prior to its disclosure to SIGMA-TAU and/or its Sub-licensees, is part of the public domain;

(b) information which, after its disclosure to SIGMA-TAU, becomes part of the public domain by publication or otherwise, except by breach of this Agreement by SIGMA-TAU;

(c) information which SIGMA-TAU can establish by competent proof was in its possession or in possession of its Sub-licenses, prior to its disclosure to SIGMA-TAU and was not acquired, directly or indirectly, from ANESIVA; and

(d) information which SIGMA-TAU can establish by competent proof was received from a third party provided, however, that it was not obtained by said third party, directly or indirectly, from ANESIVA.

5.2 SIGMA-TAU shall make the information which is obligated to keep confidential pursuant to this Article known only to those employees of SIGMA-TAU and/or its Sub-licensees who must be informed, and only to the extent necessary to serve the purpose of this Agreement.

5.3 The obligations of confidentiality and restrictions on use contained in this **Clause 5** shall remain in effect for a period of [*] from the Effective Date.

6. REGISTRATIONS

6.1 ANESIVA undertakes to:

6.1.1 successfully prepare[*] the Registration Dossier to be filed with the competent regulatory authorities under the decentralized procedure (hereinafter the "DCP") in accordance with the terms of this Agreement; in particular ANESIVA undertakes to prepare the answers to the consolidated list of questions that will be eventually issued by the competent regulatory authorities under the DCP;

6.1.2 select the reference Member State in collaboration with SIGMA-TAU for the start of the DCP for the obtainment of the Registrations by SIGMA-TAU under this Agreement;

6.1.3 [*] for the [*] in the [*] other than the [*], to collaborate with SIGMA-TAU: i) prior to the start of the [*], in order to [*] the same [*] in [*], in case SIGMA-TAU requests to do so; ii) during the [*], for the obtainment of the Registrations and after the obtainment of the Registrations, for any variations to the Registrations under the DCP;

6.1.4 promptly supply SIGMA-TAU with all the relevant information and data, including the Registration Dossier, necessary to obtain and/ or maintain the Registrations of the Product in the Territory in the name of SIGMA-TAU and/or its Sub-licensees under the DCP;

6.1.5 prepare the dossiers relevant to any variations to the initial Registrations to be provided to SIGMA-TAU and Other Anesiva Partners for the submission to the competent regulatory authorities, should a variation be originated by ANESIVA or by SIGMA-TAU as described in **Clause 6.7**;

6.1.6 Prepare any PSUR and Product renewal dossiers to be submitted in Europe according to the predefined timelines;

6.1.7 ANESIVA shall be responsible for the activities provided under this **Clause 6.1**. Upon ANESIVA' s written request, SIGMA-TAU shall make its best efforts to reasonably cooperate with ANESIVA, at [*] with regard to the activities provided under **Clauses 6.1.1** and **6.1.5**; such [*] will be [*] and [*] to [*].

6.2 [*] shall [*] of the [*] for the [*] the [*]. [*] shall be the owner of the Registrations in the Territory, including any Registrations as amended in consequence of required variations, which shall be obtained and maintained at [*] of [*]. [*] shall promptly inform [*] of any request coming from or to be addressed to the relevant regulatory authorities in each country of the Territory regarding the Product.

6.3 SIGMA-TAU shall in respect of each order for the Product be responsible for:

(a) complying with all applicable laws and regulations relating to the import, promotion and sale of the Product in the Territory (other than those agreed beforehand with Principal relating to the packaging or labelling of the Product) and shall notify the Principal of any changes in the laws and regulations in the Territory relating to the packaging or labelling of the Product;

(b) obtaining any necessary import licences, certificates of origin or other requisite documents and paying all applicable customs and duties in respect of the importation of the Product into the Territory and their sale and redistribution in the Territory.

6.4 ANESIVA shall fully cooperate with SIGMA-TAU and/or its Sub-licensees to the best of its ability by assisting SIGMA-TAU and/or its Sub-licensees in obtaining and maintaining:

(a) requisite documentation in **Clauses 6.1**, **6.2** and **6.3 a)** above;

(b) all governmental approvals required to export the Product from abroad and to import the Product into the Territory.

6.5 Should [*] fail to [*] or [*] necessary to [*], ANESIVA shall be entitled to terminate this Agreement forthwith at any time.

6.6 SIGMA-TAU will collaborate with Other Anesiva Partners during the DCP and after the obtainment of the Registrations for any variations to the Registrations under the DCP.

6.7 During the DCP, should any competent regulatory authority or any relevant law in the Territory require, for the obtaining and/or the maintenance of the Registrations and/or any governmental licences, any documentation or information not included in the Know-How, at SIGMA-TAU request, ANESIVA shall promptly provide[*] any further necessary documentation to support SIGMA-TAU' s and/or its Sub-licensees' efforts to obtain and maintain the Registrations and/or any governmental licences to import, promote, distribute and sell the Product in the Territory under this Agreement. In this latter case, SIGMA-TAU shall make and shall cause its Sub-licensees to make their best efforts to reasonably cooperate with ANESIVA, [*].

6.8 In accordance with **Clause 4.1**, during the term of this Agreement ANESIVA shall support SIGMA-TAU with any and all information and data on the Product, including Know-How, which are available or will be available to ANESIVA, so that SIGMA-TAU may take all steps which may be required by law in order to obtain and maintain the Registrations, import, promote, sell and distribute the Product in the Territory as well as carry out the Drug Release Testing. ANESIVA shall sign all necessary documents and perform all other obligations which may be required in order to assure that SIGMA-TAU will obtain and maintain the Registrations, import, promote, distribute and sell the Product in the Territory as well as carry out the Drug Release Testing in accordance with the Registrations.

6.9 Each Party shall promptly provide the other Party with any information and data relating to any serious or previously unknown side effects or adverse reactions, which occur during the use of the Product, received by or reported to one of the Parties from any sources, according to procedures which will be agreed upon by the Parties separately. Furthermore ANESIVA shall cause Other Anesiva Partners to: i) provide SIGMA-TAU with any information and data relating to any serious or previously unknown side effects or adverse reactions, which occur during the use of the Product, received by or reported to Other Anesiva Partners from any sources, in accordance with any EU applicable laws and regulations; and (ii) prepare the PSUR. In particular, any communication to the competent regulatory authority by SIGMA-TAU and Other Anesiva Partners with regard to the Product pharmacovigilance activities (PSUR, etc.) shall have an identical content. Within [*] of the execution of the Agreement the Parties will sign a Pharmacovigilance Agreement.

7. COMMERCIALIZATION

7.1 It is agreed that SIGMA-TAU obligations hereunder also include the physical promotion, sale and distribution of the Product in the Territory, directly or indirectly, as well as the distribution of written promotional material relating to the Product, whose contents shall obtain ANESIVA' s suggestion and advice. Furthermore, SIGMA-TAU will send to ANESIVA a copy of the most selected and representative promotional and marketing materials.

7.2 SIGMA-TAU and/or its Sub-licensees shall have the sole control of all commercialization decisions regarding the commercialization of the Product in the Territory. Notwithstanding the foregoing, SIGMA-TAU shall, directly or through its Sub-licensees, commercialize the Product in accordance with the Product Profile as it has been communicated in writing to SIGMA-TAU by ANESIVA. For the purpose hereof, "Product Profile" shall mean the approved indications for the Product, as set out in the Registrations.

7.3 SIGMA-TAU shall keep ANESIVA timely and completely informed about the preparation of the launching of the Product in each country of the Territory, as well as about the relevant launching dates.

7.4 SIGMA-TAU will send to ANESIVA within [*] after the end of each Marketing Year, a written report detailing sales of the Product for the previous Marketing Year in units and value and the relevant Net Sales of the Product. SIGMA-TAU shall send to ANESIVA, upon ANESIVA' s request [*] in any Marketing Year, a brief summary of the most important promotional activities connected with the Product, the activities of SIGMA-TAU' s and/or its Sub-licensees sales forces in promoting the Product, including information relating to market developments and acceptance of the Product in the Territory. Furthermore, SIGMA-TAU will send to ANESIVA [*] a written report detailing the Product inventory for the previous calendar quarter in units.

7.5 The Parties recognize that concrete [*] with regard to the Product in the Territory in any Marketing Year are unlikely to be [*]. Therefore, the Parties hereby identify [*] that SIGMA-TAU and/or its Sub-licensees may be possibly achieving in the [*], provided that such figures do not imply any [*] for SIGMA-TAU in any of said Marketing Years and have to be revised [*] before the end of each Marketing Year.

[*]

For the purpose hereof "Market Share" shall mean the market related to [*].

8. SUPPLY OF PRODUCT

8.1 ANESIVA hereby agrees to sell the Product to SIGMA-TAU and SIGMA-TAU hereby agrees to purchase from ANESIVA all of SIGMA-TAU' s requirements for the Product in the Territory.

8.2 From the execution of this Agreement and until the date upon which ANESIVA' s [*] for the Product in the Territory is approved in accordance with the applicable EU laws (approximately [*]), SIGMA-TAU shall launch and commercialize only in [*] the Product supplied from ANESIVA' s [*] as approved in accordance with the applicable EU laws. In the unlikely event that ANESIVA' s [*] does not obtain the above said approval [*], then ANESIVA is obliged to supply SIGMA-TAU with the Product from its approved [*] also for the [*] of the [*] other than [*]. Therefore, [*], SIGMA-TAU may initiate the commercialization of the Product in such other countries of the Territory. ANESIVA shall use commercially reasonable efforts consistent with demand for the Product, to obtain the approval by the competent regulatory authorities of a [*].

8.3

Each month, not later than the [*], SIGMA-TAU shall provide ANESIVA with a rolling [*] non-binding forecast broken down into SIGMA-TAU' s estimated requirements of the Product for the Territory for each calendar month. The first [*] of the [*] forecast shall be binding. ANESIVA will acknowledge acceptance of the forecast within [*]. Each month, not later than the [*] of the month, SIGMA-TAU will place a purchase order for

each month with delivery date within [*] from the order date. ANESIVA will acknowledge the purchase order within [*]. SIGMA-TAU shall exert all reasonable efforts to make each forecast as accurate as possible and, if necessary, shall update such forecasts at the [*] to reflect actual and projected demand.

8.4 In accordance with **Clause 8.3** above, the first [*] of each rolling forecast shall be considered firm orders. SIGMA-TAU shall provide ANESIVA with a written firm purchase order specifying delivery date(s) which shall be within [*] from the date of the order. Each revised estimate in terms of increasing of the Product' s quantity originally ordered, if communicated less than [*] in advance, shall be submitted to feasibility analysis. ANESIVA shall inform SIGMA-TAU within [*] about the feasibility of meeting the requirements exceeding the forecast originally delivered.

8.5 If SIGMA-TAU has to make any change to the packaging material for the Product due to requests of the competent regulatory authorities, ANESIVA shall be given a lead time to supply the Product in that new packaging material of at least [*] from SIGMA-TAU' s approval of the last component of the packaging material, [*], unless a shorter time is requested by the competent regulatory authorities. If SIGMA-TAU wishes to make any change to the packaging material for the Product, ANESIVA shall be given a lead time to supply the Product in that new packaging material of at least [*] from SIGMA-TAU' s approval of the last component of the packaging material, [*]. In this latter case, it is understood between the Parties that SIGMA-TAU can make changes to the packaging material for the Product [*]. Should components of old packaging materials, which in no case shall be equal to [*], be stocked in ANESIVA' s or its Manufacturer warehouse and should these components not be used for packaging the Product, all the relevant direct costs of destruction shall be charged to [*]. For the sake of clarity, [*] shall no bear any direct costs of destruction for components of old packaging materials exceeding the above said [*].

8.6 Each of SIGMA-TAU' s purchase orders shall be for full lot sizes, the quantities per lot size are set forth in **Appendix B**. Delivery of the Product to SIGMA-TAU or its Sub-licensees shall be CIP (ICC Incoterms 2000) location to be communicated separately by SIGMA-TAU.

8.7 ANESIVA undertakes to Manufacture or have Manufactured, use, and handle the Product, to comply with: i) "the Rules governing Medicinal Products in the European Community Volume IV - Guidelines for Good Manufacturing Practice for Medicinal Products" ("GMP"), ii) all relevant applicable law; iii) the specifications of the Product as set out in the Registrations, and iv) the positive assessment of the Release Site (hereinafter collectively the "Specifications"). For the purpose hereof, "Manufacture" and "Manufactured" shall mean the following Manufacturing activities with regard to the Product carried out by the approved Manufacturer(s) before delivery to SIGMA-TAU:

(i) the purchase, receipt and testing of the raw materials, including active ingredient and excipients;

(ii) the processing of the raw materials into the Product;

(iii) the packing of the Product into its primary packing material (needleless syringe);

(iv) the final packaging;

(v) the finished product QC testing and drug release;

(vi) the storage of the Product and shipment to Europe when the European Release Site has taken place.

8.8 The Product shall be supplied [*] in accordance with any applicable laws and regulations in the Territory. SIGMA-TAU shall prepare, at its own expense, the artwork of packaging materials, labels and insert brochures of the Product in compliance with GMP and the Registrations and in a format specified by ANESIVA. SIGMA-TAU shall send to ANESIVA the descriptions therein and designs thereof to and shall take care of ANESIVA' s suggestion and advice. ANESIVA shall then source such labels and packages from approved vendors.

8.9 SIGMA-TAU acknowledges that ANESIVA will carry out the Manufacturing of the Product in the approved facilities in accordance with any applicable laws and regulations, including the Release Site as described in the Registration Dossier. Any variation of the Manufacturing site required by ANESIVA shall be promptly communicated in writing to SIGMA-TAU and will be subject to a variation to the Registrations according to **Clause 6.1.5**. ANESIVA acknowledges that any variation to the approved Manufacturing facilities will be implemented only after the approval by the competent regulatory authorities and, at the same time, ANESIVA shall ensure in good faith that any variation to the Manufacturing site shall not materially impede or delay the supply of the Product to SIGMA-TAU in accordance with this **Clause 8**. A material shortfall in the supply of the Product ordered by SIGMA-TAU equal to [*] or a [*] delay in the supply of the ordered Product to SIGMA-TAU will [*] by ANESIVA. In this case, [*] may [*] the [*] forthwith by [*] to [*] and [*] shall apply. SIGMA-TAU shall promptly file with the competent regulatory authorities any application for the variation of the Manufacturing site, *provided*, however, *that* ANESIVA supplies any and all relevant required documentation.

8.10 SIGMA-TAU may, at periodic intervals, audit the ANESIVA operation and facility where the Product is Manufactured to ensure that the Manufacturing is carried out in accordance with and as provided for in **Clause 8.7**. ANESIVA upon SIGMA-TAU' s reasonable prior notice, will permit SIGMA-TAU' s representatives, for the purpose of quality audit, all reasonable access to its Manufacturing and warehousing, areas, during normal business hours.

8.11

SIGMA-TAU will ask the European Release Site to permit representatives of ANESIVA to inspect the facilities for Drug Release Testing and to take samples of Product during normal business hours. Such inspection is limited to [*] and shall be subject to a [*]

notice period; provided, however, that SIGMA-TAU will make its best efforts to cause the Release Site to permit representatives of ANESIVA to make additional inspections in the event the Parties become aware of Product material quality problems. Upon ANESIVA reasonable request, SIGMA-TAU will provide ANESIVA with any Product information and documentation relating to the Drug Release Testing.

8.12 Any claims concerning weight, loss, damage or deviation from the Specifications shall be made in writing by SIGMA-TAU to ANESIVA within [*] after taking delivery of Product by or on behalf of SIGMA-TAU. After said [*] term, if no claim is made, the Product shall be considered accepted by SIGMA-TAU and ANESIVA shall be discharged from any responsibility for defect(s), except for intrinsic defects of the Product. In any case, should the Product show a latent defect becoming evident after the said [*], not due to other causes attributable to SIGMA-TAU, ANESIVA will replace it as indicated here under. In case of justifiable claim for defect in any portion of the delivered Product because of its failure to conform to the Specifications, ANESIVA shall, without charge, replace the defective portion with supplies which are in compliance with the Specifications. In any other cases, the Product received by SIGMA-TAU shall not be returned to ANESIVA. If the Parties are unable to resolve their differences, then either Party may refer the matter for final analysis to a specialized firm of international reputation acceptable to both Parties. The analysis of such firm shall be binding on both Parties hereto. The Party at fault shall pay the cost for such specialized firm. SIGMA-TAU shall, at ANESIVA' s request and expense, follow any reasonable instructions to return to ANESIVA or dispose of any Product which are not in compliance with the Specifications.

9. COMPENSATION

9.1 In consideration for the rights granted herein, SIGMA-TAU shall make the following [*] payments to ANESIVA:

9.1.1 [*] Payment:

SIGMA-TAU shall pay ANESIVA:

[*]

Such payment shall be made within [*] from receipt of the relevant invoice by wire transfer to an account promptly communicated in writing by ANESIVA to SIGMA-TAU.

Should the [*], ANESIVA shall, at SIGMA-TAU' s request, promptly [*] the [*], except in the case [*] under this Agreement.

In accordance with the LOI, the [*] equal to [*] made by SIGMA-TAU to ANESIVA shall be [*] such [*] payments.

9.1.2 Sales Milestone Payments:

Furthermore, SIGMA-TAU will pay ANESIVA an overall sum up to [*] divided in certain sales milestones, provided that, however, the Net Sales of Product in the Territory [*] the following [*] during a Marketing Year:

[*]

For the sake of clarity, each of the above sales milestones payments [*] and [*].

For example, if in the [*] the Net Sales exceed [*], the [*] sales milestone payment will become payable [*] in which the Net Sales in a Marketing Year have [*] such [*]. If in the [*] the Net Sales [*], the [*] sales milestone payment will become payable only that first time in which the Net Sales in a Marketing Year have [*] such [*] and so for the [*] sales milestone payment.

No payments shall accrue on the sales of SIGMA-TAU to its Sub-licensees as well as on any transactions between such entities. Payments shall accrue only on sales to unrelated third parties in arm' s length transactions.

9.2 All sales milestone payments shall be made within [*] from receipt of the relevant invoice by wire transfer to an account promptly communicated in writing by ANESIVA to SIGMA-TAU.

9.3 SIGMA-TAU shall keep or cause to be kept such records as are required to determine Net Sales in a manner consistent with SIGMA-TAU statutory filings. At the request (and expense) of ANESIVA, SIGMA-TAU and its Sub-licensees shall permit an independent certified public accountant appointed by ANESIVA and reasonably acceptable to SIGMA-TAU, at reasonable times and upon [*] notice, to examine only those records as may be necessary to determine, with respect to any Marketing Year ending not more than [*] to ANESIVA' s request, the correctness or completeness of any Net Sales report or payment made under this Agreement. The foregoing right of review may be exercised only [*] and only [*] with respect to [*] periodic report. Results of any such examination shall be limited to information relating to the Product and subject to **Clause 5**. In the event that the audit of SIGMA-TAU' s Net Sales results in reaching thresholds for milestone payments listed in **Clause 9.1.2**, when SIGMA-TAU reported not meeting these thresholds for a given Marketing Year, SIGMA-TAU will bear the cost of the audit and pay any milestone owed within [*] of the audit result.

10. SUPPLY PRICE

10.1 The supply prices to be paid by SIGMA-TAU to ANESIVA for the Product supplied pursuant to this Agreement shall be equal to the [*] of [*] or [*] of the [*], on a country-by-country basis, CIP (ICC Incoterms 2000). The [*] for each country of the Territory shall be promptly communicated in writing by SIGMA-TAU to ANESIVA starting from the [*] with respect to that country and until the [*], and by [*] of each calendar year thereafter on a country-by-country basis.

10.2 Should ANESIVA change its [*] to a [*] and the [*] of the Product is [*], then the Parties shall discuss and agree in good faith an appropriate [*] in the [*].

10.3 ANESIVA recognizes and agrees that in case at any time SIGMA-TAU has to [*] in a country of the Territory in order to [*] the [*] and [*] of the Product in that country of the Territory due to the occurrence of any [*], then the Parties will [*] the [*] and [*] the [*] and the [*]. If no [*] can be found within [*] after a [*] of such [*] and a [*] is probably not [*] for [*], each Party shall be [*] to [*] this [*] as a [*] or for the [*] of the [*] concerned by [*] of [*] to the other [*] with [*] to [*].

10.4 The Parties agree to [*] the [*] of the [*] in accordance with the provision set forth **Appendix E** attached hereto.

10.5 SIGMA-TAU shall pay to ANESIVA the price of each shipment of the Product within [*] from the date of the relevant invoice. Payment shall be remitted by wire transfer in immediately available funds in the invoiced currency (i.e. U.S. Dollar), to a bank and account to be designated in writing from time to time by ANESIVA.

11. INTELLECTUAL PROPERTIES

11.1 Subject to **Clause 3.2**, SIGMA-TAU will sell the Product under the Trademark, which is and shall remain the property of ANESIVA. In this case, ANESIVA shall take care of the maintenance, defence and enforcement of the Trademark in the Territory.

11.2 ANESIVA shall retain the control of all right, title and interest in and to the Patents, and it shall, at its own expenses, maintain, defend and enforce the Patents in the Territory.

11.3 Nothing in this Agreement shall be construed as granting or transferring to SIGMA-TAU any right, title or interest in and to the Trademark and/or the Patents except the right to use the same as herein provided during the term of this Agreement.

11.4 Either Party shall communicate to the other Party any actual or possible infringement of the Trademark or Alternate Trademark, as the case may be, and/or Patents in the Territory by any third party as soon as possible when it comes to its knowledge. ANESIVA and SIGMA-TAU shall consult together in order to determine the appropriate action to be taken for the elimination of any infringement in the Territory and SIGMA-TAU shall assist and cooperate with ANESIVA, at ANESIVA' s expense, provided, that in the case of any infringement of the Alternate Trademark, ANESIVA shall assist and cooperate with SIGMA TAU for the elimination of such infringement at SIGMA TAU' s expense.

12. INDEMNIFICATION

12.1

SIGMA-TAU will indemnify and hold harmless ANESIVA from and against any and all losses, liabilities, claims, damages, penalties, fines, costs and expenses (including reasonable legal fees and other litigation costs, regardless of outcome) arising out of any and all third party claims if and to the extent that such claims are caused by SIGMA-TAU

and/or its Sub-licensees storage, use, promotion, distribution and sale of the Product in the Territory, *provided, however*, that SIGMA-TAU shall have no obligation to indemnify or hold ANESIVA harmless when or if ANESIVA and/or its Manufacturer have been negligent whether in Manufacturing, storing, handling or otherwise dealing with the Product or in case said claims arise out of or are attributable to any breach of this Agreement by ANESIVA.

12.2 ANESIVA shall defend and hold harmless SIGMA-TAU and/or its Sub-licensees from and against any and all losses, liabilities, claims, damages, penalties, fines, costs and expenses (including reasonable legal fees and other litigation costs regardless of outcome) arising as a result of any third party product liability claims or mandatory or voluntary recall of the Product if and to the extent that such losses are caused by (i) infringement of third parties' intellectual property rights with regard to the Product (ii) failure of the Product to conform to the Specifications under the relevant Registrations; (iii) any willful or negligence act or omission of ANESIVA and/or its Manufacturer in relation to the Product provided, however, that ANESIVA shall have no obligation to indemnify or hold SIGMA-TAU and/or its Sub-licensees harmless when or if SIGMA-TAU has been negligent whether in testing, storing, handling or otherwise dealing with the Product or in case said claims arise out of or are attributable to any breach of this Agreement by SIGMA-TAU. In case of [*] of the Product, [*] shall apply.

12.3 Any Party seeking to be indemnified hereunder (the "Indemnified Party") shall notify the other Party from which indemnification is sought (the "Indemnifying Party") in writing no later than [*] after becoming aware of any claims or proceedings made or instituted against it or which may be made or instituted against it in respect of which indemnification may be sought hereunder. If any action is threatened or brought against the Indemnified Party, and it notifies the Indemnifying Party thereof, the Indemnifying Party shall have the right, but not the obligation, to defend against, control the defence of, and settle any such claim. after notice by the Indemnifying Party of its election to assume the defence of any claim, the Indemnified Party shall no longer be liable for any legal or other expense subsequently incurred by the Indemnifying Party in connection with the defence thereof. The Indemnified Party shall co-operate with the Indemnifying Party in the defence of any claim. The Indemnified Party shall be entitled to participate in the defence of such action provided, however, the decisions of counsel for the Indemnifying Party shall be controlling and the Indemnified Party shall be responsible for the expenses of its own counsel, if any. The Parties agree that there shall be no settlements, whether agreed to in court or out of court, without the prior written consent of the Indemnifying Party. The right to indemnification hereunder is conditional upon the provision of prompt notification by the Indemnified Party to the Indemnifying Party and the opportunity to handle and control the defence of the action by the Indemnifying Party.

12.4

Subject to the provisions of **Clause 12.3**, ANESIVA agrees to hold SIGMA-TAU and/or its Sub-licensees harmless and to indemnify SIGMA-TAU and/or Sub-licensees against any liability to third parties caused by any infringement of the patents, trademark or other intellectual property rights of any third party resulting from the registration, import, use,

promotion, distribution and sale of the Product by SIGMA-TAU and/or its Sub-licensee in the Territory in accordance with the terms of this Agreement. SIGMA-TAU shall co-operate with and shall permit ANESIVA at ANESIVA' s own expense, to defend any such action.

13. TERM & TERMINATION

13.1 This Agreement shall become legally effective as of the Effective Date and shall have a duration of [*] starting from the [*] or until [*], whichever [*] (hereinafter the "License Term"), unless otherwise provided herein.

13.2 This Agreement [*] for [*] of [*], unless [*] by [*] giving to the other [*] in [*], such [*] to be [*] at the [*] of the [*] referred or at the [*] of any of its [*].

13.3 After the License Term or after [*] under [*], SIGMA-TAU shall have a perpetual exclusive fully-paid up license, with the right to sub-license, to import, promote, distribute and sell the Product in the Territory under the Know-How, Registrations and/or Registration Dossier and the Trademark, if applicable, provided that SIGMA-TAU purchases the Product from ANESIVA at a transfer price to be agreed in good faith between the Parties as to be consistent with the then current market conditions. It is understood between the Parties that this Clause shall not apply in case of termination of this Agreement by ANESIVA due to material breach by SIGMA-TAU.

13.4 SIGMA-TAU or ANESIVA may terminate this Agreement forthwith upon prior written notice, with respect to such country of the Territory for which the relevant Registration has not been granted within [*] after the [*] of the [*] in a country of the Territory.

13.5 Upon failure of either Party to fulfil any of its material obligations hereunder, or in case of any other material breach or violation of this Agreement, the Party aggrieved by such default, breach or violation may give to the other Party written notification of such default, breach or violation. If after [*] from the date of such notification, the Party concerned has failed or refused to remedy, this Agreement may be terminated forthwith by written notice sent by registered mail and/or fax and/or email accompanied by a confirmed receipt. Such termination shall be without prejudice to any other rights or claims the aggrieved Party may have against the other Party.

13.6 Either Party shall have the right to terminate this Agreement effective upon written notice to the other Party in the event the non-notifying Party becomes insolvent, bankrupt, or makes an assignment for the benefit of creditors, or in the event that insolvency proceedings are instituted against the non-notifying Party or on the non-notifying Party' s behalf.

13.7 Expiry or termination of this Agreement for any reason shall be without prejudice to the obligations of confidentiality provided for in **Clause 5** hereof and any other claim or remedies which either Party may then or thereafter have hereunder or otherwise.

13.8 In case of termination of this Agreement due to breach of SIGMA-TAU, SIGMA-TAU shall immediately cease commercializing the Product and using the Trademark or Alternate Trademark, as the case may be, and shall transfer to ANESIVA, free of charge, all the Know-How which it has received hereunder and any and all documentation, authorization and approval, including the Registrations, obtained or received with regard to the Product and all rights to the Alternate Trademark. To the extent assignment or transfer of authorization, approvals and Registrations is not permitted under local law in the Territory, SIGMA-TAU shall co-operate in their cancellation and reissuance to ANESIVA. SIGMA-TAU shall be entitled to retain in its legal department one copy of all materials returned which shall only be used for legal purposes thereafter.

13.9 In case of termination of this Agreement due to material breach of ANESIVA, SIGMA-TAU shall be [*] from [*] a [*] between the Parties within [*] of the effective date of such termination. Such [*] shall include: [*] by ANESIVA of SIGMA-TAU' s [*] to [*] in connection with this Agreement; [*] of any [*] made to [*] under [*], and [*] of an [*] to SIGMA-TAU' s [*] in connection with this Agreement during the [*] before termination of this Agreement; such [*] to be [*] and [*] by SIGMA-TAU. In no event, however, shall ANESIVA be [*] to [*] to SIGMA-TAU, including any [*]. In the event that no [*] is found, the Parties shall [*] an [*] of [*] which shall [*] the [*] of the [*] based on the [*] set forth above. The [*] for the [*] of the [*] based on such [*] by the [*] shall be [*] between the Parties. ANESIVA shall [*] SIGMA-TAU the [*] so [*] to the other Party within [*] from receipt by ANESIVA of the [*] relating to the above mentioned [*]. In the event that the Parties are even unable to agree on the [*] of the [*],[*] shall apply.

13.10 Upon expiry or termination of this Agreement by SIGMA-TAU due to fault of ANESIVA, SIGMA-TAU shall have the right, at its option, to: i) [*] in SIGMA-TAU' s [*] (on the terms and conditions of this Agreement) for a period not exceeding [*] from the date of expiry or termination of this Agreement, if applicable, or ii) to [*] to ANESIVA any [*] in SIGMA-TAU' s [*] at the [*] by SIGMA-TAU at the time of termination. In case of termination of this Agreement by ANESIVA due to fault of SIGMA-TAU, ANESIVA shall have the right, at its option, to: i) allow SIGMA-TAU to [*] in SIGMA-TAU' s [*] (on the terms and conditions of this Agreement) for a period not exceeding [*] from the date of expiry or termination of this Agreement, if applicable, or ii) to purchase from SIGMA-TAU any [*] in SIGMA-TAU' s [*] at the [*] by SIGMA-TAU at the time of termination.

14. NOTICES

14.1 Any notice required to be given hereunder shall be considered properly given if sent by registered airmail, telecopier or by personal courier delivery to the respective address of each Party as follows:

If to ANESIVA:
Anesiva Inc.
650 Gateway Boulevard

South San Francisco, CA 94080 USA
Attn: General Counsel
Tel: (001) 650 246 6911
Fax: (001) 650 871 5603

If to SIGMA-TAU:
Sigma-Tau Industrie Farmaceutiche Riunite S.p.A.
Via Pontina, Km 30, 400
00040 Pomezia, Rome
Italy
Attn: General Counsel
Tel: 0039 06 91393962
Fax: 0039 06 91394235

or to such other address or addressee as a Party may designate in writing. Any such notice, information or communication shall be effective as of the date of mailing only when it duly arrives in the hands of the addressee.

15. MISCELLANEOUS

15.1 Governing Law. This Agreement will be governed by the laws of [*]. In the case of disputes, efforts shall first be made to reach resolution through discussions between senior executives of the Parties; thereafter through non-binding mediation using a mutually acceptable industry expert and only if all good faith attempts have failed, the Parties shall submit to binding arbitration under the commercial arbitration rules of [*] with such arbitration proceedings to be held in [*].

15.2 Assignment. Unless otherwise provided in this Agreement, either Party shall not at any time, without the prior written consent of the other Party having been obtained, assign, transfer or in any manner make over the benefits or obligations of this Agreement to any person, firm, organisation or company whomsoever. Notwithstanding the foregoing, SIGMA-TAU shall have the right to assign, transfer or in any manner make over the benefits or obligations of this Agreement to any of its Affiliated Companies, upon prior written notice to ANESIVA.

15.3 Waiver: A waiver by either Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any subsequent breach thereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be in limitation of any other remedy, right, undertakings, obligation or agreement of either Party.

15.4

Force Majeure: If the fulfillment by any Party hereto of any of its obligations hereunder is prevented, restricted or interfered with, e.g. by reason of flood, fire, explosion, breakdown of plant, strike, lock-out, labour dispute, casualty or accident, war, revolution, civil commotion, act of public enemies, blockage or embargo, or any law, order,

proclamation, regulation, ordinance, demand or requirement of any subdivision, authority or representative of any such government, or any other cause whatsoever, whether similar or dissimilar to those above enumerated, beyond the reasonable control of such Party, then the Party so affected shall be excused from performance hereunder to the extent and for the duration of such prevention, provided it first notifies the other Party in writing the matters constituting force majeure together with such evidence as it reasonably can give and specifying the period for which it is estimated that such prevention or delay will continue. The Parties shall cooperate in order to take all reasonable steps to minimise the effects of force majeure on the performance of this Agreement and shall, if necessary, agree on appropriate measures to be taken. In the event force majeure prevents the other Party from fulfilling its obligations for more than [*], the affected Party may terminate this Agreement.

15.5 Severability: Should a court of competent jurisdiction hold any provision of this Agreement to be invalid, illegal or unenforceable and such holding is not reversed in an appeal, it shall be considered severed from this Agreement. All other provisions, rights and obligations shall continue with regards to this severed provision, provided that the remaining provisions of this Agreement are in accordance with the intention of the Parties.

15.6 Entire Agreement: This Agreement contains the entire agreement and understanding between the Parties as to the subject matter hereof and supersedes any and all previous agreements, negotiations, commitments and writings as to the subject matter hereof, including the LOI mentioned in the second WHEREAS of the premises. Neither of the Parties shall be bound by any conditions, definitions, warranties, understandings or representations as to such subject matter other than as expressly provided herein or as fully set forth subsequent to the date hereof in a written instrument signed by a proper and duly authorised officer or representative of the Parties.

15.7 Relationship: This Agreement is not intended, nor shall it be construed to be, the formation of a partnership, syndicate, association, joint venture or organization of whatsoever kind between the Parties.

15.8 Counterparts: This Agreement can be executed in counterparts of which are deemed to be an original, but all of which taken together shall constitute one and the same document.

15.9 Cooperation: Each Party agrees to execute such further papers, agreements, documents and instruments as may be necessary or desirable to effect the purpose of this Agreement and to carry out its provisions.

15.10 Third-Party Beneficiaries: None of the provisions of this Agreement shall be for the benefit of or enforceable by any third party including, without limitation, any creditor of any Party hereto. No such third party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any Party hereto.

15.11 Survival: Any term or provision of this Agreement which expressly purports to survive, or which a reasonable person would assume to be intended to survive, termination hereof shall be in force during the teen of this Agreement and any extension hereof and shall survive termination or expiration of this Agreement and shall remain in full force and effect. The provisions of this Agreement which do not survive termination or expiration hereof shall nonetheless be controlling on, and shall be used in construing and interpreting the rights and obligations of the Parties.

IN WITNESS THEREOF, the Parties hereto have executed this Agreement by their duly authorized representatives in duplicate, as of the Effective Date.

Anesiva, Inc.	**Sigma-Tau Industrie Farmaceutiche Riunite S.p.A.**
/s/ Samantha Miller	/s/ Ugo Di Francesco
By: Samantha Miller	By: Mr. Ugo Di Francesco
Title: Vice President, Business Development	Title: Vice President & CEO
Date: February 4, 2008	Date: February 4, 2008

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

APPENDIX A

Patents

[*]

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CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

APPENDIX B

Product

[*]

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APPENDIX C

Territory

[*]

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APPENDIX D

Trademark

[*]

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APPENDIX E

Exchange Rate Fluctuation

[*]

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EXHIBIT 10.62

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

FIRST AMENDMENT TO LICENSE AGREEMENT

This First Amendment to License Agreement (the "First Amendment") is made effective this 15th day of April 2008, by and between **Anesiva, Inc.** a company organized and existing pursuant to the laws of Delaware, USA and having a principal place of business at 650 Gateway Boulevard, South San Francisco, California 94080 USA ("Anesiva") and **Sigma-Tau Industrie Farmaceutiche Riunite S.p.A.**, a company subject to the direction and coordination of Sigma-Tau Finanziaria S.p.A., organized and existing under the laws of Italy and having its registered offices in Rome, 47 Viale Shakespeare, 00144, Italy ("Sigma-Tau" and together with Anesiva the "Parties").

PREMISES

WHEREAS, the Parties have entered into a License Agreement dated February 4, 2008 (the "License Agreement"); and

WHEREAS, the Parties desire to amend the License Agreement as set forth herein.

NOW, THEREFORE, for good and valuable consideration contained herein, the exchange, receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Amended Appendix C

The License Agreement is hereby amended by deleting and replacing in its entirety the Appendix C "Territory" attached to the License Agreement with the new Appendix C-1 "Territory" attached hereto.

2. Compensation

In consideration of the fact that the rights granted by ANESIVA to SIGMA-TAU under the License Agreement have been extended to [*] in accordance with the terms of this First Amendment, SIGMA-TAU shall make the following [*] payments to ANESIVA:

[*]

Such payments shall be made within [*] from receipt of the relevant invoice by wire transfer to an account promptly communicated in writing by ANESIVA to SIGMA-TAU. This consideration shall be in addition to any other consideration payable under the existing License Agreement.

3. No Other Changes

Except as expressly amended by this First Amendment, the License Agreement remains unchanged and in full force and effect.

IN WITNESS THEREOF, this First Amendment has been executed by the Parties hereto through their duly authorized officers as of the date set forth above.

Anesiva, Inc.	**Sigma Tau Industrie Farmaceutiche Riunite S.p.A.**
By: /s/ Samantha Miller	By: /s/ Ugo Di Francesco
Name: Samantha Miller	Name: Ugo Di Francesco
Title: Vice President, Business Development	Title: Vice President & CEO
Date: April 15, 2008	Date: April 15, 2008

APPENDIX C-1

Territory

[*]

3

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

EXHIBIT 10.63

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

LICENSE AND DISTRIBUTION AGREEMENT

THIS LICENSE AND DISTRIBUTION AGREEMENT is made and entered into as of 16th day of April, 2008, by and between Anesiva, Inc., a Delaware corporation, having a principal place of business at 650 Gateway Boulevard, South San Francisco, California 94080 (hereinafter referred to collectively as, "ANESIVA") and GREEN VISION COMPANY with its principal place of business at Al Azizya, Doha, Qatar (hereinafter referred to as "GVC"), which hereby agree as follows:

RECITALS

WHEREAS ANESIVA owns the patent rights, Methods and Technical Know-How relating to the manufacture and use of their proprietary Product, and

WHEREAS ANESIVA owns certain trade names, trademarks, logos, emblems and indicia of origin which are used in association with the Product, and

WHEREAS GVC is desirous of obtaining from ANESIVA the exclusive right and license to market and sell the Product as well as the methods and Technical Know-How (as such term is hereinafter defined) in the Territory (as such term is hereinafter defined) under the Proprietary Marks (as such term is hereinafter defined), upon the terms and subject to the conditions hereinafter set forth; and

NOW, THEREFORE, this Agreement witnesses that in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto hereby covenant and agree with each other as follows:

1. Definitions

Where used in this Agreement the following terms shall have the following meanings:

1.1. "**Affiliate**" means, with respect to any Person, any other Person who directly or indirectly controls, is controlled by, or is under direct or indirect common control with, such Person, and includes any Person in like relation to an Affiliate. A Person is deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such other Person, whether through the ownership of voting securities, by contract or otherwise; and the term "controlled" has a corresponding meaning.

1.2. "**Agreement**" means this Agreement as is or it may be amended or supplemented from time to time, and the expressions "hereof", "herein", "hereto", "hereunder", "hereby" and similar expressions refer to this Agreement and not to any particular section (hereinafter "§")or other portion of this Agreement.

ANESIVA' s Initials_____

GVC' s Initials_____

1.3. "**Business Day**" shall mean a day other than Saturday, Sunday or any day on which banks located in the Territory, are authorized or obligated to close. Whenever this Agreement refers to a number of days, such number shall refer to calendar days unless Business Days (or business days) are specified.

1.4. "**Commercially Reasonable**" shall mean a Party' s reasonable efforts and diligence in manufacturing and commercializing the Product in accordance with its business, legal, medical and scientific judgment, such reasonable efforts and diligence to be in accordance with the efforts and resources the Party would use for a product owned by it or to which it has rights, which is of similar market potential at a similar stage in its product life, taking into account the competitiveness of the marketplace, the ability of a contract manufacturer to deliver product, the proprietary position of the compound, the regulatory structure involved, the profitability of the applicable Product, and other relevant factors including, without limitation, technical, legal, scientific or medical factors.

1.5. "**Customer**" shall mean any [*] for the Product, in the Territory.

1.6. "**Documents**" means, collectively, all books, pamphlets, bulletins, memoranda, letters, notices or other publications or documents prepared by or on behalf of ANESIVA for use by GVC, setting forth information, formulae, production specifications, advice, standards, requirements, operating procedures, instructions or policies relating to the Product.

1.7. "**Effective Date**" shall mean the date of last signature of the Parties hereto.

1.8. "**GMP**" shall mean current Good Manufacturing Practices promulgated by U.S. Food and Drug Administration.

1.9. "**Government Regulatory Authority**" shall mean any court, tribunal, arbitrator, authority, agency, commission, official or other instrumentality of the United States of America, Ministry of Health / National Health Authority in the countries of the Territory (Territory Health authority) and/or other political subdivision in the Territory or other governmental instrumentality of a United Nations recognized sovereign state having subject matter jurisdiction over the Product(s) as the case may be.

1.10. "**Generally Accepted Accounting Principles**" shall mean accounting rules used to prepare, present, and report financial statements for a wide variety of entities, including publicly-traded and privately-held companies, non-profit organizations, and governments. Generally GAAP includes local applicable Accounting Framework, related accounting law, rules and Accounting Standard.

1.11. "**Ministry of Health / National Health Authority**" shall mean the department of the government of each country in the territory with responsibility for national public health, and any successor agency thereto.

1.12. "**Improvements**" means any future innovations, inventions, designs, plans, drawings, specifications, techniques, data and technical information relevant to the use (indications) or sale of the Product including, but not limited to, modified packaging.

1.13. "**Law**" or "**Laws**", as the case may be, shall mean all laws, statutes, rules, regulations, ordinances, guidelines and other pronouncements having the effect of law in any country with jurisdiction over either of the Parties and/or Product(s) or any domestic or foreign state, province, county, city or other political subdivision or of any Health Registration Authority or Regulatory Authority in the Territory.

1.14. "**Exchange Rate**" shall mean the spot Exchange Rate published in *The Wall Street Journal* as quoted by Reuters at 4:00 PM on the prior business day.

1.15. "**Manufacturing Cost**" shall mean, with respect to Product, the sum of the following, all of which shall be calculated in accordance with U.S. Generally Accepted Accounting Principles:

(a) The amounts paid by ANESIVA to any third party for (i) providing raw materials and packaging materials for producing the Product, (ii) manufacturing, filling and/or finishing Product or any component thereof, (iii) storing, insuring and packaging Product, and (iv) release and stability testing Product, including with respect to the foregoing, all taxes (other than income taxes) and customs duty charges imposed by governmental authorities with respect thereto, to the extent paid by ANESIVA and not reimbursed or refunded by a third party;

(b) The direct costs and charges incurred by ANESIVA in connection with the manufacture, filling, finishing, testing (including direct quality control and quality assurance activities), storing, insuring and packaging Product not otherwise accounted for pursuant to subsection (a) above;

(c) A reasonable allocation of indirect labor, administration costs and facilities costs (including electricity, water, sewer, waste disposal, property taxes and depreciation over the expected life of buildings and equipment) attributable to the manufacture, filling, finishing, testing, storing, insuring and packaging of Product; provided that such indirect labor, administration costs and facilities costs shall only include an allocation, to the units or sections directly engaged in the activities listed in the subsection (b) above, of such indirect labor, administration costs and/or facilities costs incurred by ANESIVA.

Without limiting the generality of the foregoing provisions of this §1.14, Manufacturing Cost shall exclude, all costs and charges related to or occasioned by unused manufacturing capacity; the manufacture of other products at ANESIVA' s or a third party contractor' s facility; depreciation of property, plant or equipment not specifically related to manufacturing Product; allocation of administrative costs and general corporate overhead of ANESIVA or its third party contractors; ANESIVA' s cost of capital, whether or not such capital is attributable to the manufacturing of any Product; and any employee costs associated with equity incentive plans.

1.16. "**Marketing Authorization**" shall mean the final approval of registrations and permits required by applicable Government Regulatory Authority in the Territory, for the importation into and for the marketing, sale and distribution of the Product in such Territory.

1.17. "**Methods and Technical Know-How**" means all information, knowledge and experience of a technical and commercial nature, including trade secrets, the Specifications, the Documents, information and data relating to techniques for, methods of or practices in the use and sale of the Product.

1.18. "**Net Sales**" shall mean, in accordance with the Generally Accepted Accounting Principles published by the Financial Accounting Standards Board of the United States, the amount invoiced by GVC sales of the Product in the Territory to a Third Party, less:

(a) discounts (including without limitation cash discounts and quantity discounts), charge-back payments, and customer rebates;

(b) credits or allowances actually granted upon claims, damaged goods, rejections, or returns of Product other than any such credits or allowances arising from manufacturing defects or any defect attributable to ANESIVA, including but not limited to credits, allowances and related costs attributable to Product recalls.

1.19. "**Party**" means a Party to this Agreement and any reference to a Party includes its successors and permitted assigns; "**Parties**" means every Party.

1.20. "**Person**" shall mean any legal person including, for example, an individual, corporation, partnership, Limited Liability Company, trust, business trust, association, Joint Stock Company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority or any other form of entity.

1.21. "Pre-registration Sales" means sales generated prior to the registration of Zingo in territory. In this case GVC will raise a purchase order to ANESIVA specifying the quantity and the name of the account to be supplied. Upon receiving the purchase order from GVC, ANESIVA will supply the account mentioned in the purchase order with the requested quantity. ANESIVA will issue the invoice for the supplied quantity to GVC and will issue a letter to the account along with the shipment requesting the account to pay directly to GVC for the quantity shipped. GVC will invoice the account directly for the quantity supplied by ANESIVA. GVC shall further remit the payment to ANESIVA.

1.22. "**Product**" means ANESIVA' s (lidocaine hydrochloride monohydrate) powder intradermal injection system, 0.5mg, indicated for use on intact skin to provide topical local analgesia prior to venipuncture or peripheral intravenous cannulation and marketed in the United States under the brand name Zingo™.

1.23. "**Proprietary Marks**" means the marks, trademarks, trade names and other commercial symbols and related logos relating to the Product for use in the Territory, together with such other trade names, trademarks, symbols, logos, distinctive names, service marks, marks, logo designs, insignia or otherwise which may be designated by ANESIVA. Proprietary Marks may be updated from time to time.

1.24. "**Quality Assurance Department**" **or** "**QA**" shall mean the group or department that performs the quality review functions. QA reviews and approves quality-related documents and procedures.

1.25. "Recall" shall have the meaning set forth in §9.3.

1.26. "**Specifications**" means all specifications, methods, applications, criteria, qualities, requirements and all other information in connection with the use, handling, distribution, marketing and/or sale of the Product published, promulgated or conveyed by or on behalf of ANESIVA to GVC in any manner whatsoever, including any manual, specification booklet, letter, notice, memorandum or other written from, from time to time.

1.27. "**Serious Adverse Events**" shall mean any adverse experience that result in any of the following outcomes: death, a life-threatening experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening or require hospitalization may be considered a serious adverse event when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

1.28. "**Term**" shall have the meaning set forth in §11

1.29. "**Territory**" shall mean [*].

1.30. "[*]" shall mean a [*] used for [*] of a [*] device. [*] is not intended to work as a [*] and does not provide any [*].

2. Terms, Grant of Licences, Regulatory Submissions and Drug Release Testing, and Governance

2.1. The sole and exclusive license granted in §2 shall have a Term composed of the [*] and [*] or [*].

2.2. The Initial Term shall begin as of the Effective Date of this Agreement between the Parties and shall continue in effect until [*] from the date of execution of this Agreement.

2.3. [*] Terms shall be the [*] of this Agreement for [*] of [*] unless [*] the [*] that it does not intend to [*] no less than [*] to the [*] of the [*] or [*].

2.4. Subject to the provisions of this Agreement, and solely during the Term, ANESIVA hereby:

(a) covenants and agrees to license exclusive right to the Product [*] to GVC in the Territory to enable GVC to promote, market and sell the Product in the Territory;

(b) grants to GVC the exclusive right and license to use the Proprietary Marks in connection with the marketing, distribution and sale of the Product within the Territory and

(c) grants GVC a royalty-bearing license to all intellectual property related to the Product including, but not limited to, the Proprietary Marks for GVC' s use in the Territory as may be necessary and required under the Laws and regulations and a fully paid license to all governmental authorizations, product documentation, marketing materials and the like. All costs associated with registering or maintaining the Proprietary Marks or other intellectual property will be [*].

2.5. GVC shall be responsible for the application, prosecution and maintenance of Marketing Authorizations in the Territory for the Product, with the Market Authorization remaining in GVC' s name during the term of the Agreement, under the following conditions:

(a) GVC agrees to [*] the Marketing Authorization application and maintenance [*] which are [*] to Territory Health Authority, including [*] related to any required amendments to the initial application;

(b) ANESIVA agrees to provide GVC with a current and complete copy of the U.S. approved regulatory dossier for the Product and to supplement this regulatory dossier as new data becomes available. GVC agrees to modify this dossier in accordance with the requirements of the Territory for submission in the Territory.

(c) ANESIVA agrees to support GVC in addressing any Territory Health Authority questions subsequent to submission and approval.

(d) Marketing authorizations for the Product shall remain in GVC' s name and under its control during the term of the license. GVC and ANESIVA will [*] of any Territory Health Authority manufacturing site inspection that requires [*] on site at ANESIVA or ANESIVA contract manufacturer. In the case where Territory Health Authority requires a [*] that is not required by either U.S. or EU regulatory authorities, then this [*] will be [*] by [*].

(e) GVC agrees to conduct and [*] drug release testing before the shipment of Product for human use in the Territory, which is required pursuant by Territory Law for Product imported into the Territory. With the lab conducting such testing to be mutually agreed upon.

2.6. Both Parties shall appoint a project leader within [*] of signing the Agreement, through which all communications regarding this Agreement will be initially directed. The project leaders will facilitate direct communication between functional experts as needed to manage activities under the Agreement.

2.7. The Parties shall make all reasonable efforts to amicably resolve any disputes which may arise out of or relating to the application of this Agreement through discussions between senior executives of the Parties. In the event that the Parties fail to resolve any dispute, the Parties will seek resolution through a non-binding mediation using a mutually acceptable industry expert. Only if all good faith attempts have failed, then the dispute shall be finally settled by arbitration under the rules of the International Chamber of Commerce by one (1) arbitrator appointed in accordance with the said Rules. The proceedings shall take place in [*] and shall be conducted in [*]. This provision shall not preclude the right of either Party to address any competent Court or Tribunal in respect of obtaining interim measures.

3. Proprietary Rights

3.1. ANESIVA shall register the Proprietary Marks and such other intellectual property rights as required for the Territory within a Commercially Reasonable time after its execution of this Agreement if such Proprietary Marks and other intellectual property rights have not already been registered. All registrations shall be at [*].

3.2. GVC confirms that all right, title and interest in the Proprietary Marks or related to the Proprietary Marks is the sole property of ANESIVA and this Agreement shall not operate to convey any interest in the Proprietary Marks to GVC.

3.3. ANESIVA shall include the applicable Proprietary Marks on all packages of the Product delivered to GVC (or as directed by GVC to its customs brokers). GVC shall make use of the Proprietary Marks in all materials and activities related to the marketing, sale and distribution of the Product. The Proprietary Marks used by GVC shall comply with the form of the Proprietary Marks as registered in the Territory.

3.4. At all times, GVC shall use the ANESIVA registered trademarks in reference to the applicable Product in the Territory unless prohibited by Law of the Territory. In any such event, ANESIVA and GVC shall meet to resolve any such legal prohibition in accordance with the Laws and regulations of the Territory.

4. Payment and Prices

4.1. GVC shall pay ANESIVA a [*] of [*] as follows:

[*]

4.2. GVC shall pay ANESIVA a [*] milestone payment of [*] upon [*] of the Product in the Territory. This payment of [*] will be [*] to the [*] of the territory [*] and to be paid within [*] from issuing the [*].

4.3. GVC shall purchase the Product from ANESIVA at ANESIVA' s Manufacturing Cost. Such payments shall be made [*] after the Product is received by GVC, subject to inspection by GVC.

4.4. Sales Milestone Payments:

GVC will also pay ANESIVA certain sales milestones that will become due [*] the Net Sales of Licensed Product in the Territory [*] the following [*] during a Marketing Year:

[*]

4.5. Royalty on Net Sales: GVC shall pay a [*] royalty of [*] of Net Sales to ANESIVA.

4.6. Within [*] after the [*] of any [*] GVC shall deliver to ANESIVA a true and accurate report of Net Sales during such [*]. Any payments due under this Agreement shall be made in U.S. Dollars, calculated based on Exchange Rate and paid by wire transfer to a bank and account designated in writing by ANESIVA. For payments, ANESIVA will submit written invoices on the day Product is shipped to GVC. Payment of each such invoice not subject to a good faith dispute will be due in full within [*] following receipt of invoice. Invoices shall be sent to the following address:

GREEN VISION COMPANY
Al Azizya
Doha - Qatar
P.O Box 55272
Telephone: +974 4517815
Fax: +974 4517247

5. Product Supply, Shipping, Ordering

5.1. Product sold to GVC for use in the Territory shall be [*] for commercial sale and are FCA (INCOTERMS 2000) ANESIVA' s manufacturing plant (or any plant of a designated contract manufacturer) or at such other place as the Parties may mutually agree from time to time.

5.2. In consideration of the rights granted to GVC by ANESIVA pursuant to the provisions of §2, GVC will exclusively purchase its needs for the Territory of the Product subject to this license from ANESIVA (or from a contract manufacturer designated by ANESIVA) during [*] or [*] or [*] of the Agreement.

5.3. In this regard, GVC agrees to:

(a) provide ANESIVA a [*] rolling forecast in unit terms [*] to each [*]. The first [*] of the [*] forecast shall be [*]. ANESIVA will acknowledge acceptance of the forecast within [*]. GVC will place a Purchase order for each [*] to the [*] of the [*]. ANESIVA will acknowledge the PO within [*].

(b) [*] prior to anticipated launch, GVC will provide ANESIVA with the first [*] rolling forecast in unit terms from launch date and a [*] forecast. [*] on [*], GVC will provide ANESIVA a [*] forecast for the next [*].

(c) provide ANESIVA with not less than [*] lead time on: (i) all Product orders; (ii) all packing/labeling specifications for shipping; and (iii) all orders for literature and marketing materials, if any; and

5.4. Minimum purchase order volume for the Territory will be [*] units. ANESIVA shall package and deliver Product ordered by GVC no later than [*] after receipt of such order. For the product supply to the [*] prior to the registration from the Territory Health Authority, GVC shall be entitled to the purchase orders less than [*] units. Minimum purchase order volume applies only after registration in the Territory.

5.5. GVC shall place purchase orders for the Product demand prior to the registration in the Territory. GVC will raise a purchase order to ANESIVA specifying the quantity and the name of the account to be supplied. Upon receiving the purchase order from GVC, ANESIVA will supply the account mentioned in the purchase order with the requested quantity and will issue a letter to the account requesting the account to pay GVC directly for the quantity supplied. GVC will invoice the account directly and further remit the proceeds to ANESIVA.

5.6. The Product supplied to GVC shall be exactly same as the Product marketed in United States of America, with the exception of a customized label for the Territory (in English and Arabic). There shall be no other changes in the Product or packaging features or QA/QC testing requirements for the Territory.

5.7. The Product supplied to GVC or its designee shall have a shelf life of at least [*] with at least [*] shelf life remaining at delivery. ANESIVA shall not be required to replace Product held in inventory by GVC whose shelf life has expired.

5.8. Product orders shall be packed and labelled by ANESIVA for international shipping, as specified by GVC, and picked up by the customs broker or shipping agent specified by GVC at ANESIVA' s manufacturing facility or at any other mutually agreeable location pursuant to §5.1 above.

(a) GVC shall comply with the Specifications and ensure that packaging, labeling and delivery of the Product is in accordance with the applicable standards and Laws in the Territory; and

(b) GVC shall prepare, at its own expense, labels and package inserts for the Product in compliance with GMPs and the Marketing Authorization. GVC shall provide copy artwork in a format specified by ANESIVA for all printed components including product label, pouch, insert, carton, and shipper label content. GVC shall send such copy artwork to ANESIVA to obtain ANESIVA' s suggested changes and final written approval. ANESIVA shall then source such labels and packages from approved vendors at ANESIVA' s expense.

5.9. ANESIVA shall refrain from directly or indirectly selling the Product in the Territory to any Third Party during the Term

5.10. All expenses incurred by GVC in the handling, distribution, marketing and sale of the Product and in carrying out its obligations under this Agreement shall be paid by or on behalf of GVC.

6. Quality Agreement

6.1. GVC and ANESIVA shall comply with the terms and conditions of the Quality Assurance Agreement, which will be agreed by the Parties and signed within [*] after the signing of this Agreement.

6.2. During the term of this Agreement and any renewal thereof, ANESIVA agrees to, in accordance with the Quality Agreement,:

a. assist GVC in the handling, sales and service of the Product by transmitting to GVC such Specifications and other information reasonably required by it for such handling, sales and service as is available to ANESIVA, including copies of the Documents, and to advise GVC in writing, in advance of any change to the Specifications or shipping, storage or handling procedures for the Product; and

b. furnish to GVC such continuing technical assistance and guidance as is from time to time reasonably required by GREEN VISION; however, in no event shall ANESIVA' s response to such request for technical assistance shall be no later than [*] after receipt of such request; and

c. upon and subject to the terms and conditions of this Agreement, to manufacture, or to cause a third Party to manufacture, and to supply GVC with a sufficient supply of the Product to meet the needs of the Territory. Such Product shall be manufactured and packaged in accordance with GMP and shall conform to the specifications for the product as contained in the Marketing Authorization applications; and

d. to retain a reasonable and customary number of sample Product for quality assurance and control purposes (GVC agrees that any samples provided for QA/QC purposes shall not enter the commercial stream); and

6.3. ANESIVA acknowledges and agrees that the implementation of this Agreement requires the co-operation of both Parties and that the ability of each Party to carry out its obligations hereunder shall be dependent upon the other Party performing its obligations (including its responsibilities pursuant to the Quality Assurance Agreement and the Pharmacovigilance Agreement).

7. Representations and Warrants of ANESIVA

ANESIVA hereby represents and warrants to and in favour of GVC as follows:

7.1. ANESIVA is a corporation duly incorporated validly subsisting under the Law of the State of Delaware and has the corporate power to enter into this Agreement and to perform its obligations hereunder.

7.2. This Agreement has each been duly authorized, executed and delivered by ANESIVA and is a legal, valid and binding obligation of ANESIVA.

7.3. ANESIVA has the right to enter into this Agreement and to grant to PL the licensing arrangements outlined herein.

7.4. As of the Effective Date:

(a) to the best of ANESIVA knowledge, the use or practice of the Methods and Technical Know-How does not infringe any patent right owned by any third Party in the Territory;

(b) ANESIVA is the sole record and beneficial owner or exclusive licensee of the Methods and Technical Know-How;

(c) ANESIVA has not granted any other licences or rights of any kind in the Product or the Methods and Technical Know-How to any third Party in the Territory;

7.5. ANESIVA expressly warrants and represents that the Product supplied to GVC shall conform to the Specifications therefore and be free from defects; be manufactured in accordance with GMP and such other applicable Laws and regulations in the Territory and in accordance with the approved Product specifications therefore in the Territory and in accordance with the Quality Agreement; and be fit for the intended use.

7.6. The execution and delivery of this Agreement do not conflict with or violate any requirement of applicable Laws or regulations.

8. Representations and Warrants of GREEN VISION

GVC hereby represents and warrants to and in favour of ANESIVA as follows:

8.1. GVC is a corporation duly incorporated validly subsisting under the Law of Qatar and has the corporate power to enter into this Agreement and to perform its obligations hereunder.

8.2. This Agreement has each been duly authorized, executed and delivered by GVC and is a legal, valid and binding obligation of GVC.

8.3. GVC has the right to enter into this Agreement and to receive from ANESIVA the licensing arrangements outlined herein.

8.4. The execution and delivery of this Agreement do not conflict with or violate any requirement of applicable Laws or regulations.

9. Notification of Side-Effects and Regulatory Requirements

9.1. GVC and ANESIVA shall comply with the terms and conditions of the Pharmacovigilance Agreement, which shall comply with the Adverse Event Reporting Requirements and shall be finalized within [*] after signing this License and Distribution Agreement.

9.2. In accordance with procedures to be mutually agreed between the Parties and which address the Laws and regulations of the Territory; both ANESIVA and GVC shall promptly appraise each other of any Serious Adverse Events occurring as a result of the use of the Product in order to comply with ICH requirements for reports of such events in each respective licensing territory.

9.3. In the event either Party believes it may be necessary to conduct a recall, field correction, market withdrawal, stock recovery, or other similar action with respect to any Product which were sold by ANESIVA or its Affiliates to GVC or its Affiliates under this Agreement (a "Recall"), ANESIVA and GVC shall consult with each other as to how best to proceed, it being understood and agreed that the final decision as to any Recall of any Product shall be made by ANESIVA; provided, however, that GVC shall not be prohibited hereunder from taking any action that it is required to take by applicable Laws. GVC and ANESIVA shall work together to mutually agree on the details of any Recall decision; however GVC is responsible for executing a Recall of GVC distributed Product. ANESIVA QA is responsible for notifying GVC QA of all quarantined Product related to Recall in ANESIVA' s possession. If a Recall arises from the manufacture of the Product or ANESIVA' s breach of its representations, warranties, including but not limited to the ANESIVA Warrants herein or obligations hereunder, the cost of goods sold, distribution expenses and third-Party recall expenses (collectively, the "Recall Costs") shall be [*]. If a Recall arises from GVC' s acts or omissions in the marketing, distribution, storage or handling of such Product, Recall Costs shall be [*]. GVC shall maintain records of all sales of Product and customers sufficient to adequately administer a Recall for the period required by applicable Laws.

10. Confidentiality and Public Disclosure

10.1. The Parties expressly agree that their previously executed Confidential Disclosure Agreement ("CDA") [*], is made a part hereof by reference and that all terms, conditions and provisions of the original CDA, unless specifically modified herein, are to apply to this Agreement and are made a part of this Agreement as though expressly included; provided, however, the CDA shall be extended in duration for the period ending with the expiration or sooner termination of this Agreement or until it expires as set forth in the CDA, whichever term is longer.

10.2. Except for such disclosure as is deemed necessary, in the reasonable judgment of a Party, to comply with applicable Laws, no announcement, news release, public statement, publication, or presentation relating to the existence of this Agreement, the subject matter hereof, or either Party' s performance hereunder will be made without the other Party' s prior written approval, which approval shall not be unreasonably withheld. The Parties agree that they will use reasonable efforts to coordinate the initial announcement or press release relating to the existence of this Agreement.

10.3. Neither Party shall be required to seek the approval of the other Party to repeat any information regarding the terms of this Agreement that has already been publicly disclosed by such Party, or by the other Party, in accordance with Section §10.1, provided that such information remains accurate and complete.

11. Termination

11.1. ANESIVA shall have the right to terminate this Agreement, without prejudice to the enforcement of any other legal right or remedy, immediately in the event of the default in the due and punctual payment of any amount payable under this Agreement by GVC to ANESIVA when and as same shall become due and payable, and such default shall continue for a period of [*] after written notice thereof has been given to GVC.

11.2. Notwithstanding any other termination rights set forth in this Agreement, either Party shall be entitled at any time, by written notice to the other, to terminate this Agreement immediately if the other Party commits or permits a material breach or default of any of the provisions of this Agreement and fails to remedy or cure such breach or default within [*] after receipt of written notice by the non-breaching Party.

11.3. ANESIVA may prematurely terminate this Agreement with at least [*] prior notice in writing with respect to the Territory if the Product sales are [*] of the annual forecasted unit sales in provision or if the Product sales are [*] in [*] at least [*] after [*].

11.4. Either Party shall be entitled at any time, by written notice to the other, to terminate this Agreement immediately if (i) the other Party makes an assignment for the benefit of its creditors; (ii) the other Party is adjudicated bankrupt or becomes voluntarily or involuntarily subject to any proceedings for the benefit of its creditors, or (iii) a receiver of the property of the other Party is appointed or if any judgment or execution against it or its property remains unsatisfied for such period which would permit its property or any substantial part thereof to be sold.

11.5. Upon termination of this Agreement for any reason, the following shall apply:

(a) GVC shall immediately cease marketing and selling the Product in the Territory, the use of the Methods and Technical Know-How and the Proprietary Marks

(b) GVC shall have no further rights to market or sell, directly or indirectly, the Product;

(c) GVC shall forthwith deliver to ANESIVA original copies of all documents and records in its possession in connection with regulatory approvals applied for or obtained in the Territory referred to in §2.5;

(d) GVC shall return or destroy, at ANESIVA' s discretion, any unsold Product, or if permitted by ANESIVA, GVC may sell all Product held in inventory or in the process of production at the time of such expiration or termination, provided that GVC shall pay to ANESIVA all amounts which would have been required to be paid under this Agreement through the date of final sale of all Product.

11.6. All in-Territory Product licenses, registrations or Marketing Authorizations will be transferred to ANESIVA if these are held in the name of GVC, its designates, importers or promoters where allowed by Law at the sole cost an expenses of ANESIVA necessary to accomplish any such transfer or transfers as the case may be.

11.7. The Parties agree that this Agreement may be assigned to any successor corporations with the prior written permission of the other Party, which permission shall not reasonably be withheld.

11.8. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination and the provisions of §9.3 as it pertains to Recalls, §11.6 as it pertains to transfer of the Marketing Authorizations, §10, §11.8, §14, §15 and §16 through §25 shall survive any expiration or termination of this Agreement.

12. Sales Training and [*]:

12.1. Whenever possible, representatives of GVC may attend a regularly scheduled ANESIVA training session and be certified to train GVC sales representatives to demonstrate, market, and sell the Product. In the event that attendance at such a training session is not possible, an ANESIVA representative will train the GVC trainer at a mutually convenient time and place. ANESIVA will provide GVC copies of training materials for training at GVC facilities.

12.2. [*] can be [*] by GVC. Such [*] will exclusively be used to generate sales from customers through local clinical evaluations and will not be sold under any circumstances. At [*] prior to an anticipated launch, GVC will provide ANESIVA with the first [*] rolling forecast of [*] from launch date.

12.3. The label and instructions on the [*] shall be in English language only at delivery and GVC may re-label the [*] according to the customs and laws of the Territory.

13. Marketing:

13.1. GVC shall [*] in the [*] and [*] of the Product throughout the Territory during the [*] of [*] and [*] or [*] thereof. During the term of any licensing agreement GVC will commit to providing a [*] of resources of the Product to customers who may reasonably be expected to purchase or recommend the purchase of any of the Product.

13.2. GVC shall send to ANESIVA, upon ANESIVA' s request no more frequently than [*] in any [*], a brief summary of the most important promotional activities connected with the Product, the activities of GVC' s sales forces in promoting the Product, including information relating to market developments and acceptance of the Product in the Territory.

13.3. ANESIVA will provide [*] of [*] of any [*] used in the United States of America to market, promote or sell any the Product.

13.4. Should GVC elect to use any of the [*] prepared for the United States market without modification [*], ANESIVA will assist GVC in obtaining a [*] of such [*] from current vendors. Any costs incurred to obtain these marketing materials will be [*].

13.5. ANESIVA will also provide [*] of any [*] used to [*] the Product so GVC can maintain a [*] for the Product. The cost for any [*] generated from these [*] will be [*].

(a) GVC represents and warrants that any locally produced marketing materials will fully comply with any Territory Law or Territory Regulatory Authority regulation in all respects. market and sell the Product in accordance with applicable Laws of the Territory, including, without limitation, in accordance with any certification required by a legislated or regulatory body, if applicable; and

(b) GVC shall comply with all Laws and regulations in any applicable country with jurisdiction over the Parties or with jurisdiction over the subject matter of this Agreement, including but not limited to, if applicable, the Laws of Qatar, United States of America and/or any applicable Laws in the Territory relating to the marketing and sale of the Product within the Territory and to obtain any and all required permits, certificates and licenses in connection with the foregoing.

(c) Any changes or amendments to Product packaging must be approved in advance by GVC and ANESIVA by mutual agreement.

13.6. GVC shall refrain from directly or indirectly selling the Product outside of the Territory during the term of this Agreement; and

13.7. GVC shall not [*] any [*] (other than the Product) during the Term.

13.8. GVC acknowledges and agrees that the implementation of this Agreement requires the co-operation of both Parties and that the ability of each Party to carry out its obligations hereunder shall be dependent upon the other Party performing its obligations (including its responsibilities pursuant to the Quality Assurance Agreement, and the Pharmacovigilance Agreement).

14. Insurance

14.1. ANESIVA shall, at its sole cost and expense, take out and keep in full force and effect throughout the term of this Agreement and any renewal thereof, such insurance coverage, including but not limited to Product liability insurance coverage, in an amount that is customary in the pharmaceutical industry. All costs in connection with the placing and maintaining of such insurance coverage shall be borne solely by ANESIVA.

14.2. GVC shall take out and keep in full force and effect for the term of this Agreement and any renewal thereof, such insurance coverage as required by Laws in the Territory protecting against loss or damage occurring in connection with the local negligent handling and negligent sale of the Product in the Territory. All costs in connection with the placing and maintaining of such local insurance coverage in the Territory shall be borne solely by GVC, at the sole discretion of GVC.

14.3. Copies of all policies or certificates of insurance and any renewals thereof, shall be delivered promptly to ANESIVA by GVC from time to time throughout the term of this Agreement and any renewal thereof

15. Indemnification and Liability

15.1. GVC shall defend, indemnify and hold harmless ANESIVA from and against all losses, liabilities and expenses (including reasonable attorneys' fees) for personal injury or property damage to a third Party arising out of the use of the Product marketed by GVC, its affiliates insofar as any such claim for loss, liability and expense is based upon negligence of GVC, its affiliates in the handling and marketing of such Product. ANESIVA shall give GVC prompt written notice of any such claim. GVC shall be entitled to assume complete control of the defense of such claim. ANESIVA shall render such assistance to GVC as may be reasonably requested by GVC and GVC shall reimburse ANESIVA for its reasonable out-of-pocket expenses incurred in rendering such assistance.

15.2. ANESIVA shall defend, indemnify and hold harmless GVC from and against all losses, liabilities and expenses (including reasonable attorneys' fees) for (i) personal injury or damage arising out of the use of the Product, provided the claim for such loss, liability and expense is based upon product liability or negligence of ANESIVA, its affiliates, subsidiaries or licensees in the Specifications, the Methods and Technical Know-How, Improvements, manufacture or marketing of such Product or (ii) any suit or proceeding brought against GVC insofar as such suit or proceeding is based on a claim that the Methods and Technical Know-How and Improvements to any Product (save to the extent that the Product concerned, or any part thereof, has been developed as a result of additional technology methods or compositions of GVC) constitutes an infringement of any patent, copyright, trade secret or other intellectual property right of any person other than ANESIVA or GVC. For greater certainty, in no event shall ANESIVA have any liability (whether direct or indirect, in contract or tort or otherwise) to GVC or any other person asserting claims on behalf of or in right of GVC hereunder which have resulted primarily from the negligence or wilful misconduct of GVC or its representatives. GVC shall give ANESIVA prompt written notice of any such claim. ANESIVA shall be entitled to assume complete control of the defense of such claim. GVC shall render such assistance to ANESIVA as may be reasonably requested by ANESIVA and ANESIVA shall reimburse GVC for its reasonable out-of-pocket expenses incurred in rendering such assistance.

16. *Force Majeure*

The Parties hereto shall not be liable for any damage if the performance of all or parts of this Agreement is hindered or prevented by causes beyond the performing Party' s control and without its fault or negligence, including but not limited to acts of God or of public enemy, nuclear incidents, acts, Laws, orders or regulations of any Government Regulatory Authority or department or agency thereof acting in either its sovereign or contractual capacity, fires, floods, epidemics, earthquakes and other natural disasters, quarantine restrictions, strikes, work stoppages, slowdowns or other job actions, freight embargoes, shortages of fuel or other items, delays in transportation, boycotts, unusually severe weather and riots, insurrections, revolutions, wars or other civil or military disturbances.

17. Entire Agreement

This Agreement constitutes the entire agreement between the Parties hereto with respect to the subject-matter herein contained, and its execution has not been induced by, nor do either of the Parties hereto rely upon or regard as material, any representations or writings whatsoever not

incorporated herein and made a part hereof. This Agreement shall not be amended, altered or qualified except by an instrument in writing, signed by each of the Parties hereto and any amendments; alterations or qualifications hereof shall not be binding upon or affect the rights of any Party who has not given its consent as aforesaid. All previous agreements or arrangements between the Parties, written or oral, relating to the subject matter hereof are hereby cancelled and superseded, except for the Confidentiality Agreement [*] between the Parties.

18. Counterparts

This Agreement may be executed by the Parties in separate counterparts each of which when so executed and delivered in original form or by facsimile transmission shall be an original, but all such counterparts shall together constitute one and the same instrument, and shall be equally valid and binding on the Parties.

19. Notices

All notices, requests, demands or other communications made by the terms hereof required or permitted to be given by one Party to the other shall be given in writing by personal delivery or by facsimile transmission, addressed to such other Party or delivered to such other Party as follows:

If to GREEN VISION COMPANY:

Green Vision Company
Attention: Business Development &
Marketing Department
Al Azizya
P.O Box 55272
Doha, Qatar
Tel: 974 4517815
Fax: 974 4517247

If to ANESIVA:

Anesiva, Inc.
Attention: General Counsel

650 Gateway Boulevard
South San Francisco, CA 94080

Tel: 650-624-9600
Fax: 650-624-7540

or to such other address as the addressee may have specified by a notice given under this provision. Any such notice or other communication shall be deemed to have been given when received and, if sent by facsimile transmission, shall be deemed to have been given when the appropriate answerback is received.

20. Severability

Should any of the provisions of this Agreement be or become unenforceable or invalid for any reason whatsoever, such unenforceability or invalidity shall not affect the enforceability or validity of the remaining provisions of the Agreement and such unenforceable or invalid portion shall be severable from the remainder of this Agreement.

21. Waiver

The failure at any time to require performance of any provision of this Agreement shall not affect the full right to require performance at any later time. The waiver of a breach of any provision of this Agreement shall not constitute a waiver of the provision or of any succeeding breach.

22. No Assignment and Permitted Assignment.

22.1. Neither Party shall, without the prior written consent (not to be unreasonably withheld or delayed) of the other Party having been obtained, assign or transfer this Agreement to any person or entity, in whole or in part, provided that, each Party may assign or transfer this Agreement to any Affiliate or to any successor by merger of such Party, or upon a sale of all or substantially all of such Parties assets, provided that such assigning Party shall remain liable for its obligations hereunder.

22.2. All of the terms and provisions of this Agreement shall be binding upon and inure to the benefit of and be enforceable by the Parties hereto and their respective successors and assigns.

23. Partnership, Agency Denied

This Agreement does not and shall not be construed to create any partnership, joint venture or agency whatsoever as between the Parties and neither Party shall, by reason of any provision herein contained, be deemed to be the partner, joint venturer, agent or legal representative of the other nor shall either have the ability, right or authority to assume or create, in writing or otherwise, any obligation of any kind, express or implied, in the name of or on behalf of the other Party.

24. Headings

The division of this Agreement into articles and sections is for convenience of reference only and shall not affect the interpretation or construction of this Agreement

25. Currency

Except as specifically noted otherwise, all monetary amounts stated in this Agreement are expressed in United States Dollars.

26. Applicable Law/Jurisdiction

26.1. This Agreement is construed in accordance with and shall exclusively be governed by the Laws of [*] in [*].

26.2. All disputes arising out of or relating to this Agreement shall be submitted to the exclusive jurisdiction of the appropriate courts of [*] in [*].

26.3. All trade terms used in this Agreement shall be interpreted in accordance with INCOTERMS 2000 (International Rules for Interpretation of Trade Terms, International Chamber of Commerce, Publ. 560, 1999).

27. Singular and Plural Forms

The use herein of the singular form shall also denote the plural form, and the use herein of the plural form shall denote the singular form, as in each case the context may require.

28. English Language

The Parties hereto have required that this Agreement and all documents and notices relating hereto be drawn up in the English language.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed in duplicate, as of the Effective Date, by their duly authorized representatives.

READ AND ACCEPTED BY:

ANESIVA INC.

Per: /s/ Samantha Miller
Name: Samantha Miller M.S.c, MBA
Title: VP Business Development.
Date:

READ AND ACCEPTED BY:

GREEN VISION COMPANY

Per: /s/ Amer A. Salameh
Name: Amer A. Salameh B.Sc. Pharmacy
Title: Managing Partner
Business Development & Marketing.

CONFIDENTIAL ANESIVA' s Initials_____

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Exhibit 31.1

CERTIFICATION

I, John P. McLaughlin, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Anesiva, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant' s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant' s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant' s internal control over financial reporting that occurred during the registrant' s most recent fiscal quarter (the registrant' s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant' s internal control over financial reporting; and

5. The registrant' s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant' s auditors and the audit committee of registrant' s board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant' s ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant' s internal control over financial reporting.

Date: May 8, 2008

/s/ John P. McLaughlin

John P. McLaughlin
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Jean-Frédéric Viret, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Anesiva, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant' s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant' s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant' s internal control over financial reporting that occurred during the registrant' s most recent fiscal quarter (the registrant' s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant' s internal control over financial reporting; and

5. The registrant' s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant' s auditors and the audit committee of registrant' s board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant' s ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant' s internal control over financial reporting.

Date: May 8, 2008

/s/ Jean-Frédéric Viret

Jean-Frédéric Viret, Ph.D.
Vice President and Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), John P. McLaughlin, Chief Executive Officer of Anesiva, Inc., a Delaware corporation (the "Company") hereby certifies that, to the best of his knowledge, as follows:

The Company' s Quarterly Report on Form 10-Q for the period ended March 31, 2008, to which this Certification is attached as Exhibit 32.1 (the "***Periodic Report***") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and that the information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned has set his hand hereto as of this 8th day of May 2008.

By: /s/ John P. McLaughlin

John P. McLaughlin
Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), has been provided to Anesiva, Inc. and will be retained by Anesiva, Inc. and furnished to the Securities and Exchange Commission or its staff upon request. This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Anesiva, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), JEAN-FRÉDÉRIC VIRET, Vice President and Chief Financial Officer of Anesiva, Inc., a Delaware corporation (the "Company") hereby certifies that, to the best of his knowledge, as follows:

The Company' s Quarterly Report on Form 10-Q for the period ended March 31, 2008, to which this Certification is attached as Exhibit 32.2 (the "***Periodic Report***") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and that the information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned has set his hand hereto as of this 8th day of May 2008.

By: /s/ Jean-Frédéric Viret

Jean-Frédéric Viret

Vice President and Chief Financial Officer

(Principal Financial Officer)

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), has been provided to Anesiva, Inc. and will be retained by Anesiva, Inc. and furnished to the Securities and Exchange Commission or its staff upon request. This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Anesiva, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.