BRIGHT HORIZONS FAMILY SOLUTIONS INC.
Form DEF 14A
April 14, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

SCHEDULE 14A

Proxy Statement Pursuant to Section 14(a) of the

Securities Exchange Act of 1934

(Amendment No.)

Filed by the Registrant x Filed by a party other than the Registrant ¨

Check the appropriate box:

¨ Preliminary Proxy Statement
¨ **Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))**
x Definitive Proxy Statement
¨ Definitive Additional Materials
¨ Soliciting Material Pursuant to §240.14a-12

BRIGHT HORIZONS FAMILY SOLUTIONS INC.

(Name of Registrant as Specified In Its Charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

Payment of Filing Fee (Check the appropriate box):

x No fee required.

¨ Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.

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1) Amount Previously Paid:

2) Form, Schedule or Registration Statement No.:

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200 Talcott Avenue South

Watertown, Massachusetts 02472

April 14, 2014

Dear Shareholder:

We cordially invite you to attend our 2014 Annual Meeting of Shareholders on Monday, May 12, 2014, at 8:30 a.m. (local time), to be held at our offices at 200 Talcott Avenue South, Watertown, Massachusetts 02472.

The proxy statement accompanying this letter describes the business we will consider at the meeting. Your vote is important regardless of the number of shares you own. Whether or not you plan to attend the Annual Meeting, we encourage you to consider the matters presented in the proxy statement and vote as soon as possible. Instructions for Internet and telephone voting are attached to your proxy card. If you prefer, you can vote by mail by completing and signing your proxy card and returning it in the enclosed envelope.

We hope that you will be able to join us on May 12th.

Sincerely,

David Lissy

Chief Executive Officer

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Bright Horizons Family Solutions Inc.

NOTICE OF ANNUAL MEETING OF SHAREHOLDERS

May 12, 2014

The Annual Meeting of Shareholders of Bright Horizons Family Solutions Inc. (the Company) will be held at our offices at 200 Talcott Avenue South, Watertown, Massachusetts 02472 on Monday, May 12, 2014, at 8:30 a.m. (local time) for the following purposes as further described in the proxy statement accompanying this notice:

To elect the three directors specifically named in the proxy statement, each for a term of three years.

To ratify the appointment of Deloitte & Touche LLP as the independent registered public accounting firm of the Company for the current fiscal year.

Any other business properly brought before the meeting.

Shareholders of record at the close of business on April 9, 2014 are entitled to notice of, and entitled to vote at, the Annual Meeting and any adjournments or postponements thereof.

To attend the Annual Meeting, you must demonstrate that you were a Bright Horizons shareholder as of the close of business on April 9, 2014, or hold a valid proxy for the Annual Meeting from such a shareholder. The proxy card includes an admission ticket for one shareholder to attend the Annual Meeting of Shareholders. You may alternatively present a brokerage statement showing proof of your ownership of Bright Horizons stock as of April 9, 2014. **All shareholders must also present a valid form of government-issued picture identification in order to attend.** Please allow additional time for these procedures.

By Order of the Board of Directors

Stephen Dreier

Secretary

Watertown, Massachusetts

April 14, 2014

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Bright Horizons Family Solutions Inc.

ANNUAL MEETING OF SHAREHOLDERS

May 12, 2014

PROXY STATEMENT

The Board of Directors of Bright Horizons Family Solutions Inc., or Bright Horizons, is soliciting your proxy for the 2014 Annual Meeting. Attendance in person or by proxy of a majority of the shares outstanding and entitled to vote at the meeting is required for a quorum for the meeting.

You may vote on the Internet, using the procedures and instructions described on the proxy card and other enclosures. You may vote by telephone using the toll-free telephone number on the proxy card. Both Internet and telephone voting provide easy-to-follow instructions and have procedures designed to authenticate your identity and permit you to confirm that your voting instructions are accurately reflected. Street name holders may vote by Internet or telephone if their banks or brokers make those methods available, in which case the banks or brokers will enclose the instructions with the proxy statement. All stockholders may vote by signing and returning the enclosed proxy card.

You may revoke your proxy at any time before it is voted by voting later by telephone or Internet, returning a later-dated proxy card, or delivering a written revocation to the Secretary of Bright Horizons.

Shareholders of record at the close of business on April 9, 2014 are entitled to vote at the meeting. As of March 31, 2014 there were 65,840,369 shares of common stock outstanding and each is entitled to one vote.

This proxy statement, the proxy card and the Annual Report on Form 10-K for our fiscal year ended December 31, 2013 (fiscal 2013) are being first mailed to shareholders on or about the date of the notice of meeting. Our address is 200 Talcott Avenue South, Watertown, Massachusetts 02472.

Important Notice Regarding the Availability of Proxy Materials for the Annual Meeting To Be Held on May 12, 2014: Our proxy statement is attached. Financial and other information concerning Bright Horizons is contained in our annual report to shareholders for the fiscal year ended December 31, 2013. The proxy statement and our fiscal 2013 annual report to shareholders are available on the Investor Relations section of our website at www.brighthorizons.com. Additionally, you may access our proxy materials at www.brighthorizons.com/proxy2014, a site that does not have cookies that identify visitors to the site.

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BOARD OF DIRECTORS AND COMMITTEES OF THE BOARD

Board structure and committee composition

We have an Audit Committee and a Compensation Committee with the composition and responsibilities described below. Each committee operates under a charter that has been approved by our Board of Directors. A copy of each charter can be found by clicking on Corporate Governance in the Investor Relations section of our website, *www.brighthorizons.com*. The members of each committee are appointed by the Board of Directors and each member serves until his or her successor is elected and qualified, unless he or she is earlier removed or resigns. In addition, from time to time, special committees may be established under the direction of the Board of Directors when necessary to address specific issues.

Because we are taking advantage of exceptions applicable to controlled companies under the New York Stock Exchange (the NYSE) listing rules, we do not have a majority of independent directors, we do not have a nominating committee, and our Compensation Committee is not composed entirely of independent directors as defined under such rules. The responsibilities that would otherwise be undertaken by a nominating committee will be undertaken by our Board of Directors, or at its discretion, by a special committee established under the direction of our Board of Directors. The controlled company exception does not modify the independence requirements for our Audit Committee. The rules applicable to our Audit Committee require that our Audit Committee be composed of at least three members, a majority of whom were required to be independent within 90 days of the completion of our initial public offering, and all of whom were required to be independent prior to January 25, 2014. Each member of our Audit Committee currently qualifies as independent under these rules.

Our Board of Directors held four meetings in fiscal 2013. During fiscal 2013, each director attended at least 75% of the Board meetings and the total meetings held by all of the committees on which he or she served during the periods that he or she served with the exception of Roger Brown, who attended two of the four Board meetings.

During fiscal 2013, the Board of Directors had two standing committees: the Audit Committee and the Compensation Committee. The table below provides information about the membership of these committees during fiscal 2013:

Name	Audit	Compensation
Lawrence M. Alleva	X*	
Joshua Bekenstein		X*
Roger H. Brown		
E. Townes Duncan**	X	
Jordan Hitch		X
David Humphrey		X
Marguerite Kondracke	X	
Dr. Sara Lawrence-Lightfoot		
David Lissy		
Linda Mason		
Mary Ann Tocio		
Number of meetings during fiscal 2013	9	4

* Chair

** Mr. Duncan was appointed to the Board in January 2014

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Audit Committee

The purpose of the Audit Committee is set forth in the Audit Committee charter. The Audit Committee s primary duties and responsibilities are to:

- Appoint or replace, compensate and oversee the outside auditors for the purpose of preparing or issuing an audit report or related work or performing other audit, review or attest services for us. The outside auditors report directly to the Audit Committee.

- Pre-approve all auditing services and permitted non-audit services (including the fees and terms thereof) to be performed for us by our outside auditors, subject to de minimis exceptions which are approved by the Audit Committee prior to the completion of the audit.

- Review and discuss with management and the outside auditors the annual audited and quarterly unaudited financial statements, our disclosures under Management s Discussion and Analysis of Financial Condition and Results of Operations, and the selection, application and disclosure of critical accounting policies and practices used in such financial statements.

- Review and approve all related party transactions.

- Discuss with management and the outside auditors significant financial reporting issues and judgments made in connection with the preparation of our financial statements, including any significant changes in our selection or application of accounting principles, any major issues as to the adequacy of our internal controls and any special steps adopted in light of material control deficiencies.

The Audit Committee consists of Lawrence Alleva, E. Townes Duncan and Marguerite Kondracke. Our Board of Directors has determined that Mr. Alleva, Mr. Duncan and Ms. Kondracke are independent directors pursuant Rule 10A-3(b)(1) under the Securities Exchange Act of 1934, as amended (the Exchange Act), and Section 303A.02 of the New York Stock Exchange Listed Company Manual. Mr. Alleva is also an audit committee financial expert within the meaning of Item 407 of Regulation S-K, and serves as chair of the Audit Committee. A copy of the charter, which satisfies the applicable standards of the Securities and Exchange Commission (the SEC) and the NYSE is available on our website.

Compensation Committee

The purpose of the Compensation Committee is to assist the Board of Directors in fulfilling its responsibilities relating to oversight of the compensation of our directors, executive officers and other employees and the administration of our benefits and equity-based compensation programs. The Compensation Committee reviews and recommends to our Board of Directors compensation plans, policies and programs and approves specific compensation levels for all executive officers. The Compensation Committee consists of Joshua Bekenstein, Jordan Hitch and David Humphrey. A copy of the charter, which satisfies the applicable standards of the Securities and Exchange Commission (the SEC) and the NYSE is available on our website. Pursuant to its charter, the Compensation Committee may delegate to subcommittees of the Compensation Committee any of the responsibilities of the full committee.

Compensation Committee Interlocks and Insider Participation

All compensation and related matters are reviewed by the Compensation Committee. Each of Messrs. Bekenstein, Hitch and Humphrey is affiliated with Bain Capital Partners, LLC. For additional information regarding transactions between Bain Capital Partners, LLC and us, please see Transactions with Related Persons below.

Our Board s Role in Risk Oversight

It is management s responsibility to manage risk and bring to the Board s attention risks that are material to Bright Horizons. The Board has oversight responsibility for the systems established to report and monitor the most significant risks applicable to Bright Horizons. The Board administers its risk oversight role directly and through its committee structure and the committees regular reports to the Board at Board meetings. The Board reviews strategic, financial and execution risks and exposures associated with the annual plan and multi-year plans, major litigation and other matters that may present material risk to the Company s operations, plans, prospects or the Company s reputation, acquisitions and divestitures and senior management succession planning. The Audit Committee reviews risks associated with financial and accounting matters, including financial reporting, accounting, disclosure, internal controls over financial reporting, ethics and compliance programs, regulatory compliance, and data security. The Compensation Committee reviews risks related to executive compensation and the design of compensation programs, plans and arrangements.

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2013 Director Compensation

The following table sets forth information concerning the compensation earned by our directors during fiscal 2013. Compensation for Mr. Lissy and Ms. Tocio is included with that of our other named executive officers.

Name	Fees paid in cash ($)	Option awards ($)(1)(2)	Non-equity incentive plan compensation ($)	All other compensation	Total ($)
Lawrence Alleva	55,000	61,730			116,730
Roger Brown	18,000	41,829			59,829
Marguerite Kondracke	21,500	41,829			63,329
Sara Lawrence-Lightfoot	23,000	41,829			64,829
Linda Mason	122,765(3)			1,430(4)	124,195

(1) For fiscal 2013, amounts shown reflect the fair value of options awarded in 2013 determined in accordance with ASC Topic 718. Assumptions used in the calculation of these amounts are included in note 12 to our audited consolidated financial statements included in our 2013 Annual Report on Form 10-K.

(2) As of December 31, 2013, our directors held the following options to purchase shares of our common stock: Lawrence Alleva 5,272 options, Roger Brown 22,482 options, Marguerite Kondracke 13,336 options, Sara Lawrence-Lightfoot 3,000 options, and Linda Mason 69,941 options.

(3) Amount shown reflects compensation earned by Ms. Mason in her capacity as an employee of the Company, consisting of $81,843 in salary and a $40,922 bonus paid in 2014. In 2013, Ms. Mason did not receive any compensation separately in respect of her service as Chairman. As of January 1, 2014 Ms. Mason is being compensated solely in her capacity as Chairman, a non-employee position.

(4) Amount shown includes matching contributions made to Ms. Mason under the 401(k) Plan, in her capacity as an employee.

Pursuant to the revised compensation program adopted in connection with our initial public offering, the following policy for the compensation for all independent directors was effective for all director compensation payments in 2013:

Annual Retainer. Each independent director receives an Annual Board Retainer of $10,000 in cash, payable at the quarterly rate of $2,500 and an annual equity grant valued at $40,000.

Meeting Fees. Each independent director receives $4,000 for each Board meeting attended in person or $1,000 for each Board meeting attended by conference call.

Each independent member of the Compensation Committee also receives $1,500 for each committee meeting attended in person or $500 for each committee meeting attended by conference call. Additionally, the independent chair of the Compensation Committee receives an annual retainer of $20,000.

Each independent member of the Audit Committee also receives $1,500 for each committee meeting attended in person or $500 for each committee meeting attended by conference call. Additionally, the independent chair of the Audit Committee receives an annual retainer of $20,000.

Each independent member of the Nominating and Governance Committee, when such Committee is activated, also receives $1,000 for each committee meeting attended in person or $500 for each committee meeting attended by conference call. Additionally, the independent chair of the Nominating and Governance Committee receives an annual retainer of $5,000.

Prior to our initial public offering, each member of our board of directors who was not an employee of the company was eligible to receive an annual retainer of $5,000 for board services, a meeting fee of $2,500 per in person meeting, and a meeting fee of $1,000 per telephonic meeting. We have not, since our going-private transaction, compensated directors affiliated with the Sponsor for their board service and, while the Sponsor

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controls a majority of our outstanding common stock, none of the directors affiliated with the Sponsor will be compensated for their board service.

Effective January 1, 2014, the board compensation program was amended to provide an annual retainer of $95,000 for the Chair of the Board payable at the quarterly rate of $23,750.

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PROPOSAL 1

ELECTION OF DIRECTORS

Bright Horizons has a classified Board of Directors currently consisting of three Directors with terms expiring in 2014 (Class I), four Directors with terms expiring in 2015 (Class II) and four Directors with terms expiring in 2016 (Class III). At each Annual Meeting of Shareholders, Directors in one class are elected for a full term of three years to succeed those Directors whose terms are expiring. This year, the three Class I Director nominees will stand for election to a three-year term expiring at the 2017 Annual Meeting. The persons named in the enclosed proxy will vote to elect David Lissy, David Humphrey and Sara Lawrence-Lightfoot as Directors unless the Proxy is marked otherwise. Each of the nominees has indicated his or her willingness to serve, if elected. However, if a nominee should be unable to serve, the shares of common stock represented by proxies may be voted for a substitute nominee designated by the Board. Management has no reason to believe that any of the above-mentioned nominees will not serve his or her term as a director.

We seek nominees with established strong professional reputations, sophistication, business acumen and experience in multi-site operations and/or contracted business services in the employee benefits arena. We also seek nominees with experience in substantive areas that are important to our business such as international operations; accounting, finance and capital structure; strategic planning and leadership of complex organizations; human resources and development practices; and strategy and innovation. Our nominees hold or have held senior executive positions in large, complex organizations or in businesses related to important substantive areas, and in these positions have also gained experience in core management skills and substantive areas relevant to our business. Our nominees also have experience serving on boards of directors and board committees of other organizations, and each of our nominees has an understanding of public company corporate governance practices and trends.

In addition, all of our nominees have prior service on our Board, which has provided them with significant exposure to both our business and the industry in which we compete. We believe that all our nominees possess the professional and personal qualifications necessary for board service, and we have highlighted particularly noteworthy attributes for each director in the individual biographies below.

Nominees for Election for Terms Expiring in 2017 (Class I Directors)

The individuals listed below have been nominated and are standing for election at this year s Annual Meeting. If elected, they will hold office until our 2017 Annual Meeting of Shareholders and until their successors are duly elected and qualified. All of these directors were previously elected to the Board by shareholders.

Your Board of Directors unanimously recommends that you vote FOR the election of each of the nominees as director.

David Humphrey, 36

Director since 2008

Mr. Humphrey has been a managing director at Bain Capital Partners, LLC since December 2012 having joined the firm in 2001. From December 2008 to December 2012 Mr. Humphrey served as a Principal, and from 2006 to December 2008 Mr. Humphrey served as Vice President, at Bain Capital Partners, LLC. Mr. Humphrey serves on the board of directors of Bloomin Brands, Inc., Genpact Limited, Burlington Coat Factory Warehouse Corporation, Skillsoft plc and BMC Software, Inc. Prior to joining Bain Capital, Mr. Humphrey was an investment banker in the mergers and acquisitions group at Lehman Brothers from 1999 to 2001. Mr. Humphrey received an M.B.A. from Harvard Business School and a B.A. from Harvard University. Mr. Humphrey has

substantial knowledge of the capital markets from his experience as an investment banker and is valuable to the Board of Directors discussions of capital and liquidity needs.

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Dr. Sara Lawrence-Lightfoot, 69

Director since 1993

Dr. Lawrence-Lightfoot is the Emily Hargroves Fisher Professor of Education at Harvard University and has been on the faculty since 1972. Dr. Lawrence-Lightfoot served as a director of the John D. and Catherine T. MacArthur Foundation from 1991 to 2007 and as Chairman from 2001 to 2007. She is currently Deputy Chair of the Board of Directors of Atlantic Philanthropies, where she has served since 2007, and previously served as Chair of the Academic Affairs Committee of the Board of Trustees of Berklee College of Music from September 2007 until March 2012. She was re-elected to the Berklee Board of Trustees in March 2014 and is a Trustee of the WGBH Educational Foundation where she has served since 2001. Dr. Lawrence-Lightfoot s expertise in child development, teacher training, classroom structures and processes, curriculum development, parent/teacher relationships, educational policies and organizational matters will continue to provide an invaluable resource to the Board.

David H. Lissy, 48

Director since 2001

Mr. Lissy has served as Chief Executive Officer of the Company since January 2002. Mr. Lissy served as Chief Development Officer of the Company from 1998 until January 2002. He also served as Executive Vice President from June 2000 to January 2002. He joined Bright Horizons in August 1997 and served as Vice President of Development until the merger with CorporateFamily Solutions, Inc. in July 1998. Prior to joining Bright Horizons, Mr. Lissy served as Senior Vice President/General Manager at Aetna U.S. Healthcare, the employee benefits division of Aetna, Inc., in the New England region. His experience prior to joining the Company, his leadership at the Company and at many charitable, business services, and educational organizations, including his current service on the boards of the March of Dimes, Altegra Health, Jumpstart and Ithaca College, provides him with the experience and management skills necessary to serve as a director of the Company.

Directors with Terms Expiring in 2015 (Class II Directors)

E. Townes Duncan, 60

Director since 2014

Mr. Duncan is the Managing Partner of Solidus Company LP, a private investment firm, and has served in that capacity since its inception in 1997. From 1993 to 1997, Mr. Duncan was the Chairman of the Board of Directors and Chief Executive Officer of Comptronix Corporation, a provider of electronics contract manufacturing services. Mr. Duncan also served as a Vice President and principal of Massey Burch Investment Group, Inc., a venture capital firm and the predecessor of Massey Burch Capital Corp., from 1985 to 1993. In addition, Mr. Duncan is a director of numerous private companies and previously served on the board of directors of several private and public companies, including J. Alexander s Corporation, an owner and operator of casual dining restaurants. Mr. Duncan was also a member of our Board of Directors from 1998 until May 2008. Mr. Duncan s many years of experience both as a senior executive of an investment firm and as a director of companies in various business sectors, including the child care sector in connection with his previous service on our Board, make him highly qualified to serve on our Board.

Jordan Hitch, 47

Director since 2008

Mr. Hitch has been a managing director at Bain Capital Partners, LLC since 1997. Prior to joining Bain Capital in 1997, Mr. Hitch was a consultant at Bain & Company where he worked in the financial services, healthcare and utility industries. Mr. Hitch serves on the board of directors of Guitar Center Holdings, Inc., The Gymboree Corporation and Burlington Coat Factory Warehouse Corporation. As a result of these and other professional experiences, Mr. Hitch brings to our board significant experience in and knowledge of corporate finance and

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strategy development, which strengthen the collective qualifications, skills and experience of our Board of Directors.

Linda Mason, 59

Director since 1986

Ms. Mason co-founded Bright Horizons in 1986, and served as director and its president from 1986 to 1998. She has served as a director and Chairman of the Board of the Company since 1998. Prior to co-founding Bright Horizons, Ms. Mason was a co-director of the Save the Children relief and development effort in the Sudan and worked as a program officer with CARE in Thailand. In addition to her duties as Chairman of our Board of Directors, from 1998 through 2013 Ms. Mason served as a part-time employee of the Company, with responsibilities that include participation in Company trainings, conferences and culture-building and representing the Company from time to time on industry matters and in public policy discussions. Ms. Mason is the wife of Roger H. Brown, who is also a director of the Company. From 1993 to 2007, Ms. Mason served as director of Whole Foods Market. Ms. Mason currently serves on the boards of Horizons for Homeless Children, the Advisory Board of the Yale University School of Management, Carnegie Endowment for International Peace, Mercy Corps and the Packard Foundation. Ms. Mason has extensive experience with the Company and her child advocacy work brings valuable perspective to the Board.

Mary Ann Tocio, 65

Director since 2001

Ms. Tocio has served as Chief Operating Officer of the Company since 1998. She was appointed President in June 2000. Ms. Tocio joined Bright Horizons in 1992 as Vice President and General Manager of Child Care Operations, and served as Chief Operating Officer from November 1993 until the merger with CorporateFamily Solutions, Inc. in July 1998. Ms. Tocio has more than thirty years of experience managing multi-site service organizations, twenty years of which were with the Company. She was previously the Senior Vice President of Operations for Health Stop Medical Management, Inc., a national provider of ambulatory care and occupational health services. Ms. Tocio also currently serves as a member of the board of directors of Harvard Pilgrim Health Care, a health benefits and insurance organization, and Horizons for Homeless Children, a non-profit organization that provides support for homeless children and their families. Ms. Tocio served as a member of the board of directors of Mac-Gray Corporation, a provider of laundry facilities management services from 2006 to 2013. Her public company board experience and expertise with managing growing organizations render her an invaluable resource as a director.

Directors with Terms Expiring in 2016 (Class III Directors)

Lawrence Alleva, 64

Director since 2012

Mr. Alleva is a Certified Public Accountant (inactive) and spent his professional career with PricewaterhouseCoopers LLP (PwC), including 28 years as a partner, from 1971 until his retirement in 2010. At PwC he served clients ranging from Fortune 500 and multi-national companies to rapid-growth companies pursuing initial public offerings. Mr. Alleva also served in a senior national leadership role for PwC s Ethics and Compliance Group to manage the design and implementation of best practice procedures, internal controls and monitoring activities, including PwC s response to inspection reports issued by the Public Company Accounting Oversight Board (PCAOB). Mr. Alleva currently serves as a director and chair of the audit committee of Tesaro, Inc. and, through December 2013, served in a similar capacity for GlobalLogic, Inc. He has served as a trustee of Ithaca College for over 20 years, including in the vice chair role for ten years. Mr. Alleva brings valuable experience to our Board through his financial and Sarbanes-Oxley Act expertise, and his professional focus on areas such as corporate governance, control and financial reporting best practices.

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Joshua Bekenstein, 55

Director since 1986

Mr. Bekenstein has been a managing director at Bain Capital Partners, LLC since 1986. Prior to joining Bain Capital in 1984, Mr. Bekenstein spent several years at Bain & Company, where he was involved with companies in a variety of industries. Mr. Bekenstein serves as a director of Michaels Stores, Inc., Bombardier Recreational Products Inc., Dollarama Capital Corporation, Toys R Us, Inc., Burlington Coat Factory Warehouse Corporation, The Gymboree Corporation, Canada Goose, Bob s Discount Furniture, and Waters Corporation. Mr. Bekenstein s many years of experience both as a senior executive of a large investment firm and as a director of companies in various business sectors, including ours, make him highly qualified to serve on our Board.

Roger Brown, 57

Director since 1986

Mr. Brown has served as President of Berklee College of Music since June 2004. Mr. Brown was Chief Executive Officer of the Company from June 1999 until December 2001, President of the Company from July 1998 until May 2000 and Executive Chairman of the Company from June 2000 until June 2004. Mr. Brown co-founded Bright Horizons and served as Chairman and Chief Executive Officer of Bright Horizons from its inception in 1986 until the merger with CorporateFamily Solutions in July 1998. Mr. Brown is the husband of Linda A. Mason, who is Chairman of the Board of Directors. Prior to 1986, he worked as a management consultant for Bain & Company, Inc. Mr. Brown is a co-founder of Horizons for Homeless Children, a non-profit that provides support for children and their families. He serves on the board of Wheaton College in Norton, Massachusetts. Mr. Brown s management expertise, combined with his longstanding ties to and intimate knowledge of the Company will continue to serve the Company well throughout his tenure as director.

Marguerite Kondracke, 67

Director since 2004

Ms. Kondracke served as founder and CEO of CorporateFamily Solutions, Inc. from 1987 to 1998. She served as CEO of the Company for one year and then as Co-Chair of the Board of Directors of the Company from 1999 until 2001 and served as a director until 2003. She began serving as a director of the Company in 1998, and from 2003 to 2004 she served as Staff Director for the U.S. Senate Subcommittee on Children and Families. Ms. Kondracke returned to the Company s Board in 2004, and from 2004 until May 2012, also served as President and CEO of America s Promise Alliance, a nonprofit organization founded by Colin Powell that advocates for the strength and well-being of America s children and youth. Ms. Kondracke serves on the boards of LifePoint Hospitals, Rosetta Stone, Teachscape, and The American Academy. Ms. Kondracke brings knowledge of developmental child care and education as well as extensive leadership experience to the Board.

OUR COMPANY S EXECUTIVE OFFICERS

David H. Lissy, Chief Executive Officer please see above

Mary Ann Tocio, President and Chief Operating Officer please see above

Elizabeth J. Boland has served as Chief Financial Officer of the Company since June 1999. Ms. Boland joined Bright Horizons in September 1997 and served as Chief Financial Officer and, subsequent to the merger between Bright Horizons and CorporateFamily Solutions, Inc. in July 1998, served as Senior Vice President of Finance for the Company until June 1999. From 1994 to 1997, Ms. Boland was Chief Financial Officer of The Visionaries, Inc., an independent television production company. From 1990 to 1994, Ms. Boland served as Vice President-Finance for Olsten Corporation, a publicly traded provider of home-health care and temporary staffing services. From 1981 to 1990, she worked on the audit staff at Price Waterhouse, LLP in Boston, completing her tenure as a senior audit manager.

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Stephen I. Dreier has served as Chief Administrative Officer and Secretary of the Company since 1997. He joined Bright Horizons as Vice President and Chief Financial Officer in August 1988 and became its Secretary in November 1988 and Treasurer in September 1994. Mr. Dreier served as Bright Horizons Chief Financial Officer and Treasurer until September 1997, at which time he was appointed to the position of Chief Administrative Officer. From 1976 to 1988, Mr. Dreier was Senior Vice President of Finance and Administration for the John S. Cheever/Paperama Company.

Danroy T. Henry, Sr. has served as the Chief Human Resource Officer since December 2007. Mr. Henry joined Bright Horizons in May 2004 as the Senior Vice President of Global Human Resources. From 2001 to 2004, Mr. Henry was the Executive Vice President for FleetBoston Financial where he had responsibility for the metropolitan Boston consumer banking market. Prior to 2001 Mr. Henry served roles in human resources management at Blinds To Go Superstores, Staples, Inc. and Pepsi Cola Company. Mr. Henry is the past board chair of the North East Human Resources Association and has served on the board of the Society of Human Resource management foundation. He is also currently the chair and co-founder of the DJ Dream Fund.

Stephen H. Kramer has served as the Chief Development Officer since January 2014. Mr. Kramer served as Senior Vice President, Strategic Growth & Global Operations from January 2010 until December 2013. He served as Managing Director, Europe based in the UK from January 2008 until December 2009. He joined Bright Horizons in September 2006 through the acquisition of College Coach, which he cofounded and led for eight years. Previously he was an Associate at Fidelity Ventures, the venture capital arm of Fidelity Investments and a Consultant with Arthur D. Little. Mr. Kramer received a B.S. from Babson College and an MBA from Harvard Business School. He serves on the board of Building Excellent Schools.

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CORPORATE GOVERNANCE

Board Independence. Our Corporate Governance Guidelines provide that our Board of Directors shall consist of such number of directors who are independent as is required and determined in accordance with applicable laws and regulations and requirements of the NYSE. The Board evaluates any relationships of each director and nominee with Bright Horizons and makes an affirmative determination whether or not such director or nominee is independent. Under our Corporate Governance Guidelines, an independent director is one who meets the qualification requirements for being an independent director under applicable laws and the corporate governance listing standards of the NYSE. Our Board reviews any transactions and relationships between each non-management director or any member of his or her immediate family and Bright Horizons. The purpose of this review is to determine whether there were any such relationships or transactions and, if so, whether they were inconsistent with a determination that the director was independent. As a result of this review, our Board has affirmatively determined that Mr. Alleva, Mr. Duncan, Ms. Kondracke and Ms. Lawrence-Lightfoot are independent under the governance and listing standards of the NYSE.

Diversity and Board Expertise. We seek to have a Board that represents diversity as to experience, gender and ethnicity/race, but we do not have a formal policy with respect to diversity. We also seek a Board that reflects a range of talents, ages, skills, character and expertise, particularly in the areas of accounting and finance, management, domestic and international markets, leadership and corporate governance and the child care, education and related industries in which we operate sufficient to provide sound and prudent guidance with respect to our operations and interests. All of our directors are financially literate, and one member of our Audit Committee is an audit committee financial expert.

Board Annual Performance Reviews. Our Corporate Governance Guidelines provides that the Board shall be responsible for annually conducting a self-evaluation of the Board as a whole. In addition, the written charter of the Audit Committee provides that it shall evaluate its performance on an annual basis.

Board Nominees. Under our Corporate Governance Guidelines, the Board is responsible for identifying and reviewing candidates for director positions and for selecting its own members for election by the stockholders. The Corporate Governance Guidelines provide that the Board shall review the appropriate skills and characteristics required of Board members in the context of its current make-up. It is the policy of the Board that directors should possess the highest personal and professional ethics, integrity and values. Board members are expected to become and remain informed about the Company, its business and its industry and rigorously prepare for, attend and participate in all Board and applicable committee meetings. The committee evaluates each individual in the context of the Board as a whole, with the objective of recommending a group that can best perpetuate the success of our business and represent shareholder interests through the exercise of sound judgment using its diversity of experience. In addition, the Board considers, in light of our business, each director nominee s experience, qualifications, attributes and skills that are identified in the biographical information contained under Proposal 1 Election of Directors.

The Board considers properly submitted recommendations for candidates to the Board of Directors from shareholders. Any shareholder may submit in writing one candidate for consideration for each shareholder meeting at which directors are to be elected by not later than the 120th calendar day before the first anniversary of the date that we released our proxy statement to shareholders in connection with the previous year s annual meeting. Any shareholder recommendations for consideration by the Board should include the candidate s name, biographical information, information regarding any relationships between the candidate and Bright Horizons within the last three years, a statement of recommendation of the candidate from the shareholder, a description of our shares beneficially owned by the shareholder, a description of all arrangements between the candidate and the recommending shareholder and any other person pursuant to which the candidate is being recommended, a written indication of the candidate s willingness to serve on the Board of Directors, any other information required to be provided under securities laws and regulations, and a written indication to provide such other information as the Board may reasonably request. Recommendations should be sent to Stephen Dreier, Corporate Secretary, Bright Horizons Family Solutions Inc., 200 Talcott Avenue South, Watertown, MA 02472. The Board evaluates candidates for the position of director recommended by shareholders or others in the same manner as candidates from other sources. The Board will determine whether to interview any candidates and may seek additional information about candidates from third-party sources.

Board Leadership Structure. Under our Corporate Governance Guidelines, our Board may select a Chairman of the Board of Directors at any time, who may also be an executive officer of the Company. The Board has currently chosen to separate the roles of Chairman and Chief Executive Officer. Linda Mason, our current non-executive Chairman of the Board of Directors, co-founded Bright Horizons in 1986 and served as director and president from 1986 to 1998 and as director and Chairman of the Board since 1998. The Board believes that the separate roles of Ms. Mason and Mr. Lissy, our Chief Executive Officer, are in the best interest of Bright Horizons and its stockholders. Ms. Mason has wide-ranging, in-depth knowledge of our business arising from her many years of service to Bright Horizons and, as a result, provides effective leadership for the Board and support for Mr. Lissy and other management. The structure permits Mr. Lissy to devote his attention to leading Bright Horizons and focusing on our business strategy.

Policies Relating to Directors. It is our policy that directors, other than the Chief Executive Officer, who are also employees of the Company must retire from the Board at the same time they retire from employment with the Company. In addition, it is our policy that directors who retire or otherwise change from the principal occupation or background association they held when they were originally invited to the Board should volunteer to resign from the Board. The Board does not believe that such directors should necessarily leave the Board, but it is our policy that there should be an opportunity for the Board to review the continued appropriateness of that director s membership under the circumstances. We encourage each of our directors to attend the Annual Meeting of Shareholders.

Code of Business Ethics and Conduct. We have adopted a written Code of Business Conduct and Ethics Applicable to all Directors, Officers and Employees and a written Code of Ethics for Senior Managers and Financial Officers, which are designed to ensure that our business is conducted with integrity. These codes cover, among other things, professional conduct, conflicts of interest, accurate recordkeeping and reporting, public communications and the protection of confidential information, as well as adherence to laws and regulations applicable to the conduct of our business. Copies of these codes can be found by clicking on Corporate Governance in the Investor Relations section of our website, *www.brighthorizons.com*. We intend to disclose any future amendments to, or waivers from, these codes of ethics for Bright Horizons executive officers within four business days of the waiver or amendment through a website posting or by filing a Current Report on Form 8-K with the SEC.

Communications with Directors. Security holders and other interested parties may communicate directly with the Board, the non-management directors or the independent directors as a group, or specified individual directors by writing to such individual or group c/o Office of the Corporate Secretary, Bright Horizons Family Solutions Inc., 200 Talcott Avenue South, Watertown, Massachusetts 02472. The Secretary will forward such communications to the relevant group or individual at or prior to the next meeting of the Board.

Online Availability of Information. The current versions of our Corporate Governance Guidelines, Code of Business Conduct and Ethics Applicable to all Directors, Officers and Employees, Code of Ethics for Senior Managers and Financial Officers and charters for our Audit Committee and Compensation Committee are available on our website at *www.brighthorizons.com*.

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TRANSACTIONS WITH RELATED PERSONS

Arrangements with Our Investors

In 2008, in connection with our going private transaction we entered into a stockholders agreement and a registration rights agreement with certain of the stockholders of the Company. These agreements contained provisions relating to election of directors, participation rights, restrictions on transfer of shares, tag along rights, drag along rights, a call right exercisable by us upon departure of a manager, a right of first offer upon disposition of shares, registration rights and other actions requiring the approval of stockholders. In addition, we entered into a management agreement with an affiliate of the Bain Capital Partners, LLC (the Sponsor) for the provision of certain consulting and management advisory services to us.

Stockholders Agreement

In connection with our going private transaction, we entered into a stockholders agreement with the Sponsor and certain other investors, stockholders and executive officers. In connection with the consummation of our initial public offering in January 2013, the provisions of the stockholders agreement, other than those relating to lock-up obligations in connection with registered offerings of our securities, terminated in accordance with the terms of the stockholders agreement, and the agreement was amended and restated to eliminate the terminated provisions. Our amended and restated stockholders agreement obligates the stockholders parties thereto, subject to the limited exceptions described in the amended and restated stockholders agreement, to enter into customary lock-up agreements with the underwriters in the event of underwritten public offerings of our shares of common stock.

Prior to our initial public offering, the stockholders agreement contained provisions relating to (i) voting of shares, which generally required each stockholder to vote in favor of the election of the directors designated by the Sponsor and also to vote in the same manner as the Sponsor to approve any sale, recapitalization, merger or other acquisition transaction, (ii) restrictions on transfer of shares, which generally prohibited stockholders from transferring shares of common stock other than in connection with a tag along right, a drag along transaction, our exercise of a call right upon departure of a manager, or otherwise in limited circumstances to affiliates or for estate planning purposes, (iii) tag along rights in connection with any sale of shares by the Sponsor, (iv) drag along rights in favor of the Sponsor in connection with any sale of at least 20% of the shares held by the Sponsor, and (v) a call right exercisable by us upon departure of a manager at a price per share that depended upon whether the manager s employment terminated with or without cause and whether the manager had violated any non-competition obligation owed to us. Each of our current directors has been elected in accordance with the terms of the stockholder agreement. All of the foregoing provisions of the stockholders agreement terminated, in accordance with their terms, upon the closing of our initial public offering and are not included in the amended and restated stockholders agreement.

Registration Rights Agreement

In connection with our going private transaction, we entered into a registration rights agreement with the Sponsor and certain other stockholders. In connection with the consummation of our initial public offering, the registration rights agreement was amended. The registration rights agreement, as amended, provides the Sponsor with certain demand registration rights following the expiration of any applicable lockup period in respect of the shares of our common stock held by them. In addition, if we from time to time register additional shares of common stock for sale to the public, we are required to give notice of such registration to the Sponsor and the other stockholders party to the agreement of our intention to effect such a registration, and, subject to certain limitations, the Sponsor and such holders have piggyback registration rights providing them with the right to require us to include shares of common stock held by them in such registration. We are required to bear the registration expenses, other than underwriting discounts and commissions and transfer taxes, associated with any registration of shares by the Sponsor or other holders described above.

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The registration rights agreement includes customary indemnification provisions in favor of any person who is or might be deemed a controlling person within the meaning of Section 15 of the Securities Act of 1933, as amended (the Securities Act), or Section 20 of the Exchange Act and related parties against liabilities under the Securities Act incurred in connection with the registration of any of our debt or equity securities. These provisions provide indemnification against certain liabilities arising under the Securities Act and certain liabilities resulting from violations of other applicable laws in connection with any filing or other disclosure made by us under the securities laws relating to any such registrations. We have agreed to reimburse such persons for any legal or other expenses incurred in connection with investigating or defending any such liability, action or proceeding, except that we will not be required to indemnify any such person or reimburse related legal or other expenses if such loss or expense arises out of or is based on any untrue statement or omission made in reliance upon and in conformity with written information provided by such person.

Management Agreement

In connection with the going private transaction, we entered into a management agreement with the Sponsor pursuant to which the Sponsor provided us with certain consulting and management advisory services. In exchange for these services, we paid an aggregate annual management fee equal to $2.5 million, and we reimbursed the Sponsor for out-of-pocket expenses incurred by it, its members, or its affiliates in connection with the provision of services pursuant to the management agreement, which totaled less than $20,000 per year in 2011, 2012 and 2013. In addition, the Sponsor was entitled to a transaction fee in connection with any financing, acquisition, disposition or change of control transaction equal to 1% of the gross transaction value, including assumed liabilities, for such transaction. The Sponsor did not receive any transaction fees under the management agreement in 2010, 2011 or 2012 and in connection with the termination of the management agreement, the Sponsor waived any right to receive a transaction fee under the management agreement in connection with the initial public offering.

The management agreement included customary exculpation and indemnification provisions in favor of the Sponsor and its affiliates. The management agreement terminated immediately prior to our initial public offering in exchange for a payment to the Sponsor of approximately $7.5 million. The indemnification and exculpation provisions in favor of the Sponsor and its affiliates survive such termination.

Policies and procedures for related party transactions

We believe that we executed all of the transactions set forth above on terms no less favorable to us than we could have obtained from unaffiliated third parties. It is our intention to ensure that all future transactions between us and our officers, directors and principal stockholders and their affiliates, are approved by the Audit Committee, and are on terms no less favorable to us than those that we could obtain from unaffiliated third parties. In addition, the Company s Code of Ethics for Senior Managers and Financial Officers states that such employees may not (i) own an interest in a company that competes or does business with the Company or (ii) participate in a joint venture, partnership or other business arrangement with the Company, in each case without the prior written approval of the Company s Compliance Officer.

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Stock Ownership Information

The following table sets forth information regarding the beneficial ownership of our common stock as of March 31, 2014 by

- each person or group of affiliated persons known by us to be the beneficial owner of more than 5% of our common stock;

- each of our named executive officers and directors; and

- all of our directors and named executive officers as a group.

The percentage ownership information shown in the table below is based upon 65,840,369 shares of common stock outstanding as of March 31, 2014.

Information with respect to beneficial ownership has been furnished by each director, officer or beneficial owner of more than 5% of our common stock. We have determined beneficial ownership in accordance with the rules of the Securities and Exchange Commission. These rules generally attribute beneficial ownership of shares to persons who possess sole or shared voting or investment power with respect to such shares. The information does not necessarily indicate beneficial ownership for any other purpose. Under these rules, the number of shares of common stock deemed outstanding includes shares issuable upon exercise of options and held by the respective person or group which may be exercised or converted within 60 days after March 31, 2014. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person or entity, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person or entity.

Unless otherwise indicated below, the address for each listed director, officer and stockholder is c/o Bright Horizons Family Solutions Inc., 200 Talcott Avenue South, Watertown, Massachusetts 02472. The inclusion in the following table of those shares, however, does not constitute an admission that the named stockholder is a direct or indirect beneficial owner. Unless otherwise indicated and subject to applicable community property laws, to our knowledge, each stockholder named in the following table possesses sole voting and investment power over the shares listed, except for those jointly owned with that person s spouse.

Name	Number of Shares(1)	Percentage
Beneficial holders of 5% or more of our outstanding coming stock:		
Bain Capital Fund X, L.P. and related funds(1)	34,033,737	51.7%
Baron Capital Group, Inc. and related funds(2)	4,478,079	6.8
Directors and executive officers:		
Lawrence Alleva	2,400	*
Joshua Bekenstein(3)		*
Elizabeth J. Boland(4)	400,472	*

Roger H. Brown(5)	389,907	*
Stephen I. Dreier(6)	197,105	*
E. Townes Duncan	100	*
Danroy T. Henry, Sr.(7)	28,628	*
Jordan Hitch(8)		*
David Humphrey(9)		*
Marguerite W. Kondracke(9)	20,336	*
Stephen H. Kramer(10)	81,218	*
Sara Lawrence-Lightfoot		*
David H. Lissy(11)	1,018,209	1.5
Linda A. Mason(12)	389,907	*
Mary Ann Tocio(13)	905,542	1.4
All Directors, Nominees and Executive Officers as a Group (15 persons)(14)	3,043,917	4.5%

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* Indicates less than one percent.

(1) The shares included in the table consist of: (i) 33,640,612 shares of common stock owned by Bain Capital Fund X, L.P., whose managing partner is Bain Capital Partners X, L.P., whose managing partner is Bain Capital Investors, LLC (BCI), (ii) 4,462 shares of common stock owned by BCIP Associates-G, whose managing partner is BCI, (iii) 236,151 shares of common stock owned by BCIP Associates III, LLC, whose manager is BCIP Associates III, (iv) 42,872 shares of common stock owned by BCIP Associates III-B LLC, whose manager is BCIP Associates III-B, (v) 102,540 shares of common stock owned by BCIP T Associates III, LLC, whose manager is BCIP Trust Associates III and (vi) 7,100 shares of common stock owned by BCIP T Associates III-B, LLC whose managing partner is BCIP Trust Associates III-B. BCI is the managing partner of BCIP Associates III, BCIP Associates, III-B, BCIP Trust Associates

Nitroglycerin	Acute angina	FDA Approved	-

III and BCIP Trust Associates III-B. As a result of the relationships described above, BCI may be deemed to share beneficial ownership of the sh5.4pt; PADDING-BOTTOM: 0in; BORDER-LEFT: black 1pt solid; PADDING-TOP: 0in; BORDER-BOTTOM: black 1pt solid" valign="bottom" width="121">

	NitroMist™			
Product Candidates				
ZolpiMist™	Zolpidem tartrate	Sleeplessness	NDA submitted; FDA acceptance January 23, 2008	-
Sumatriptan	Sumatriptan succinate	Migraines	Pilot Efficacy study complete	-
Ropinirole	Ropinirole	Idiopathic Parkinson’s Disease	Clinical development	-
Tizanidine	Tizanidine hydrochloride	Spasticity	Clinical development	-
Zensana™	Ondansetron	Anti-emetic	Clinical development	Hana Biosciences/Par Pharmaceuticals

NitroMist™ (nitroglycerin lingual aerosol). This product is indicated for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease, and was approved by the FDA in November 2006. Previously, this product was partnered with Par Pharmaceuticals, or Par; however, on August 1, 2007, we announced that Par returned the rights to NitroMist™ to us as part of Par's strategy to concentrate its resources on supportive care in AIDS and oncology markets. We are currently investigating strategic partners for this product.

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ZolpiMist™ (zolpidem oral spray). Zolpidem is the active ingredient in Ambien®, the leading hypnotic marketed by Sanofi-Aventis. A pilot pharmacokinetic, or PK, study in zolpidem oral spray with 10 healthy subjects, completed in the first half of calendar 2005, suggested that our formulation of zolpidem oral spray had a comparable PK profile to the Ambien® tablet but with a more rapid time to detectable drug levels. In October 2006, we announced positive results from a pilot pharmacokinetic study comparing our formulation of ZolpiMist™ to Ambien® tablets. In the study, 10 healthy male volunteers received ZolpiMist™ or Ambien® tablets in 5mg or 10mg doses. For fasting subjects, fifteen minutes after dosing, 80% of subjects using ZolpiMist™ achieved blood concentrations of greater than 20 ng/ml, compared to 33% of subjects in the 5mg Ambien® tablet group and 40% of subjects in the 10mg Ambien® tablet group. The difference between the oral spray groups and tablet groups was statistically significant (p=0.016). Twenty ng/ml is a level generally believed to approximate the lower limit of the therapeutic range for zolpidem. Additionally, drug concentrations were measured at five and ten minutes post-dosing. At these early time points, the oral spray groups achieved drug levels five-to-thirty times greater than subjects in the corresponding tablet groups. These differences were also statistically significant. ZolpiMist™ has the potential to provide patients with the meaningful benefit of faster onset of sleep as compared to existing sleep remedies should future studies validate the already completed Pilot PK study. We submitted the NDA for our zolpidem product candidate in the second half of 2007, and the FDA indicated acceptance of this NDA filing in January 2008. We may obtain final approval from the FDA by the fourth quarter of 2008.

Sumatriptan oral spray. Sumatriptan is the active ingredient in Imitrex® which is the largest selling migraine remedy marketed by GlaxoSmithKline, or GSK. A pilot PK study of our sumatriptan oral spray with 9 healthy subjects, completed in the second half of calendar 2004, suggested that the formulation achieved plasma concentrations of sumatriptan in the therapeutic range. In September 2006 we announced positive results from an additional pilot pharmacokinetic study, with our oral spray formulation of sumatriptan which demonstrated that sumatriptan oral spray achieves a statistically significant increase in absorption rate as compared with Imitrex® tablets. The rate of drug absorption is believed to be the most important predictor of the degree and speed of migraine relief. Sumatriptan oral spray was evaluated in a four-arm, crossover pharmacokinetic study comparing 50mg Imitrex® tablets to 20mg and 30mg of the oral spray in 10 healthy male volunteers under fasting conditions. At least 90% of subjects receiving sumatriptan oral spray had detectable drug levels at three minutes post-dosing, while at the same timepoint, only 10% of subjects receiving 50mg Imitrex® tablets had detectable drug levels. These differences are statistically significant. At 3 to 6 minutes post dosing, all oral spray groups had statistically significantly higher mean concentration levels compared to 50mg Imitrex® tablets. Using published data for the currently marketed Imitrex® nasal spray as a proxy for therapeutic blood levels, we observed that by 6 minutes post-dosing, 100% of the 20mg oral spray users achieved these critical plasma concentration levels while none of the subjects from the Imitrex® tablet group did so by this timepoint. This result was also statistically significant. Furthermore, the study indicates up to a 50% increase in relative bioavailability of oral spray in comparison to the Imitrex® tablet. Additionally, the pharmacokinetics of 20mg oral spray after a meal were evaluated. Sumatriptan oral spray was well tolerated.

While Imitrex® nasal spray was not included in this clinical study, the following represents a discussion of the results of our clinical study as compared to published data for Imitrex® nasal spray. Time to the first peak plasma concentration of sumatriptan -- which represents drug absorbed directly across the oral mucosa -- was approximately 70% faster with the 20mg oral spray than what has been reported in the literature for the same dose of the Imitrex® nasal spray (6 min. vs. 20 min.). The mean concentration level achieved during this critical first phase of absorption is approximately 30% greater for the oral spray than what was observed in published studies of the nasal spray (10.9 ng/mL vs. 8.5 ng/mL). Relative bioavailability after administration of 20mg oral spray appears to be greater than published estimates for the same dose of the Imitrex® nasal spray.

Sumatriptan oral spray may provide clinical benefits to migraine sufferers including, possibly, faster relief than Imitrex® tablets as well as greater tolerability than triptan nasal sprays. Further, if proven to be safe and effective, sumatriptan oral spray may be attractive to patients who have trouble taking oral medications due to nausea and vomiting caused by the migraine attack. Previously, we were targeting an NDA submission for our sumatriptan product candidate in the first half of calendar 2008; however, due primarily to funding constraints, at the present time, we are unable to make predictions for this program relative to sufficient funding, timing, future strategic partnerships, regulatory pathway or approval with the FDA. Furthermore, during the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, including sumatriptan, as we did not believe that we had sufficient cash to sustain such activities. As of the current date, we have not yet secured additional financing, and have therefore not resumed clinical development activity. There can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities.

Tizanidine oral spray. Tizanidine is indicated for the treatment of spasticity, a symptom of several neurological disorders, including multiple sclerosis, spinal cord injury, stroke and cerebral palsy, which leads to involuntary tensing, stiffening and contracting of muscles. Tizanidine treats spasticity by blocking nerve impulses through pre-synaptic inhibition of motor neurons. This method of action results in decreased spasticity without a corresponding reduction in muscle strength. Because patients experiencing spasticity may have difficulty swallowing the tablet formulation of the drug, our tizanidine oral spray may provide patients suffering from spasticity with a very convenient solution to this serious treatment problem. We were previously targeting an NDA submission for our tizanidine product candidate in calendar 2008. However, in June 2007, we announced our near-term clinical development strategy and our intention to focus the majority of our research and development resources on our two lead product candidates, zolpidem and sumatriptan oral spray. Furthermore, during the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, including tizanidine, as we did not believe that we had sufficient cash to sustain such activities. As of the current date, we have not yet secured additional financing, and have therefore not resumed clinical development activity. There can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities.

Ropinirole oral spray. Ropinirole is indicated for the treatment of the signs and symptoms of idiopathic Parkinson's disease. Ropinirole oral spray is ideal for the geriatric population who may be suffering from dysphagia (difficulty swallowing); 85% of sufferers of Parkinson's are 65 years of age or older and it is estimated that 45% of elderly people have some difficulty in swallowing. Our formulation of ropinirole oral spray may represent a more convenient way for the patient or healthcare provider to deliver ropinirole to patients suffering stiffness and/or tremors. We were previously targeting an NDA submission for our ropinirole product candidate in calendar 2008. However, in June 2007, we announced our near-term clinical development strategy and our intention to focus the majority of our research and development resources on our two lead product candidates, zolpidem and sumatriptan oral spray. Furthermore, during the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, including ropinirole, as we did not believe that we had sufficient cash to sustain such activities. As of the current date, we have not yet secured additional financing, and have therefore not resumed clinical development activity. There can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities.

Zensana™ (ondansetron oral spray). Ondansetron is the active ingredient in Zofran®, the leading anti-emetic marketed by GSK. Through July 31, 2007, this product candidate was licensed to Hana Biosciences, who was overseeing all clinical development and regulatory approval activities for this product in the U.S. and Canada. On July 31, 2007, we entered into a Product Development and Commercialization Sublicense Agreement with Hana Biosciences and Par, pursuant to which Hana Biosciences granted a sublicense to Par to develop and commercialize Zensana™. Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana™ in the United States and Canada, including the development and re-filing of the NDA in the United States. In addition, we entered into an Amended and Restated License Agreement with Hana Biosciences, pursuant to which Hana Biosciences relinquished its right to pay reduced royalty rates to us until such time as Hana Biosciences had recovered one-half of its costs and expenses incurred in developing Zensana™ from sales of Zensana™ and we agreed to surrender for cancellation all 73,121 shares of the Hana Biosciences common stock we acquired in connection with execution of the original license agreement with Hana Biosciences. Par has announced that it expects to complete clinical development on the revised formulation of Zensana™ during 2008, and expects to submit a new NDA for Zensana™ by the end of 2008.

In January 2006, Hana Biosciences announced positive study results of a pivotal clinical trial for Zensana™. Hana Biosciences submitted its NDA on June 30, 2006, and such NDA was accepted for review by the FDA in August 2006. Previously, Hana Biosciences targeted final approval from the FDA and commercial launch in calendar 2007. However, on February 20, 2007, we announced that Hana Biosciences notified us that ongoing scale-up and stability experiments indicate that there is a need to make adjustments to the formulation and/or manufacturing process, and that there is likely to be a delay in the FDA approval and commercial launch of Zensana™ as a result thereof. On March 23, 2007, Hana Biosciences announced its plan to withdraw, without prejudice, its pending NDA for Zensana™ with the FDA.

We will receive a milestone payment from Hana Biosciences upon final approval from the FDA. In addition, we will receive double-digit royalty payments based upon a percentage of net sales. We retain the rights to our ondansetron oral spray outside of the U.S. and Canada.

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Propofol oral spray. Propofol is the active ingredient in Diprivan®, a leading intravenous anesthetic marketed by AstraZeneca. We continue to support our partner, Manhattan Pharmaceuticals, Inc., or Manhattan Pharmaceuticals, who will oversee all clinical development and regulatory approval for this product candidate. On July 10, 2007, Manhattan Pharmaceuticals announced its intention to pursue appropriate sub-licensing opportunities for this product candidate.

Veterinary. Our veterinary initiatives are being carried out largely by our partner, Velcera, Inc., or Velcera. In June 2007, Velcera announced that it had entered into a global license and development agreement with Novartis Animal Health. The agreement calls for Novartis Animal Health to develop, register and commercialize a novel canine product utilizing Velcera's Promist™ platform, which is based on our patented oral spray technology.

BUSINESS DEVELOPMENT

To date, we have entered into license agreements with (i) Hana Biosciences, for the development and marketing rights in the U.S. and Canada for our ondansetron oral spray, (ii) Par, for the marketing rights in the U.S. and Canada for NitroMist™, (iii) Manhattan Pharmaceuticals, in connection with propofol, and (iv) Velcera, in connection with veterinary applications for currently marketed veterinary drugs. In addition, we have entered into a sub-license agreement with Hana Biosciences and Par, pursuant to which Hana Biosciences granted a sublicense to Par to develop and commercialize Zensana™. Lindsay A. Rosenwald, M.D., a significant stockholder, directly and indirectly, of us, is the Chairman and sole shareholder of Paramount BioCapital, Inc., Paramount. In the regular course of its business and the business of its affiliates, and outside of its arrangement with us, Paramount and/or its affiliates identify, evaluate and pursue investment opportunities in biomedical and pharmaceutical products, technologies and companies. In addition, as of March 19, 2008, Dr. Rosenwald may be deemed to beneficially own approximately 14% of our outstanding common stock (assuming exercise of certain warrants beneficially owned by Dr. Rosenwald). Dr. Rosenwald and Paramount may be deemed to be our affiliates. Dr. Rosenwald and Paramount may also be deemed to be affiliates of Manhattan Pharmaceuticals, Velcera and Hana Biosciences.

In July 2007, the Company, entered into a Product Development and Commercialization Sublicense Agreement (the "Sublicense Agreement") with Hana Biosciences and Par Pharmaceutical, Inc. ("Par"), pursuant to which Hana Biosciences granted a non-transferable, non-sublicenseable, royalty-bearing, exclusive sublicense to Par to develop and commercialize Zensana™. In connection therewith, the Company and Hana Biosciences amended and restated their existing License and Development Agreement, as amended, relating to the development and commercialization of Zensana™ (the "Amended and Restated License Agreement") to coordinate certain of the terms of the Sublicense Agreement. Under the terms of the Sublicense Agreement, Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana™ in the United States and Canada. The Company retains its rights to Zensana™ outside of the United States and Canada.

In addition, under the terms of the Amended and Restated License Agreement, Hana Biosciences relinquished its right to pay reduced royalty rates to the Company until such time as Hana Biosciences had recovered one-half of its costs and expenses incurred in developing Zensana™ from sales of Zensana™ and the Company agreed to surrender for cancellation all 73,121 shares of the Hana Biosciences common stock acquired by the Company in connection with execution of the original License Agreement.

Also in July 2007, the Company and Par agreed to terminate the agreement relating to NitroMist™. The Company is currently investigating strategic partners for the commercialization of NitroMist™. During the three months ended September 30, 2007, the Company recorded $177,000 of revenue to write-off the remaining deferred revenue relating to this agreement.

We intend to enter into additional license agreements and strategic alliances, including:

- Marketing partners outside of North America for Zensana™, for which we retain marketing rights outside of North America;
- Marketing partners for our zolpidem oral spray and sumatriptan oral spray, to commercialize these products assuming that we are successful in attaining approval for these products from the FDA; and
- Additional marketing partners and strategic alliances as may be appropriate for the remaining present and future products in our development pipeline.

AGREEMENT WITH PAR PHARMACEUTICAL, INC. AND HANA BIOSCIENCES, INC.

In October 2004, we entered into a 20-year license and development agreement with Hana Biosciences, whereby Hana Biosciences would develop and market our oral spray version of ondansetron, a leading anti-emetic for preventing chemotherapy-induced nausea and vomiting. Under the agreement, Hana Biosciences was granted exclusive rights to market, sell and distribute our ondansetron oral spray in the U.S. and Canada. We are entitled to receive milestone payments at several junctures of development, including completion of a pharmacokinetic study, filing of an IND, FDA acceptance of the NDA and NDA approval. In August 2005, our license and development agreement with Hana Biosciences was amended to transfer the responsibility to Hana Biosciences of selecting and managing a contract manufacturer who will provide clinical and commercial quantities of the ondansetron oral spray product. Double-digit royalties on net sales of the product may be due to us if and when the product launches. In October 2004, in exchange for $1 million, Hana Biosciences purchased 400,000 newly issued shares of our common stock, at a price of $2.50 per share, and has issued to us, for no additional consideration, 73,121 shares of its common stock, valued at $500,000 based upon the average price of Hana Biosciences' common stock during the 10 business days prior to the effective date of the agreement ($6.84 per share).

On July 31, 2007, we entered into a Product Development and Commercialization Sublicense Agreement with Hana Biosciences and Par, pursuant to which Hana Biosciences granted a sublicense to Par to develop and commercialize Zensana™. Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana™ in the United States and Canada, including the development and re-filing of the NDA in the United States. In addition, we entered into an Amended and Restated License Agreement with Hana Biosciences, pursuant to which Hana Biosciences relinquished its right to pay reduced royalty rates to us until such time as Hana Biosciences had recovered one-half of its costs and expenses incurred in developing Zensana™ from sales of Zensana™ and we agreed to surrender for cancellation all 73,121 shares of the Hana Biosciences common stock we acquired in connection with execution of the original license agreement with Hana Biosciences.

We will receive a milestone payment from Hana Biosciences upon final approval from the FDA. In addition, we will receive double-digit royalty payments based upon a percentage of net sales. We retain the rights to our ondansetron oral spray outside of the U.S. and Canada.

LICENSE AND SUPPLY AGREEMENT WITH PAR PHARMACEUTICAL, INC.

In July 2004, we entered into a 10-year license and supply agreement with Par, a wholly owned subsidiary of Par Pharmaceutical Companies, Inc., whereby Par has the exclusive rights to market, sell and distribute our nitroglycerin lingual spray in the U.S. and Canada. The terms of the agreement call for an upfront license fee which was paid to us in July 2004, a milestone payment made to us upon the FDA's acceptance of an NDA for our nitroglycerin lingual spray for review in September 2004, another potential milestone payment if and when the NDA is approved for marketing in the U.S., and double-digit percentage royalties on net sales of the product in the U.S. and Canada. We are responsible for obtaining regulatory approval for the product and for supplying the product to Par.

In July 2007, the Company and Par agreed to terminate the agreement relating to NitroMist™. The Company is currently investigating strategic partners for the commercialization of NitroMist™. During the three months ended September 30, 2007, the Company recorded $177,000 of revenue to write-off the remaining deferred revenue relating to this agreement.

AGREEMENT WITH MANHATTAN PHARMACEUTICALS, INC.

In April 2003, we entered into a 10-year license and development agreement with Manhattan Pharmaceuticals for the worldwide, exclusive rights to our oral spray technology to deliver propofol for pre-procedural sedation. Manhattan Pharmaceuticals is a development stage company and has no revenues to date. The terms of the agreement require Manhattan Pharmaceuticals to achieve certain milestones and to make certain up-front license fee payments to us, the first $500,000 of which we received from June 2003 through November 2003.

AGREEMENT WITH VELCERA PHARMACEUTICALS, INC. (FORMERLY VETCO)

In June 2004, we announced the granting of an exclusive worldwide 20-year license for our proprietary oral spray technology to Velcera, a veterinary company. We received an equity stake of 529,500 shares of common stock in Velcera, along with an upfront cash technology fee of $1,500,000 in September 2004. At the time of the signing of the agreement with Velcera it was determined that the Velcera common stock had a deminimus value. Such investment continues to be carried at its cost basis of $0 as of December 31, 2007. In February 2007, Velcera merged with Denali Sciences, Inc., a publicly reporting Delaware corporation. The common stock of Denali Sciences, Inc. is not traded on any stock exchange. The agreement, which amends an earlier agreement, provides that Velcera shall make certain milestone payments to us upon the achievement of key events associated with product development. Velcera will be obligated to make additional similar payments to us for each product developed by it, and double-digit royalty payments on product sales will be due to us. Products will be formulated by Velcera, at Velcera's expense, and Velcera will fund all development and regulatory expenses.

BUSINESS STRATEGY

Strategy

Our goal is to become a leading specialty pharmaceutical company that develops and commercializes improved formulations of existing drugs using our patented oral spray technology. We believe that our technology has application to a broad number of therapeutic areas and product categories. Our strategy is to concentrate our product development activities primarily on pharmaceutical products which meet the following characteristics:

- Significant prescription sales already exist;
- Our proprietary novel drug delivery technology enhances the performance of the active ingredient of the target compound, potentially addressing unmet patient needs;
- Increasing focus on products in targeted therapeutic areas (e.g., neurology) where the benefits of our technology may apply to multiple target compounds, and where we can achieve distribution with a small specialized sales and marketing group; and
- Applicability of an efficient regulatory pathway to approval using the 505(b)(2) pathway.

In today's environment of escalating drug development costs and time to market, we believe that the ability to bring products with some degree of differentiation and competitive advantage to the marketplace in a timely and cost-effective manner is a viable strategy.

Products

We currently have six product candidates in our pipeline. One of these product candidates, Zensana™, is currently licensed to a marketing partner who will commercialize this product candidate, with us receiving milestone and royalty income from revenue upon product approval. For our NitroMist™ product which is approved, and for our zolpidem oral spray and sumatriptan oral spray, currently in development, we will most likely seek marketing partners to commercialize these product candidates, as their broad distribution will require significant resources. No current marketing partners exist for these product candidates. We expect to secure marketing partners for these product candidates after we have generated sufficient clinical data to demonstrate the effectiveness of these product candidates, and would anticipate that such marketing partners would provide us with milestone payments and royalties based on revenues.

Our two remaining product candidates, tizanidine and ropinirole, are targeted for a specific therapeutic area: neurology. Similarly to our other products, we will seek to secure marketing partners once we have generated sufficient clinical data to demonstrate performance.

In addition to our existing product candidates, we intend to continue to identify and pursue additional product candidates for development.

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PATENTED AND PATENT PENDING DELIVERY SYSTEMS

We have certain patents and pending patent applications for our oral spray delivery system. FDA approval is not a prerequisite for patent approval. The expected year of marketability of a given product candidate will vary depending upon the specific drug product with which the delivery system will be utilized. Each individual use of the delivery system will require registration with and/or approval by the FDA or other relevant health authority prior to marketability, and the amount of regulatory oversight required by the FDA or other regulatory agencies will also depend on the specific type of drug product for which the delivery system is implemented. Our aerosol and pump spray formulations release drugs in the form of a fine mist into the buccal portion of the mouth for rapid absorption into the bloodstream via the mucosal membranes. Ourproprietary technology offers, in comparison to conventional oral dosage forms, the potential for faster absorption of drugs into the bloodstream leading to quicker onset of therapeutic effects and possibly reduced first pass liver metabolism, which may result in lower doses. Oral sprays eliminate the requirement for water or the need to swallow, potentially improving patient convenience and adherence. Our oral spray technology is focused on addressing unmet medical needs for a broad array of existing and future pharmaceutical products.

MARKETING AND DISTRIBUTION

To date, we have chosen to license products developed with our technology to other drug companies. We intend to pursue additional strategic alliances, as well as to consider fully developing and commercializing product candidates internally.

We anticipate that promotion of our product candidates, whether conducted by us or by a strategic partner, will be characterized by an emphasis on their distinguishing characteristics, such as dosage form and packaging, as well as possible therapeutic advantages of such product candidates. We intend to position our product candidates as alternatives or as line extensions to brand-name products. We believe that to the extent our formulated products are patent-protected, such formulations may offer brand-name manufacturers the opportunity to expand their product lines. Alternatively, products which are not patented may be offered to brand-name manufacturers as improved substitute products after patent protection on existing products expire.

Inasmuch as we do not have the financial or other resources to undertake extensive marketing activities, we generally intend to seek to enter into marketing arrangements, including possible joint ventures or license or distribution arrangements, with third parties. We believe that such third-party arrangements will permit us to maximize the promotion and distribution of pharmaceutical products while minimizing our direct marketing and distribution costs. If we are unable to enter into additional agreements, we may not be able to successfully market our product candidates.

We have not yet determined strategies relating to marketing of our other proposed formulated products; these will be formulated in advance of anticipated completion of development activities relating to the particular formulated product. As a company, we have no experience in marketing or distribution of our product candidates, and our ability to fund such marketing activities will require us to raise additional funds and/or consummate a strategic alliance or combination with a well-funded business partner.

MANUFACTURING

We intend to contract out the manufacturing of our product candidates. Our current facility does not yet have a pilot manufacturing operation that meets current Good Manufacturing Practices, or cGMP, and would require additional investment in order to attain that capability. We will have to contract out manufacturing and/or invest additional funds in the current facility in order to provide internal manufacturing capability.

The manufacture of our pharmaceutical product candidates is subject to cGMP prescribed by the FDA and pre-approval inspections by the FDA and foreign authorities prior to the commercial manufacture of any such products. See Item 1, Business-“Raw Materials and Suppliers” and “Government Regulation.”

On November 18, 2004, we entered into a manufacturing and supply agreement with INyX USA, Ltd, or INyX, whereby INyX will manufacture and supply our nitroglycerin lingual spray. For a five-year period that began November 18, 2004, INyX will be the exclusive provider of the nitroglycerin lingual spray to us worldwide, excluding Poland, Byelorussia, the former Russian Republics of Ukraine, Latvia, Lithuania, Estonia and the United Arab Emirates. Pursuant to the terms and conditions of the agreement, it will be INyX’s responsibility to manufacture, package and supply the nitroglycerin lingual spray in such territories. Thereafter, INyX will have a non-exclusive right to manufacture such spray for an additional five years.

In July 2007, INyX announced it filed for protection under the Chapter 11 bankruptcy laws. The Company is taking all necessary steps to ensure that any assets of the Company located at INyX are protected.

In February 2008, we entered into a Master Services Agreement with Rechon Life Sciences (Malmo, Sweden), whereby Rechon will provide services related to the manufacturing development and the manufacture of clinical supplies for our products. Rechon provides these services on a fee-for-service basis.

RAW MATERIALS AND SUPPLIERS

We believe that the active ingredients used in the manufacture of our product candidates are presently available from numerous suppliers located in the U.S., Europe and Japan and can be delivered to our manufacturing facility by such suppliers. We intend to enter into arrangements with such third-party suppliers for supplies of active and inactive pharmaceutical ingredients and packaging materials used in the manufacture of our product candidates. Accordingly, we may be subject to various import duties applicable to both finished products and raw materials and may be affected by various other import and export restrictions as well as other developments impacting upon international trade. These international trade factors will, under certain circumstances, have an impact on the manufacturing costs (which will, in turn, have an impact on the cost of our product candidates). To the extent that transactions relating to the purchase of raw materials involve currencies other than U.S. dollars, our operating results will be affected by fluctuations in foreign currency exchange rates.

Generally, certain raw materials, including inactive ingredients, are available from a limited number of suppliers and certain packaging materials intended for use in connection with our product candidates may be available only from sole source suppliers. Although we believe that we will not encounter difficulties in obtaining the inactive ingredients or packaging materials necessary for the manufacture of our products, we may not be able to enter into satisfactory agreements or arrangements for the purchase of commercial quantities of such materials. A failure to enter into agreements or otherwise arrange for adequate or timely supplies of principal raw materials and the possible inability to secure alternative sources of raw material supplies could have a material adverse effect on our ability to manufacture formulated products.

Development and regulatory approval of our product candidates are dependent upon our ability to procure active ingredients and certain packaging materials from FDA-approved sources. Since the FDA approval process requires manufacturers to specify their proposed suppliers of active ingredients and certain packaging materials in their applications, FDA approval of a supplemental application to use a new supplier would be required if active ingredients or such packaging materials were no longer available from the specified supplier, which could result in manufacturing delays. Accordingly, we intend to locate alternative FDA approved suppliers.

GOVERNMENT REGULATION

FDA approval process

In the United States, pharmaceutical products are subject to extensive regulation by the U.S. Food and Drug Administration, or the FDA. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications or NDAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical product development in the U.S. typically involves preclinical laboratory and animal tests, the submission to the FDA of a notice of claimed investigational exemption or an investigational new drug application or IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has not commented on or questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations, good clinical practices or GCP, as well as under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial subjects. The study protocol and informed consent information for subjects in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB’s requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses and, if possible, early evidence of effectiveness. Phase 2 usually involves trials in a limited patient population, to determine the effectiveness of the drug for a particular indication or indications, dosage tolerance and optimum dosage, and identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug.

Under the Pediatric Research Equity Act of 2003, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee, currently $1,178,000, and the manufacturer and/or sponsor under an approved new drug application are also subject to annual product and establishment user fees, currently $65,030 per product and $392,700 per establishment. These fees are typically increased annually.

The FDA has 60 days from its receipt of a NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of new drug applications. Most such applications for non-priority drug products are reviewed within ten months. The review process may be extended by FDA for three additional months to consider certain new information or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with good clinical practices, or GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. FDA will not approve the product unless compliance with current good manufacturing practices is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication proposed for marketing.

After FDA evaluates the NDA and the manufacturing facilities, it issues an approval letter, an approvable letter or a not-approvable letter. Both approvable and not-approvable letters generally outline the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. FDA has committed to reviewing such resubmissions in 2 or 6 months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy and may impose other conditions, including labeling restrictions which can materially affect the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

The Hatch-Waxman Act

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant’s product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. ANDA applicants are not required to conduct or submit results of pre-clinical or clinical tests to prove the safety or effectiveness of their drug product, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA’s Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product’s listed patents or that such patents are invalid is called a Paragraph IV certification. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired. Federal law provides a period of five years following approval of a drug containing no previously approved active ingredients, during which ANDAs for generic versions of those drugs cannot be submitted unless the submission contains a Paragraph IV challenge to a listed patent, in which case the submission may be made four years following the original product approval. Federal law provides for a period of three years of exclusivity following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials conducted by or for the sponsor, during which FDA cannot grant effective approval of an ANDA based on that listed drug.

Section 505(b)(2) New Drug Applications

Most drug products obtain FDA marketing approval pursuant to an NDA or an ANDA. A third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2) NDA, which enables the applicant to rely, in part, on the safety and efficacy data of an existing product, or published literature, in support of its application.

505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon certain preclinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Thus, approval of a 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

We expect that the majority of our product candidates in development will require the filing of 505(b)(2) NDAs because, although such products contain previously approved chemical entities, we or our licensees may seek to make new claims regarding therapeutic effects or lessened side effects, or both.

Our partner, Hana Biosciences, submitted an NDA under Section 505(b)(2) for Zensana™ in June 2006. Previously, Hana Biosciences targeted final approval from the FDA and commercial launch in calendar 2007. However, on February 20, 2007, we announced that Hana Biosciences notified us that ongoing scale-up and stability experiments indicate that there is a need to make adjustments to the formulation and/or manufacturing process, and that there is likely to be a delay in the FDA approval and commercial launch of Zensana™ as a result thereof. On March 23, 2007, Hana Biosciences announced its plan to withdraw, without prejudice, its pending NDA for Zensana™ with the FDA, and that it plans to re-direct the development plan for Zensana™ using our patent-protected European formulation of the product. On July 31, 2007, we entered into a Product Development and Commercialization Sublicense Agreement with Hana Biosciences and Par Pharmaceutical, pursuant to which Hana Biosciences granted a sublicense to Par to develop and commercialize Zensana™. Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana™ in the United States and Canada, including the development and re-filing of the NDA in the United States. Subject to successful scale-up and manufacturing tests of the new formulation of ondansetron, Par expects to conduct the appropriate clinical trials and re-file the NDA for Zensana™ by the end of 2008. Because we rely upon Par to develop and file the NDA for Zensana™ we can give no assurances that Par will be able to re-file the NDA for Zensana™ in 2008, if at all, and ultimately receive final FDA approval. The safety and efficacy of the drug is based on a demonstration of the bioequivalence of Zensana™ to oral ondansetron, marketed under the tradename Zofran®. This Zofran® formulation is protected by one unexpired patent, which is scheduled to expire in September 2011, and is subject to a period of pediatric exclusivity expiring in March 2012. Additionally, this Zofran® formulation was covered by another patent which, after pediatric exclusivity, expired in December 2006. Hana Biosciences' Section 505(b)(2) NDA contained a paragraph III certification acknowledging that the now expired patent would expire in December 2006, and a paragraph IV certification to the patent which is due to expire in March 2012. Based on the paragraph IV certification, it is possible that the NDA holder or the patent owner will sue us, Hana Biosciences, and/or Par for patent infringement, and that the FDA will be prevented from approving our application until the earliest of 30 months, settlement of the lawsuit, or a decision in an infringement case that is favorable to us. Hana Biosciences previously announced that it had not received any objections related to these patent certifications.

Other Regulatory Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, FDA closely regulates the marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet.

Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, risk minimization action plans, and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control as well as drug manufacture, packaging, and labeling procedures must continue to conform to current good manufacturing practices, or cGMPs, after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies, and are subject to periodic inspections by the FDA during which the agency inspects manufacturing facilities to access compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Anti-Kickback, False Claims Laws & The Prescription Drug Marketing Act

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Physician Drug Samples

As part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. The Prescription Drug Marketing Act, or the PDMA, imposes requirements and limitations upon the provision of drug samples to physicians, as well as prohibits states from licensing distributors of prescription drugs unless the state licensing program meets certain federal guidelines that include minimum standards for storage, handling and record keeping. In addition, the PDMA sets forth civil and criminal penalties for violations.

COMPETITION

The markets which we intend to enter are characterized by intense competition, often from organizations which are larger and/or better capitalized than us. We will be competing against established pharmaceutical companies which currently market products which are equivalent or functionally similar to those we intend to market. Prices of drug products are significantly affected by competitive factors and tend to decline as competition increases. In addition, numerous companies are developing or may, in the future, engage in the development of products competitive with our proposed products. We expect that technological developments will occur at a rapid rate and that competition is likely to intensify as enhanced delivery system technologies gain greater acceptance. Additionally, the markets for formulated products which we have targeted for development are intensely competitive, involving numerous competitors and products. We intend to enhance our competitive position by focusing our efforts on our novel dosage forms.

We are aware of several companies that are selling or developing oral spray products. Sciele Pharma Inc. (formerly First Horizon Pharmaceutical Corporation), headquartered in Alpharetta, Georgia, currently markets Nitrolingual® Pumpspray, a nitroglycerin oral spray which is an "air" propelled dispensing system (our nitroglycerin lingual spray is a "propellant" based dispensing system). Generex Biotechnology Corporation, based in Toronto, Canada, is developing an insulin formulation that is delivered directly into the mouth via its RapidMist™ device. This product was approved in Ecuador, certain Middle Eastern countries, and India. They also state that they have begun research on four specific target molecules for their RapidMist™ delivery system: morphine, fentanyl, heparin and flu vaccine. Generex Biotechnology Corporation is listed as the assignee on 15 U.S. patents. RapidMist™ is a pending trademark of Generex Biotechnology Corporation. There are several other companies that we are aware of that develop and/or market oral spray products containing vitamins and homeopathic ingredients. GW Pharmaceuticals plc, based in the UK, has developed a cannabinoid lingual spray called Sativex®. Sativex® was approved by Health Canada in April 2005 for the relief of neuropathic pain in Multiple Sclerosis, or MS, and was launched in Canada in June 2005 by Bayer HealthCare, who will exclusively market Sativex® in Canada. Sosei Co. Ltd. is conducting Phase III clinical studies for its Fentanyl sublingual spray (AD923), an opioid analgesic for the treatment of cancer breakthrough pain. Insys Therapeutics Inc. is developing a Fentanyl sublingual spray for breakthrough cancer pain in opioid-tolerant patients.

We also face, and will continue to face, competition from colleges, universities, governmental agencies and other public and private research organizations. These competitors are becoming more active in seeking patent protection and licensing arrangements to collect royalties for use of technology that they have developed. Some of these technologies may compete directly with the technologies that we are developing. These institutions will also compete with us in recruiting highly qualified scientific personnel. We expect that developments in the areas in which we are active may occur at a rapid rate and that competition will intensify as advances in this field are made. As a result, we need to continue to devote substantial resources and efforts to research and development activities.

PATENTS AND PROTECTION OF PROPRIETARY INFORMATION

We have applied for U.S. and foreign patent protection for our buccal spray delivery systems which are the primary focus of our development activities as well as for our delayed contact allergy topical formulations. Eight U.S. patents, three Canadian patents and sixty-eight European patents have been issued. The sixty-eight patents in Europe consist of four unique patents which have been issued in seventeen different countries. We have over ninety patent applications pending in the U.S. and overseas. Additional patent applications may not be granted, or, if granted, may not provide adequate protection to us. We also intend to rely on whatever protection the law affords to trade secrets, including unpatented know-how. Other companies, however, may independently develop equivalent or superior technologies or processes and may obtain patents or similar rights with respect thereto.

Although we believe that we have developed our technology independently and have not infringed, and do not infringe, on the patents of others, third parties may make claims, however, that our technology does infringe on their patents or other intellectual property. In the event of infringement, we may, under certain circumstances, be required to modify our infringing product or process or obtain a license. We may not be able to do either of those things in a timely manner if at all, and failure to do so could have a material adverse effect on our business. In addition, we may not have the financial or other resources necessary to enforce a patent infringement or proprietary rights violation action or to defend ourselves against such actions brought by others. If any of the products we develop infringe upon the patent or proprietary rights of others, we could, under certain circumstances, be enjoined or become liable for damages, which would have a material adverse effect on our business.

We also rely on confidentiality and nondisclosure agreements with our licensees and potential development candidates to protect our technology, intellectual property and other proprietary property. Pursuant to the foregoing and for other reasons, we face the risk that our competitors may acquire information which we consider to be proprietary, that such parties may breach such agreements or that such agreements will be inadequate or unenforceable.

BUCCAL NONPOLAR SPRAYS. On April 12, 1996, we filed an application with the U.S. Patent and Trademark Office, or the USPTO, with claims directed to our buccal spray composition containing certain amounts of propellant, a non-polar solvent, and certain classes of drugs, as well as specific drugs within those classes. The application also included claims directed to soft-bite gelatin capsules containing these drugs. On September 1, 1998, the USPTO allowed the claims directed to buccal spray propellant compositions, but rejected the claims directed to the capsules. In November 1998, we deleted the capsule claims from this application to pursue issuance of a patent with claims directed to the buccal non-polar spray compositions and methods of administering the class of drugs using the buccal spray compositions. On September 21, 1999, U.S. Patent No. 5,955,098 was issued to us with claims directed to the above-described buccal non-polar spray propellant compositions and methods. This patent expires on April 12, 2016.

On February 21, 1997, we filed an application under the Patent Cooperation Treaty, or the PCT, (PCT Application No. WO 97/38663) for the above-subject matter. The International Preliminary Examination Authority issued an International Preliminary Examination Report alleging that the subject matter of the invention lacked novelty and/or lacked an inventive step. This opinion, with which we disagree, is not dispositive.

With respect to the above PCT application, in October and November 1998, we entered the national phase in Canada and Europe, with claims directed to the above subject matter. On April 16, 2003, European Patent No. EP 0 904 055 was granted to us with claims directed to propellant containing buccal non-polar spray compositions containing similar drugs (i.e., anti-histamines, steroid hormones, non-steroidal anti-inflammatories, benzodiazepines, anti-depressants and nicotine) to those in the corresponding issued U.S. patent. This European patent has been validated in the UK, Germany, France, Italy, Belgium, Switzerland/Liechtenstein, Austria, Sweden, Denmark, Finland, Luxembourg, the Netherlands, Spain, Greece, Monaco, Portugal and Ireland so that there is patent protection in these countries. We have filed a divisional application based on this European patent with claims directed to a buccal spray composition containing a propellant, a non-polar solvent and an active compound selected from alkaloids and analgesics. With respect to the Canadian application, we filed a request for examination with the Canadian Patent Office on February 7, 2002. We received an Office Action from the Canadian Patent Office dated April 13, 2004, pursuant to which we were requested to elect for prosecution either claims directed to buccal spray compositions or claims to the soft-bite gelatin capsules. We elected to prosecute the claims directed to buccal spray compositions. The Canadian Patent Office granted the application on December 27, 2005 as Canadian Patent No. 2,252,050. The allowed claims are similar to those granted by the European Patent Office.

BUCCAL POLAR SPRAYS. On April 12, 1996, we filed an application with the USPTO with claims directed to propellant free buccal polar spray compositions containing certain amounts of a polar solvent and certain classes of drugs (i.e., non-steroidal anti-inflammatories, anti-histamines, steroid hormones, benzodiazepams, and anti-depressants), as well as specific drugs within those classes. The application also contained claims to soft-bite gelatin capsules containing such drugs. A continuation-in-part, or CIP, application was filed directed to this subject matter before the original application was allowed to go abandoned. The USPTO initially rejected the claims in the CIP application. We deleted the claims from this application (including the soft-bite capsule claims) and replaced them with claims directed to methods of using the above-described propellant free buccal polar spray compositions to administer the drugs. On August 29, 2000, U.S. Patent No. 6,110,486 was issued to us with claims directed to the above-described methods of administering the drugs. This patent expires on April 12, 2016.

On February 21, 1997, we filed an application under the PCT (PCT Application No. WO 97/38662) for the above-described subject matter. The International Preliminary Examination Authority issued an International Preliminary Examination Report alleging that the subject matter of the invention lacked novelty and/or lacked an inventive step. This opinion, with which we disagree, is not dispositive.

With respect to the above PCT application, in October and November 1998, we entered the national phase in Canada and Europe, respectively, with claims directed to the above subject matter. On February 2, 2005, European Patent No. 0 910 339 was granted to us with claims directed to use of polar solvent containing pump sprays containing similar drugs to those in the corresponding issued U.S. patent. This European patent has been validated in the UK, Germany, France, Italy, Belgium, Switzerland/Liechtenstein, Austria, Sweden, Denmark, Finland, Luxembourg, the Netherlands, Spain, Greece, Monaco, Portugal and Ireland so that there is patent protection in these countries. In November 2005, Akzo Nobel N.V. filed an opposition against this patent in the European Patent Office alleging "lack of inventive step" and "insufficient disclosure." We have filed a Response to the Opposition. The Opposition Proceeding is currently pending before the European Patent Office. We have also filed a divisional application based on this European patent with claims directed to a buccal spray composition containing a propellant, a non-polar solvent and an active compound selected from alkaloids and analgesics. With respect to the Canadian application, we filed a request for examination with the Canadian Patent Office on February 7, 2002. We received an Office Action from the Canadian Patent Office dated April 13, 2004, pursuant to which we were requested to elect for prosecution either claims directed to buccal spray compositions or claims to the soft-bite gelatin capsules. We elected to prosecute the claims directed to buccal spray compositions. On February 10, 2006, the Canadian Patent Office issued a Notice of Allowance for this application.

BUCCAL NONPOLAR SPRAY FOR NITROGLYCERIN. On April 12, 1996, we filed an application with the USPTO with claims directed to a buccal spray containing certain amounts of nitroglycerin, a non-polar solvent, and a propellant. The claims were allowed and on February 9, 1999, the USPTO issued U.S. Patent No. 5,869,082 to us for said nitroglycerin buccal spray. This patent expires on April 12, 2016.

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On February 21, 1997, we filed a PCT application (PCT Application No. WO 97/38687) directed to the above-described subject matter. The International Preliminary Examination Authority issued an International Preliminary Examination Report alleging that the subject matter of the invention lacks an inventive step. This opinion, with which we disagree, is not dispositive. Nevertheless, Greek Patent, GRO904055 was issued on March 18, 2004, for our nitroglycerin buccal, non-polar spray or capsule.

In October 1998, we entered the national phase in Canada. We filed a request for examination on February 7, 2002. The Canadian Patent Office issued a second office action to us dated July 11, 2005. We responded to the office action on January 11, 2006 and await further communication from the Canadian Patent Office.

In November 1998, we entered the national phase in Europe. European Patent No. 0 927 032 was granted to us on April 16, 2003, with claims directed to a buccal spray containing certain amounts of nitroglycerin, a non-polar solvent and a propellant. This European patent has been validated in the UK, Germany, France, Italy, Belgium, Switzerland/Liechtenstein, Austria, Sweden, Denmark, Finland, Luxembourg, the Netherlands, Spain, Greece, Monaco, Portugal and Ireland so that there is patent protection in these countries.

BUCCAL POLAR/NONPOLAR SPRAYS OR CAPSULES. On October 1, 1997, we filed a PCT application (PCT Application No. WO 99/16417) designating a large number of countries including the U.S., directed to the buccal sprays and soft-bite capsules. The application included claims directed to: (A) a buccal spray composition containing either (1) a polar solvent with certain classes of drugs, as well as specific drugs in those classes with or without a propellant or (2) a non-polar solvent with or without a propellant with certain classes of drugs, as well as specific drugs in those classes; (B) buccal spray composition containing a non-polar solvent, a flavoring agent and certain classes of drugs; and (C) methods of administering these drugs using the buccal spray compositions. The application also contained claims to soft-bite gelatin capsules containing such drugs. This application differs from the first three applications, discussed above, in that the claimed compositions include different classes of drugs from those described in the first three applications. The International Preliminary Examination Authority issued an International Preliminary Examination Report alleging that the subject matter of the invention lacked novelty and/or lacked an inventive step. This opinion, with which we disagree, is not dispositive.

On March 29, 2000, we entered the national phase in the U.S. by filing a CIP of the above-identified PCT application with the USPTO. The CIP application included claims directed to propellant free buccal spray compositions containing certain amounts of polar or non-polar solvents, and certain classes of drugs, as well as specific drugs in those classes; buccal spray compositions containing certain amounts of a propellant, a polar or non-polar solvent and certain classes of drugs, as well as specific drugs in those classes; and methods of administering said drugs using these types of buccal spray compositions. The application is currently being prosecuted with claims directed to the propellant free buccal spray compositions and methods of administering said drugs using these types of buccal spray compositions. Subsequently, we filed two divisional applications claiming priority to the CIP. The first divisional application is currently being prosecuted with claims directed to the buccal spray compositions containing certain amounts of a propellant, a polar or non-polar solvent and certain classes of drugs, as well as specific drugs in those classes and methods of administering said drugs using these types of buccal spray compositions. The second divisional application was issued to us as U.S. Patent No. 6,676,931. This patent expires on October 1, 2017. The claims of this patent are directed to a propellant free pump spray composition containing certain amounts of a polar solvent, certain amounts of a flavoring agent and certain amounts of cyclosporin or ondansetron hydrochloride. Another application has been filed directed to the additional classes of drugs and specific drugs that were not included in the claims of U.S. Patent No. 6,676,931.

Based on the above-identified PCT application, we entered the national phase in Canada on March 29, 2000. We filed a request for examination in Canada on August 29, 2002. An office action has been received from the Canadian Patent Office and we have responded to that office action. Based on the above-identified PCT application, we also entered the national phase in Japan on April 3, 2000. We filed a request for examination of this Japanese application on September 30, 2004.

Based on the above-identified PCT application, we also entered the national phase in Europe in April 2000. The European application includes claims directed to propellant free buccal spray compositions containing certain amounts of a polar solvent and certain classes of drugs, as well as specific drugs in those classes and the use thereof to prepare a medicament for use as a buccal spray for transmucosal administration. We have filed three applications related to this application in Europe. The first application included claims directed to buccal spray compositions containing certain amounts of a non-polar solvent, a propellant and certain classes of drugs as well as specific drugs in those classes and the use thereof to prepare a medicament for use as a buccal spray for transmucosal administration. The second application included claims directed to propellant free buccal spray compositions containing certain amounts of a non-polar solvent and certain classes of drugs, as well as specific drugs in those classes. The third application included claims directed to a buccal spray composition containing certain amounts of a polar solvent, a propellant and certain classes of drugs, as well as specific drugs in those classes. Each of the above-identified European applications is currently being prosecuted.

Furthermore, in August 2002, we filed a number of U.S. patent applications directed to buccal spray compositions containing certain classes of drugs as well as specific drugs for treating particular types of disorders. In August 2003, we filed PCT applications related to these U.S. applications. We have subsequently filed corresponding applications in Europe, Japan and Canada for the subject matter for a majority of these CIP applications.

STABLE HYDROALCOHOLIC ORAL SPRAY FORMULATIONS AND METHODS. On April 19, 2007, we filed an application with the USPTO with claims directed to hydroalcoholic spray compositions and methods. The application was published on October 25, 2007, and is currently pending. Substantive examination of the application by the USPTO has not yet begun. On April 19, 2007 we also filed a corresponding PCT application

ANTI-MIGRAINE ORAL SPRAY FORMULATIONS AND METHODS. On July 27, 2007 we filed an application with the USPTO with claims directed to compositions comprising a selective 5-hydroxytryptamine receptor subtype agonist and methods of treatment. The application was published on February 7, 2008, and is currently pending. Substantive examination of the application by the USPTO has not yet begun. On July 27, 2007 we also filed a corresponding PCT application.

ANTIHISTAMINE SYRUP AND OINTMENT. On November 10, 1997, we filed an application with the USPTO with claims directed to a spray composition for topical administration containing an antihistamine and a polar solvent or an antihistamine, a non-polar solvent and a propellant. In October 1998, the PTO rejected the claims. The claims were deleted and replaced with a claim directed to a method of controlling the occurrence of delayed contact dermatitis by applying a lotion composition containing certain amounts of certain antihistamines in certain amounts of a polar or non-polar solvent. On May 21, 2002, U.S. Patent No. 6,391,282 was issued to us for the above-described method. This patent expires on November 10, 2017.

GENERAL COMMENT WITH RESPECT TO ENTERING THE NATIONAL PHASE FOR EACH OF THE FOREGOING PCT APPLICATIONS. In addition to our patents and patent applications in the U.S., we are interested in entering the national phase and obtaining patent protection in Europe and Canada. At the present time, it is not possible to accurately predict the expenses involved in pursuing the foregoing applications in Canada and Europe. For example, we anticipate that, in the case of the European applications, it may become necessary to file appeals with the Board of Appeals in Munich. Expenses may exceed $100,000 (in the aggregate) before a final disposition is obtained. We expect that this process may take between two and four years.

EMPLOYEES

As of March 19, 2008, we had 14 total employees, all of whom were full-time employees.

The names and ages of our Directors and Executive Officers as of the date of filing this Annual Report are set out below. All Directors are elected annually, to serve until the next annual meeting of stockholders and until their successors are duly elected and qualified. Executive Officers are elected annually by the Board of Directors and serve at the Board of Directors' pleasure. The Board of Directors has determined that the following individuals are the Executive Officers of the Company: Mr. Ratoff, Dr. Bergstrom, Mr. Spicer and Dr. Zodda.

NAME	AGE	POSITION WITH THE COMPANY
Mark J. Baric	49	Director
Thomas E. Bonney	43	Director
William F. Hamilton, Ph.D.	68	Director
J. Jay Lobell	45	Director
Charles Nemeroff, M.D., Ph.D.	58	Director
Steven B. Ratoff	65	Chairman of the Board of Directors, Interim President and Chief Executive Officer
David H. Bergstrom, Ph.D.	53	Senior Vice President and Chief Operating Officer
Michael E. Spicer	54	Chief Financial Officer and Corporate Secretary
Deni M. Zodda, Ph.D.	54	Senior Vice President and Chief Business Officer

Mark J. Baric, Director, 49. Mr. Baric was elected to the Board in February 2007. Since 2005, Mr. Baric has been the President and co-founder of CeNeRx BioPharma, Inc., a privately-held development company with a therapeutic focus on diseases of the central nervous system. In 2001 he co-founded and served, until 2005, as Chief Executive Officer and Chairman of 2ThumbZ Entertainment Inc., a privately-held company which develops and markets entertainment applications for users of handheld wireless devices and networks. From 1996 to 2001, Mr. Baric was Chairman and Chief Executive Officer of Virtus Entertainment Corporation, an emerging company in the fast-growing interactive entertainment industry. From 1990 to 1996, Mr. Baric held various leadership positions, including Chief Operating Officer and Chief Financial and Administrative Officer of Seer Technologies Inc. (now known as Cicero, Inc.), a provider of business integration software. Prior to 1990, Mr. Baric held various leadership positions at several firms, including CS First Boston and Coopers and Lybrand. Mr. Baric serves on the boards of CeNeRx BioPharma, Inc., 2ThumbZ Entertainment Inc. and Concert Technologies, a privately-held company focused on rich media technology and licensing. Mr. Baric received an M.B.A. from the Wharton School of the University of Pennsylvania and a B.S. from Clarion University. He is a member of our Audit Committee and a member of our Compensation Committee.

Thomas E. Bonney, CPA, Director, 43. Mr. Bonney was elected to the Board in March 2005. From 2002 to the present, Mr. Bonney has been Managing Director of CMF Associates, LLC, a financial and management consulting firm. Since December 2006, Mr. Bonney has been a General Partner in West Place LLC, and West Place Restaurant Group, LLC, privately-held companies that invest in and manage hotels and real estate. Since June 2005, Mr. Bonney has been a Director of Leblon Holdings LLC, a privately-held beverage supplier and from June 2005 through July 2007 was the Chief Financial Officer of Leblon Holdings, LLC. From 2001 to 2002, he was Chief Financial Officer of Akcelerant Holdings, Inc., a technology holding company. From 1995 to 2001, Mr. Bonney was President and a Director of Polaris Consulting & Information Technologies, a technology solutions provider. Mr. Bonney was at Deloitte & Touché from 1987 to 1995 in various positions including Senior Manager. Mr. Bonney received his B.S. in Accounting at the Pennsylvania State University and is a member of the Pennsylvania Institute of Certified Public Accountants. He is a member and chair of our Audit Committee and a member of our Corporate Governance and Nominating Committee.

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William F. Hamilton, Ph.D., Director, 68. Dr. Hamilton was elected to the Board in March 2003. In January 2006, Dr. Hamilton was appointed Lead Independent Director. Dr. Hamilton has served on the University of Pennsylvania faculty since 1967, and is the Landau Professor of Management and Technology, and Director of the Jerome Fisher Program in Management and Technology at The Wharton School and the School of Engineering and Applied Science. He serves as a director of Neose Technologies, Inc., a publicly-traded company developing proprietary drugs. Dr. Hamilton is also a director of Yaupon Therapeutics, Inc., a privately-held specialty pharmaceutical company that develops small molecule pharmaceuticals licensed from under-served academic laboratories, Avid Radiopharmaceuticals, Inc., a privately-held clinical-stage product-focused molecular imaging company and Neuro Diagnostic Devices, a privately-held development-stage medical device company. Dr. Hamilton received his B.S. and M.S. in chemical engineering and his M.B.A. from the University of Pennsylvania, and his Ph.D. in applied economics from the London School of Economics. Dr. Hamilton is a member of our Audit Committee and a member and chair of our Corporate Governance and Nominating Committee.

J. Jay Lobell, Director, 45. Mr. Lobell was elected to the Board in December 2005. Mr. Lobell has served as Chief Executive Officer, Secretary and a member of the Board of Directors of Paramount Acquisition Corp. since October 2005. Mr. Lobell has served as President and Chief Operating Officer of Paramount BioCapital Asset Management, Inc. and Paramount Biosciences, LLC since January 2005, and is a registered representative of Paramount BioCapital, Inc. Mr. Lobell also serves as President and Secretary of Sitka Sciences, Inc. and Norton Sound Acquisition Corp. which are affiliates of Paramount BioCapital, Inc. From 1996 until January 2005, Mr. Lobell was a partner at Covington & Burling, a law firm. Mr. Lobell received his B.A. from Queens College and his J.D. from Yale Law School. Mr. Lobell is a director of Innovive Pharmaceuticals, Inc., a publicly-traded biopharmaceutical company, and Chem Rx Corporation, a publicly-traded long-term care pharmacy, as well as several private biotechnology companies. Mr. Lobell is a member and chair of our Compensation Committee.

Charles Nemeroff, M.D., Ph.D., Director, 58. Dr. Nemeroff was elected to the Board in September 2003. Dr. Nemeroff has been the Reunette W. Harris Professor and Chairman of the Department of Psychiatry and Behavioral Sciences at Emory University School of Medicine in Atlanta, Georgia, since 1991. Dr. Nemeroff serves on the Scientific Advisory Board of numerous publicly-traded pharmaceutical companies, including Astra-Zeneca Pharmaceuticals, Forest Laboratories, Janssen and Quintiles. In 2002, he was elected to the Institute of Medicine of the National Academy of Sciences. Dr. Nemeroff received his B.S. from the City College of New York, his M.S. from Northeastern University, his Ph.D. and post doctorate training from the University of North Carolina and his M.D. from the University of North Carolina. Dr. Nemeroff is chair of our Scientific Advisory Board. He is also a member of our Compensation Committee and is a member of our Corporate Governance and Nominating Committee.

Steven B. Ratoff, Chairman of the Board, Interim President and Chief Executive Officer, 65. Mr. Ratoff was elected to the Board in January 2006 and was elected Chairman of the Board on September 15, 2006. He was appointed as Interim President and Chief Executive Officer of NovaDel on July 23, 2007. Mr. Ratoff is a private investor and since December 2004 has served as a venture partner with ProQuest Investments, a health care venture capital firm. Mr. Ratoff has been a director, since May 2005, and was Chairman of the Board, from September 2005 to October 2006, of Torrey Pines Therapeutics Inc. (formerly Axonyx Inc.), a NASDAQ development stage pharmaceutical company. Mr. Ratoff served as a director of Inkine Pharmaceuticals, Inc. from February 1998 to its sale to Salix, Inc. in September 2005. He also served as a board member since March 1995 and as Chairman of the Board and Interim Chief Executive Officer of CIMA Labs, Inc. from May 2003 to its sale to Cephalon, Inc. in August 2004. Mr. Ratoff also served as a director, since 1998 and as President and Chief Executive Officer of MacroMed, Inc. from February to December, 2001. From December 1994 to February 2001, Mr. Ratoff served as Executive Vice President and Chief Financial Officer of Brown-Forman Corporation, a publicly-traded diversified manufacturer of consumer products. Mr. Ratoff received his B.S. in Business Administration from Boston University and an M.B.A. with Distinction from the University of Michigan.

David H. Bergstrom, Ph.D., Senior Vice President and Chief Operating Officer, 53.Dr. Bergstrom joined NovaDel in December 2006 as Senior Vice President and Chief Operating Officer.From 1999 to November 2006, Dr. Bergstrom served in several capacities at Cardinal Health, Inc., including Vice President, Research & Development and Senior Vice President and General Manager. From 1998 to 1999, Dr. Bergstrom was Vice President of Pharmaceutical & Chemical Development at Guilford Pharmaceuticals Inc. Dr. Bergstrom was employed by Hoechst Marion Roussel, Inc. as the Director of Pharmaceutical and Analytical Sciences from 1996 to 1998. Dr. Bergstrom served as Director of Pharmaceutical and Analytical Development for the predecessor company, Hoechst-Roussel Pharmaceuticals Inc., from 1991 to 1996, and Group Manager, Formulations, Pharmaceutical Research from 1990 to 1991. Prior thereto, Dr. Bergstrom held various positions at Ciba-Geigy Corporation. Dr. Bergstrom received his Ph.D. in Pharmaceutics at the University of Utah in 1985. In addition, he received his M.S. in Pharmaceutical Chemistry at the University of Michigan in 1982 and his B.S. degree in Pharmacy in 1978 at Ferris State University.

Michael E. Spicer, CPA, Chief Financial Officer and Corporate Secretary, 54. Mr. Spicer joined NovaDel as Chief Financial Officer in December 2004 and was named Corporate Secretary in April 2006. From December 2001 to December 2004, Mr. Spicer was Chief Financial Officer of Orchid Biosciences, Inc. (now known as Orchid Cellmark Inc.). From September 1998 to December 2001, Mr. Spicer served as Vice President, Chief Financial Officer of Lifecodes Corporation until it was acquired by Orchid. Mr. Spicer is a Certified Public Accountant and holds an undergraduate degree in Accounting from the University of Virginia and an M.B.A. from Harvard Business School.

Deni M. Zodda, Ph.D., Senior Vice President and Chief Business Officer, 54. Dr. Zodda joined NovaDel in February 2007 as Senior Vice President and Chief Business Officer. From May 2006 to February 2007, Dr. Zodda was Principal of Medignostica, LLC, a consulting firm he owns which provided business development services to various clients and was acting Chief Executive Officer of StemCapture, Inc., a privately-held stem cell research company. From 2000 to May 2006, Dr. Zodda served in varying capacities, including Senior Vice President, Business Development and Principal Financial Officer of Discovery Laboratories, Inc. From 1998 to 2000, Dr. Zodda served as Managing Director of the Life Sciences Practice at KPMG. During the course of his career, Dr. Zodda also held senior management positions in business development, marketing and commercial operations at Cephalon, Inc., Wyeth, Baxter International Inc. and SmithKline Beckman, Inc. Dr. Zodda received his M.B.A. in Marketing and Finance from the University of Santa Clara in 1986, his Ph.D. in Biology from the University of Notre Dame in 1980 and his B.S. in Biology from Villanova University in 1975.

AVAILABLE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission, or the Commission. You may read and copy any document we file with the Commission at the Commission's public reference rooms at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the Commission at 1-800-SEC-0330 for further information on the public reference room. Our Commission filings are also available to the public from the Commission's Website at "http://www.sec.gov." We make available free of charge our annual, quarterly and current reports, proxy statements and other information upon request. To request such materials, please send an e-mail to mspicer@novadel.com or contact Michael Spicer, our Chief Financial Officer at 25 Minneakoning Road, Flemington, New Jersey, 08822 or at 908-782-3431, ext. 2550.

We maintain a website at "http://www.novadel.com" (this is not a hyperlink; you must visit this website through an Internet browser). Our website and the information contained therein or connected thereto are not incorporated into this Annual Report on Form 10-K.

ITEM 1A. RISK FACTORS

This report contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed in this report. Factors that could cause or contribute to these differences include, but are not limited to, those discussed below, elsewhere in this report, and in any documents incorporated in this report by reference.

RISKS RELATED TO OUR BUSINESS

OUR AUDITORS HAVE EXPRESSED SUBSTANTIAL DOUBT ABOUT OUR ABILITY TO CONTINUE AS A GOING CONCERN.

Our audited financial statements for the year ended December 31, 2007, were prepared under the assumption that we will continue our operations as a going concern. We were incorporated in 1982, and have a history of losses. As a result, our independent registered public accounting firm in their audit report has expressed substantial doubt about our ability to continue as a going concern. Continued operations are dependent on our ability to complete equity or debt formation activities or to generate profitable operations. Such capital formation activities may not be available or may not be available on reasonable terms. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we cannot continue as a viable entity, our shareholders may lose some or all of their investment in the Company.

WE WILL REQUIRE SIGNIFICANT CAPITAL FOR PRODUCT DEVELOPMENT AND COMMERCIALIZATION IN THE NEAR TERM.

The research, development, testing and approval of our product candidates involve significant expenditures, and, accordingly, we require significant capital to fund such expenditures. Due to our small revenue base, low level of working capital and, until recently, our relative inability to increase the number of development agreements with pharmaceutical companies, we have been unable to pursue aggressively our product development strategy. Until and unless our operations generate significant revenues and cash flow, we will attempt to continue to fund operations from cash on hand and through the sources of capital described below. Our long-term liquidity is contingent upon achieving sales and positive cash flows from operating activities, and/or obtaining additional financing. The most likely sources of financing include private placements of our equity or debt securities or bridge loans to us from third-party lenders, license payments from current and future partners, and royalty payments from sales of approved product candidates by partners. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs, or on terms favorable to us. During the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. Despite this reduction in expenditures for clinical activities, we require capital to sustain our existing organization until such time as clinical activities can be resumed. Given the current level of spending, we estimate that we will have sufficient cash on hand to fund operations through the middle of the second quarter, 2008. Funding for the Company’s future development activities could be secured through new strategic partnerships and/or the sale of our common stock or other securities. There can be no assurance that such capital will be available to us in a timely manner or on favorable terms, if at all. There are a number of risks and uncertainties related to our attempt to complete a financing or strategic partnering arrangement that are outside our control. We may not be able to obtain additional financing on terms acceptable to us, or at all. If we are unsuccessful at obtaining additional financing as needed, we may be required to significantly curtail or cease operations. We will need additional financing thereafter until we achieve profitability, if ever.

WE MAY NEED ADDITIONAL CAPITAL TO FUND OUR OPERATIONS UNTIL WE ARE ABLE TO GENERATE A PROFIT.

Our operations to date have required significant cash expenditures. Our future capital requirements will depend on the results of our research and development activities, and preclinical studies.

Although we have significantly reduced clinical development activities on our product candidate pipeline since the fourth quarter 2007, we do not expect that our revenue and/or cash will cover our expenses during the next twelve months. As a result, we will need to obtain more funding in the future through collaborations or other arrangements with research institutions and corporate partners or public and private offerings of our securities, including debt or equity financing. We may not be able to obtain adequate funds for our operations from these sources when needed or on acceptable terms. Future collaborations or similar arrangements may require us to license valuable intellectual property to, or to share substantial economic benefits with, our collaborators. If we raise additional capital by issuing additional equity or securities convertible into equity, our stockholders may experience dilution and our share price may decline. Any debt financing may result in restrictions on our spending.

If we are unable to raise additional funds, we will need to do one or more of the following:

- further delay, scale-back or eliminate some or all of our research and product development programs;
- license third parties to develop and commercialize products or technologies that we would otherwise seek to develop and commercialize ourselves;
- attempt to sell our company;
- cease operations; or
- declare bankruptcy.

We will continue to maintain current levels of spending over the upcoming fiscal year, given the uncertainties inherent in our business and our current liquidity position. We believe that at the current rate of spending, we should have sufficient cash funds to maintain our present operations through the middle of the second quarter 2008.

WE ARE A PRE-COMMERCIALIZATION COMPANY, HAVE A LIMITED OPERATING HISTORY AND HAVE NOT GENERATED ANY REVENUES FROM THE SALE OF PRODUCTS TO DATE.

We are a pre-commercialization specialty pharmaceutical company developing oral spray formulations of a broad range of marketed treatments. There are many uncertainties and complexities with respect to such companies. We have not generated any revenue from the commercial sale of our proposed products and do not expect to receive such revenue in the near future. We have no material licensing or royalty revenue or products ready for sale or licensing in the marketplace. This limited history may not be adequate to enable one to fully assess our ability to develop our technologies and proposed products, obtain U.S. Food and Drug Administration, or FDA, approval and achieve market acceptance of our proposed products and respond to competition. The filing of a New Drug Application, or NDA, with the FDA is an important step in the approval process in the U.S. Acceptance for filing by the FDA does not mean that the NDA has been or will be approved, nor does it represent an evaluation of the adequacy of the data submitted. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist™. Previously, this product was partnered with Par Pharmaceutical, or Par; however, on August 1, 2007, we announced that Par returned the rights to NitroMist™ to us as part of Par's strategy to concentrate its resources on supportive care in AIDS and oncology markets. On January 23, 2008, we announced that our NDA filing for ZolpiMist™, our zolpidem oral spray, was accepted by the FDA. Based on this acceptance, we would anticipate a final response from the FDA during the second half of 2008. We are currently investigating strategic partners for both NitroMist™ and ZolpiMist™. We cannot be certain as to when to anticipate commercializing and marketing any of our product candidates in development, if at all, and do not expect to generate sufficient revenues from proposed product sales to cover our expenses or achieve profitability in the near future. During the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. As of the current date, we have not yet secured additional financing, and have therefore not resumed clinical development activity. There can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities.

We had an accumulated deficit as of December 31, 2007 of approximately $65.2 million. We incurred losses in each of our last ten fiscal years, including net losses of approximately $17.0 million for the year ended December 31, 2007, $3.8 million for the five months ended December 31, 2006, $10.1 million for the fiscal year ended July 31, 2006 and $9.5 million for the fiscal year ended July 31, 2005. Additionally, we have reported negative cash flows from operations of approximately $15.2 million for the year ended December 31, 2007, $1.8 million for the five months ended December 31, 2006, $8.9 million for the fiscal year ended July 31, 2006 and $6.3 million for the fiscal year ended July 31, 2005. We anticipate that we will incur substantial operating expenses in connection with continued research and development, clinical trials, testing and approval of our proposed products, and expect these expenses will result in continuing and, perhaps, significant operating losses until such time, if ever, that we are able to achieve adequate product sales levels. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our product candidates, obtain the required regulatory approvals and manufacture, market and sell our product candidates.

OUR ADDITIONAL FINANCING REQUIREMENTS COULD RESULT IN DILUTION TO EXISTING STOCKHOLDERS.

The additional financings we require may be obtained through one or more transactions which effectively dilute the ownership interests of our existing stockholders. Further, we may not be able to secure such additional financing on terms acceptable to us, if at all. We have the authority to issue additional shares of our common stock, as well as additional classes or series of ownership interests or debt obligations which may be convertible into any one or more classes or series of ownership interests. We are authorized to issue a total of 200,000,000 shares of common stock and 1,000,000 shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders.

OUR TECHNOLOGY PLATFORM IS BASED SOLELY ON OUR PROPRIETARY DRUG DELIVERY TECHNOLOGY. OUR ONGOING CLINICAL TRIALS FOR CERTAIN OF OUR PRODUCT CANDIDATES MAY BE DELAYED, OR FAIL, WHICH WILL HARM OUR BUSINESS.

Our strategy is to concentrate our product development activities primarily on pharmaceutical products for which there already are significant prescription sales, where the use of our proprietary, novel drug delivery technology could potentially enhance speed of onset of therapeutic effect, could potentially reduce side effects through a reduction of the amount of active drug substance required to produce a given therapeutic effect and improve patient convenience or compliance. Our most recent new product candidates, tizanidine and ropinirole, are focused on the neurology segment, where we believe that the benefits of our proprietary drug delivery technology may apply to a number of different pharmaceutical products.

On November 3, 2006, we announced that the FDA has approved our NitroMist™ (nitroglycerin lingual aerosol) for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease. NitroMist™ is our first approval that utilizes our proprietary oral spray technology.

Through July 31, 2007, our ondansetron oral spray product candidate, Zensana™ was licensed to Hana Biosciences, who was overseeing all clinical development and regulatory approval activities for this product in the U.S. and Canada. On July 31, 2007, we entered into a Product Development and Commercialization Sublicense Agreement with Hana Biosciences and Par, pursuant to which Hana Biosciences granted a sublicense to Par to develop and commercialize Zensana™. Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana™ in the United States and Canada. In January 2006, Hana Biosciences announced positive study results of a pivotal clinical trial for Zensana™. Hana Biosciences submitted its NDA on June 30, 2006. Such NDA was accepted for filing by the FDA in August 2006. Previously, Hana Biosciences targeted final approval from the FDA and commercial launch in calendar year 2007. However, on February 20, 2007, we announced that Hana Biosciences notified us that ongoing scale-up and stability experiments indicate that there is a need to make adjustments to the formulation and/or manufacturing process, and that there is likely to be a delay in the FDA approval and commercial launch of Zensana™ as a result thereof. On March 23, 2007, Hana Biosciences announced its plan to withdraw, without prejudice, its pending NDA for Zensana™ with the FDA.

We completed pilot pharmacokinetic studies of certain of our product candidates during late calendar year 2004 and early calendar year 2005. These products are oral spray formulations of ondansetron, sumatriptan, propofol and zolpidem. In addition, in September and October 2006, we completed a pharmacokinetic study of our improved oral spray formulation of sumatriptan and zolpidem, respectively. The goal of these pilot pharmacokinetic studies is to determine whether or not a specific oral spray can achieve therapeutic blood levels of an active ingredient via administration through the oral mucosa. If desired therapeutic blood levels are not achieved, it could result in the need to reformulate the oral spray and/or to terminate work on a specific compound which would have a material adverse effect on our operations.

We have also completed pilot pharmacokinetic studies for two antihistamine oral sprays (loratadine and clemastine), an estradiol oral spray, an alprazolam oral spray and a progesterone oral spray. In addition, we completed phase 2 clinical trials for the clemastine oral spray. However, additional development work on these product candidates has been put on hold.

We have also commenced formulation work on two new product candidates, tizanidine oral spray and ropinirole oral spray.

Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials. Data obtained from tests are susceptible to varying interpretations which may delay, limit or prevent regulatory approval. In addition, companies may be unable to enroll patients quickly enough to meet expectations for completing clinical trials. The timing and completion of current and planned clinical trials of our product candidates depend on, among other factors, the rate at which patients are enrolled, which is a function of many factors, including:

- the number of clinical sites;
- the size of the patient population;
- the proximity of patients to the clinical sites;
- the eligibility criteria for the study;
- the existence of competing clinical trials; and
- the existence of alternative available products.

Delays in patient enrollment in clinical trials may occur, which would likely result in increased costs, program delays or both.

THERE ARE CERTAIN INTERLOCKING RELATIONSHIPS AND POTENTIAL CONFLICTS OF INTEREST.

Lindsay A. Rosenwald, M.D., a significant stockholder, directly and indirectly, of us, is the Chairman and sole shareholder of Paramount. In the regular course of its business and the business of its affiliates, and outside of its arrangement with us, Paramount and/or its affiliates identify, evaluate and pursue investment opportunities in biomedical and pharmaceutical products, technologies and companies. As of March 19, 2008, Dr. Rosenwald beneficially owns approximately 14% of our outstanding common stock (assuming exercise of certain warrants beneficially owned by Dr. Rosenwald). As such, Dr. Rosenwald and Paramount may be deemed to be our affiliates. Dr. Rosenwald has the ability to designate an individual to serve on our Board of Directors, or the Board, and has exercised such ability by designating Mr. J. Jay Lobell to serve on the Board. Although Mr. Lobell is a designee of Dr. Rosenwald's, he does not have any voting or dispositive control over the shares held directly or indirectly by Dr. Rosenwald. On December 14, 2005 based upon the recommendation of the Corporate Governance and Nominating Committee, the Board elected Mr. Lobell as a member of the Board. Pursuant to the listing standards of the American Stock Exchange, or AMEX, Mr. Lobell has been deemed to be an independent director by our Board as of September 15, 2006. Dr. Rosenwald and Paramount may also be deemed to be affiliates of Manhattan Pharmaceuticals, Velcera and Hana Biosciences. In addition, Paramount has assisted us in the placement of shares in connection with various private placements. Refer to Note 6 "Related Party Transactions and License and Development Agreements" of the Financial Statements included in this Annual Report for additional information. Generally, Delaware corporate law requires that any transactions between us and any of our affiliates be on terms that, when taken as a whole, are substantially as favorable to us as those then reasonably obtainable in an arms length transaction from a person who is not an affiliate. Nevertheless, neither Dr. Rosenwald nor Paramount, nor their affiliates, are obligated pursuant to any agreement or understanding with us to make any additional products or technologies available to us, nor can there be any assurance, and we do not expect and our stockholders should not expect, that any biomedical or pharmaceutical product or technology identified by Dr. Rosenwald or Paramount, or their affiliates, in the future will be made available to us. In addition, certain of our current officers and directors or any officers or directors hereafter appointed by us may from time to time serve as officers or directors of other biopharmaceutical or biotechnology companies. Such other companies may have interests in conflict with our interests.

OUR BUSINESS AND REVENUE IS DEPENDENT ON THE SUCCESSFUL DEVELOPMENT OF OUR PRODUCTS.

Revenue received from our product development efforts consists of payments by pharmaceutical companies for research and bioavailability studies, pilot clinical trials and similar milestone-related payments. Our future growth and profitability will be dependent upon our ability to successfully raise additional funds to complete the development of, obtain regulatory approvals for and license out or market our product candidates. Accordingly, our prospects must be considered in light of the risks, expenses and difficulties frequently encountered in connection with the establishment of a new business in a highly competitive industry, characterized by frequent new product introductions. We anticipate that we will incur substantial operating expenses in connection with the development, testing and approval of our product candidates and expect these expenses to result in continuing and significant operating losses until such time, if ever, that we are able to achieve adequate levels of sales or license revenues. We may not be able to raise additional financing, increase revenues significantly, or achieve profitable operations. During the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. As of the current date, we have not yet secured additional financing, and have therefore not resumed clinical development activity. There can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities. See “Risk Factors - We Will Require Significant Capital For Product Development And Commercialization” and “Our Strategy Includes Entering Into Collaboration Agreements With Third Parties For Certain of our Product Candidates And We May Require Additional Collaboration Agreements. If We Fail To Enter Into These Agreements Or If We Or The Third Parties Do Not Perform Under Such Agreements, It Could Impair Our Ability To Commercialize Our Proposed Products.”

SOME OF OUR PRODUCT CANDIDATES ARE IN EARLY STAGES OF CLINICAL DEVELOPMENT AND SOME ARE IN PRECLINICAL TESTING, WHICH MAY AFFECT OUR ABILITY OR THE TIME WE REQUIRE TO OBTAIN NECESSARY REGULATORY APPROVALS.

Some of our product candidates are in early stages of clinical development and some are in preclinical testing. These product candidates are continuously evaluated and assessed and are often subject to changes in formulation and technology. The regulatory requirements governing these types of products may be less well defined or more rigorous than for conventional products. As a result, we may experience delays with our preclinical and clinical testing, and a longer and more expensive regulatory process in connection with obtaining regulatory approvals of these types of product candidates as compared to others in our pipeline at later stages of development. These delays may negatively affect our business and operations.

WE DO NOT HAVE COMMERCIALLY AVAILABLE PRODUCTS.

Our principal efforts are the development of, and obtaining regulatory approvals for, our product candidates. We anticipate that marketing activities for our product candidates, whether by us or one or more of our licensees, if any, will not begin until the second half of calendar 2008 at the earliest. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist™. Previously, this product was partnered with Par Pharmaceutical, or Par; however, on August 1, 2007, we announced that Par returned the rights to NitroMist™ to us as part of Par's strategy to concentrate its resources on supportive care in AIDS and oncology markets. On January 23, 2008, we announced that our NDA filing for ZolpiMist™, our zolpidem oral spray, was accepted by the FDA. Based on this acceptance, we would anticipate a final response from the FDA during the second half of 2008. We are currently investigating strategic partners for both NitroMist™ and ZolpiMist™. Accordingly, it is not anticipated that we will generate any revenues from royalties or sales of our product candidates until regulatory approvals are obtained, if ever, and marketing activities begin. Any one or more of our product candidates may not prove to be commercially viable, or if viable, may not reach the marketplace on a basis consistent with our desired timetables. The failure or the delay of any one or more of our proposed product candidates to achieve commercial viability would have a material adverse effect on us. During the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. We have not yet secured additional financing, and have therefore not resumed clinical development activity. There can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities.

WE HAVE NOT COMPLETED PRODUCT DEVELOPMENT.

We have not completed the development of our product candidates and we will be required to devote considerable effort and expenditures to complete such development. In addition to obtaining adequate financing, satisfactory completion of development, testing, government approval and sufficient production levels of such product candidates must be obtained before the product candidates will become available for commercial sale. On November 3, 2006, we announced that we received an approval letter from the FDA regarding our NDA for NitroMist™. Previously, this product was partnered with Par Pharmaceutical, or Par; however, on August 1, 2007, we announced that Par returned the rights to NitroMist™ to us as part of Par's strategy to concentrate its resources on supportive care in AIDS and oncology markets. On January 23, 2008, we announced that our NDA filing for ZolpiMist™, our zolpidem oral spray, was accepted by the FDA. Based on this acceptance, we would anticipate a final response from the FDA during the second half of 2008. We are currently investigating strategic partners for both NitroMist™ and ZolpiMist™. Other potential products remain in the conceptual or very early development stage and remain subject to all the risks inherent in the development of pharmaceutical products, including unanticipated development problems and possible lack of funds to undertake or continue development. These factors could result in abandonment or substantial change in the development of a specific formulated product. We may not be able to successfully develop any one or more of our product candidates or develop such product candidates on a timely basis. Further, such product candidates may not be commercially accepted if developed. The inability to successfully complete development, or a determination by us, for financial or other reasons, not to undertake to complete development of any product candidates, particularly in instances in which we have made significant capital expenditures, could have a material adverse effect on our business and operations. Furthermore, during the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. As of the current date, we have not yet secured additional financing, and have therefore not resumed clinical development activity. There can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities.

WE DO NOT HAVE DIRECT CONSUMER MARKETING EXPERIENCE.

We have no experience in marketing or distribution at the consumer level of our product candidates. Moreover, we do not have the financial or other resources to undertake extensive marketing and advertising activities. Accordingly, we intend generally to rely on marketing arrangements, including possible joint ventures or license or distribution arrangements with third-parties. Except for our agreements with Par, Manhattan Pharmaceuticals, Velcera and Hana Biosciences, we have not entered into any significant agreements or arrangements with respect to the marketing of our product candidates. We may not be able to enter into any such agreements or similar arrangements in the future and we may not be able to successfully market our products. If we fail to enter into these agreements or if we or the third parties do not perform under such agreements, it could impair our ability to commercialize our products.

We have stated our intention to possibly market our own products in the future, although we have no such experience to date. Substantial investment will be required in order to build infrastructure and provide resources in support of marketing our own products, particularly the establishment of a marketing force. If we do not develop a marketing force of our own, then we will depend on arrangements with corporate partners or other entities for the marketing and sale of our remaining products. The establishment of our own marketing force, or a strategy to rely on third party marketing arrangements, could adversely affect our profit margins.

WE MUST COMPLY WITH GOOD MANUFACTURING PRACTICES.

The manufacture of our pharmaceutical products under development will be subject to current Good Manufacturing Practices, or cGMP, prescribed by the FDA, pre-approval inspections by the FDA or comparable foreign authorities, or both, before commercial manufacture of any such products and periodic cGMP compliance inspections thereafter by the FDA. We, or any of our third party manufacturers, may not be able to comply with cGMP or satisfy pre- or post-approval inspections by the FDA or comparable foreign authorities in connection with the manufacture of our product candidates. Failure or delay by us or any such manufacturer to comply with cGMP or satisfy pre- or post-approval inspections would have a material adverse effect on our business and operations.

WE ARE DEPENDENT ON OUR SUPPLIERS.

We believe that the active ingredients used in the manufacture of our product candidates are presently available from numerous suppliers located in the U.S., Europe, India and Japan. We believe that certain raw materials, including inactive ingredients, are available from a limited number of suppliers and that certain packaging materials intended for use in connection with our spray products currently are available only from sole source suppliers. Although we do not believe we will encounter difficulties in obtaining the inactive ingredients or packaging materials necessary for the manufacture of our product candidates, we may not be able to enter into satisfactory agreements or arrangements for the purchase of commercial quantities of such materials. We have a written supply agreement with Dynamit Nobel for certain raw materials for our nitroglycerin lingual spray and a written supply agreement in place with INyX USA, Ltd., which intends to manufacture our nitroglycerin lingual spray in its Manatee, Puerto Rico facility. On July 3, 2007, INyX, our manufacturer for our NitroMist™ product candidate, announced it filed for protection under the Chapter 11 bankruptcy laws. The Company is taking all necessary steps to ensure that any limited assets of NovaDel at the manufacturer's facility are protected.

In February 2008, we entered into a Master Services Agreement with Rechon Life Sciences (Malmo, Sweden), whereby Rechon will provide services related to the manufacturing development and the manufacture of clinical supplies for our products. Rechon provides these services on a fee-for-service basis.

With respect to other suppliers, we operate primarily on a purchase order basis beyond which there is no contract memorializing our purchasing arrangements. The inability to enter into agreements or otherwise arrange for adequate or timely supplies of principal raw materials and the possible inability to secure alternative sources of raw material supplies, or the failure of Dynamit Nobel, INyX USA, Ltd., or Rechon Life Sciences to comply with their supply obligations to us, could have a material adverse effect on our ability to arrange for the manufacture of formulated products. In addition, development and regulatory approval of our products are dependent upon our ability to procure active ingredients and certain packaging materials from FDA-approved sources. Since the FDA approval process requires manufacturers to specify their proposed suppliers of active ingredients and certain packaging materials in their applications, FDA approval of a supplemental application to use a new supplier would be required if active ingredients or such packaging materials were no longer available from the originally specified supplier, which may result in manufacturing delays. If we do not maintain important manufacturing relationships, we may fail to find a replacement manufacturer or to develop our own manufacturing capabilities. If we cannot do so, it could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete any profit margins. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

FAILURE TO ACHIEVE AND MAINTAIN EFFECTIVE INTERNAL CONTROLS IN ACCORDANCE WITH SECTION 404 OF THE SARBANES-OXLEY ACT OF 2002 COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS AND OPERATING RESULTS. IN ADDITION, CURRENT AND POTENTIAL STOCKHOLDERS COULD LOSE CONFIDENCE IN OUR FINANCIAL REPORTING, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR STOCK PRICE.

Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our operating results and financial condition could be harmed.

We are required to document and test our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, which requires annual management assessments of the effectiveness of our internal controls over financial reporting and reports by our independent registered public accounting firm addressing these assessments and our internal controls. During the course of our testing we may identify deficiencies which we may not be able to remediate in time to meet the deadline imposed by the Sarbanes-Oxley Act of 2002 for compliance with the requirements of Section 404. In addition, if we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002. Failure to achieve and maintain an effective internal control environment could also cause investors to lose confidence in our reported financial information, which could have a material adverse effect on the price of our common stock.

COMPLIANCE WITH CHANGING REGULATION OF CORPORATE GOVERNANCE AND PUBLIC DISCLOSURE MAY RESULT IN ADDITIONAL EXPENSES.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new regulations promulgated by the Securities and Exchange Commission, or SEC, and American Stock Exchange, or AMEX rules, are creating uncertainty for companies such as ours. These new or changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, our efforts to comply with evolving laws, regulations and standards have resulted in, and are likely to continue to result in, increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. In particular, our recent efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and the related regulations regarding our required assessment of our internal controls over financial reporting and our independent registered public accounting firm's audit of that assessment requires the commitment of significant financial and managerial resources. In addition, it has become more difficult and more expensive for us to obtain director and officer liability insurance. We expect these efforts to require the continued commitment of significant resources. Further, our Board members, Chief Executive Officer and Chief Financial Officer could face an increased risk of personal liability in connection with the performance of their duties. As a result, we may have difficulty attracting and retaining qualified board members and executive officers, which could harm our business. If our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, our reputation may be harmed.

WE FACE INTENSE COMPETITION.

The markets which we intend to enter are characterized by intense competition. We, or our licensees, may be competing against established, larger and/or better capitalized pharmaceutical companies with currently marketed products which are equivalent or functionally similar to those we intend to market. Prices of drug products are significantly affected by competitive factors and tend to decline as competition increases. In addition, numerous companies are developing or may, in the future, engage in the development of products competitive with our product candidates. We expect that technological developments will occur at a rapid rate and that competition is likely to intensify as enhanced dosage from technologies gain greater acceptance. Additionally, the markets for formulated products which we have targeted for development are intensely competitive, involving numerous competitors and products. Most of our prospective competitors possess substantially greater financial, technical and other resources than we do. Moreover, many of these companies possess greater marketing capabilities than we do, including the resources necessary to enable them to implement extensive advertising campaigns. We may not be able to compete successfully with such competitors.

Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA or comparable foreign approval or commercializing products before us. If we commence commercial product sales, we will compete against companies with greater marketing and manufacturing capabilities who may successfully develop and commercialize products that are more effective or less expensive than ours. Our competitors may be more successful in receiving third party reimbursements from government agencies and others for their commercialized products which are similar to our products. If we cannot receive third party reimbursement for our products, we may not be able to commercialize our products. These are areas in which, as yet, we have limited or no experience. In addition, developments by our competitors may render our product candidates obsolete or noncompetitive.

We are aware of several companies that are selling or developing oral spray products. Sciele Pharma Inc. (formerly First Horizon Pharmaceutical Corporation), headquartered in Alpharetta, Georgia, currently markets Nitrolingual® Pumpspray, a nitroglycerin oral spray which is an "air" propelled dispensing system (our nitroglycerin lingual spray is a "propellant" based dispensing system). Generex Biotechnology Corporation, based in Toronto, Canada, is developing an insulin formulation that is delivered directly into the mouth via its RapidMist™ device. This product was approved in Ecuador, certain Middle Eastern countries, and India. They also state that they have begun research on four specific target molecules for their RapidMist™ delivery system: morphine, fentanyl, heparin and flu vaccine. Generex Biotechnology Corporation is listed as the assignee on 15 U.S. patents. RapidMist™ is a pending trademark of Generex Biotechnology Corporation. There are several other companies that we are aware of that develop and/or market oral spray products containing vitamins and homeopathic ingredients. GW Pharmaceuticals plc, based in the UK, has developed a cannabinoid lingual spray called Sativex®. Sativex® was approved by Health Canada in April 2005 for the relief of neuropathic pain in Multiple Sclerosis, or MS, and was launched in Canada in June 2005 by Bayer HealthCare, who will exclusively market Sativex® in Canada. Sosei Co. Ltd. is conducting Phase III clinical studies for its Fentanyl sublingual spray (AD923), an opioid analgesic for the treatment of cancer breakthrough pain. Insys Therapeutics Inc. is developing a Fentanyl sublingual spray for breakthrough cancer pain in opioid-tolerant patients.

We also face, and will continue to face, competition from colleges, universities, governmental agencies and other public and private research organizations. These competitors are becoming more active in seeking patent protection and licensing arrangements to collect royalties for use of technology that they have developed. Some of these technologies may compete directly with the technologies that we are developing. These institutions will also compete with us in recruiting highly qualified scientific personnel. We expect that developments in the areas in which we are active may occur at a rapid rate and that competition will intensify as advances in this field are made. As a result, we need to continue to devote substantial resources and efforts to research and development activities.

LIMITED PRODUCT LIABILITY INSURANCE COVERAGE MAY AFFECT OUR BUSINESS.

We may be exposed to potential product liability claims by end-users of our products. Although we obtain product liability insurance per contractual obligations, before the commercialization of any of our product candidates, we cannot guarantee such insurance will be sufficient to cover all possible liabilities to which we may be exposed. Any product liability claim, even one that was not in excess of our insurance coverage or one that is meritless and/or unsuccessful, could adversely affect our cash available for other purposes, such as research and development. In addition, the existence of a product liability claim could affect the market price of our common stock. In addition, certain food and drug retailers require minimum product liability insurance coverage as a condition precedent to purchasing or accepting products for retail distribution. Product liability insurance coverage includes various deductibles, limitations and exclusions from coverage, and in any event might not fully cover any potential claims. Failure to satisfy such insurance requirements could impede the ability of us or our distributors to achieve broad retail distribution of our product candidates, which could have a material adverse effect on us.

EXTENSIVE GOVERNMENT REGULATION MAY AFFECT OUR BUSINESS.

The development, manufacture and commercialization of pharmaceutical products is generally subject to extensive regulation by various federal and state governmental entities. The FDA, which is the principal U.S. regulatory authority over pharmaceutical products, has the power to seize adulterated or misbranded products and unapproved new drugs, to request their recall from the market, to enjoin further manufacture or sale, to publicize certain facts concerning a product and to initiate criminal proceedings. As a result of federal statutes and FDA regulations pursuant to which new pharmaceuticals are required to undergo extensive and rigorous testing, obtaining pre-market regulatory approval requires extensive time and expenditures. Under the Federal Food, Drug, and Cosmetic Act, or FFDCA, as amended (21 U.S.C. 301 et. seq.), a new drug may not be commercialized or otherwise distributed in the U.S. without the prior approval of the FDA or pursuant to an applicable exemption from the FFDCA. The FDA approval processes relating to new drugs differ, depending on the nature of the particular drug for which approval is sought. With respect to any drug product with active ingredients not previously approved by the FDA, a prospective drug manufacturer is required to submit an NDA, which includes complete reports of pre-clinical, clinical and laboratory studies to prove such product’s safety and efficacy. Prior to submission of the NDA, it is necessary to submit an Investigational New Drug, or IND, to obtain permission to begin clinical testing of the new drug. Such clinical trials are required to meet good clinical practices under the FFDCA. Given that our current product candidates are based on a new technology for formulation and delivery of active pharmaceutical ingredients that have been previously approved and that have been shown to be safe and effective in previous clinical trials, we believe that we will be eligible to submit what is known as a 505(b)(2). We estimate that the development of new formulations of pharmaceutical products, including formulation, testing and NDA submission, generally takes two to three years under the 505(b)(2) NDA process. Our determinations may prove to be inaccurate or pre-marketing approval relating to our proposed products may not be obtained on a timely basis, if at all. The failure by us to obtain necessary regulatory approvals, whether on a timely basis or at all, would have a material adverse effect on our business. The filing of an NDA with the FDA is an important step in the approval process in the U.S. Acceptance for filing by the FDA does not mean that the NDA has been or will be approved, nor does it represent an evaluation of the adequacy of the data submitted.

THE CLINICAL TRIAL AND REGULATORY APPROVAL PROCESS FOR OUR PRODUCTS IS EXPENSIVE AND TIME CONSUMING, AND THE OUTCOME IS UNCERTAIN.

In order to sell our proposed products, we must receive separate regulatory approvals for each product. The FDA and comparable agencies in foreign countries extensively and rigorously regulate the testing, manufacture, distribution, advertising, pricing and marketing of drug products like our products. This approval process for an NDA includes preclinical studies and clinical trials of each pharmaceutical compound to establish its safety and effectiveness and confirmation by the FDA and comparable agencies in foreign countries that the manufacturer maintains good laboratory and manufacturing practices during testing and manufacturing. Clinical trials generally take two to five years or more to complete. Even if favorable testing data is generated by clinical trials of drug products, the FDA may not accept an NDA submitted by a pharmaceutical or biotechnology company for such drug product for filing, or if accepted for filing, may not approve such NDA.

The approval process is lengthy, expensive and uncertain. It is also possible that the FDA or comparable foreign regulatory authorities could interrupt, delay or halt any one or more of our clinical trials. If we, or any regulatory authorities, believe that trial participants face unacceptable health risks, any one or more of our trials could be suspended or terminated. We also may fail to reach agreement with the FDA and/or comparable foreign agencies on the design of any one or more of the clinical studies necessary for approval. Conditions imposed by the FDA and comparable agencies in foreign countries on our clinical trials could significantly increase the time required for completion of such clinical trials and the costs of conducting the clinical trials. Data obtained from clinical trials are susceptible to varying interpretations which may delay, limit or prevent regulatory approval.

Delays and terminations of the clinical trials we conduct could result from insufficient patient enrollment. Patient enrollment is a function of several factors, including the size of the patient population, stringent enrollment criteria, the proximity of the patients to the trial sites, having to compete with other clinical trials for eligible patients, geographical and geopolitical considerations and others. Delays in patient enrollment can result in greater costs and longer trial timeframes. Patients may also suffer adverse medical events or side effects.

The FDA and comparable foreign agencies may withdraw any approvals we obtain. Further, if there is a later discovery of unknown problems or if we fail to comply with other applicable regulatory requirements at any stage in the regulatory process, the FDA may restrict or delay our marketing of a product or force us to make product recalls. In addition, the FDA could impose other sanctions such as fines, injunctions, civil penalties or criminal prosecutions. To market our products outside the U.S., we also need to comply with foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products. Other than the approval of NitroMist™, the FDA and foreign regulators have not yet approved any of our products under development for marketing in the U.S. or elsewhere. If the FDA and other regulators do not approve any one or more of our products under development, we will not be able to market such products.

WE EXPECT TO FACE UNCERTAINTY OVER REIMBURSEMENT AND HEALTHCARE REFORM.

In both the U.S. and other countries, sales of our products will depend in part upon the availability of reimbursement from third-party payers, which include government health administration authorities, managed care providers and private health insurers. Third-party payers are increasingly challenging the price and examining the cost effectiveness of medical products and services.

OUR STRATEGY INCLUDES ENTERING INTO COLLABORATION AGREEMENTS WITH THIRD PARTIES FOR CERTAIN OF OUR PRODUCT CANDIDATES AND WE MAY REQUIRE ADDITIONAL COLLABORATION AGREEMENTS. IF WE FAIL TO ENTER INTO THESE AGREEMENTS OR IF WE OR THE THIRD PARTIES DO NOT PERFORM UNDER SUCH AGREEMENTS, IT COULD IMPAIR OUR ABILITY TO COMMERCIALIZE OUR PROPOSED PRODUCTS.

Our strategy for the completion of the required development and clinical testing of certain of our product candidates and for the manufacturing, marketing and commercialization of such product candidates includes entering into collaboration arrangements with pharmaceutical companies to market, commercialize and distribute the products.

Through June 30, 2007, we entered into strategic license agreements with Hana Biosciences, for the marketing rights in the U.S. and Canada for our ondansetron oral spray, (ii) Par for the marketing rights in the U.S. and Canada for our nitroglycerin oral spray, (iii) Manhattan Pharmaceuticals, in connection with propofol, and (iv) Velcera, in connection with veterinary applications for currently marketed veterinary drugs. Subsequent to June 30, 2007, the following events occurred with respect our strategic license agreements:

On July 10, 2007, Manhattan Pharmaceuticals announced that as part of its change in strategic focus it intends to pursue appropriate out-licensing opportunities for this product candidate.

On July 31, 2007, we entered into a Product Development and Commercialization Sublicense Agreement with Hana Biosciences and Par, or the Sublicense Agreement, pursuant to which Hana Biosciences granted a non-transferable, non-sublicenseable, royalty-bearing, exclusive sublicense to Par to develop and commercialize Zensana™, our oral spray version of ondansetron. In connection therewith, we and Hana Biosciences amended and restated their existing License and Development Agreement, as amended, relating to the development and commercialization of Zensana™, or the Amended and Restated License Agreement, to coordinate certain of the terms of the Sublicense Agreement. Under the terms of the Sublicense Agreement, Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana™ in the United States and Canada, with us able to collaborate on development in certain instances. We retain its rights to Zensana™ outside of the United States and Canada. In addition, under the terms of the Amended and Restated License Agreement, Hana Biosciences relinquished its right to reduced royalty rates to us until such time as Hana Biosciences had recovered one-half of its costs and expenses incurred in developing Zensana™ from sales of Zensana™ or payments or other fees from a sublicense and we agreed to surrender for cancellation all 73,121 shares of the Hana Biosciences common stock acquired by us in connection with execution of the original License Agreement.

On July 31, 2007, we and Par agreed to terminate the Development, Manufacturing and Supply Agreement, dated July 28, 2004, or the DMS Agreement, relating to NitroMist™. Under the DMS Agreement, Par had exclusive rights to market, sell and distribute NitroMist™ in the U.S. and Canada, with us entitled to royalty payments based upon a percentage of net sales. We are currently investigating strategic partners for the commercialization of NitroMist™.

Our success depends upon obtaining additional collaboration partners and maintaining our relationships with our current partners. In addition, we may depend on our partners’ expertise and dedication of sufficient resources to develop and commercialize proposed products. We may, in the future, grant to collaboration partners, rights to license and commercialize pharmaceutical products developed under collaboration agreements. Under these arrangements, our collaboration partners may control key decisions relating to the development of the products. The rights of our collaboration partners could limit our flexibility in considering alternatives for the commercialization of such product candidates. If we fail to successfully develop these relationships or if our collaboration partners fail to successfully develop or commercialize such product candidates, it may delay or prevent us from developing or commercializing our proposed products in a competitive and timely manner and would have a material adverse effect on our business.

IF WE CANNOT PROTECT OUR INTELLECTUAL PROPERTY, OTHER COMPANIES COULD USE OUR TECHNOLOGY IN COMPETITIVE PRODUCTS. IF WE INFRINGE THE INTELLECTUAL PROPERTY RIGHTS OF OTHERS, OTHER COMPANIES COULD PREVENT US FROM DEVELOPING OR MARKETING OUR PRODUCTS.

We seek patent protection for our technology so as to prevent others from commercializing equivalent products in substantially less time and at substantially lower expense. The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend in part on our ability and that of parties from whom we license technology to:

- defend our patents and otherwise prevent others from infringing on our proprietary rights;
- protect our trade secrets; and
- operate without infringing upon the proprietary rights of others, both in the U.S. and in other countries.

The patent position of firms relying upon biotechnology is highly uncertain and involves complex legal and factual questions for which important legal principles are unresolved. To date, the U.S. Patent and Trademark Office, or USPTO, has not adopted a consistent policy regarding the breadth of claims that the USPTO allows in biotechnology patents or the degree of protection that these types of patents afford. As a result, there are risks that we may not develop or obtain rights to products or processes that are or may seem to be patentable.

Section 505(b)(2) of the FFDCA was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. For example, the Hatch-Waxman Act permits an applicant to rely upon the FDA’s findings of safety and effectiveness for an approved product. The FDA may also require companies to perform one or more additional studies or measurements to support the change from the approved product. The FDA may then approve the new formulation for all or some of the label indications for which the referenced product has been approved, or a new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on the FDA’s findings for an already-approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA’s Orange Book publication. Specifically, the applicant must certify that: (1) the required patent information has not been filed (paragraph I certification); (2) the listed patent has expired (paragraph II certification); (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration (paragraph III certification); or (4) the listed patent is invalid or will not be infringed by the manufacture, use or sale of the new product (paragraph IV certification). If the applicant does not challenge the listed patents, the Section 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired, and once any pediatric exclusivity expires. The Section 505(b)(2) application may also not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired.

If the applicant has provided a paragraph IV certification to the FDA, the applicant must also send notice of the paragraph IV certification to the NDA holder and patent owner once the NDA has been accepted for filing by the FDA. The NDA holder and patent owner may then initiate a legal challenge to the paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of their receipt of a paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA until the earliest of 30 months, expiration of the patent, settlement of the lawsuit or a decision in an infringement case that is favorable to the Section 505(b)(2) applicant. Thus, a Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized. Alternatively, if the NDA holder or patent owner does not file a patent infringement lawsuit within the required 45-day period, the applicant's NDA will not be subject to the 30-month stay.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), this could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that we submit.

Our partner, Hana Biosciences, submitted an NDA under Section 505(b)(2) for Zensana™ in June 2006. The safety and efficacy of the drug will be based on a demonstration of the bioequivalence of Zensana™ to oral ondansetron, marketed under the tradename Zofran®. This Zofran® formulation is protected by one unexpired patent, which is scheduled to expire in September 2011, and is subject to a period of pediatric exclusivity expiring in March 2012. Additionally, this Zofran® formulation was covered by another patent which, after pediatric exclusivity, expired in December 2006. Hana Biosciences' Section 505(b)(2) NDA contained a paragraph III certification acknowledging that the now expired patent would expire in December 2006, and a paragraph IV certification to the patent which is due to expire in March 2012. Based on the paragraph IV certification, it is possible that the NDA holder or the patent owner will sue us and/or Hana Biosciences for patent infringement, and that the FDA will be prevented from approving our application until the earliest of 30 months, settlement of the lawsuit, or a decision in an infringement case that is favorable to us. Hana Biosciences has announced that it has not received any objections related to these patent certifications. On March 23, 2007, Hana Biosciences announced its plan to withdraw, without prejudice, its pending NDA for Zensana™ with the FDA.

We have received a request for information from a third party in response to the information we have set forth in the paragraph IV certification of the NDA we have filed for NitroMist™. Such request no longer has any effect on PDUFA dates for such NDA. However, the request may be a precursor for a patent infringement claim by such third party. We do not believe that we have infringed on any intellectual property rights of such party and if such a claim is filed, we intend to vigorously defend our rights in response to such claim.

EVEN IF WE OBTAIN PATENTS TO PROTECT OUR PRODUCTS, THOSE PATENTS MAY NOT BE SUFFICIENTLY BROAD AND OTHERS COULD COMPETE WITH US.

We, and the parties licensing technologies to us, have filed various U.S. and foreign patent applications with respect to the products and technologies under our development, and the USPTO and foreign patent offices have issued patents with respect to our products and technologies. These patent applications include international applications filed under the Patent Cooperation Treaty. Currently, we have eight patents which have been issued in the U.S. and 71 patents which have been issued outside of the U.S. Additionally, we have over 90 patents pending around the world. Our pending patent applications, those we may file in the future and those we may license from third parties, may not result in the USPTO or any foreign patent office issuing patents. Also, if patent rights covering our products are not sufficiently broad, they may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar products and technologies. Furthermore, if the USPTO or foreign patent offices issue patents to us or our licensors, others may challenge the patents or circumvent the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from or to third parties may not provide any protection against competitors.

Furthermore, the life of our patents is limited. Such patents, which include relevant foreign patents, expire on various dates. We have filed, and when possible and appropriate, will file, other patent applications with respect to our product candidates and processes in the U.S. and in foreign countries. We may not be able to develop additional products or processes that will be patentable or additional patents may not be issued to us. See also "Risk Factors - If We Cannot Meet Requirements Under our License Agreements, We Could Lose the Rights to our Products."

INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES COULD LIMIT OUR ABILITY TO MARKET OUR PRODUCTS.

Our commercial success also significantly depends on our ability to operate without infringing the patents or violating the proprietary rights of others. The USPTO keeps U.S. patent applications confidential while the applications are pending. As a result, we cannot determine which inventions third parties claim in pending patent applications that they have filed. We may need to engage in litigation to defend or enforce our patent and license rights or to determine the scope and validity of the proprietary rights of others. It will be expensive and time consuming to defend and enforce patent claims. Thus, even in those instances in which the outcome is favorable to us, the proceedings can result in the diversion of substantial resources from our other activities. An adverse determination may subject us to significant liabilities or require us to seek licenses that third parties may not grant to us or may only grant at rates that diminish or deplete the profitability of the products to us. An adverse determination could also require us to alter our products or processes or cease altogether any related research and development activities or product sales.

IF WE CANNOT MEET REQUIREMENTS UNDER OUR LICENSE AGREEMENTS, WE COULD LOSE THE RIGHTS TO OUR PRODUCTS.

We depend, in part, on licensing arrangements with third parties to maintain the intellectual property rights to our products under development. These agreements may require us to make payments and/or satisfy performance obligations in order to maintain our rights under these licensing arrangements. All of these agreements last either throughout the life of the patents, or with respect to other licensed technology, for a number of years after the first commercial sale of the relevant product.

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

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

WE RELY ON CONFIDENTIALITY AGREEMENTS THAT COULD BE BREACHED AND MAY BE DIFFICULT TO ENFORCE.

Although we believe that we take reasonable steps to protect our intellectual property, including the use of agreements relating to the non-disclosure of confidential information to third parties, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them, the agreements can be difficult and costly to enforce. Although we seek to obtain these types of agreements from our consultants, advisors and research collaborators, to the extent that they apply or independently develop intellectual property in connection with any of our projects, disputes may arise as to the proprietary rights to this type of information. If a dispute arises, a court may determine that the right belongs to a third party, and enforcement of our rights can be costly and unpredictable. In addition, we will rely on trade secrets and proprietary know-how that we will seek to protect in part by confidentiality agreements with our employees, consultants, advisors or others. Despite the protective measures we employ, we still face the risk that:

- they will breach these agreements;
- any agreements we obtain will not provide adequate remedies for this type of breach or that our trade secrets or proprietary know-how will otherwise become known or competitors will independently develop similar technology; and
- our competitors will independently discover our proprietary information and trade secrets.

WE ARE DEPENDENT ON EXISTING MANAGEMENT AND BOARD MEMBERS.

Our success is substantially dependent on the efforts and abilities of the principal members of our management team and our directors. Decisions concerning our business and our management are and will continue to be made or significantly influenced by these individuals. The loss or interruption of their continued services could have a materially adverse effect on our business operations and prospects. Although our employment agreements with members of management generally provide for severance payments that are contingent upon the applicable officer’s refraining from competition with us, the loss of any of these persons’ services could adversely affect our ability to develop and market our products and obtain necessary regulatory approvals, and the applicable noncompetition provisions can be difficult and costly to monitor and enforce. Further, we do not maintain key-man life insurance.

On January 17, 2006, we announced the election of Mr. Steven B. Ratoff as a member of our Board.

On April 24, 2006, Ms. Jean Frydman ceased to serve as Vice President, General Counsel and Corporate Secretary.

On September 15, 2006, our Board appointed Steven B. Ratoff as Chairman of the Board, with Dr. Egberts remaining a member of our Board.

On December 4, 2006, our Board appointed David H. Bergstrom, Ph.D. as Senior Vice President and Chief Operating Officer.

On January 4, 2007, Mr. Barry Cohen ceased to serve as Vice President, Business and New Product Development.

On February 2, 2007, we announced the election of Mr. Mark J. Baric as a member of our Board, effective February 1, 2007.

On February 22, 2007, our Board appointed Deni M. Zodda, Ph.D. as Senior Vice President and Chief Business Officer.

On July 23, 2007, our Board accepted the resignation of Jan H. Egberts, M.D., President, Chief Executive Officer and Director, effective July 25, 2007.

On July 23, 2007, our Board appointed Steven B. Ratoff, our current Chairman, as Interim President and Chief Executive Officer, effective July 25, 2007.

On December 14, 2007, our Board renewed the employment agreement of Michael E. Spicer, as Chief Financial Officer and Corporate Secretary, effective December 20, 2007.

Our future success also will depend in part on the continued service of our key scientific and management personnel and our ability to identify, hire and retain additional personnel, including scientific, development and manufacturing staff.

RISKS RELATED TO OUR COMMON STOCK

WE MAY RECEIVE NOTICE FROM THE AMERICAN STOCK EXCHANGE THAT WE FAIL TO COMPLY WITH CERTAIN OF ITS CONTINUED LISTING STANDARDS, WHICH MAY RESULT IN A DELISTING OF OUR COMMON STOCK FROM THE EXCHANGE.

Our common stock is currently listed for trading on the American Stock Exchange, or AMEX, and the continued listing of our common stock on the AMEX is subject to our compliance with a number of listing standards. These listing standards include the requirement for maintaining stockholders’ equity of at least $6,000,000. As of December 31, 2007, our net worth position was $4,174,000, which is below the minimum net worth continued listing requirement. Unless we can increase our net worth position above the required minimum, we may receive notice from the AMEX informing us that we are not in compliance with the AMEX listing standard, and we may be required to submit a plan to the AMEX advising the actions we have taken, or will take, that would bring us into compliance with all of the continued listing standards. If we are not in compliance with the continued listing standards at the end of the plan period, or if we don not make progress consistent with the plan during the plan period, the AMEX staff may initiate delisting proceedings. There can be no assurance that we will be able to make progress consistent with such plan.

If our common stock were no longer listed on the AMEX, investors might only be able to trade on the OTC Bulletin Board® or in the Pink Sheets® (a quotation medium operated by Pink Sheets LLC). This would impair the liquidity of our securities not only in the number of shares that could be bought and sold at a given price, which might be depressed by the relative illiquidity, but also through delays in the timing of transactions and reduction in media coverage.

WE ARE INFLUENCED BY CURRENT STOCKHOLDERS, OFFICERS AND DIRECTORS.

Our directors, executive officers and principal stockholders and certain of our affiliates have the ability to influence the election of our directors and most other stockholder actions. As of March 19, 2008, management and our affiliates currently beneficially own, including shares they have the right to acquire, approximately 20% of the common stock on a fully-diluted basis. This determination of affiliate status is not necessarily a conclusive determination for other purposes. Specifically, Dr. Rosenwald has the ability to exert significant influence over the election of the Board and other matters submitted to our stockholders for approval. Dr. Rosenwald has the ability to designate an individual to serve on our Board and has exercised such ability by designating Mr. J. Jay Lobell to serve on the Board. Although Mr. Lobell is a designee of Dr. Rosenwald's, he does not have any voting or dispositive control over the shares held directly or indirectly by Dr. Rosenwald. On December 14, 2005 based upon the recommendation of the Corporate Governance and Nominating Committee, the Board elected Mr. Lobell as a member of the Board. Pursuant to the listing standards of the AMEX, Mr. Lobell has been deemed to be an independent director by our Board on September 15, 2006.

Such positions may discourage or prevent any proposed takeover of us, including transactions in which our stockholders might otherwise receive a premium for their shares over the then current market prices. Our directors, executive officers and principal stockholders may influence corporate actions, including influencing elections of directors and significant corporate events.

THE MARKET PRICE OF OUR STOCK AND OUR EARNINGS MAY BE ADVERSELY AFFECTED BY MARKET VOLATILITY.

The market price of our common stock, like that of many other development stage pharmaceutical or biotechnology companies, has been and is likely to continue to be volatile. In addition to general economic, political and market conditions, the price and trading volume of our common stock could fluctuate widely in response to many factors, including:

- announcements of the results of clinical trials by us or our competitors;
- adverse reactions to products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;
- changes in the U.S. or foreign regulatory policy during the period of product development;
- developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- announcements of technological innovations by us or our competitors;
- announcements of new products or new contracts by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
- conditions and trends in the pharmaceutical and other industries;
- new accounting standards; and
- the occurrence of any of the risks set forth in these Risk Factors and other reports, including this Annual Report and other filings filed with the Securities and Exchange Commission from time to time.

Our common stock has been listed for quotation on the AMEX since May 11, 2004 under the symbol "NVD". Prior to May 11, 2004, our common stock was traded on the OTC Bulletin Board® of the National Association of Securities Dealers, Inc. During the year ended December 31, 2007, the closing price of our common stock has ranged from $0.21 to $1.81. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the year ended December 31, 2007, the average daily trading volume in our common stock was approximately 151,000 shares. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

In the past, following periods of volatility in the market price of the securities of companies in our industry, securities class action litigation has often been instituted against companies in our industry. If we face securities litigation in the future, even if without merit or unsuccessful, it would result in substantial costs and a diversion of management attention and resources, which would negatively impact our business.

BECAUSE THE AVERAGE DAILY TRADING VOLUME OF OUR COMMON STOCK IS LOW, THE ABILITY TO SELL OUR SHARES IN THE SECONDARY TRADING MARKET MAY BE LIMITED.

Because the average daily trading volume of our common stock on the AMEX is low, the liquidity of our common stock may be impaired. As a result, prices for shares of our common stock may be lower than might otherwise prevail if the average daily trading volume of our common stock was higher. The average daily trading volume of our common stock may be low relative to the stocks of exchange-listed companies, which could limit investors’ ability to sell shares in the secondary trading market.

WE LIKELY WILL ISSUE ADDITIONAL EQUITY SECURITIES, WHICH WILL DILUTE CURRENT STOCKHOLDERS’ SHARE OWNERSHIP.

We likely will issue additional equity securities to raise capital and through the exercise of options and warrants that are outstanding or may be outstanding. These additional issuances will dilute current stockholders’ share ownership.

PENNY STOCK REGULATIONS MAY IMPOSE CERTAIN RESTRICTIONS ON MARKETABILITY OF OUR SECURITIES.

The SEC has adopted regulations which generally define a “penny stock” to be any equity security that has a market price of less than $5.00 per share or an exercise price of less than $5.00 per share, subject to certain exceptions. As a result, our common stock is subject to rules that impose additional sales practice requirements on broker dealers who sell such securities to persons other than established customers and accredited investors (generally those with assets in excess of $1,000,000 or annual income exceeding $200,000, or $300,000 together with their spouse). For transactions covered by such rules, the broker dealer must make a special suitability determination for the purchase of such securities and have received the purchaser’s written consent to the transaction prior to the purchase. Additionally, for any transaction involving a penny stock, unless exempt, the rules require the delivery, prior to the transaction, of a risk disclosure document mandated by the SEC relating to the penny stock market. The broker dealer must also disclose the commission payable to both the broker dealer and the registered representative, current quotations for the securities and, if the broker dealer is the sole market maker, the broker dealer must disclose this fact and the broker dealer’s presumed control over the market. Finally, monthly statements must be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. Broker-dealers must wait two business days after providing buyers with disclosure materials regarding a security before effecting a transaction in such security. Consequently, the “penny stock” rules restrict the ability of broker dealers to sell our securities and affect the ability of investors to sell our securities in the secondary market and the price at which such purchasers can sell any such securities, thereby affecting the liquidity of the market for our common stock.

Stockholders should be aware that, according to the SEC, the market for penny stocks has suffered in recent years from patterns of fraud and abuse. Such patterns include:

- control of the market for the security by one or more broker-dealers that are often related to the promoter or issuer;
- manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases;
- “boiler room” practices involving high pressure sales tactics and unrealistic price projections by inexperienced sales persons;
- excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and
- the wholesale dumping of the same securities by promoters and broker-dealers after prices have been manipulated to a desired level, along with the inevitable collapse of those prices with consequent investor losses.

Our management is aware of the abuses that have occurred historically in the penny stock market.

ADDITIONAL AUTHORIZED SHARES OF OUR COMMON STOCK AND PREFERRED STOCK AVAILABLE FOR ISSUANCE MAY ADVERSELY AFFECT THE MARKET.

We are authorized to issue a total of 200,000,000 shares of common stock and 1,000,000 shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders. As of March 19, 2008, there were 60,692,260 shares of common stock issued and outstanding. However, the total number of shares of our common stock issued and outstanding does not include shares reserved in anticipation of the exercise of options or warrants. As of March 19, 2008, we had outstanding stock options and warrants to purchase approximately 35.1 million shares of common stock, the exercise prices of which range between $0.45 per share and $3.18 per share, and we have reserved shares of our common stock for issuance in connection with the potential exercise thereof.

The following table provides an overview of our stock options and corresponding plans:

Plan	Shares Authorized	Options Outstanding at March 19, 2008	Remaining Shares Available for Issuance	Comments
1992 Stock Option Plan	500,000	40,000	—	Plan Closed
1997 Stock Option Plan	500,000	100,000	—	Plan Closed
1998 Stock Option Plan	3,400,000	1,619,300	1,485,700	—
2006 Equity Incentive Plan	6,000,000	4,116,800	683,200	—
Non-Plan	n/a	2,553,200	n/a	—

To the extent such options or warrants are exercised, the holders of our common stock will experience further dilution.

In addition, in the event that any future financing should be in the form of, be convertible into or exchangeable for, equity securities, and upon the exercise of options and warrants, investors may experience additional dilution.

See "Risk Factors - Our Additional Financing Requirements Could Result In Dilution To Existing Stockholders" included herein. The exercise of the outstanding derivative securities will reduce the percentage of common stock held by our stockholders in relation to our aggregate outstanding capital stock. Further, the terms on which we could obtain additional capital during the life of the derivative securities may be adversely affected, and it should be expected that the holders of the derivative securities would exercise them at a time when we would be able to obtain equity capital on terms more favorable than those provided for by such derivative securities. As a result, any issuance of additional shares of our common stock may cause our current stockholders to suffer significant dilution which may adversely affect the market.

In addition to the above referenced shares of our common stock which may be issued without stockholder approval, we have 1,000,000 shares of authorized preferred stock, the terms of which may be fixed by our Board. We presently have no issued and outstanding shares of preferred stock and while we have no present plans to issue any shares of preferred stock, our Board has the authority, without stockholder approval, to create and issue one or more series of such preferred stock and to determine the voting, dividend and other rights of holders of such preferred stock. The issuance of any of such series of preferred stock may have an adverse effect on the holders of our common stock.

SHARES ELIGIBLE FOR FUTURE SALE MAY ADVERSELY AFFECT THE MARKET.

From time to time, certain of our stockholders may be eligible to sell all or some of their shares of our common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act of 1933, as amended, subject to certain limitations. In general, pursuant to Rule 144, a stockholder (or stockholders whose shares are aggregated) who has satisfied a six-month holding period may, under certain circumstances, sell within any three month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale. Rule 144 also permits, under certain circumstances, the sale of securities, without any limitation, by our stockholders that are non-affiliates that have satisfied a one-year holding period. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market price of our common stock.

LIMITATION ON DIRECTOR/OFFICER LIABILITY.

As permitted by Delaware law, our certificate of incorporation limits the liability of our directors for monetary damages for breach of a director’s fiduciary duty except for liability in certain instances. As a result of our charter provision and Delaware law, stockholders may have limited rights to recover against directors for breach of fiduciary duty. In addition, our certificate of incorporation provides that we shall indemnify our directors and officers to the fullest extent permitted by law.

WE HAVE NO HISTORY OF PAYING DIVIDENDS ON OUR COMMON STOCK.

We have never paid any cash dividends on our common stock and do not anticipate paying any cash dividends on our common stock in the foreseeable future. We plan to retain any future earnings to finance growth. If we decide to pay dividends to the holders of our common stock, such dividends may not be paid on a timely basis.

PROVISIONS OF OUR CERTIFICATE OF INCORPORATION AND DELAWARE LAW COULD DETER A CHANGE OF OUR MANAGEMENT WHICH COULD DISCOURAGE OR DELAY OFFERS TO ACQUIRE US.

Provisions of our certificate of incorporation and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in management would be beneficial to our stockholders. For example, our certificate of incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board also has the authority to issue preferred stock without further stockholder approval, including large blocks of preferred stock. As a result, our Board could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of our common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock.

SALES OF LARGE QUANTITIES OF OUR COMMON STOCK, INCLUDING THOSE SHARES ISSUABLE IN CONNECTION WITH PRIVATE PLACEMENT TRANSACTIONS, COULD REDUCE THE PRICE OF OUR COMMON STOCK.

On July 20, 2006, we filed a shelf registration statement on Form S-3 registering for sale by us of up to 14,000,000 shares of our common stock. Such shelf registration statement was declared effective by the SEC on August 2, 2006. We may offer and sell such shares from time to time, in one or more offerings in amounts and at prices, and on terms determined at the time of the offering. Such offerings of our common stock may be made through agents we select or through underwriters and dealers we select. If we use agents, underwriters or dealers, we will name them and describe their compensation at the time of the offering. As of the filing date of this Annual Report, such shelf registration statement is no longer effective.

In December 2006, we sold securities in a private placement transaction resulting in the issuance of 9,823,983 shares of our common stock, and warrants to purchase 4,383,952 shares of our common stock. The sale of the shares of common stock and warrants resulted in gross proceeds to us of approximately $14.2 million, prior to offering expenses.

In April 2006, we sold securities in a private placement transaction resulting in the issuance of 8,092,796 shares of our common stock, and warrants to purchase 2,896,168 shares of our common stock. The sale of the shares of common stock and warrants resulted in gross proceeds to us of approximately $11.8 million, prior to offering expenses.

In May 2005, we sold securities in a private placement transaction resulting in the issuance of 6,733,024 shares of our common stock, and certain warrants to purchase 2,693,210 shares of our common stock. The sales of the shares of common stock and warrants resulted in gross proceeds to us of $7.1 million, prior to offering expenses.

The offering of, and/or resale of our common stock and the exercise of the warrants described immediately above in this risk factor are subject to currently effective registration statements filed by us on Forms S-3. There can be no assurance as to the prices at which our common stock will trade in the future, although they may continue to fluctuate significantly. Prices for our common stock will be determined in the marketplace and may be influenced by many factors, including the following:

- The depth and liquidity of the markets for our common stock;
- Investor perception of us and the industry in which we participate; and
- General economic and market conditions.

Any sales of large quantities of our common stock could reduce the price of our common stock. The holders of the shares may sell such shares at any price and at any time, as determined by such holders in their sole discretion without limitation. If any such holders sell such shares in large quantities, our common stock price may decrease and the public market for our common stock may otherwise be adversely affected because of the additional shares available in the market.

As of March 19, 2008, we have 60,692,260 shares of common stock issued and outstanding and approximately 35.1 million shares of common stock issuable upon the exercise of outstanding stock options and warrants. In the event we wish to offer and sell shares of our common stock in excess of the 200,000,000 shares of common stock currently authorized by our certificate of incorporation, we will first need to receive stockholder approval. Such stockholder approval has the potential to adversely affect the timing of any potential transactions.

THE SECURITIES ISSUED IN OUR DECEMBER 2006 PRIVATE PLACEMENT ARE RESTRICTED SECURITIES.

At the time of the offer and sale of the common stock (and the shares of common stock underlying the warrants) in our December 2006 private placement, the common stock was not registered under the Securities Act or the securities laws of any state. Accordingly, these securities may not be sold or otherwise transferred unless such sale or transfer is subsequently registered under the Securities Act and applicable state securities laws or unless exemptions from such registration are available. The registration statement covering these securities was declared effective by the SEC on January 26, 2007. Notwithstanding our registration obligations regarding these securities, investors may be required to hold these securities for an indefinite period of time. All investors who purchase these securities are required to make representations that it will not sell, transfer, pledge or otherwise dispose of any of the securities in the absence of an effective registration statement covering such transaction under the Securities Act and applicable state securities laws, or the receipt by us of an opinion of counsel to the effect that registration is not required.

WE HAVE BROAD DISCRETION AS TO THE USE OF THE PROCEEDS FROM THE DECEMBER 2006 PRIVATE PLACEMENT AND MAY USE THE PROCEEDS IN A MANNER WITH WHICH YOU DISAGREE.

Our Board and management will have broad discretion over the use of the net proceeds of the December 2006 private placement. Stockholders may disagree with the judgment of the Board and management regarding the application of the proceeds of the December 2006 private placement. We cannot predict that investments of the proceeds will yield a favorable, or any, return.

WE MAY INCUR SIGNIFICANT COSTS FROM CLASS ACTION LITIGATION DUE TO OUR EXPECTED STOCK VOLATILITY.

In the past, following periods of large price declines in the public market price of a company’s stock, holders of that stock occasionally have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring this type of lawsuit against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit. The lawsuit also could divert the time and attention of our management, which would hurt our business. Any adverse determination in litigation could also subject us to significant liabilities.

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THE UNCERTAINTY CREATED BY CURRENT ECONOMIC CONDITIONS AND POSSIBLE TERRORIST ATTACKS AND MILITARY RESPONSES THERETO COULD MATERIALLY ADVERSELY AFFECT OUR ABILITY TO SELL OUR PRODUCTS, AND PROCURE NEEDED FINANCING.

Current conditions in the domestic and global economies continue to present challenges. We expect that the future direction of the overall domestic and global economies will have a significant impact on our overall performance. Fiscal, monetary and regulatory policies worldwide will continue to influence the business climate in which we operate. If these actions are not successful in spurring continued economic growth, we expect that our business will be negatively impacted, as customers will be less likely to buy our products, if and when we commercialize our products. The potential for future terrorist attacks or war as a result thereof has created worldwide uncertainties that make it very difficult to estimate how the world economy will perform going forward.

OUR INABILITY TO MANAGE THE FUTURE GROWTH THAT WE ARE ATTEMPTING TO ACHIEVE COULD SEVERELY HARM OUR BUSINESS.

We believe that, given the right business opportunities, we may expand our operations rapidly and significantly. If rapid growth were to occur, it could place a significant strain on our management, operational and financial resources. To manage any significant growth of our operations, we will be required to undertake the following successfully:

- We will need to improve our operational and financial systems, procedures and controls to support our expected growth and any inability to do so will adversely impact our ability to grow our business. Our current and planned systems, procedures and controls may not be adequate to support our future operations and expected growth. Delays or problems associated with any improvement or expansion of our operational systems and controls could adversely impact our relationships with customers and harm our reputation and brand.
- We will need to attract and retain qualified personnel, and any failure to do so may impair our ability to offer new products or grow our business. Our success will depend on our ability to attract, retain and motivate managerial, technical, marketing, and administrative personnel. Competition for such employees is intense, and we may be unable to successfully attract, integrate or retain sufficiently qualified personnel.

If we are unable to hire, train, retain or manage the necessary personnel, we may be unable to successfully introduce new products or otherwise implement our business strategy. If we are unable to manage growth effectively, our business, results of operations and financial condition could be materially adversely affected.

WE MAY BE OBLIGATED, UNDER CERTAIN CIRCUMSTANCES, TO PAY LIQUIDATED DAMAGES TO HOLDERS OF OUR COMMON STOCK.

We have entered into agreements with the holders of our common stock that requires us to continuously maintain as effective, a registration statement covering the underlying shares of common stock. Such registration statements were declared effective on January 26, 2007, May 30, 2006 and July 28, 2005 and must continuously remain effective for a specified term. If we fail to continuously maintain such a registration statement as effective throughout the specified term, we may be subject to liability to pay liquidated damages.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

Our executive offices, laboratory, and warehousing space are located at 25 Minneakoning Road, Flemington, New Jersey, known as the New Facility. The New Facility, constituting approximately 31,800 square feet, is occupied under a 10-year lease, expiring in August 2013. Presently, we are only occupying a portion of our space in the New Facility. Through the lease expiration date of December 31, 2005, we also occupied approximately 4,500 square feet of laboratory and office space at 31 Route 12 West, Flemington, New Jersey, known as the Old Facility, which also formerly housed our executive offices. During the five months ended December 31, 2006, we paid rent for the New Facility of approximately $184,000. During the year ended December 31, 2007, we paid rent for the New Facility of approximately $443,000. The New Facility does not yet have a pilot manufacturing operation that meets current Good Manufacturing Practices, or cGMP, and would require additional investment in order to attain that capability. With the expiration of the lease on the Old Facility, we have contracted out manufacturing for our product candidates. The manufacture of our product candidates is subject to cGMP prescribed by the Food & Drug Administration, or FDA, and pre-approval inspections by the FDA and foreign authorities prior to the commercial manufacture of any such products. See Item 1, “Business- Raw Materials and Suppliers” and Business-Government Regulations.”

ITEM 3. LEGAL PROCEEDINGS.

We are not a named party in any material legal proceedings.

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

None.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is traded on the American Stock Exchange, or AMEX, under the ticker symbol "NVD" since May 11, 2004. The following table sets forth the range of high and low closing sales prices of our common stock as reported by the AMEX during the year ended December 31, 2007, the five months ended December 31, 2006 and for each fiscal quarter for the fiscal years ended July 31, 2006 and 2005.

	CLOSING SALE PRICES	
	($) HIGH	LOW
YEAR ENDED DECEMBER 31, 2007		
First Quarter (January 1, 2997 through March 31, 2007)	1.81	1.30
Second Quarter (April 1, 2007 through June 30, 2007)	1.33	1.02
Third Quarter (July 1, 2007 through September 30, 2007)	1.11	0.50
Fourth Quarter (October 1, 2007 through December 31, 2007)	0.54	0.21
FIVE MONTHS ENDED DECEMBER 31, 2006		
First Quarter (August 1, 2006 through October 31, 2006)	1.35	1.13
Two Months Ended December 31, 2006	1.86	1.24
FISCAL 2006		
First Quarter (August 1, 2005 through October 31, 2005)	1.85	1.21
Second Quarter (November 1, 2005 through January 31, 2006)	1.44	1.16
Third Quarter (February 1, 2006 through April 30, 2006)	1.90	1.22
Fourth Quarter (May 1, 2006 through July 31, 2006)	1.80	1.11

The last closing sales price of our common stock as reported on the AMEX on March 19, 2008 was $0.32. As of March 19, 2008, there were approximately 115 record holders of our common stock.

We have never declared or paid a dividend on our common stock and management expects that all or a substantial portion of our future earnings will be retained for expansion or development of our business. The decision to pay dividends, if any, in the future is within the discretion of our Board of Directors and will depend upon our earnings, capital requirements, financial condition and other relevant factors such as contractual obligations. Management does not anticipate that we will pay dividends on our common stock in the foreseeable future. Moreover, we may never issue dividends in the future.

EQUITY COMPENSATION PLANS

The following table provides information with respect to our compensation plans under which equity compensation is authorized as of December 31, 2007.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders	5,876,000	$ 1.66	3,269,000
Equity compensation plans not approved by security holders	2,553,000	1.87	—
Total	8,429,000	$ 1.69	3,269,000

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PERFORMANCE GRAPH

The graph below compares changes in the cumulative total stockholder return (change in stock price plus reinvested dividends) for the period from July 31, 2002 through December 31, 2007 of an initial investment of $100 invested in (a) NovaDel Pharma Inc.'s common stock, (b) the Total Return Index for the AMEX Composite and (c) the Research Data Group (RDG) Microcap Pharmaceutical Index. Total Return Index values are prepared by the Research Data Group. The stock price performance is not included to forecast or indicate future price performance.

	7/02	7/03	7/04	7/05	7/06	12/06	12/07
NovaDel Pharma Inc.	$ 100.00	$ 119.41	$ 100.59	$ 73.53	$ 70.59	$ 96.47	$ 14.12
AMEX Composite	$ 100.00	$ 110.80	$ 143.68	$ 190.27	$ 230.38	$ 249.13	$ 290.15
RDG MicroCap Pharmaceutical	$ 100.00	$ 160.07	$ 132.98	$ 120.17	$ 98.53	$ 89.04	$ 52.15

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA.

The following Selected Financial Data should be read in conjunction with our Financial Statements and the related Notes thereto, Management's Discussion and Analysis of Financial Condition and Results of Operations and other financial information included elsewhere in this Annual Report on Form 10-K. The data set forth below with respect to our Statements of Operations for the year ended December 31, 2007, the five months ended December 31, 2006 and for the fiscal years ended July 31, 2006, and 2005 and the Balance Sheet data as of December 31, 2007, December 31, 2006 and fiscal year ended July 31, 2006 are derived from our Financial Statements which are included elsewhere in this Annual Report on Form 10-K and are qualified by reference to such Financial Statements and related Notes thereto. The data set forth below for the year ended December 31, 2006 and for the five months ended December 31, 2005, are unaudited. In Management's Discussion and Analysis of Financial Condition and Results of Operations, the year ended December 31, 2007 is compared to the unaudited year ended December 31, 2006, and the five months ended December 31, 2006 are compared to the unaudited five months ended December 31, 2005. There are no seasonal or other significant factors which affect comparability. The data set forth below with respect to our Statements of Operations for the fiscal years ended July 31, 2004, 2003 and 2002 and the Balance Sheets data as of July 31, 2006, July 31, 2005, July 31, 2004 and 2003 are derived from our Financial Statements, which are not included elsewhere in this Annual Report. Our historical results are not necessarily indicative of future results of operations.

	Years Ended December 31,		**Five Months Ended December 31,**		**Years Ended July 31,**			
Statement of Operations Data:	**2007**	**2006**	**2006**	**2005**	**2006**	**2005**	**2004**	**2003**
		(unaudited)		**(unaudited)**				
Total Revenues	$ 469,000	$ 3,280,000	$ 2,067,000	$ 677,000	$ 1,890,000	$ 439,000	$ 466,000	$ 2,000
Total Expenses	18,656,000	13,544,000	6,519,000	5,429,000	12,454,000	10,217,000	7,119,000	7,091,000
Loss from Operations	(18,187,000)	(10,264,000)	(4,452,000)	(4,752,000)	(10,564,000)	(9,778,000)	(6,653,000)	(7,089,000)
Interest Income	632,000	337,000	180,000	67,000	224,000	87,000	98,000	49,000
Income Tax Benefit	(658,000)	(467,000)	(467,000)	(256,000)	(256,000)	(241,000)	(214,000)	(84,000)
Net Loss	$ (16,963,000)	(9,460,000)	$ (3,805,000)	(4,429,000)	$ (10,084,000)	$ (9,450,000)	$ (6,341,000)	$ (6,956,000)
Basic and Diluted Loss Per Common Share	$ (.29)	$ (.20)	$ (.08)	$ (.11)	$ (.23)	$ (.27)	$ (.24)	$ (.45)
Weighted Average Number of Shares of Common Stock Used in Computation of Basic and Diluted Loss Per Share	59,497,000	46,732,000	49,522,000	40,619,000	43,000,000	34,808,000	26,269,000	15,419,000

BALANCE SHEET DATA:	December 31, 2007	2006	July 31, 2006	2005	2004	2003
Cash, cash equivalents, and short-term investments	$ 6,384,000	$ 20,276,000	$ 10,138,000	$ 8,223,000	$ 8,377,000	$ 3,086,000
Total Assets	10,363,000	24,316,000	14,822,000	13,028,000	11,486,000	4,327,000
Total Current Liabilities	4,211,000	3,146,000	2,200,000	2,405,000	1,086,000	457,000
Total Liabilities	6,189,000	5,718,000	4,777,000	5,079,000	1,463,000	457,000
Accumulated deficit	(65,243,000)	(48,280,000)	(44,475,000)	(34,391,000)	(24,941,000)	(18,600,000)
Total Stockholders' Equity	$ 4,174,000	$ 18,598,000	$ 10,045,000	$ 7,949,000	$ 10,023,000	$ 3,870,000

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ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion of our financial condition and result of operations should be read in conjunction with the financial statements and the notes to those statements included elsewhere in this Annual Report on Form 10-K. The discussion includes forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth in Item 1A. "Risk Factors" of this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward looking statements.

GENERAL

NovaDel Pharma Inc. is a specialty pharmaceutical company developing oral spray formulations for a broad range of marketed drugs. Our proprietary technology offers, in comparison to conventional oral dosage forms, the potential for faster absorption of drugs into the bloodstream leading to quicker onset of therapeutic effects and possibly lower doses. Oral sprays eliminate the requirement for water or the need to swallow, potentially improving patient convenience and compliance. Our oral spray technology is focused on addressing unmet medical needs for a broad array of existing and future pharmaceutical products. Our most advanced oral spray candidates target angina, nausea, insomnia, migraine headaches and disorders of the central nervous system. We plan to develop these and other products independently and through collaborative arrangements with pharmaceutical and biotechnology companies. Currently, we have eight patents which have been issued in the U.S. and 71 patents which have been issued outside of the U.S. Additionally, we have over 90 patents pending around the world. We look for drug compounds that are off patent or are coming off patent in the near future, and we formulate these compounds in conjunction with our proprietary drug delivery method. Once formulated, we file for new patent applications on these formulated compounds that comprise our product candidates. Our patent portfolio includes patents and patent applications with claims directed to the pharmaceutical formulations, methods of use and methods of manufacturing for our product candidates.

We have had a history of recurring losses, giving rise to an accumulated deficit as of December 31, 2007 of $65,243,000, as compared to $48,280,000 as of December 31, 2006. We have had negative cash flow from operating activities of $15,240,000 for the year ended December 31, 2007, $1,782,000 for the five-months ended December 31, 2006, $8,855,000 for the fiscal year ended July 31, 2006, and $6,258,000 for the fiscal year ended July 31, 2005. As of December 31, 2007, we had working capital of $3,811,000, as compared to $18,686,000 as of December 31, 2006, representing a net decrease in working capital of approximately $14,875,000.

During the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. Despite this reduction in expenditures for clinical activities, we require capital to sustain our existing organization until such time as clinical activities can be resumed. Given the current level of spending, we estimate that we will have sufficient cash on hand to fund operations through the middle of the second calendar quarter, 2008. Funding for the Company's future development activities could be secured through new strategic partnerships and/or the sale of our common stock or other securities. There can be no assurance that such capital will be available to us in a timely manner or on favorable terms, if at all. There are a number of risks and uncertainties related to our attempt to complete a financing or strategic partnering arrangement that are outside our control. We may not be able to obtain additional financing on terms acceptable to us, or at all. If we are unsuccessful at obtaining additional financing as needed, we may be required to significantly curtail or cease operations. We will need additional financing thereafter until we achieve profitability, if ever.

Our audited financial statements for the fiscal year ended December 31, 2007, were prepared under the assumption that we will continue our operations as a going concern. We were incorporated in 1982, and do not have a history of earnings. As a result, our independent registered public accounting firm in their audit report has expressed substantial doubt about our ability to continue as a going concern. Continued operations are dependent on our ability to complete equity or debt formation activities or to generate profitable operations. Such capital formation activities may not be available or may not be available on reasonable terms. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we cannot continue as a viable entity, our shareholders may lose some or all of their investment in the Company.

Since inception, substantially all of our revenues have been derived from consulting activities, primarily in connection with product development for various pharmaceutical companies. More recently, we have begun to derive revenues from license fees and milestone payments stemming from our partnership agreements. Our future growth and profitability will be principally dependent upon our ability to successfully develop our products and to market and distribute the final products either internally or with the assistance of a strategic partner.

On June 28, 2006, our Board of Directors approved a change of our fiscal year end from July 31 to December 31. Accordingly, our new fiscal year begins on January 1 and ends on December 31. We filed a Transition Report on Form 10-K for the five months ended December 31, 2006. As such, the end of the quarters in the new fiscal year does not coincide with the end of the quarters in the previous fiscal years. Due to the significant costs, the Company is not recasting the quarterly data from the previous fiscal year as such costs would exceed any potential benefits. Instead, the Company is presenting financial statements and other financial information, including Management's Discussion and Analysis of Financial Condition and Results of Operations, for the years ended December 31, 2007, the five months ended December 31, 2006, and the fiscal years ended July 31, 2006 and July 31, 2005. In Management's Discussion and Analysis of Financial Condition and Results of Operations, the year ended December 31, 2007 are compared to the unaudited year ended December 31, 2006, and the five months ended December 31, 2006 are compared to the unaudited five months ended December 31, 2005. There are no seasonal or other significant factors which affect comparability.

Highlights for the year ended December 31, 2007, and additionally through the date of filing of this prospectus, include the following:

Product Pipeline

- Announced that the Company's New Drug Application for ZolpiMist™ to treat insomnia was accepted for filing by the U.S. Food and Drug Administration

- Announced that Par Pharmaceuticals has been granted a sublicense for the development and commercialization of Zensana™.

- Announced that Par Pharmaceuticals has returned the rights to NitroMist™ to us.

- Announced that two clinical studies comparing our zolpidem oral spray with zolpidem tablets met their primary pharmacokinetic and pharmacodynamic and safety objectives.

- Announced that Hana Biosciences has notified us that ongoing scale-up and stability experiments indicate that there is a need to make adjustments to the formulation and/or manufacturing process, and that there will be a delay in the FDA approval and commercial launch of Zensana™ .

Intellectual Property

- Received notification of the issuance of additional patents in Canada and Europe which further strengthens our intellectual property position in the oral delivery of pharmaceuticals. The issued patents cover the use of multiple classes of drugs in oral sprays, including those for the treatment of pain, and for central nervous system disorders under our oral spray delivery system in Canada, and analgesics, alkaloids, and nicotine in Europe.

Executive Team and Board of Directors

- Appointed Steven B. Ratoff, our current Chairman of the Board, to serve as interim President and Chief Executive Officer.

- Announced that Jan H. Egberts, M.D. resigned as President, Chief Executive Officer and Director.

- Appointed Mr. Mark J. Baric as a member of the Board of Directors.
- Appointed Deni M. Zodda, Ph.D. as Senior Vice President and Chief Business Officer.
- Announced that Mr. Barry C. Cohen will no longer serve as Vice President, Business and New Product Development, and the execution of a related settlement/release agreement.
- Renewed the employment agreement of Mr. Michael E. Spicer as Chief Financial Officer.

Drug development in the U.S. and most countries throughout the world is a process that includes several steps defined by the U.S. Food and Drug Administration, or FDA, or comparable regulatory authorities in foreign countries. The FDA approval processes relating to new drugs differ, depending on the nature of the particular drug for which approval is sought. With respect to any drug product with active ingredients not previously approved by the FDA, a prospective drug manufacturer is required to submit a New Drug Application, or NDA, which includes complete reports of pre-clinical, clinical and laboratory studies to prove such product's safety and efficacy. Prior to submission of the NDA, it is necessary to submit an Investigational New Drug, or IND, to obtain permission to begin clinical testing of the new drug. Given that our current product candidates are based on a new technology for formulation and delivery of active pharmaceutical ingredients that have been previously approved and that have been shown to be safe and effective in previous clinical trials, we believe that we will be eligible to submit what is known as a 505(b)(2) NDA. We estimate that the development of new formulations of our pharmaceutical product candidates, including formulation, testing and submission of an NDA, will require significantly less time and lower investments in direct research and development expenditures than is the case for the discovery and development of new chemical entities. However, our estimates may prove to be inaccurate; or pre-marketing approval relating to our proposed products may not be obtained on a timely basis, if at all, and research and development expenditures may significantly exceed management's expectations.

It is not anticipated that we will generate any revenues from royalties or sales of our product candidates until regulatory approvals are obtained and marketing activities begin. Any one or more of our product candidates may not prove to be commercially viable, or if viable, may not reach the marketplace on a basis consistent with our desired timetables, if at all. The failure or the delay of any one or more of our proposed products to achieve commercial viability would have a material adverse effect on us.

The successful development of our product candidates is highly uncertain. Estimates of the nature, timing and estimated expenses of the efforts necessary to complete the development of, and the period in which material net cash inflows are expected to commence from, any of our product candidates are subject to numerous risks and uncertainties, including:

- the scope, rate of progress and expense of our clinical trials and other research and development activities;
- results of future clinical trials;
- the expense of clinical trials for additional indications;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the expense and timing of regulatory approvals or changes in the regulatory approval process;
- the expense of establishing clinical and commercial supplies of our product candidates and any products that we may develop;
- the effect of competing technologies and market developments; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

We expect to continue to spend significant amounts on the development of our product candidates and we expect our costs to increase as we continue to develop and ultimately commercialize our product candidates. The following table summarizes our product candidates:

	Active Ingredient or Class of Molecule	Indications	Stage of Development	Partner
Approved Product				
NitroMist™	Nitroglycerin	Acute angina	FDA Approved	-
Product Candidates				
ZolpiMist™	Zolpidem tartrate	Sleeplessness	NDA submitted – FDA acceptance January 23, 2008	-
Sumatriptan	Sumatriptan succinate	Migraines	Pilot Efficacy study complete	-
Ropinirole	Ropinirole	Idiopathic Parkinson's Disease	Clinical development	-
Tizanidine	Tizanidine hydrochloride	Spasticity	Clinical development	-
Zensana™	Ondansetron	Anti-emetic	Clinical development	Hana Biosciences/Par Pharmaceuticals

NitroMist™ (nitroglycerin lingual aerosol). This product is indicated for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease, and was approved by the FDA in November 2006. Previously, this product was partnered with Par Pharmaceuticals, or Par; however, on August 1, 2007, we announced that Par returned the rights to NitroMist™ to us as part of Par's strategy to concentrate its resources on supportive care in AIDS and oncology markets. We are currently investigating strategic partners for this product.

ZolpiMist™ (zolpidem oral spray). Zolpidem is the active ingredient in Ambien®, the leading hypnotic marketed by Sanofi-Aventis. A pilot pharmacokinetic, or PK, study in zolpidem oral spray with 10 healthy subjects, completed in the first half of calendar 2005, suggested that our formulation of zolpidem oral spray had a comparable PK profile to the Ambien® tablet but with a more rapid time to detectable drug levels. In October 2006, we announced positive results from a pilot pharmacokinetic study comparing our formulation of ZolpiMist™ to Ambien® tablets. In the study, 10 healthy male volunteers received ZolpiMist™ or Ambien® tablets in 5mg or 10mg doses. For fasting subjects, fifteen minutes after dosing, 80% of subjects using ZolpiMist™ achieved blood concentrations of greater than 20 ng/ml, compared to 33% of subjects in the 5mg Ambien® tablet group and 40% of subjects in the 10mg Ambien® tablet group. The difference between the oral spray groups and tablet groups was statistically significant (p=0.016). Twenty ng/ml is a level generally believed to approximate the lower limit of the therapeutic range for zolpidem. Additionally, drug concentrations were measured at five and ten minutes post-dosing. At these early time points, the oral spray groups achieved drug levels five-to-thirty times greater than subjects in the corresponding tablet groups. These differences were also statistically significant. ZolpiMist™ has the potential to provide patients with the meaningful benefit of faster onset of sleep as compared to existing sleep remedies should future studies validate the already completed Pilot PK study. We submitted the NDA for our zolpidem product candidate in the second half of 2007, and the FDA indicated acceptance of this NDA filing in January 2008. We may obtain final approval from the FDA by the fourth quarter of 2008.

Sumatriptan oral spray. Sumatriptan is the active ingredient in Imitrex® which is the largest selling migraine remedy marketed by GlaxoSmithKline, or GSK. A pilot PK study of our sumatriptan oral spray with 9 healthy subjects, completed in the second half of calendar 2004, suggested that the formulation achieved plasma concentrations of sumatriptan in the therapeutic range. In September 2006 we announced positive results from an additional pilot pharmacokinetic study, with our oral spray formulation of sumatriptan which demonstrated that sumatriptan oral spray achieves a statistically significant increase in absorption rate as compared with Imitrex® tablets. The rate of drug absorption is believed to be the most important predictor of the degree and speed of migraine relief. Sumatriptan oral spray was evaluated in a four-arm, crossover pharmacokinetic study comparing 50mg Imitrex® tablets to 20mg and 30mg of the oral spray in 10 healthy male volunteers under fasting conditions. At least 90% of subjects receiving sumatriptan oral spray had detectable drug levels at three minutes post-dosing, while at the same timepoint, only 10% of subjects receiving 50mg Imitrex® tablets had detectable drug levels. These differences are statistically significant. At 3 to 6 minutes post dosing, all oral spray groups had statistically significantly higher mean concentration levels compared to 50mg Imitrex® tablets. Using published data for the currently marketed Imitrex® nasal spray as a proxy for therapeutic blood levels, we observed that by 6 minutes post-dosing, 100% of the 20mg oral spray users achieved these critical plasma concentration levels while none of the subjects from the Imitrex® tablet group did so by this timepoint. This result was also statistically significant. Furthermore, the study indicates up to a 50% increase in relative bioavailability of oral spray in comparison to the Imitrex® tablet. Additionally, the pharmacokinetics of 20mg oral spray after a meal were evaluated. Sumatriptan oral spray was well tolerated.

While Imitrex® nasal spray was not included in this clinical study, the following represents a discussion of the results of our clinical study as compared to published data for Imitrex® nasal spray. Time to the first peak plasma concentration of sumatriptan -- which represents drug absorbed directly across the oral mucosa -- was approximately 70% faster with the 20mg oral spray than what has been reported in the literature for the same dose of the Imitrex® nasal spray (6 min. vs. 20 min.). The mean concentration level achieved during this critical first phase of absorption is approximately 30% greater for the oral spray than what was observed in published studies of the nasal spray (10.9 ng/mL vs. 8.5 ng/mL). Relative bioavailability after administration of 20mg oral spray appears to be greater than published estimates for the same dose of the Imitrex® nasal spray.

Sumatriptan oral spray may provide clinical benefits to migraine sufferers including, possibly, faster relief than Imitrex® tablets as well as greater tolerability than triptan nasal sprays. Further, if proven to be safe and effective, sumatriptan oral spray may be attractive to patients who have trouble taking oral medications due to nausea and vomiting caused by the migraine attack. Previously, we were targeting an NDA submission for our sumatriptan product candidate in the first half of calendar 2008; however, due primarily to funding constraints, at the present time, we are unable to make predictions for this program relative to sufficient funding, timing, future strategic partnerships, regulatory pathway or approval with the FDA. During the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, including sumatriptan, as we did not believe that we had sufficient cash to sustain such activities. As of the current date, we have not yet secured additional financing, and have therefore not resumed clinical development activity. There can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities.

Tizanidine oral spray. Tizanidine is indicated for the treatment of spasticity, a symptom of several neurological disorders, including multiple sclerosis, spinal cord injury, stroke and cerebral palsy, which leads to involuntary tensing, stiffening and contracting of muscles. Tizanidine treats spasticity by blocking nerve impulses through pre-synaptic inhibition of motor neurons. This method of action results in decreased spasticity without a corresponding reduction in muscle strength. Because patients experiencing spasticity may have difficulty swallowing the tablet formulation of the drug, our tizanidine oral spray may provide patients suffering from spasticity with a very convenient solution to this serious treatment problem. We were previously targeting an NDA submission for our tizanidine product candidate in calendar 2008. However, in June 2007, we announced our near-term clinical development strategy and our intention to focus the majority of our research and development resources on our two lead product candidates, zolpidem and sumatriptan oral spray. Furthermore, during the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, including tizanidine, as we did not believe that we had sufficient cash to sustain such activities. As of the current date, we have not yet secured additional financing, and have therefore not resumed clinical development activity. There can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities.

Ropinirole oral spray. Ropinirole is indicated for the treatment of the signs and symptoms of idiopathic Parkinson's disease. Ropinirole oral spray is ideal for the geriatric population who may be suffering from dysphagia (difficulty swallowing); 85% of sufferers of Parkinson's are 65 years of age or older and it is estimated that 45% of elderly people have some difficulty in swallowing. Our formulation of ropinirole oral spray may represent a more convenient way for the patient or healthcare provider to deliver ropinirole to patients suffering stiffness and/or tremors. We were previously targeting an NDA submission for our ropinirole product candidate in calendar 2008. However, in June 2007, we announced our near-term clinical development strategy and our intention to focus the majority of our research and development resources on our two lead product candidates, zolpidem and sumatriptan oral spray. Furthermore, during the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, including ropinirole, as we did not believe that we had sufficient cash to sustain such activities. As of the current date, we have not yet secured additional financing, and have therefore not resumed clinical development activity. There can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities.

Zensana™ (ondansetron oral spray). Ondansetron is the active ingredient in Zofran®, the leading anti-emetic marketed by GSK. Through July 31, 2007, this product candidate was licensed to Hana Biosciences, who was overseeing all clinical development and regulatory approval activities for this product in the U.S. and Canada. On July 31, 2007, we entered into a Product Development and Commercialization Sublicense Agreement with Hana Biosciences and Par, pursuant to which Hana Biosciences granted a sublicense to Par to develop and commercialize Zensana™. Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana™ in the United States and Canada, including the development and re-filing of the NDA in the United States. In addition, we entered into an Amended and Restated License Agreement with Hana Biosciences, pursuant to which Hana Biosciences relinquished its right to pay reduced royalty rates to us until such time as Hana Biosciences had recovered one-half of its costs and expenses incurred in developing Zensana™ from sales of Zensana™ and we agreed to surrender for cancellation all 73,121 shares of the Hana Biosciences common stock we acquired in connection with execution of the original license agreement with Hana Biosciences. Par has announced that it expects to complete clinical development on the revised formulation of Zensana™ during 2008, and expects to submit a new NDA for Zensana™ by the end of 2008.

In January 2006, Hana Biosciences announced positive study results of a pivotal clinical trial for Zensana™. Hana Biosciences submitted its NDA on June 30, 2006 and such NDA was accepted for review by the FDA in August 2006. Previously, Hana Biosciences targeted final approval from the FDA and commercial launch in calendar 2007. However, on February 20, 2007, we announced that Hana Biosciences notified us that ongoing scale-up and stability experiments indicate that there is a need to make adjustments to the formulation and/or manufacturing process, and that there is likely to be a delay in the FDA approval and commercial launch of Zensana™ as a result thereof. On March 23, 2007, Hana Biosciences announced its plan to withdraw, without prejudice, its pending NDA for Zensana™ with the FDA.

We will receive a milestone payment from Hana Biosciences upon final approval from the FDA. In addition, we will receive double-digit royalty payments based upon a percentage of net sales. We retain the rights to our ondansetron oral spray outside of the U.S. and Canada.

Propofol oral spray. Propofol is the active ingredient in Diprivan®, a leading intravenous anesthetic marketed by AstraZeneca. We continue to support our partner, Manhattan Pharmaceuticals, Inc., or Manhattan Pharmaceuticals, who will oversee all clinical development and regulatory approval for this product candidate. On July 10, 2007, Manhattan Pharmaceuticals announced its intention to pursue appropriate sub-licensing opportunities for this product candidate.

Veterinary. Our veterinary initiatives are being carried out largely by our partner, Velcera, Inc., or Velcera. In June 2007, Velcera announced that it had entered into a global license and development agreement with Novartis Animal Health. The agreement calls for Novartis Animal Health to develop, register and commercialize a novel canine product utilizing Velcera's Promist™ platform, which is based on our patented oral spray technology.

As discussed above, certain of our product candidates are in early stages of clinical development and some are in preclinical testing. These product candidates are continuously evaluated and assessed and are often subject to changes in formulation and technology. As a result, these product candidates are subject to a more difficult, time-consuming and expensive regulatory path in order to commence and complete the preclinical and clinical testing of these product candidates as compared to other product candidates in later stages of development.

CRITICAL ACCOUNTING POLICIES

USE OF ESTIMATES - The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the U.S. This requires our management to make estimates about the future resolution of existing uncertainties that affect the reported amounts of assets, liabilities, revenues and expenses which in the normal course of business are subsequently adjusted to actual results. Actual results could differ from such estimates. In preparing these financial statements, management has made its best estimates and judgments of the amounts and disclosures included in the financial statements giving due regard to materiality.

REVENUE RECOGNITION – We receive revenue from consulting services and license agreements. Consulting revenues from contract clinical research are recognized in the period in which the services are rendered, provided that collection is reasonably assured. Upfront license agreement payments are initially deferred and subsequently amortized into revenue over the contractual period. Milestone payments related to license agreements are recognized as revenue when earned.

VALUATION OF LONG-LIVED ASSETS – We assess the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Long-lived assets of the Company as of December 31, 2007 were represented by property and equipment, as the Company has no intangible assets on its balance sheet. Factors we consider important which could trigger an impairment review include the following:

- significant underperformance relative to expected historical or projected future operating results;
- significant changes in the manner of our use of the acquired assets or the strategy for our overall business;
- significant negative industry or economic trends; and
- significant decrease in the market value of the assets.

The impairment test is based upon a comparison of the estimated undiscounted cash flows to the carrying value of the long-lived assets. If we determine that the carrying value of long-lived assets may not be recoverable based upon the existence of one or more of the above indicators of impairment, we measure any impairment based on projected discounted cash flows. The cash flow estimates used to determine the impairment, if any, contain management’s best estimate using appropriate assumptions and projections at that time. Net long-lived property and equipment as of December 31, 2007 was $2.0 million. The Company reviewed its long-lived property and equipment as of December 31, 2007, and has determined that their estimated fair value exceeds the carrying amount of such assets; therefore, the Company has not recognized an impairment loss for its long-lived property and equipment.

STOCK-BASED COMPENSATION – In December 2004, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards No. 123 (revised 2004), “Share-Based Payment,” SFAS 123R, which revises “Accounting for Stock-Based Compensation,” SFAS 123 and superseded Accounting Principles Board APB Opinion No. 25, “Accounting for Stock Issued to Employees,” APB 25, which provided for the use of the intrinsic value method of accounting for employees stock options. SFAS 123R required all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values beginning with the first quarter of the first annual reporting period that began after June 15, 2005. Under SFAS 123R, the use of the intrinsic value method and pro forma disclosures previously permitted under SFAS 123 are no longer an alternative to financial statement recognition.

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We have adopted the provisions of Statement of Financial Accounting Standards, or SFAS, No. 123 (revised 2004), “Share-Based Payment,” or SFAS 123R, effective August 1, 2005 and have selected the Black-Scholes method of valuation for share-based compensation. SFAS 123R requires that compensation cost be recorded as earned for all unvested stock options outstanding at the beginning of the first quarter of adoption of SFAS 123R and for all options granted after the date of adoption. The charge is being recognized in research and development and consulting, selling, general and administrative expenses over the remaining service period after the adoption date based on the original estimate of fair value of the options as of the grant date. Using the fair value method required by SFAS 123R, for the years ended December 31, 2007 and 2006, we recorded share-based compensation of $910,000, or $0.02 per share, and $1,179,000, or $0.03 per share. For the five months ended December 31, 2006 and 2005, we recorded share-based compensation of approximately $498,000 or $0.01 per share and $520,000 or $0.01 per share, respectively. For the fiscal year ended July 31, 2006, we recorded share-based compensation expense of approximately $1.2 million or $0.03 per share. Share-based compensation for the year ended December 31, 2007 included a $0.5 million credit relating to the modification and accelerated vesting of stock options issued to our former President and CEO, Dr. Jan Egberts. We will continue to incur share-based compensation charges in future periods. As of December 31, 2007, unamortized stock-based compensation expense of $2.0 million remains to be recognized, which is comprised of $1.2 million related to non-performance based stock options to be recognized over a weighted average period of 1.4 years, $0.1 million related to restricted stock to be recognized over a weighted average period of 1.9 years, and $0.7 million related to performance-based stock options which vest upon reaching certain milestones. Expenses related to the performance-based stock options will be recognized if and when the Company determines that it is probable that the milestone will be reached.

As a result of cashless exercise provisions in our employee stock option agreements, the Company used variable accounting treatment under the Financial Accounting Standards Board’s Interpretation 44, for issued and outstanding stock options from January 2002 through July 2005. On October 20, 2004, the Company’s Board of Directors rescinded the cashless exercise provision for all of the Company’s outstanding option grants. Through July 31, 2005, variable plan accounting continued to be applied for approximately 310,000 outstanding options, for which option exercise prices were modified from the original agreement.

The following table illustrates the pro forma effect on the Company’s net loss and net loss per common share as if the Company had adopted the fair-value-based method of accounting for share-based compensation under SFAS 123 (R) for the fiscal year ended July 31, 2005:

		July 31, 2005	
Net loss – as reported	$	(9,450,000	)
Compensation credit resulting from variable plan accounting		(106,000	)
Total share-based employee compensation expense using the fair value based method for all awards		(854,000	)
Pro forma net loss	$	(10,410,000	)
Basic and diluted net loss per common share:			
As reported	$	(0.27	)
Pro forma net loss		(0.30	)

The fair values of options granted during the fiscal year ended July 31, 2005 were estimated at the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions, respectively: risk-free interest rates of 4.0%, dividend yield of 0.0%, volatility factors of the expected market price of the Company’s common stock of 66%, and an expected life of the options of five to ten years.

RESEARCH AND DEVELOPMENT EXPENSES - Research and development costs are expensed as incurred.

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RESULTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2007 AND DECEMBER 31, 2006 (UNAUDITED)

License fees and milestone fees earned from related parties for the year ended December 31, 2007 were $469,000, as compared to $3.2 million for the unaudited fiscal year ended December 31, 2006. The decrease is primarily due to non-recurring milestone payments received in connection with our license and development agreement with Hana Biosciences in the year ended December 31, 2006.

Consulting revenues from related parties for the year ended December 31, 2007 were $0, as compared to $118,000 for the year ended December 31, 2006. The decrease is due to lower revenue from Velcera for veterinary products. We are not currently performing any development work for Velcera.

Research and development expenses for the year ended December 31, 2007 were $11,940,000 as compared to $6,589,000 for the year ended December 31, 2006. Research and development costs consist primarily of salaries and benefits, contractor and consulting fees, clinical drug supplies of preclinical and clinical development programs, consumable research supplies and allocated facility and administrative costs. Below is a summary of our research and development expenses for the years ended December 31, 2007 and December 31, 2006 (unaudited).

	Fiscal Year Ended December 31, 2007	**December 31, 2006**
		(Unaudited)
NitroMist™	$ 558,000	$ 1,331,000
Zolpidem	5,669,000	1,719,000
Sumatriptan	813,000	394,000
Zensana™	213,000	—
Propofol	—	—
Tizanidine	75,000	161,000
Ropinirole	3,000	58,000
Other research and development costs	1,763,000	1,110,000
Internal costs	2,847,000	1,816,000
Total research and development expenses	$ 11,940,000	$ 6,589,000

In the preceding table, research and development expenses are set forth in the following categories:

- NitroMist™, Zolpidem, Sumatriptan, Tizanidine and Ropinirole - third-party direct project expenses relating to the development of the respective product candidates. The majority of our research and development resources were devoted to our zolpidem and sumatriptan product candidates. During the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. As of the current date, we have not yet secured additional financing, and have therefore not resumed clinical development activity. There can be no assurances that we will be able to secure additional capital, and as a result, there can be no assurances as to whether, and when, we will be able to resume our clinical development activities;

- Zensana™ and Propofol - third-party direct project expenses relating to the development of Zensana™ and our Propofol product candidate. As our partners for the Propofol product candidate, Manhattan Pharmaceuticals, and for Zensana™, Par, are overseeing all clinical development and regulatory approval activities, we do not expect to devote a significant amount of resources to these product candidates. In light of Hana Biosciences' announcements in February 2007 and March 2007 regarding the status of Zensana™, as described above, we devoted resources to this project during the three months ended March 31, 2007, including approximately $204,000 in third-party costs;

- Other research and development costs – direct expenses not attributable to a specific product candidate; and

- Internal costs – costs related primarily to personnel and overhead. We do not allocate these expenses to specific product candidates as these costs relate to all research and development activities.

Research and development expenses in the year ended December 31, 2007 increased primarily as a result of the following items:

- $3,950,000 increase primarily related to product development costs for our Zolpidem product candidate, including costs for clinical trials, manufacturing preparedness and other NDA preparatory costs;
- $419,000 increase primarily related to product development costs for our Sumatriptan product candidate, including costs for clinical trials and manufacturing preparedness;
- $1,031,000 increase in internal costs primarily due to an increase in payroll and other compensation costs as of result of research and development related higher headcount; and
- $773,000 decrease in costs associated with our NitroMist™ product candidate primarily due to process validation and method transfer activities in the year ended December 31, 2006, which did not recur in the year ended December 31, 2007.

General and administrative expenses for the year ended December 31, 2007 were $6,716,000 as compared to $6,955,000 for the year ended December 31, 2006. General and administrative expenses consist primarily of salaries and related expenses for executive, finance, legal and other administrative personnel, recruitment expenses, professional fees and other corporate expenses. The slight decrease in general and administrative expenses is primarily attributable to lower stock compensation charges and a greater proportion of payroll associated with research and development activities, partially offset by higher legal expenses.

Primarily as a result of the factors described above, total expenses for the year ended December 31, 2007 were $18,656,000, as compared to $13,544,000 for the year ended December 31, 2006.

Other Loss, net for the year ended December 31, 2007 is comprised of the following items:

		December 31, 2007	
Other than temporary impairment of investment in marketable equity security	$	(360,000	)
Loss from return of investment in marketable equity security to issuer		(140,000	)
Write-off of deferred revenue relating to investment in marketable equity security		434,000	
Total Other Loss, net	$	(66,000	)

- $360,000 non-cash charge recorded to write-down our investment in Hana Biosciences as we determined that the decline in market value was other than temporary;

- $140,000 non-cash charge to account for the return of Hana Biosciences' shares, as a result of the Amended and Restated License Agreement with Hana Biosciences; and

- $434,000 benefit to write-off the remaining deferred revenue related to the shares received Hana Biosciences.

Interest income for the year ended December 31, 2007 was $632,000, as compared to $337,000 for the year ended December 31, 2006 due to higher average cash and short-term investment balances.

Income tax benefit for the year ended December 31, 2007 was $658,000, as compared to $467,000 for the year ended December 31, 2006. These increased income tax benefits resulted from the sale of our New Jersey Net Operating Losses.

The resulting net loss for the year ended December 31, 2007 was $16,963,000, as compared to $9,460,000 for the year ended December 31, 2006.

FIVE MONTHS ENDED DECEMBER 31, 2006 AND 2005 (UNAUDITED)

License fees and milestone fees earned from related parties for the five months ended December 31, 2006 were $2,067,000, as compared to $568,000 for the unaudited five months ended December 31, 2005. The increase is primarily due to milestone payments received in connection with our license and development agreements for Zensana™ with Hana Biosciences and NitroMist™ with Par Pharmaceuticals.

Consulting revenues from related parties for the five months ended December 31, 2006 were $0 as compared to $109,000 for the five months ended December 31, 2005. The decrease is primarily attributable to lower levels of revenue from Velcera related to veterinary products.

Research and development expenses for the five months ended December 31, 2006 were $3,396,000, as compared to $2,082,000 for the five months ended December 31, 2005. Research and development costs consist primarily of salaries and benefits, contractor and consulting fees, clinical drug supplies of preclinical and clinical development programs, consumable research supplies and allocated facility and administrative costs. Below is a summary of our research and development expenses for the five months ended December 31, 2006 and 2005.

	2006	**2005**
		(Unaudited)
NitroMist™	$ 602,000	$ 355,000
Zolpidem	1,216,000	380,000
Sumatriptan	109,000	118,000
Zensana™	—	221,000
Propofol	—	—
Alprazolam	—	—
Tizanidine	161,000	—
Ropinirole	43,000	—
Other research and development costs	467,000	283,000
Internal costs	798,000	725,000
Total research and development expenses	$ 3,396,000	$ 2,082,000

In the preceding table, research and development expenses are set forth in the following categories:

- NitroMist™, Zolpidem, Sumatriptan, Tizanidine and Ropinirole - third-party direct project expenses relating to the development of the respective product candidates. We expect to devote the majority of our research and development resources to our zolpidem and sumatriptan product candidates and expect that costs associated with these product candidates should increase in future periods;

- Zensana™ and Propofol - third-party direct project expenses relating to the development of Zensana™. As our partners, Hana Biosciences and Manhattan Pharmaceuticals, are overseeing all clinical development and regulatory approval activities for these product candidates, we do not expect to devote a significant amount of resources to these product candidates;

- Alprazolam – third-party direct project expenses relating to the development of our alprazolam oral spray product candidate. We have determined that, in order to devote sufficient resources to other product candidates, it is appropriate to defer further efforts on alprazolam;

- Other research and development costs – direct expenses not attributable to a specific product candidate; and

- Internal costs – costs related primarily to personnel and overhead. We do not allocate these expenses to specific product candidates as these costs relate to all research and development activities.

Research and development expenses in the five months ended December 31, 2006 increased primarily as a result of the following items:

- $247,000 increase related to the establishment of a reserve for certain raw materials and process validation batches for our NitroMist™ product candidate;

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- $836,000 increase primarily related to product development and clinical trial costs for our zolpidem product candidate;

- $161,000 increase primarily related to product development costs for our tizanidine product candidate; and

- $221,000 decrease related to clinical trail material costs for Zensana™ incurred during the five months ended December 31, 2005. Such costs did not recur during the five months ended December 31, 2006.

Consulting, selling, general and administrative expenses for the five months ended December 31, 2006 were $3,123,000 as compared to $3,347,000 for the five months ended December 31, 2005. Consulting, selling, general and administrative expenses consist primarily of salaries and related expenses for executive, finance, legal and other administrative personnel, recruitment expenses, professional fees and other corporate expenses. The decrease in consulting, selling, general and administrative costs is primarily related to lower payroll and other personnel related costs during the period, partially offset by higher costs associated with external consultants.

Total costs and expenses for the five months ended December 31, 2006 were $6,519,000 as compared to $5,429,000 for the five months ended December 31, 2005 primarily due to the increase in research and development expenses, partially offset by the decrease in selling general and administrative expenses noted above.

Interest income for the five months ended December 31, 2006 was $180,000 as compared to $67,000 for the five months ended December 31, 2005 due to higher average cash and short-term investment balances and a general increase in interest rates.

Income tax benefit for the five months ended December 31, 2006 was $467,000 as compared to $256,000 for the five months ended December 31, 2005. These increased income tax benefits resulted from the sale of our New Jersey Net Operating Losses.

The resulting net loss for the five months ended December 31, 2006 was $3,805,000 as compared to $4,429,000 for the five months ended December 31, 2005.

FISCAL YEARS ENDED JULY 31, 2006 AND 2005

License fees and milestone fees earned from related parties for the fiscal year ended July 31, 2006 were $1,622,000, as compared to $141,000 for the fiscal year ended July 31, 2005. The increase is primarily due to milestone payments received in connection with our license and development agreement for ondansetron with Hana Biosciences.

Consulting revenues from related parties for the fiscal year ended July 31, 2006 were $228,000 as compared to $298,000 for the fiscal year ended July 31, 2005. The decrease is primarily attributable to lower levels of revenue from Velcera and Manhattan Pharmaceuticals, related to veterinary products and propofol, respectively.

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Research and development expenses for the fiscal year ended July 31, 2006 were $5,275,000, as compared to $3,826,000 for the fiscal year ended July 31, 2005. Research and development costs consist primarily of salaries and benefits, contractor and consulting fees, clinical drug supplies of preclinical and clinical development programs, consumable research supplies and allocated facility and administrative costs. Below is a summary of our research and development expenses for the fiscal years ended July 31, 2006 and 2005.

	2006	**2005**
NitroMist™	$ 1,084,000	$ 689,000
Zolpidem	883,000	116,000
Sumatriptan	403,000	186,000
Zensana™	221,000	99,000
Propofol	—	—
Alprazolam	—	238,000
Tizanidine	—	—
Ropinirole	15,000	—
Other research and development costs	926,000	385,000
Internal costs	1,743,000	2,113,000
Total research and development expenses	$ 5,275,000	$ 3,826,000

In the preceding table, research and development expenses are set forth in the following categories:

- NitroMist™, Zolpidem, Sumatriptan, Tizanidine and Ropinirole - third-party direct project expenses relating to the development of the respective product candidates. We expect to devote the majority of our research and development resources to our zolpidem and sumatriptan product candidates and expect that costs associated with these product candidates should increase in future periods;

- Zensana™ and Propofol - third-party direct project expenses relating to the development of Zensana™. As our partners, Hana Biosciences and Manhattan Pharmaceuticals, are overseeing all clinical development and regulatory approval activities for these product candidates, we do not expect to devote a significant amount of resources to these product candidates;

- Alprazolam – third-party direct project expenses relating to the development of our alprazolam oral spray product candidate. We have determined that, in order to devote sufficient resources to other product candidates, it is appropriate to defer further efforts on alprazolam;

- Other research and development costs – direct expenses not attributable to a specific product candidate; and

- Internal costs – costs related primarily to personnel and overhead. We do not allocate these expenses to specific product candidates as these costs relate to all research and development activities.

Research and development expenses in the fiscal year ended July 31, 2006 increased primarily as a result of the following items:

- $395,000 increase related to process validation and method transfer activities for our NitroMist™ product candidate;

- $767,000 increase primarily related to product development costs for our zolpidem product candidate;

- $217,000 increase primarily related to product development costs for our sumatriptan product candidate;

- $541,000 increase related to other research and development costs primarily as a result of higher lab supplies expense;

- $238,000 decrease related to our alprazolam product candidate as we have decided to defer further efforts on this product candidate; and

- $370,000 decrease related to internal costs primarily as a result of lower headcount in the fiscal year ended July 31, 2006, as compared to the fiscal year ended July 31, 2005.

Consulting, selling, general and administrative expenses for the fiscal year ended July 31, 2006 were $7,179,000 as compared to $6,391,000 for the fiscal year ended July 31, 2005. Consulting, selling, general and administrative expenses consist primarily of salaries and related expenses for executive, finance, legal and other administrative personnel, recruitment expenses, professional fees and other corporate expenses. The increase in consulting, selling, general and administrative costs is primarily related to the following items:

- $1,038,000 non-cash charge in the fiscal year ended July 31, 2006 for stock-compensation expense;

- $440,000 decrease in outside legal costs; and

- $307,000 decrease attributable to a non-cash charge recorded in the fiscal year ended July 31, 2005 for restricted shares of our common stock awarded to a consultant.

Total costs and expenses for the fiscal year ended July 31, 2006 were $12,454,000 as compared to $10,217,000 for the fiscal year ended July 31, 2005 primarily due to the net increases in research and development and selling general and administrative expenses noted above.

Interest income for the fiscal year ended July 31, 2006 was $224,000 as compared to $87,000 for fiscal year ended July 31, 2005 due to a general increase in interest rates.

Income tax benefit for the fiscal year ended July 31, 2006 was $256,000 as compared to $241,000 for the fiscal year ended July 31, 2005. These benefits resulted from the sale of our New Jersey Net Operating Losses.

The resulting net loss for the fiscal year ended July 31, 2006 was $10,084,000 as compared to $9,450,000 for the fiscal year ended July 31, 2005.

LIQUIDITY AND CAPITAL RESOURCES

From our inception, our principal sources of capital have been consulting revenues, private placements and public offerings of our securities, as well as loans and capital contributions from our principal stockholders. We have had a history of recurring losses, giving rise to an accumulated deficit as of December 31, 2007 of $65,243,000, as compared to $48,280,000 as of December 31, 2006. We have had negative cash flow from operating activities of $15,240,000 for the year ended December 31, 2007, $1,782,000 for the five-months ended December 31, 2006, $8,855,000 for the fiscal year ended July 31, 2006, and $6,258,000 for the fiscal year ended July 31, 2005. As of December 31, 2007, we had working capital of $3,811,000, as compared to $18,686,000 as of December 31, 2006, representing a net decrease in working capital of approximately $14,875,000. As explained further below, such decrease is primarily attributable to a net decrease in cash, short-term investments and investment in marketable equity security and an increase in accounts payable.

Net cash used in operating activities was $15,240,000 for the year ended December 31, 2007, as compared to $6,764,000 for the year ended December 31, 2006. The $8,476,000 increase is primarily due to the following:

- $7,503,000 increase in net loss in the year ended December 31, 2007 compared with the year ended December 31, 2006. As more fully described above, the increase in the net loss is primarily due to a decrease in revenues and an increase in total expenses;

- $628,000 decrease in deferred revenue for the year ended December 31, 2007, as compared to a $162,000 decrease for the year ended December 31, 2006. Such fluctuation is attributable to the write-off and recognition in the statement of operations of deferred revenue associated with the Hana Biosciences' shares and upfront license payments from Par during the fiscal year ended December 30, 2007;

- $574,000 increase in prepaid expenses and other current assets for the year ended December 31, 2007, as compared to a $66,000 increase for the year ended December 31, 2006. Such fluctuation is attributable to an increase in prepaid supplies associated with increased clinical and manufacturing activities for our key products, zolpidem and sumatriptan; and

- $500,000 non-cash charge in the year ended December 31, 2007 related to the write-down and subsequent return to issuer of an investment in Hana Biosciences, offset by a $551,000 non-cash charge in the year ended December 31, 2006 for an increase to the reserve for inventory.

Net cash provided by investing activities was approximately $3,612,000 for the year ended December 31, 2007, as compared to $2,710,000 used in investing activities for the year ended December 31, 2006. The difference is primarily a result of higher net maturities of short-term investments in the year ended December 31, 2007.

Cash provided by financing activities was approximately $1,426,000 for the year ended December 31, 2007, as compared to $22,821,000 for the year ended December 31, 2006. The $21,395,000 decrease is primarily attributable to the year ended December 31, 2006 including $22,342,000 of net proceeds from private placements we completed in April 2006 and December 2006, as compared to the year ended December 31, 2007 including the remaining $1,395,000 of net proceeds received in January 2007 from the private placement we completed in December 2006.

Until and unless our operations generate significant revenues and cash flow, we will attempt to continue to fund operations from cash on hand and through the sources of capital described below. Our long-term liquidity is contingent upon achieving sales and positive cash flows from operating activities, and/or obtaining additional financing. The most likely sources of financing include private placements of our equity or debt securities or bridge loans to us from third-party lenders, license payments from current and future partners, and royalty payments from sales of approved drugs by partners. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. On December 27, 2006, we completed a private placement of our common stock and warrants to purchase shares of common stock in which we received gross proceeds of $14.2 million and approximate net proceeds of $13.1 million, of which $11.7 million was received in December 2006 and $1.4 million was received in January 2007.

During the fourth quarter 2007, we significantly reduced clinical development activities on our product candidate pipeline, as we did not believe that we had sufficient cash to sustain such activities. Despite this reduction in expenditures for clinical activities, we require capital to sustain our existing organization until such time as clinical activities can be resumed. Given the current level of spending, we estimate that we will have sufficient cash on hand to fund operations through the middle of the second calendar quarter, 2008. Funding for the Company’s future development activities could be secured through new strategic partnerships and/or the sale of our common stock or other securities. There can be no assurance that such capital will be available to us in a timely manner or on favorable terms, if at all. There are a number of risks and uncertainties related to our attempt to complete a financing or strategic partnering arrangement that are outside our control. We may not be able to obtain additional financing on terms acceptable to us, or at all. If we are unsuccessful at obtaining additional financing as needed, we may be required to significantly curtail or cease operations. We will need additional financing thereafter until we achieve profitability, if ever.

Our audited financial statements for the fiscal year ended December 31, 2007, were prepared under the assumption that we will continue our operations as a going concern. We were incorporated in 1982, and do not have a history of earnings. As a result, our independent registered public accounting firm in their audit report has expressed substantial doubt about our ability to continue as a going concern. Continued operations are dependent on our ability to complete equity or debt formation activities or to generate profitable operations. Such capital formation activities may not be available or may not be available on reasonable terms. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in the Company.

OFF-BALANCE SHEET ARRANGEMENTS

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, results of operations, liquidity or capital resources.

CONTRACTUAL OBLIGATIONS

The following table sets forth our aggregate contractual cash obligations as of December 31, 2007.

	Payments Due By Period				
	Total	**<1 year**	**1-3 years**	**3-5 years**	**5 years +**
Capital leases	$ 312,000	$ 164,000	$ 144,000	$ 4,000	$ —
Operating leases	2,049,000	343,000	732,000	731,000	243,000
Consulting agreement	223,000	223,000	—	—	—
Employment agreements	1,417,000	824,000	593,000	—	—
Total contractual cash obligations	$ 4,001,000	$ 1,554,000	$ 1,469,000	$ 735,000	$ 243,000

We expect to continue to incur substantial additional operating losses from costs related to the continued development of our product candidates, clinical trials, and administrative activities. For a full discussion of risks and uncertainties regarding our need for additional financing, see Item 1A. “Risk Factors-We will Require Significant Capital for Product Development and Commercialization.”

On September 13, 2007, in connection with his resignation, Dr. Egberts and the Company entered into a Separation, Consulting and General Release Agreement (the “Agreement”). Under the terms of the Agreement, Dr. Egberts will provide the Company with certain consulting services, not to exceed forty (40) hours in any calendar month, for a period of twelve (12) months, ending July 25, 2008 (the “Term”). Dr. Egberts shall receive fees for such services at a rate of $363,000 per annum, payable in equal bi-weekly installments during the Term. In addition, options previously granted to Dr. Egberts which were outstanding as of July 25, 2007 but not otherwise vested and exercisable, immediately vested and became exercisable under the Agreement and shall remain outstanding until the expiration of the Term. The Agreement contains customary provisions concerning confidentiality and non-competition.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We invest primarily in short-term, highly-rated investments, including U.S. government securities and certificates of deposit guaranteed by banks. Our market risk exposure consists principally of exposure to changes in interest rates. Because of the short-term maturities of our investments, however, we do not believe that a decrease in interest rates would have a significant negative impact on the value of our investment portfolio.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The financial statements required by this Item are included as a separate section of this report commencing on page F-1.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A(T). CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures or controls and other procedures that are designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, or Exchange Act, is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's, or SEC, rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports that a company files or submits under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

We carried out an evaluation, under the supervision and with the participation of our Chief Executive and Chief Financial Officers, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act) as of December 31, 2007. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that as of December 31, 2007, our disclosure controls and procedures were effective at providing reasonable assurance that the information required to be disclosed by us in reports filed under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms; and (ii) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding disclosure.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act and is a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel, 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 and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of the company's internal control over financial reporting as of December 31, 2007. In making this assessment, the company's management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework.*

Based on its evaluation, our management has concluded that, as of December 31, 2007, our internal control over financial reporting was effective. This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report.

Changes in Internal Controls over Financial Reporting

During the fourth quarter 2007, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(e) and Rule 15d-15(f) under the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Certain of the information required to be disclosed by this Item with respect to our executive officers is set forth under the caption “Executive Officers and Directors” contained in Part I, Item 1 of this Annual Report on Form 10-K.

Certain information required to be disclosed by this Item about our board of directors is incorporated in this Annual Report on Form 10-K by reference from the section entitled “Election of Directors,” and “Board of Directors and Committees” contained in our definitive proxy statement for our annual meeting of stockholders scheduled to be held in June 2008, which we intend to file within 120 days of the end of our fiscal year (December 31, 2007).

Information required to be disclosed by this Item about the Section 16(a) compliance of our directors and executive officers is incorporated in this Annual Report on Form 10-K by reference from the section entitled “Section 16(a) Beneficial Ownership Reporting Compliance” contained in our definitive proxy statement for our annual meeting of stockholders scheduled to be held in June 2008, which we intend to file within 120 days of the end of our fiscal year (December 31, 2007).

Information required to be disclosed by this Item about our board of directors, the audit committee of our board of directors, our audit committee financial expert, our Business Conduct Policy, and other corporate governance matters is incorporated in this Annual Report on Form 10-K by reference from the section entitled “Meetings and Committees of our Board” contained in our definitive proxy statement related to our annual meeting of stockholders scheduled to be held in June 2008, which we intend to file within 120 days of the end of our fiscal year (December 31, 2007).

The text of our Business Conduct Policy, which applies to all of our directors, officers and employees is posted in the “Corporate Governance” section of our website, www.novadel.com. A copy of the Business Conduct Policy can be obtained free of charge on our website or can be obtained and will be provided to any person without charge upon written request to our Corporate Secretary at our executive offices, 25 Minneakoning Road, Flemington, New Jersey 08822. We intend to disclose on our website any amendments to, or waivers from, our Business Conduct Policy that are required to be disclosed pursuant to the rules of the Securities and Exchange Commission and American Stock Exchange.

ITEM 11. EXECUTIVE COMPENSATION.

Incorporated by reference to “Compensation Discussion and Analysis,” “Compensation Committee Report,” “Summary Compensation Table,” “Grants of Plan-Based Awards,” “Outstanding Equity Awards,” “Option Exercises and Stock Vested,” “Potential Payments Upon Termination” and “Directors Compensation” and “Compensation Committee Interlocks and Insider Participants” contained in our definitive proxy statement related to our annual meeting of stockholders scheduled to be held in June 2008, which we intend to file within 120 days of the end of our fiscal year (December 31, 2007).

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

Incorporated by reference to “Stock Ownership of Directors, Management and Certain Beneficial Owners” contained in our definitive proxy statement related to our annual meeting of stockholders scheduled to be held in June 2008, which we intend to file within 120 days of the end of our fiscal year (December 31, 2007).

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE.

Incorporated by reference to “Certain Relationships and Related Transactions” and “Independence of Directors” contained in our definitive proxy statement related to our annual meeting of stockholders scheduled to be held in June 2008, which we intend to file within 120 days of the end of our fiscal year (December 31, 2007).

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

Incorporated by reference to "Independent Registered Public Accounting Firm's Fee Summary" contained in our definitive proxy statement related to our annual meeting of stockholders scheduled to be held in June 2008, which we intend to file within 120 days of the end of our fiscal year (December 31, 2007).

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

(a) Financial Statements and Schedules:

1. Financial Statements

The following financial statements and report of independent registered public accounting firm are included herein:

2. Financial Statement Schedules

Not applicable.

3. List of Exhibits

INDEX TO EXHIBITS

The following exhibits are included with this Annual Report on Form 10-K. All management contracts or compensatory plans or arrangements are marked with an asterisk.

EXHIBIT NO.	DESCRIPTION	METHOD OF FILING
3.1	Restated Certificate of Incorporation of the Company	Incorporated by reference to Exhibit 3.1 of the Company’s Quarterly Report on Form 10-QSB, as filed with the SEC on June 14, 2004
3.2	Certificate of Amendment to the Certificate of Incorporation of the Company	Incorporated by reference to Exhibit 3.1 of the Company’s Annual Report on Form 10-K, as filed with the SEC on March 26, 2007
3.3	Amended and Restated By-laws of the Company	Incorporated by reference to Exhibit 3.1 of the Company’s Form 8-K, as filed with the SEC on September 9, 2005
4.1	Form of Class C Warrant for the Purchase of Shares of Common Stock	Incorporated by reference to Exhibit 4.1 to the Company’s Current Report on Form 8-K, as filed with the SEC on January 12, 2004
4.2	Form of Warrant issued to certain accredited investors and placement agents	Incorporated by reference to Exhibit 4.1 of the Company’s Form 8-K, as filed with the SEC on April 17, 2006
4.3	Form of Warrant issued to certain accredited investors and the placement agent	Incorporated by reference to Exhibit 4.1 of the Company’s Current Report on Form 8-K filed with the SEC on January 4, 2007
10.1*	1992 Stock Option Plan	Incorporated by reference to the Company’s Registration Statement on Form SB-2, as filed with the SEC on August 8, 1997 (File No. 333-33201)
10.2*	Form of Incentive Stock Option Agreement under the 1992 Stock Option Plan	Incorporated by reference to the Company’s Registration Statement on Form SB-2, as filed with the SEC on August 8, 1997 (File No. 333-33201)
10.3*	1997 Stock Option Plan	Incorporated by reference to Exhibit 10.8 to the Company’s Registration Statement on Form SB-2, as filed with the SEC on August 8, 1997 (File No. 333-33201)
10.4*	Form of Non-Qualified Option Agreement under the 1997 Stock Option Plan	Incorporated by reference to the Company’s Registration Statement on Form SB-2, as filed with the SEC on August 8, 1997 (File No. 333-33201)
10.5*	1998 Stock Option Plan	Incorporated by reference to Exhibit 4.1 to the Company’s Registration Statement on Form S-8, as filed with the SEC on June 18, 2004 (File No. 333-116665)
10.6*	Form of Stock Option Agreement under the 1998 Stock Option Plan	Incorporated by reference to Exhibit 4.2 to the Company’s Registration Statement on Form S-8, as

		filed with the SEC on June 18, 2004 (File No. 333-116665)
10.7*	Form of Non-Qualified Stock Option Agreement	Incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-8, as filed with the SEC on June 18, 2004 (File No. 333-116665)

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10.8	Common Stock and Warrant Purchase Agreement, dated December 12, 2001, by and among the Company and certain purchasers	Incorporated by reference to Exhibit A to the Schedule 13D as filed by Lindsay A. Rosenwald with the SEC on December 21, 2001
10.9	Amendment No. 1, dated January 6, 2002, to the Common Stock and Warrant Purchase Agreement dated December 12, 2001 between the Company and certain purchasers	Incorporated by reference to Exhibit 10.25 to the Company's Registration Statement of Form SB-2, as filed with the SEC on April 15, 2002 (File No. 333-86262)
10.10	Lease Agreement, dated March 19, 2003, by and between the Company and Macedo Business Park, II, L.L.C.	Incorporated by reference to Exhibit 10.28 to the Company's Quarterly Report on Form 10-QSB for the period ended April 30, 2003, as filed with the SEC on June 19, 2003
10.11	Amendment Number 1 to Lease Agreement dated March 19, 2003 between Macedo Business Park, II, L.L.C. and the Company, dated as of March 19, 2003	Incorporated by reference to Exhibit 10.29 to the Company's Quarterly Report on Form 10-QSB for the period ended April 30, 2003, as filed with the SEC on June 19, 2003
10.12	License and Development Agreement, effective as of April 4, 2003, by and between the Company and Manhattan Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-KSB, as filed with the SEC on March 11, 2004
10.13	Development, Manufacturing and Supply Agreement, dated July 28, 2004, by and between the Company and Par Pharmaceutical, Inc.	Incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-KSB, as filed with the SEC on November 15, 2004
10.14	Second Amendment to License and Development Agreement, dated as of June 22, 2004, by and between the Company and the Veterinary Company, Inc.	Incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-KSB, as filed with the SEC on November 15, 2004
10.15*	Employment Agreement, dated as of May 23, 2003, by and between the Company and Barry Cohen	Incorporated by reference to Exhibit 10.30 to the Company's Quarterly Report on Form 10-QSB for the period ending April 30, 2003, as filed with the SEC on June 19, 2003
10.16*	Disclosure and Release Agreement Related to the Exchange of Non-Plan Options for Stock Options under the NovaDel Pharma Inc. 1998 Stock Option Plan by and between the Company and Thomas E. Bonney	Incorporated by reference to Exhibit 10.3 of the Company's Form 8-K, as filed with the SEC on August 2, 2005
10.17*	Disclosure and Release Agreement Related to the Exchange of Non-Plan Options for Stock Options under the NovaDel Pharma Inc. 1998 Stock Option Plan by and between the Company and William F. Hamilton	Incorporated by reference to Exhibit 10.2 of the Company's Form 8-K, as filed with the SEC on August 2, 2005
10.18*	Disclosure and Release Agreement Related to the Exchange of Non-Plan Options for Stock Options under the NovaDel Pharma Inc. 1998 Stock Option Plan by and between the Company and Charles Nemeroff	Incorporated by reference to Exhibit 10.4 of the Company's Form 8-K, as filed with the SEC on August 2, 2005
10.19*	Employment Agreement, dated as of December 20, 2004, by and between the Company and Michael Spicer	Incorporated by reference to Exhibit 10.35 of the Company's Form 8-K, as filed with the SEC on December 23, 2004
10.20*		

	Amendment to Employment Agreement dated September 2, 2005, by and between the Company and Michael E.B. Spicer	Incorporated by reference to Exhibit 10.2 of the Company's Form 8-K, as filed with the SEC on September 9, 2005
10.21*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated July 28, 2005, by and between the Company and Thomas E. Bonney	Incorporated by reference to Exhibit 10.25 of the Company's Annual Report on Form 10-KSB for the period ended July 31, 2005, as filed with the SEC on October 31, 2005

10.22*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated July 28, 2005, by and between the Company and William F. Hamilton	Incorporated by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-KSB for the period ended July 31, 2005, as filed with the SEC on October 31, 2005
10.23*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated July 28, 2005, by and between the Company and Charles Nemeroff	Incorporated by reference to Exhibit 10.29 of the Company's Annual Report on Form 10-KSB for the period ended July 31, 2005, as filed with the SEC on October 31, 2005
10.24	Amendment No. 1 to License and Development Agreement dated as of August 8, 2005, by and between the Company and Hana Biosciences Inc.	Incorporated by reference to Exhibit 99.1 of the Company's Form 8-K, as filed with the SEC on August 12, 2005
10.25	Separation, Consulting and General Release Agreement effective as of July 25, 2007, by and between NovaDel Pharma Inc. and Jan H. Egberts, M.D.	Incorporated by reference to Exhibit 10.1 of the Company's Form 8-K, as filed with the SEC on September 20, 2007
10.26*	Nonqualified Stock Option Agreement dated September 26, 2005, by and between the Company and Jan H. Egberts, M.D.	Incorporated by reference to Exhibit 10.2 of the Company's Form 8-K, as filed with the SEC on September 28, 2005
10.27*	NovaDel Pharma Inc. 2006 Equity Incentive Plan	Incorporated by reference to Exhibit 10.1 of the Company's Form 8-K, as filed with the SEC on January 23, 2006
10.28*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated December 14, 2005, by and between the Company and J. Jay Lobell	Incorporated by reference to Exhibit 10.4 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006
10.29*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and Thomas Bonney	Incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006
10.30*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and William Hamilton	Incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006
10.31*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and Charles Nemeroff	Incorporated by reference to Exhibit 10.5 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006
10.32*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and Steven Ratoff	Incorporated by reference to Exhibit 10.6 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006
10.33	Form of Securities Purchase Agreement by and between the Company and certain accredited investors (with attached schedule of parties and terms thereto)	Incorporated by reference to Exhibit 10.1 of the Company's Form 8-K, as filed with the SEC on April 17, 2006
10.34	Registration Rights Agreement by and between the Company and certain accredited investors (with attached schedule of parties and terms thereto)	Incorporated by reference to Exhibit 10.2 of the Company's Form 8-K, as filed with the SEC on April 17, 2006
10.35		

Placement Agent Agreement, dated March 15, 2006, by and between the Company, Griffin Securities, Inc. and Paramount BioCapital, Inc.	Incorporated by reference to Exhibit 10.1 of the Company's Form 8-K, as filed with the SEC on April 20, 2006

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10.36*	Employment Agreement dated December 4, 2006 by and between the Company and David H. Bergstrom, Ph.D.	Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, as filed with the SEC on December 8, 2006
10.37*	Incentive Stock Option Award between the Company and David H. Bergstrom dated December 4, 2006	Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, as filed with the SEC on December 8, 2006
10.38*	Nonqualified Stock Option Award between the Company and David H. Bergstrom, dated December 4, 2006	Incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K, as filed with the SEC on December 8, 2006
10.39	Securities Purchase Agreement by and between the Company and certain accredited investors (with attached schedule of parties and terms thereto)	Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, as filed with the SEC on January 4, 2007
10.40	Placement Agent Agreement, dated as of November 21, 2006, by and between the Company and Oppenheimer & Co., Inc.	Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, as filed with the SEC on January 4, 2007
10.41*	Employment Agreement dated February 22, 2007 by and between the Company and Deni M. Zodda, Ph.D.	Incorporated by reference to Exhibit 10.1 of the Company's Current Report on form 8-K, as filed with the SEC on February 28, 2007
10.42*	Incentive Stock Option Award between the Company and Deni M. Zodda dated February 22, 2007	Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, as filed with the SEC on February 28, 2007
10.43*	Nonqualified Stock Option Award between the Company and Deni M. Zodda dated February 22, 2007	Incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K, as filed with the SEC on February 28, 2007
10.44*	Amendment No. 2 to Employment Agreement dated March 12, 2007 by and between the Company and Michael E. Spicer	Incorporated by reference to Exhibit 10.44 of the Company's Annual Report on Form 10-K, as filed with the SEC on March 26, 2007
10.45*	Amendment 2007-1 to the NovaDel Pharma Inc. 1998 Stock Option Plan dated March 2, 2007	Incorporated by reference to Exhibit 10.45 of the Company's Annual Report on Form 10-K, as filed with the SEC on March 26, 2007
10.46*	Amendment 2007-1 to the NovaDel Pharma Inc. 2006 Equity Incentive Plan dated March 2, 2007	Incorporated by reference to Exhibit 10.46 of the Company's Annual Report on Form 10-K, as filed with the SEC on March 26, 2007
10.47	Amended and Restated License and Development Agreement, dated as of July 31, 2007, by and between NovaDel Pharma Inc. and HANA Biosciences, Inc.	Incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on November 14, 2007.
10.48	Product Development and Commercialization Sublicense Agreement, dated as of July 31, 2007, by and among NovaDel Pharma Inc., HANA Biosciences and PAR Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q, as filed with SEC on November 14, 2007.
10.49	Termination Agreement, dated as of July 31, 2007, by and between NovaDel Pharma Inc. and PAR Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on November 14, 2007.

10.50*	Employment Agreement dated January 22, 2008, by and between the Company and Michael E. Spicer.	Filed herewith
21.1	Subsidiaries of the Registrant	The registrant has no subsidiaries
23.1	Consent of J.H. Cohn LLP	Filed herewith
31.1	Certification of Chief Executive Officer under Rule 13a-14(a)	Furnished herewith

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31.2	Certification of Principal Financial Officer under Rule 13a-14(a)	Furnished herewith
32.1	Certifications of the Chief Executive Officer and Chief Financial Officer under 18 USC 1350	Furnished herewith

(b) Exhibits.
See Item 15(a)(3) above.

(c) Financial Statement Schedules.
See Item 15(a)(2) above.

SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NovaDel Pharma Inc.

Date: March 31, 2008	By:	/s/ STEVEN B. RATOFF Steven B. Ratoff Chairman, Interim President and Chief Executive Officer

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In accordance with the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

SIGNATURES	TITLE	DATE
/s/ STEVEN B. RATOFF Steven B. Ratoff	Chairman, Interim President and Chief Executive Officer (Principal Executive Officer)	March 31, 2008
/S/ MICHAEL E. SPICER Michael E. Spicer	Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2008
/S/ MARK J. BARIC Mark J. Baric	Director	March 31, 2008
/S/ THOMAS E. BONNEY Thomas E. Bonney	Director	March 31, 2008
/S/ WILLIAM F. HAMILTON William F. Hamilton, Ph.D.	Director	March 31, 2008
/S/ J. JAY LOBELL J. Jay Lobell	Director	March 31, 2008
/S/ CHARLES NEMEROFF Charles Nemeroff	Director	March 31, 2008

INDEX TO FINANCIAL STATEMENTS

The following financial statements are included in Part II, Item 8:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Stockholders and

Board of Directors

NovaDel Pharma Inc.

We have audited the accompanying balance sheets of NovaDel Pharma Inc. as of December 31, 2007 and December 31, 2006, and the related statements of operations, changes in stockholders' equity and cash flows for the year ended December 31, 2007, the five months ended December 31, 2006 and for the fiscal years ended July 31, 2006 and 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of NovaDel Pharma Inc. as of December 31, 2007 and December 31, 2006, and its results of operations and cash flows for the year ended December 31, 2007, the five months ended December 31, 2006 and for the fiscal years ended July 31, 2006 and 2005, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations and negative cash flows from operating activities that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As discussed in Note 3 to the financial statements, the Company changed the manner in which it accounts for share-based compensation in the fiscal year ended July 31, 2006.

/s/ J.H. COHN LLP

Roseland, New Jersey

March 28, 2008

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NOVADEL PHARMA INC.

BALANCE SHEETS

AS OF DECEMBER 31, 2007 and DECEMBER 31, 2006

ASSETS	December 31, 2007	December 31, 2006
Current Assets:		
Cash and cash equivalents	$ 6,384,000	$ 16,586,000
Short-term investments	—	3,690,000
Investment in marketable equity security available for sale	—	466,000
Assets held for sale	492,000	518,000
Prepaid expenses and other current assets	1,146,000	572,000
Total Current Assets	8,022,000	21,832,000
Property and equipment, net	1,972,000	2,125,000
Other assets	369,000	359,000
TOTAL ASSETS	$ 10,363,000	$ 24,316,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	1,632,000	798,000
Accrued expenses and other current liabilities	2,267,000	2,061,000
Current portion of deferred revenue	148,000	162,000
Current portion of capitalized lease obligation	164,000	125,000
Total Current Liabilities	4,211,000	3,146,000
Non-current portion of deferred revenue	1,830,000	2,444,000
Non-current portion of capitalized lease obligation	148,000	128,000
Total Liabilities	6,189,000	5,718,000
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Preferred stock, $.001 par value:		
Authorized 1,000,000 shares, none issued	—	—
Common stock, $.001 par value:		
Authorized 200,000,000 shares, Issued 59,592,260 and 58,358,818 at December 31, 2007 and December 31, 2006, respectively	59,000	58,000
Additional paid-in capital	69,364,000	66,860,000
Accumulated deficit	(65,243,000)	(48,280,000)
Accumulated other comprehensive income (loss)	—	(34,000)
Less: Treasury stock, at cost, 3,012 shares	(6,000)	(6,000)
Total Stockholders' Equity	4,174,000	18,598,000
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 10,363,000	$ 24,316,000

See accompanying notes to financial statements.

NOVADEL PHARMA INC.

STATEMENTS OF OPERATIONS

FOR THE YEAR ENDED DECEMBER 31, 2007, THE FIVE MONTHS ENDED DECEMBER 31, 2006, AND THE FISCAL YEARS ENDED JULY 31, 2006 AND 2005

	Year Ended December 31, 2007	2006 (unaudited)	Five Months Ended December 31, 2006	2005 (unaudited)	Year Ended July 31, 2006	2005
License Fees and Milestone Payments Earned from Related Parties	$ 469,000	$ 3,162,000	$ 2,067,000	$ 568,000	$1,662,000	$ 141,000
Consulting Revenues from Related Parties	—	118,000	—	109,000	228,000	298,000
Total Revenues	469,000	3,280,000	2,067,000	677,000	1,890,000	439,000
Research and Development Expenses	11,940,000	6,589,000	3,396,000	2,082,000	5,275,000	3,826,000
Consulting, Selling, General and Administrative Expenses	6,716,000	6,955,000	3,123,000	3,347,000	7,179,000	6,391,000
Total Expenses	18,656,000	13,544,000	6,519,000	5,429,000	12,454,000	10,217,000
Loss From Operations	(18,187,000)	(10,264,000)	(4,452,000)	(4,752,000)	(10,564,000)	(9,778,000)
Other Loss, net	(66,000)	—	—	—	—	—
Interest Income	632,000	337,000	180,000	67,000	224,000	87,000
Loss Before Income Tax Benefit	(17,621,000)	(9,927,000)	(4,272,000)	(4,685,000)	(10,340,000)	(9,691,000)
Income Tax Benefit	(658,000)	(467,000)	(467,000)	(256,000)	(256,000)	(241,000)
Net Loss	$ (16,963,000)	$ (9,460,000)	$ (3,805,000)	$ (4,429,000)	$(10,084,000)	$ (9,450,000)
Basic and Diluted Loss Per Common Share	$ (.29)	$ (.20)	$ (.08	$ (.11	$(.23)	$ (.27)

				)	)	
Weighted Average Number of Common Shares Used in Computation of Basic and Diluted Loss Per Common Share	59,497,000	46,732,000	49,522,000	40,619,000	43,000,000	34,808,000

See accompanying notes to financial statements.

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NOVADEL PHARMA INC.

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

FOR THE YEAR ENDED DECEMBER 31, 2007, THE FIVE MONTHS ENDED DECEMBER 31, 2006, AND THE FISCAL YEARS ENDED JULY 31, 2006 AND 2005

	Common Stock						
	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Treasury Stock	Total Stockholders' Equity
BALANCE, August 1, 2004	33,091,437	$ 33,000	$ 34,937,000	$ (24,941,000)	$ —	$ (6,000)	$ 10,023,000
Stock issued in connection with private placements, net of costs	6,733,024	7,000	6,302,000	—	—	—	6,309,000
Stock issued Hana Biosciences Inc. per license agreement	400,000	—	636,000	—	—	—	636,000
Stock issued for options and warrants exercised	172,857	—	219,000	—	—	—	219,000
Stock issued for services	200,000	1,000	306,000	—	—	—	306,000
Warrants issued for services	—	—	11,000	—	—	—	11,000
Impact of variable plan accounting	—	—	(106,000)	—	—	—	(106,000)
Net Loss	—	—	—	(9,450,000)	—	—	(9,450,000)
BALANCE, July 31, 2005	40,597,318	41,000	42,305,000	(34,391,000)	—	(6,000)	7,949,000
Share-based compensation expense	—	—	1,201,000	—	—	—	1,201,000
Stock issued in connection with private placements, net of costs	8,092,796	8,000	10,585,000	—	—	—	10,593,000
Stock issued for options and warrants exercised	433,755	—	326,000	—	—	—	326,000
Comprehensive income (loss):							
Unrealized gain on investment	—	—	—	—	60,000	—	60,000
Net loss	—	—	—	(10,084,000)	—	—	(10,084,000)
Total comprehensive loss	—	—	—	—	—	—	(10,024,000)
BALANCE, July 31, 2006	49,123,869	49,000	54,417,000	(44,475,000)	60,000	(6,000)	10,045,000
Share-based compensation expense	100,000	—	498,000	—	—	—	498,000
Stock issued in connection with private placement, net of costs	8,862,069	9,000	11,740,000	—	—	—	11,749,000
Stock issued for options and warrants exercised	272,880	—	205,000	—	—	—	205,000
Comprehensive income (loss):							
Unrealized loss on investment in marketable equity security	—	—	—	—	(94,000)	—	(94,000)
Net loss	—	—	—	(3,805,000)	—	—	(3,805,000)
Total comprehensive loss	—	—	—	—	—	—	(3,899,000)
BALANCE, December 31, 2006	58,358,818	58,000	66,860,000	(48,280,000)	(34,000)	(6,000)	18,598,000

Share-based compensation expense	—	—	910,000	—	—	—	910,000
Stock issued in connection with private placement, net of costs	961,914	1,000	1,394,000	—	—	—	1,395,000
Stock issued for options and warrants exercised	271,528	—	200,000	—	—	—	200,000
Reclassification of unrealized loss on investment in marketable security to realized loss	—	—	—	—	34,000	—	34,000
Net loss	—	—	—	(16,963,000)	—	—	(16,963,000)
BALANCE, December 31, 2007	59,592,260	$ 59,000	$ 69,364,000	$ (65,243,000)	$ —	$ (6,000)	$ 4,174,000

See accompanying notes to financial statements.

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NOVADEL PHARMA INC.

STATEMENTS OF CASH FLOWS

FOR THE YEAR ENDED DECEMBER 31, 2007, THE FIVE MONTHS ENDED DECEMBER 31, 2006, AND THE FISCAL YEARS ENDED JULY 31, 2006 AND 2005

	Year Ended December 31,		Five Months Ended December 31,		Year Ended July 31,	
	2007	2006	2006	2005	2006	2005
CASH FLOWS FROM OPERATING ACTIVITIES		(unaudited)		(unaudited)		
Net loss	$ (16,963,000)	$ (9,460,000)	$ (3,805,000)	$ (4,429,000)	$ (10,084,000)	$ (9,450,000)
Adjustments to reconcile net loss to net cash used in operating activities:						
Stock and warrants issued for services	—	—	—	—	—	318,000
Amortization of discount on short-term investments	(101,000)	(53,000)	(53,000)	—	—	—
Share-based compensation expense	910,000	1,179,000	498,000	520,000	1,201,000	—
Impact of variable plan accounting	—			—	—	(106,000)
Loss from return of investment in marketable security available for sale to issuer	140,000	—	—	—	—	—
Other than temporary impairment of investment in marketable equity security available for sale	360,000	—	—	—	—	—
Inventory reserve	—	551,000	551,000	—	55,000	—
Depreciation and amortization	685,000	667,000	286,000	202,000	583,000	380,000
Changes in operating assets and liabilities:						
Accounts receivable from related parties	—	76,000	—	32,000	108,000	22,000
Inventories	(99,000)	(40,000)	2,000	6,000	(91,000)	(549,000)
Prepaid expenses and other current assets	(574,000)	(66,000)	(81,000)	(200,000)	(185,000)	(51,000)
Other assets	(10,000)	(8,000)	(15,000)	—	7,000	—
Accounts payable	834,000	340,000	(47,000)	(721,000)	(334,000)	938,000
Accrued expenses and other current liabilities	206,000	212,000	950,000	785,000	47,000	266,000
Deferred revenue	(628,000)	(162,000)	(68,000)	(68,000)	(162,000)	1,974,000
Net cash used in operating activities	(15,240,000)	(6,764,000)	(1,782,000)	(3,873,000)	(8,855,000)	(6,258,000)
CASH FLOWS FROM INVESTING ACTIVITIES:						
Purchases of property and equipment	(179,000)	(68,000)	(54,000)	(116,000)	(130,000)	(2,305,000)
Purchases of short-term and long-term investments	(9,737,000)	(5,761,000)	(1,310,000)	1,300,000)	(5,751,000)	(5,180,000)
Maturities of short-term and long-term investments	13,528,000	3,119,000	2,124,000	3,848,000	4,843,000	9,155,000
Net cash provided by (used in) investing activities	3,612,000	(2,710,000)	760,000	2,432,000	(1,038,000)	1,670,000

CASH FLOWS FROM FINANCING ACTIVITIES:						
Proceeds from issuance of common stock through private placements	1,395,000	22,342,000	11,749,000	—	10,593,000	6,309,000
Proceeds from options and warrants exercised	200,000	531,000	205,000	—	326,000	219,000
Proceeds from shares of common stock issued to Hana Biosciences, Inc.	—	—	—	—	—	636,000
Payments of capitalized lease obligations	(169,000)	(52,000)	(33,000)	—	(19,000)	(62,000)
Net cash provided by financing activities	1,426,000	22,821,000	11,921,000	—	10,900,000	7,102,000
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(10,202,000)	13,347,000	10,899,000	(1,441,000)	1,007,000	2,514,000
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	16,586,000	3,239,000	5,687,000	4,680,000	4,680,000	2,166,000
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 6,384,000	$ 16,586,000	$ 16,586,000	$ 3,239,000	$ 5,687,000	$ 4,680,000
SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES:						
Investment in Hana Biosciences, Inc. common stock received in connection with license agreement	$ —	$ —	$ —	$ —	$ —	$ 500,000
Equipment acquired under capitalized lease obligation	$ 228,000	$ 305,000	$ 139,000	$ —	$ 166,000	$ —

See accompanying notes to financial statements.

NOVADEL PHARMA INC.

NOTES TO FINANCIAL STATEMENTS

NOTE 1 - NATURE OF THE BUSINESS

NovaDel Pharma Inc. (the “Company”) is a specialty pharmaceutical company developing oral spray formulations of a broad range of marketed pharmaceuticals. The Company’s proprietary technology offers, in comparison to conventional oral dosage forms, the potential for faster absorption of drugs into the bloodstream leading to quicker onset of therapeutic effects and possibly reduced first pass liver metabolism, which may result in lower doses. Oral sprays eliminate the requirement for water or the need to swallow, potentially improving patient convenience and compliance. The Company’s oral spray technology is focused on addressing unmet medical needs for a broad array of existing and future pharmaceutical products, with the most advanced oral spray candidates target angina, nausea, insomnia, migraine headaches and disorders of the central nervous system.

Through December 31, 2006, the Company has entered into strategic license agreements with (i) Hana Biosciences Inc. (“Hana Biosciences”), for the marketing rights in the U.S. and Canada for the Company’s ondansetron oral spray, (ii) Par Pharmaceutical, Inc. (“Par”), for the marketing rights in the U.S. and Canada for the Company’s nitroglycerin oral spray, (iii) Manhattan Pharmaceuticals, Inc. (“Manhattan Pharmaceuticals”), in connection with propofol, and (iv) Velcera Pharmaceuticals, Inc. (“Velcera”), in connection with veterinary applications for currently marketed veterinary drugs. In July 2007, the Company entered into a sublicense agreement with Hana Biosciences and Par, pursuant to which Hana Biosciences granted a non-transferable, non-sublicenseable, royalty-bearing, exclusive sublicense to Par to develop and commercialize Zensana™. In connection therewith, the Company and Hana Biosciences amended and restated their existing license agreement, as amended, relating to the development and commercialization of Zensana™ to coordinate certain of the terms of the sublicense agreement. Under the terms of the sublicense agreement, Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana™ in the United States and Canada. The Company retains its rights to Zensana™ outside of the United States and Canada. In addition, under the terms of the Amended and Restated License Agreement, Hana Biosciences relinquished its right to pay reduced royalty rates to the Company until such time as Hana Biosciences had recovered one-half of its costs and expenses incurred in developing Zensana™ from sales of Zensana™ and the Company agreed to surrender for cancellation all 73,121 shares of the Hana Biosciences common stock acquired by the Company in connection with execution of the original License Agreement.

In July 2007, the Company and Par agreed to terminate the agreement relating to NitroMist™. The Company is currently investigating strategic partners for the commercialization of NitroMist™.

On November 18, 2004, the Company entered into a manufacturing and supply agreement with INyX USA, Ltd. (“INyX”), whereby INyX manufactures and supplies the Company’s nitroglycerin lingual spray. For a five-year period that began November 18, 2004, INyX is the exclusive provider substantially worldwide of the nitroglycerin lingual spray to the Company. In July 2007, INyX announced it filed for protection under the Chapter 11 bankruptcy laws. The Company is taking all necessary steps to ensure that any limited assets of the Company at INyX are protected.

On June 28, 2006, the Company’s Board of Directors approved a change of the Company’s fiscal year end from July 31 to December 31. Accordingly, the new fiscal year began on January 1 and ended on December 31. Results of operations and the statement of cash flows presented for the year ended December 31, 2006 and the five months ended December 31, 2005 are unaudited.

NOTE 2 - LIQUIDITY AND BASIS OF PRESENTATION

The Company has reported a net loss of $16,963,000, $3,805,000, $10,084,000 and $9,450,000 and negative cash flows from operating activities of $15,240,000, $1,782,000, $8,855,000, and $6,258,000 for the year ended December 31, 2007, the five months ended December 31, 2006 and for the fiscal years ended July 31, 2006, and 2005, respectively. As of December 31, 2007, the Company had working capital of $3,811,000, and cash and cash equivalents of $6,384,000. Until and unless the Company's operations generate significant revenues and cash flow, we will attempt to continue to fund operations from cash on hand and through the sources of capital described below. The Company's long-term liquidity is contingent upon achieving sales and positive cash flows from operating activities, and/or obtaining additional financing. The most likely sources of financing include private placements of the Company's equity or debt securities or bridge loans to the Company from third-party lenders, license payments from current and future partners, and royalty payments from sales of approved product candidates by partners. The Company can give no assurances that any additional capital that it is able to obtain will be sufficient to meet its needs, or on terms favorable to it. During the fourth quarter 2007, the Company significantly reduced clinical development activities on its product candidate pipeline, as it did not believe that it had sufficient cash to sustain such activities. Despite this reduction in expenditures for clinical activities, the Company requires capital to sustain its existing organization until such time as clinical activities can be resumed. Given the current level of spending, the Company estimates that it will have sufficient cash on hand to fund operations through the middle of the second calendar quarter 2008. The Company may, however, choose to raise additional capital before December 31, 2008 to fund future development activities or to take advantage of other strategic opportunities. This could include the securing of funds through new strategic partnerships and/or the sale of common stock or other securities. There can be no assurance that such capital will be available to the Company on favorable terms, or at all. There are a number of risks and uncertainties related to the Company's attempt to complete a financing or strategic partnering arrangement that are outside its control. The Company may not be able to obtain additional financing on terms acceptable to it, or at all. If the Company is unsuccessful at obtaining additional financing as needed, it may be required to significantly curtail or cease operations. The Company will need additional financing thereafter until it achieves profitability, if ever.

Our audited financial statements for the fiscal year ended December 31, 2007, were prepared under the assumption that we will continue our operations as a going concern. We were incorporated in 1982, and have a history of losses. As a result, our independent registered public accounting firm in their audit report has expressed substantial doubt about our ability to continue as a going concern. Continued operations are dependent on our ability to complete equity or debt formation activities or to generate profitable operations. Such capital formation activities may not be available or may not be available on reasonable terms. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty.

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

REVENUE RECOGNITION – The Company receives revenue from consulting services and license agreements. Consulting revenues from contract clinical research are recognized in the period in which the services are rendered, provided that collection is reasonably assured. Upfront license agreement payments are initially deferred and subsequently amortized into revenue over the contractual period. Milestone payments related to license agreements are recognized as revenue when earned.

CASH EQUIVALENTS AND INVESTMENTS - Cash equivalents include certificates of deposit and money market instruments with original maturities of three months or less when purchased. Investments include short-term investments and an investment in marketable common stock received from a licensee (See Notes 8 and 9). Short-term investments are carried at amortized cost, which approximates fair market value, and consist of certificates of deposit and US treasury securities with maturities when purchased greater than three months and less than one year. At times, such investments may be in excess of the Federal Deposit Insurance Corporation (FDIC) insurance limit.

FINANCIAL INSTRUMENTS - Financial instruments include cash and cash equivalents, short-term investments, and accounts payable. The amounts reported for financial instruments are considered to be reasonable approximations of their fair values.

PROPERTY AND EQUIPMENT - Property and equipment, including leasehold improvements, are stated at cost. The Company provides for depreciation and amortization using the straight-line method, based upon estimated useful lives of five to ten years or the lease term, if shorter.

RESEARCH AND DEVELOPMENT COSTS - Research and development costs are expensed as incurred.

INCOME TAXES - Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Temporary differences between financial statement and income tax reporting result primarily from net operating losses. As a result of these temporary differences, the Company has recorded a deferred tax asset with an offsetting valuation allowance for the same amount. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when it is considered more likely than not that some portion or all of the deferred tax asset will not be realized.

DEFINED CONTRIBUTION RETIREMENT PLANS - During January 2004, the Company established a 401(k) retirement plan that is available to all employees and requires matching contributions by the Company. During the years ended December 31, 2007 and 2006, the five months ended December 31, 2006 and 2005, and the fiscal years ended July 31, 2006 and 2005, the Company contributed approximately $95,000, $96,000, $34,000, $39,000, $101,000, and $101,000, respectively, to this plan. Prior to January 2004, the Company had a Simple IRA retirement plan, available to all employees that provided for contributions at management's discretion.

INVENTORIES - Inventories, consisting of raw materials, are carried at the lower of cost or market. Cost is determined using the first-in, first-out ("FIFO") method.

RECLASSIFICATION – Certain prior year amounts have been reclassified to conform to the current period's presentation.

IMPAIRMENT OF LONG-LIVED ASSETS – In accordance with FAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (FAS 144), the Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An asset is considered to be impaired when the sum of the undiscounted future net cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. The amount of impairment loss, if any, is measured as the difference between the carrying amount of the asset and its estimated fair value. The Company has reviewed its long-lived property and equipment as of December 31, 2007, and has determined that their estimated fair value exceeds the carrying amount of such assets; therefore, the Company has not recognized an impairment loss for its long-lived property and equipment.

USE OF ESTIMATES – The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the U.S. This requires our management to make estimates about the future resolution of existing uncertainties that affect the reported amounts of assets, liabilities, revenues and expenses which in the normal course of business are subsequently adjusted to actual results. Actual results could differ from such estimates. In preparing these financial statements, management has made its best estimates and judgments of the amounts and disclosures included in the financial statements giving due regard to materiality.

LOSS PER SHARE – Loss per common share is computed pursuant to SFAS No. 128, "Earnings Per Share." Basic loss per common share is computed as net loss divided by the weighted average number of common shares outstanding for the period. Diluted net loss per common share is the same as basic net loss per common share, since potentially dilutive securities from the assumed exercise of all outstanding options and warrants would have an antidilutive effect because the Company incurred a net loss during each period presented. As of December 31, 2007, December 31, 2006, July 31, 2006 and July 31, 2005, there were 35.1 million, 38.4 million, 30.7 million and 26.2 million common shares, respectively, issuable upon exercise of options and warrants which were excluded from the diluted loss per common share computation. Subsequent to December 31, 2007, in accordance with its remuneration practices, the Company issued an additional 1.1 million restricted shares, including (i) 750,000 to existing executive officers and directors; and (ii) 350,000 to existing and new employees.

STOCK-BASED COMPENSATION - In December 2004, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123R"), which revised "Accounting for Stock-Based Compensation," ("SFAS 123") and superseded Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," ("APB 25"), which provided for the use of the intrinsic value method of accounting for employees stock options. SFAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values beginning with the first quarter of the first annual reporting period that began after June 15, 2005. Under SFAS 123R, the use of the intrinsic value method and pro forma disclosures previously permitted under SFAS 123 are no longer an alternative to financial statement recognition.

The Company adopted the provisions of SFAS 123R effective August 1, 2005 and selected the Black-Scholes method of valuation for share-based compensation. The Company adopted the modified prospective transition method which does not require restatement of prior periods. Instead, it requires that compensation cost be recorded as earned for all unvested stock options outstanding at the beginning of the first quarter of adoption of SFAS 123R. The charge is being recognized in research and development and consulting, selling, general and administrative expenses over the remaining service period after the adoption date based on the original estimate of fair value of the options as of the grant date. Prior to the adoption of SFAS 123R, the Company applied the intrinsic-value-based method of accounting prescribed by APB 25 and related interpretations, to account for its stock options granted to employees. Under this method, compensation cost was recorded only if the market price of the underlying common stock on the date of grant exceeded the exercise price. SFAS 123 established accounting and disclosure requirements using a fair-value-based method of accounting for share-based employee compensation plans. As permitted by SFAS 123, the Company elected to continue to apply the intrinsic-value-based method of accounting described above, and adopted only the disclosure requirements of SFAS 123, as amended. The Company recorded share-based compensation of approximately $910,000 or $.02 per share, and $1,179,000 or $0.03 per share, for the years ended December 31, 2007 and 2006, $498,000 or $0.01 per share, and $520,000 or $0.01 per share, for the five months ended December 31, 2006 and 2005, and $1,201,000, or $0.03 per share, for the fiscal year ended July 31, 2006. The Company will continue to incur share-based compensation charges in future periods. As of December 31, 2007, unamortized stock-based compensation expense of $2.0 million remains to be recognized, which is comprised of $1.2 million to be recognized over a weighted average period of 1.4 years, $0.1 million related to restricted stock to be recognized over a weighted average period of 1.9 years, and $0.7 million related to performance-based stock options which vest upon reaching certain milestones. Expenses related to the performance-based stock options will be recognized if and when the Company determines that it is probable that the milestone will be reached.

As a result of cashless exercise provisions in our employee stock option agreements, the Company used variable accounting treatment under the Financial Accounting Standards Board's Interpretation 44, for issued and outstanding stock options from January 2002 through July 2005. On October 20, 2004, the Company's Board of Directors rescinded the cashless exercise provision for all of the Company's outstanding option grants. Through July 31, 2005, variable plan accounting continued to be applied for approximately 310,000 outstanding options, for which option exercise prices were modified from the original agreement.

The following table illustrates the pro forma effect on the Company's net loss and net loss per common share as if the Company had adopted the fair-value-based method of accounting for share-based compensation under SFAS 123 for the fiscal year ended July 31, 2005:

		July 31, 2005	
Net loss – as reported	$	(9,450,000	)
Compensation credit resulting from variable plan accounting		(106,000	)
Total share-based employee compensation expense using the fair value based method for all awards		(854,000	)
Pro forma net loss	$	(10,410,000	)
Basic and diluted net loss per common share:			
As reported	$	(0.27	)
Pro forma net loss		(0.30	)

The fair values of options granted during the fiscal year ended July 31, 2005 were estimated at the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions, respectively: risk-free interest rates of 4.0%, dividend yield of 0.0%, volatility factors of the expected market price of the Company's common stock of 66%, and an expected life of the options of five to ten years.

NEW ACCOUNTING PRONOUNCEMENTS - In December 2007, the FASB issued SFAS No. 141R "*Business Combinations*" ("SFAS 141R") SFAS 141R applies to all transactions or other events in which an entity obtains control of one or more businesses. SFAS 141R is effective for fiscal years beginning after December 15, 2008. The Company does not expect the adoption of SFAS 141R to have a material impact on its results of operations or financial condition.

In December 2007, the FASB issued SFAS No. 160 "*Noncontrolling Interests in Consolidated Financial Statements*" ("SFAS 160"). SFAS No. 160 applies to all entities that prepare consolidated financial statements, but will affect only those entities that have an outstanding noncontrolling interest in one or more subsidiaries or that deconsolidate a subsidiary. SFAS 160 is effective for fiscal years beginning after December 15, 2008. The Company does not expect the adoption of SFAS 160 to have a material impact on its results of operations or on its financial condition.

In September 2006, the FASB issued SFAS No. 157, "*Fair Value Measurements*" ("SFAS 157"). SFAS 157 establishes a common definition for fair value to be applied to U.S. GAAP guidance requiring use of fair value, establishes a framework for measuring fair value, and expands disclosure about such fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007. The Company does not expect the adoption of SFAS 157 to have a material impact on its results of operations or financial condition.

In February 2007, the FASB issued SFAS No. 159, "*The Fair Value Option for Financial Assets and Financial Liabilities*" ("SFAS 159"). SFAS 159 permits entities to choose to measure many financial assets and financial liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company does not expect the adoption of SFAS 159 to have a material impact on its results of operations or financial condition.

In December 2007, FASB affirmed the conclusions of the Emerging Issues Task Force (EITF) on EITF Issue 07-1, "*Accounting for Collaborative Arrangements*" (EITF 07-1). EITF 07-1 requires collaborators to present the results of activities, for which they act as the principal, on a gross basis and report any payments received from or made to other collaborators based on other applicable accounting principles generally accepted in the United States (GAAP) or, in the absence of GAAP, based on analogy to authoritative accounting literature or a reasonable, rational and consistently applied accounting policy election. Further, EITF 07-1 clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer relationship subject to EITF 01-9 "*Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products*)".

EITF 07-1 is effective for fiscal years beginning after December 15, 2008 and will be effective for the Company on January 1, 2009. The Company currently believes that the adoption of EITF 07-1 will have no material impact on its consolidated financial position or results of operations.

In June 2007, the FASB affirmed the conclusions of the EITF with respect to EITF Issue 07-3 "*Accounting for Advance Payments for Goods or Services to be Used in Future Research and Development Activities*" (EITF 07-3). EITF 07-3 concluded that non-refundable advance payments for future research and development activities pursuant to an executory contractual arrangement should be capitalized until the goods have been delivered or the related services performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2008 and will be effective for the Company on January 1, 2009. The Company currently believes that the adoption of EITF 07-3 will have no material impact on its consolidated financial position or results of operations.

NOTE 4 – ASSETS HELD FOR SALE

The Company owns inventory with a net book value of $131,000 and fixed assets with a net book value of $361,000, which are used in the production of its NitroMist™ product line. As of the balance sheet date of December 31, 2007, the Company was in discussions with several potential buyers for these assets. In accordance with SFAS No. 144, "*Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS 144")*, the Company has classified these assets as assets held for sale on the balance sheet. The prior period balance sheet has been reclassified.

The assets held for sale are summarized as follows:

	December 31, 2007	December 31, 2006
Inventory	$ 131,000	$ 32,000
Property, plant and equipment, net	361,000	486,000
Total assets held for sale	$ 492,000	$ 518,000

NOTE 5 - PROPERTY AND EQUIPMENT

Property and equipment are summarized as follows:

	December 31, 2007	December 31, 2006
Equipment	$ 2,183,000	$ 1,783,000
Furniture and fixtures	455,000	455,000
Leasehold improvements	1,432,000	1,432,000
	4,070,000	3,670,000
Less: Accumulated depreciation		
and amortization	2,098,000	1,545,000
	$ 1,972,000	$ 2,125,000

Property and equipment as of December 31, 2007 and 2006 excludes gross fixed assets of $624,000 at the facilities of INyX. Accumulated depreciation as of December 31, 2007 and 2006 excludes accumulated depreciation of $263,000 and $138,000, respectively, on fixed assets at the facilities of INyX. Such assets are the property of the Company and cannot be used by INyX for any other business. In the event that the Company's contract with INyX is terminated for any reason, such assets are to be returned to the Company. These assets have been reclassified as "Assets Held for Sale" on the balance sheets as of December 31, 2007 and December 31, 2006. See Note 4 for further information.

As of December 31, 2007, the Company had total gross fixed assets of $627,000, with an accumulated depreciation of $80,000, recorded under a capital lease.

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An asset is considered to be impaired when the sum of the undiscounted future net cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. The amount of impairment loss, if any, is measured as the difference between the carrying amount of the asset and its estimated fair value. The Company has reviewed its long-lived property and equipment as of December 31, 2007, and has determined that their estimated fair value exceeds the carrying amount of such assets; therefore, the Company has not recognized an impairment loss for its long-lived property and equipment.

NOTE 6 - RELATED PARTY TRANSACTIONS

PLACEMENT AGENT AGREEMENTS (see Note 7) – In January 2004, May 2005 and April 2006, the Company completed private placements for which it utilized Paramount BioCapital, Inc., or Paramount, as its placement agent or co-placement agent. Paramount and its affiliates are beneficial owners of a significant amount of shares of common stock and options and warrants for the purchase of shares of common stock of the Company and, accordingly, Paramount is a related party to the Company.

COMPENSATION AND CONSULTING AGREEMENTS - In November 2005, the Company entered into a Confidential Separation Agreement and General Release (the “Separation Agreement”) and a Consulting Agreement (the “Consulting Agreement”) with Gary Shangold, M.D. Dr. Shangold is the former President and Chief Executive Officer of the Company. In December 2005, pursuant to the Separation Agreement, the Company paid Dr. Shangold a separation payment of $150,000. Pursuant to the Consulting Agreement, the Company paid Dr. Shangold $300,000 for the year ended December 31, 2006; $125,000 for the five months ended December 31, 2006; and $175,000 for the fiscal year ended July 31, 2006.

In September 2006, the Company’s Board of Directors appointed Steven B. Ratoff as Chairman of the Board. In connection with Mr. Ratoff’s appointment as Chairman of the Board, the Board entered into a consulting arrangement to compensate Mr. Ratoff for his efforts. This arrangement is on a month-to-month basis and compensates Mr. Ratoff at a rate of $17,500 per month. Pursuant to this consulting arrangement, the Company paid Mr. Ratoff approximately $207,000 and $61,000 for the years ended December 31, 2007 and 2006;, and approximately $61,000 for the five months ended December 31, 2006. In March 2007, Mr. Ratoff’s monthly compensation was reduced to $10,000 to reflect his decreased day-to-day time involvement at the Company, and in June, 2007, Mr. Ratoff’s monthly compensation was increased to $17,500 per month to reflect his appointment as the Company’s Interim President and Chief Executive Officer.

In September 2007, in connection with his resignation, Dr. Egberts and the Company entered into a Separation, Consulting and General Release Agreement (the "Agreement"). Pursuant to the Consulting Agreement, the Company paid Dr. Egberts $140,000 for the year ended December 31, 2007.

LICENSE AND DEVELOPMENT AGREEMENTS WITH RELATED PARTIES - In April 2003, the Company entered into a license and development agreement with Manhattan Pharmaceuticals for the worldwide, exclusive rights to the Company's proprietary oral spray technology to deliver propofol for pre-procedural sedation.

In June 2004, the Company entered into a 20-year worldwide exclusive license agreement with Velcera, a veterinary company. The license agreement is for the exclusive rights to the Company's proprietary oral spray technology in animals.

In October 2004, the Company entered into a license and development agreement (as amended in August 2005) with Hana Biosciences to develop and market the Company's oral spray version of ondansetron. The agreement is an exclusive license for the U.S. and Canada. In July 2007, the Company entered into a sublicense agreement with Hana Biosciences and Par, pursuant to which Hana Biosciences granted a non-transferable, non-sublicenseable, royalty-bearing, exclusive sublicense to Par to develop and commercialize Zensana™.

Lindsay A. Rosenwald, M.D., a significant stockholder of the Company, may be deemed to be an affiliate of the Company, Manhattan Pharmaceuticals, Velcera, and Hana Biosciences. Companies affiliated with Dr. Rosenwald have provided financial and other services unrelated to the Company's agreements with the parties to such agreements from time to time.

NOTE 7 - STOCKHOLDERS' EQUITY

PRIVATE PLACEMENTS – In December 2006, the Company completed a private placement of 9,823,983 shares of common stock, at a purchase price of $1.45 per share and warrants to purchase up to approximately 3,929,593 shares of common stock at an exercise price of $1.70 per share. The Company received proceeds, net of offering costs, of $13,144,000 of which $11,749,000 was received in December 2006 and $1,395,000 was received in January 2007. As such, the Company issued 8,862,069 shares in December 2006 and 961,914 shares in January 2007 for this private placement.

Oppenheimer & Co. Inc. acted as the lead placement agent for this private placement, with Griffin Securities, Inc. acting as co-placement agent. The placement agents received compensation for acting as placement agents made up of cash compensation equal to 7% of the proceeds from the sale of the common stock, or $997,000, and warrants to purchase shares of common stock equal to 5%of the shares of common stock purchased, subject to certain exclusions, or warrants to purchase 491,199 shares (such warrants have the same terms as those issued to the investors), plus expenses. On the date of grant, the warrants had an approximate fair value of $0.89 per warrant. The Company agreed to indemnify the placement agents against certain liabilities, including liabilities under the Securities Act of 1933, incurred in connection with the offering.

In April 2006, the Company closed a private placement of 8,092,796 shares of common stock and warrants to purchase a total of 2,427,839 shares of common stock with an exercise price of $1.60 per share of common stock. The Company received proceeds, net of offering costs, of approximately $10,593,000. Griffin Securities, Inc. and Paramount, a NASD broker-dealer, acted as the placement agents for this private placement. The placement agents were paid an aggregate fee for acting as placement agents of cash equal to 7% of the gross proceeds from the sale of the common stock, or $792,400, and warrants equal to 6% of the shares of common stock purchased, subject to certain exclusions, or warrants to purchase 468,329 shares of common stock. Such warrants have the same terms as those issued to the investors. On the date of grant, the warrants had an approximate fair value of $0.92 per warrant. The placement agents were also entitled to a non-accountable expense allowance of up to $55,000 as reimbursement for out of pocket expenses incurred in connection with the offering. The Company agreed to indemnify the placement agents against certain liabilities, including liabilities under the Securities Act of 1933, incurred in connection with the offering.

In May 2005, the Company closed a private placement of 6,733,024 shares of common stock and warrants to purchase a total of 2,356,559 shares of common stock, with an initial exercise price equal to $1.30 per share of common stock, subject to adjustment. The Company received net proceeds of approximately $6,309,000. In connection with the private placement, the Company paid a cash commission equal to 7% of the gross proceeds from the private placement, or approximately $495,000, to Paramount, who acted as its placement agent, and issued to Paramount a warrant to purchase 336,651 shares of common stock (the "Placement Warrant"). The Placement Warrant is exercisable at an initial exercise price equal to $1.30 per share (subject to adjustment). On the date of grant, the warrants had an approximate fair value of $0.66 per warrant. Paramount was also entitled to a non-accountable expense allowance of up to $50,000 to reimburse it for out-of-pocket expenses incurred in connection with the private placement. The Company agreed to indemnify Paramount against certain liabilities, including liabilities under the Securities Act of 1933, incurred in connection with the offering.

In January 2004, the Company completed a private placement and received net proceeds of $12,785,000 from the sale of a total of 140 units of the Company's securities. Each unit consisted of 95,238 common shares, and 28,571 warrants. Each warrant entitles the holder to purchase an additional share of the Company's common stock at an exercise price of $1.40 per share through January 2009. The sale price of each unit was $100,000. A total of 13,333,333 shares and approximately 4,000,000 warrants were issued. The securities were sold through Paramount. For its services as placement agent, the Company paid Paramount a commission of 7% of the aggregate amount raised, or approximately $1,000,000, and also issued to Paramount (and its designees) unit purchase options to purchase 1,330,303 shares of common stock at an exercise price of $1.40 per share and warrants to purchase an additional 399,091 shares of common stock at an exercise price of $1.40 per share. On the date of grant, the warrants had an approximate fair value of $0.88 per warrant. The Company also paid Paramount a non-accountable expense allowance of $25,000 to reimburse Paramount for its out-of- pocket expenses.

The Company has entered into registration rights agreements with certain holders of our common stock that require us to continuously maintain an effective registration statement covering the underlying shares of common stock. Such registration statements have been declared effective and must continuously remain effective for a specified term. If we fail to continuously maintain such registration statements as effective throughout the specified terms, the Company may be subject to liability to pay liquidated damages.

PREFERRED STOCK - The Company's Certificate of Incorporation authorizes the issuance of up to 1,000,000 shares of Preferred Stock. None of the Preferred Stock has been designated or issued through December 31, 2007. The Board is authorized to issue shares of Preferred Stock from time to time in one or more series and to establish and designate any such series and to fix the number of shares and the relative conversion and voting rights, and terms of redemption and liquidation.

NOTE 8 - COMMITMENTS AND CONTINGENCIES

EMPLOYMENT AGREEMENTS - At December 31, 2007, the Company had employment agreements with three officers of the Company providing for an aggregate salary of $824,000, $553,000, and $40,000 in the years ending December 31, 2008, 2009 and 2010, respectively, excluding potential Company matching contributions to the officers' 401(k) plan. The remaining terms of the officers' employment agreements are outlined below. Generally, in the event an officer is terminated prior to the end of such agreement, the officer is entitled to severance payments equal to the officer's salary for the shorter of six months or the remaining term of the officer's employment agreement.

The employment agreements with the Company's officers are due to expire on the following schedule: Mr. Spicer's agreement in December 2008, Dr. Bergstrom's agreement in December 2009, and Mr. Zodda's agreement in February 2010.

In September 2007, in connection with his resignation, Dr. Egberts and the Company entered into a Separation, Consulting and General Release Agreement, pursuant to which the Company must pay Dr. Egberts fees for services at a rate of $363,000 per annum through July 25, 2008. At

December 31, 2007, the Company had obligations to Dr. Egberts under the Agreement of $223,000.

All of the foregoing employment agreements provide for the potential issuance of bonuses based on certain factors. Such agreements also provide for the grant of options to purchase shares of the Company’s common stock.

LICENSE AND DEVELOPMENT AGREEMENTS - In April 2003, the Company entered into a license and development agreement with Manhattan Pharmaceuticals for the worldwide, exclusive rights to the Company's proprietary oral spray technology to deliver propofol for pre-procedural sedation. The terms of the agreement call for certain milestone and other payments, the first $125,000 of which was partially received during June 2003. In November 2003, the Company received $375,000 from Manhattan Pharmaceuticals for license fees. The Company has included these license fees in deferred revenue and is recognizing these license fees over the 20-year term of the license. During the fiscal year ended July 31, 2005, the Company invoiced Manhattan Pharmaceuticals approximately $65,000 for the Company's reimbursable expenses.

In June 2004, the Company entered into a 20-year worldwide exclusive license agreement with Velcera, a veterinary company. The license agreement is for the exclusive rights to the Company's propriety oral spray technology in animals. In September 2004, the Company received $1,500,000 from Velcera as an upfront payment in connection with the commercialization agreement. The upfront payment has been included in deferred revenue and will be recognized in income over the 20-year term of the agreement. In addition, the Company received an equity stake of 529,500 shares of common stock, approximately 15% at the time the shares were issued, in Velcera which did not have a material value. The Company may receive additional milestone payments and royalty payments over the 20-year term of the agreement. During the fiscal years ended December 31, 2006, the five months ended December 31, 2005, and for the fiscal years ended July 31, 2006 and 2005, the Company invoiced Velcera approximately $119,000, $109,000, $228,000 and $183,000, respectively, for reimbursable expenses. Additionally, during the year ended December 31, 2007, and the fiscal year ended July 31, 2005, the Company invoiced Velcera $125,000 and $50,000, respectively, for contractual milestones that were reached.

In July 2004, the Company entered into a licensing agreement with Par for the exclusive right to market, sell and distribute nitroglycerin lingual spray in the U.S. and Canada. The Company has received $250,000 in upfront and milestone payments and may receive additional fees and royalty payments over the 10-year term of the license. The upfront payment has been included in deferred revenue and will be recognized in income over the 10-year term of the agreement. In July 2007, the Company and Par agreed to terminate the agreement relating to NitroMist™. The Company is currently investigating strategic partners for the commercialization of NitroMist™.

In October 2004, the Company entered into a license and development agreement pursuant to which the Company granted to Hana Biosciences an exclusive license to develop and market the Company's oral spray version of ondansetron in the U.S. and Canada. Pursuant to the terms of the agreement, in exchange for $1,000,000, Hana Biosciences purchased 400,000 shares of the Company's common stock at a per share price equal to $2.50, a premium of $.91 per share or $364,000 over the then market value of the Company's common stock. The Company accounted for this premium as deferred revenue related to the license. In connection with the agreement, Hana Biosciences issued to the Company $500,000 worth of common stock of Hana Biosciences (73,121 shares based on a market value of $6.84 per share). The proceeds received from Hana Biosciences attributable to the premium are included in deferred revenue and are being recognized over the 20-year term of the agreement. The Company may receive additional license fees and royalties over the 20-year term of the agreement. During the five months ended December 31, 2006 and the fiscal year ended July 31, 2006, the Company received $1,000,000 and $1,500,000, respectively, in milestone payments from Hana Biosciences. During the year ended December 31, 2006, and for the fiscal years ended July 31, 2006 and 2005, the Company invoiced Hana Biosciences approximately $13,000, $13,000 and $84,000, respectively, for pass-through expenses incurred by the Company on behalf of Hana Biosciences.

In July 2007, the Company entered into a sublicense agreement with Hana Biosciences and Par, pursuant to which Hana Biosciences granted a non-transferable, non-sublicenseable, royalty-bearing, exclusive sublicense to Par to develop and commercialize Zensana™. In connection therewith, the Company and Hana Biosciences amended and restated their existing license agreement, as amended, relating to the development and commercialization of Zensana™ to coordinate certain of the terms of the sublicense agreement. Under the terms of the sublicense agreement, Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana™ in the United States and Canada. The Company retains its rights to Zensana™ outside of the United States and Canada. In addition, under the terms of the Amended and Restated License Agreement, Hana Biosciences relinquished its right to pay reduced royalty rates to the Company until such time as Hana Biosciences had recovered one-half of its costs and expenses incurred in developing Zensana™ from sales of Zensana™ and the Company agreed to surrender for cancellation all 73,121 shares of the Hana Biosciences common stock acquired by the Company in connection with execution of the original License Agreement.

On November 18, 2004, the Company entered into a manufacturing and supply agreement with INyX whereby INyX manufactures and supplies the Company's nitroglycerin lingual spray. For a five-year period that began November 18, 2004, INyX is the exclusive provider of the nitroglycerin lingual spray to the Company substantially worldwide. Pursuant to the terms and conditions of the agreement, it will be INyX's responsibility to manufacture, package and supply the nitroglycerin lingual spray in such territories. Thereafter, INyX will have a non-exclusive right to manufacture such spray for an additional five years. In July 2007, INyX announced it filed for protection under the Chapter 11 bankruptcy laws. The Company is taking all necessary steps to ensure that any limited assets of the Company at INyX are protected.

CAPITAL LEASE OBLIGATIONS – As of December 31, 2007, the Company has aggregate capital lease obligations of $312,000, of which $164,000, $122,000, $22,000 and $4,000 are scheduled to be paid in the years ending December 31, 2008, 2009, 2010, and 2011, respectively.

OPERATING LEASES - In March 2003, the Company entered into a 10-year lease for office, laboratory, manufacturing and warehouse space. During the first five years of the lease, the annual rent is approximately $332,000 plus a proportionate share of real estate taxes and common area charges. Beginning in the sixth year and continuing through the tenth year of the lease, the annual rent will be approximately $366,000 plus a proportionate share of real estate taxes and common areas. Through December 31, 2005, the Company occupied office and laboratory space at a second location. During the years ended December 31, 2007 and 2006, the five months ended December 31, 2006 and 2005, and for the fiscal years ended July 31, 2006 and 2005, the Company paid rent of approximately $443,000, $456,000, $184,000, $223,000, $495,000 and $521,000, respectively.

Future minimum rental payments subsequent to December 31, 2007 are as follows:

Years Ending December 31,	
2008	$343,000
2009	$366,000
2010	$366,000
2011	$366,000
2012	$365,000
Thereafter	$243,000
	$2,049,000

NOTE 9 – INVESTMENT IN MARKETABLE EQUITY SECURITY

As explained in Note 8, in October 2004, as part of the license agreement with Hana Biosciences, the Company received $500,000 of common stock of Hana Biosciences (73,121 shares based on a market value of $6.84 per share at the date of the agreement). As a result of restrictions on its ability to sell the shares, the Company was required by SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities," to account for those shares using the cost method through October 2005 and thereafter as marketable equity securities. At December 31, 2006, the Company had classified the shares as available for sale and recorded changes in their value as part of its comprehensive loss. Such shares had a market value of $466,000 at December 31, 2006 and, accordingly, the Company has included its $34,000 unrealized loss in accumulated comprehensive loss, a separate component of stockholders' equity, as of December 31, 2006.

As of March 31, 2007, such shares had a market value of $140,000, as compared to their original cost basis of $500,000. At such time, the Company determined that the decline in value of this investment was other than temporary and recorded a $360,000 impairment charge to the statement of operations, the only component of other loss, for the three months ended March 31, 2007 to establish a new cost basis of $140,000 for the investment as of March 31, 2007. During the three months ended September 30, 2007, as a result of the Amended and Restated License

Agreement with Hana Biosciences as described in Note 8, the Company recorded a $140,000 charge to expense that is included in other loss, net, to account for the return of Hana Biosciences' shares.

NOTE 10 – ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities are comprised of the following at December 31, 2007 and December 31, 2006:

	December 31, 2007	December 31, 2006
Accrued compensation	$ 397,000	$ 503,000
Professional fees	131,000	229,000
Accrued milestone payments	—	312,000
Product development costs	1,558,000	782,000
Insurance premiums	167,000	178,000
Other	14,000	57,000
	$ 2,267,000	$ 2,061,000

NOTE 11 - INCOME TAXES

The significant components of the Company's net deferred tax asset are summarized as follows:

	December 31, 2007	December 31, 2006
Stock-based compensation	$ 813,000	$ 560,000
Net operating loss carryforwards	21,365,000	14,828,000
Deferred revenue	791,000	1,043,000
Property and equipment	(147,000)	(157,000)
R & D credit	1,134,000	—
Other	439,000	424,000
Total gross deferred tax assets	24,395,000	16,698,000
Valuation allowance	(24,395,000)	(16,698,000)
Net deferred tax assets	$ —	$ —

At December 31, 2007, the Company had federal and state net operating loss carryforwards for financial reporting and income tax purposes of approximately $57.5 million and $30.5 million, respectively, which can be used to offset current and future federal and state taxable income, if any, through 2027 and 2014, respectively. In addition, the Company has Federal and State research and development tax credit of $0.8 million and $0.3 million respectively, which will expire beginning 2020 and 2012 respectively. A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. The Company has provided valuation allowances to offset its deferred tax assets due to the significant uncertainties related to its ability to generate future taxable income. The net increases in the total valuation allowance for the year ended December 31, 2007, for the five-months ended December 31, 2006 and for fiscal years ended July 31, 2006 and 2005 were $7.7 million, $0.8 million, $4.0 million and $3.8 million, respectively.

The tax benefits expected based on the Company's pre-tax loss for the years ended December 31, 2007 and 2006, for the five-months ended December 31, 2006 and 2005, and for fiscal years ended July 31, 2006 and 2005, utilizing the applicable statutory rates, have been reduced to an actual benefit of $658,000, $467,000, $467,000, $256,000, $256,000 and $241,000, respectively, due principally to the aforementioned increases in the valuation allowance. The benefit recognized in such fiscal years relates solely to the sale of certain of the Company's state net operating loss carryforwards.

The following is a reconciliation of the income tax benefit computed at the statutory rate to the provision for income taxes:

	Year Ended	Five Months Ended	Year Ended July 31,	
	December 31, 2007	December 31, 2006	2006	2005
Federal tax at statutory rate	(34.0%)	(34.0%)	(34.0%)	(34.0%)
State income tax	(6.0%)	(6.0%)	(6.0%)	(6.0%)
Other	0.2%	(.3%)	—	0.3%
Sale of net operating losses	(3.7%)	(10.9%)	(2.5%)	(2.5%)
Increase in valuation allowance	39.8%	40.3%	40.0%	39.7%
	(3.7)%	(10.9)%	(2.5%)	(2.5%)

The Tax Reform Act of 1986 (the Act) provides for a limitation on the annual use of NOL carryforwards (following certain ownership changes, as defined by the Act), which could significantly limit the Company's ability to utilize these carryforwards. The Company has experienced various ownership changes, as defined by the Act, as a result of past financings and may experience others in connection with future financings. Accordingly, the Company's ability to utilize the aforementioned federal operating loss carryforwards will be limited. The Company is in the process of determining the impact of ownership changes that have occurred, as defined by the Act. Additionally, because U.S. tax laws limit the time during which these carryforwards may be applied against future taxes, the Company may not be able to take full advantage of these attributes for federal income tax purposes.

SALE OF NET OPERATING LOSS CARRYFORWARDS: The State of New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell state tax loss carryforwards and state research and development credits, or net operating loss carryforwards, in order to obtain tax benefits. The Company recorded an income tax benefit of $658,000, $467,000, $467,000, $256,000, $256,000 and $241,000 for the years ended December, 31, 2007 and 2006, for the five months ended December 31, 2006 and 2005, and for the fiscal years ended July 31, 2006 and 2005, respectively, from the sale of its New Jersey net operating loss carryforwards. If still available under New Jersey law, the Company may attempt to sell its remaining New Jersey net operating loss carryforwards of $30.5 million as of December 31, 2007. The Company cannot estimate, however, what percentage of its saleable net operating loss carryforwards New Jersey will permit it to sell, how much money will be received in connection with the sale, if the Company will be able to find a buyer for its net operating loss carryforwards or if such funds will be available in a timely manner or at all.

The Company files income tax returns in the U.S. Federal jurisdiction and in the State of New Jersey. With certain exceptions, the Company is no longer subject to U.S. federal and state income tax examinations by tax authorities for years prior to 2004. The Company adopted the provisions of FIN 48, "Accounting for Uncertainty in Income Taxes – an interpretation of FASB Statement No. 109" on January 1, 2007 with no material impact to the financial statements.

The Company had no unrecognized tax benefits at December 31, 2007 that would affect the annual effective tax rate. Further, the Company is unaware of any positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within the next twelve months.

NOTE 12 - STOCK OPTIONS AND WARRANTS

At December 31, 2007, the Company had two plans which allow for the issuance of stock options and other awards: the 1998 Stock Option Plan and the 2006 Equity Incentive Plan (the “Plans”). On January 17, 2006, the stockholders of the Company, upon recommendation of the Board of Directors of the Company, approved the NovaDel Pharma Inc. 2006 Equity Incentive Plan (the “2006 Plan”). The 2006 Plan authorizes the grant of several types of stock-based awards, including stock options, stock appreciation rights and stock (including restricted stock). The number of shares of common stock originally reserved for issuance under the 2006 Plan was 6 million shares. These Plans are administered by the Compensation Committee of the Board of Directors. Incentive Stock Options (“ISOs”) may be granted to employees and officers of the Company and non-qualified options may be granted to consultants, directors, employees and officers of the Company. Options to purchase the Company’s common stock may not be granted at a price less than the fair market value of the common stock at the date of grant and will expire not more than 10 years from the date of grant, and vesting is determined by the Compensation Committee of the Board of Directors. ISOs granted to a 10% or more stockholder may not be for less than 110% of fair market value or for a term of more than five years. As of December 31, 2007, there were approximately 3.3 million shares available for issuance under the Plans. Subsequent to December 31, 2007, in accordance with its remuneration practices, the Company issued an additional 1.1 million restricted shares, including (i) 750,000 to existing executive officers and directors; and (ii) 350,000 to existing and new employees (see Note 13).

Information with respect to stock option activity for the year ended December 31, 2007, five months ended December 31, 2006 and for the fiscal year ended July 31, 2006 is as follows:

Options	**Shares (000)**	**Weighted-Average Exercise Price**	**Weighted-Average Remaining Contractual Terms (Years)**	**Aggregate Intrinsic Value ($000)**
Outstanding at August 1, 2005	6,474	$ 1.64	—	$ —
Grants	3,280	1.58	—	—
Exercises	(360)	.75	—	—
Cancellations	(1,217)	1.66	—	—
Outstanding at July 31, 2006	8,177	$ 1.65	4.4	$ 492
Exercisable at July 31, 2006	4,710	$ 1.69	3.3	$ 492
Outstanding at August 1, 2006	8,177	$ 1.64	—	—
Grants	900	1.71	—	—
Exercises	(242)	.75	—	—
Cancellations	(60)	1.56	—	—
Outstanding at December 31, 2006	8,775	$ 1.68	4.5	$ 1,203
Exercisable at December 31, 2006	5,313	$ 1.73	3.1	$ 973
Outstanding at January 1, 2007	8,775	$ 1.68	—	—
Grants	3,239	1.67	—	—
Exercises	(268)	.75	—	—
Cancellations	(3,317)	1.72	—	—

Outstanding at December 31, 2007	8,429	$ 1.69	5.9	$ —
Exercisable at December 31, 2007	5,549	$ 1.75	5.0	$ —

The Company recorded share-based compensation for options using the fair value method required by SFAS 123R of approximately $910,000, or $.02 per share, for the year ended December 31, 2007; $1,179,000, or $0.03 per share, for the year ended December 31, 2006; $498,000 or $0.01 per share, for the five months ended December 31, 2006; $520,000, or $0.01 per share, for the five months ended December 31, 2005; and $1,201,000 or $0.03 per share, for the fiscal year ended July 31, 2006, which amounts are included in the Company's net loss for each period.

- During the year ended December 31, 2007, the Company granted 3.2 million additional stock options, including 0.7 million options which vest upon reaching certain milestones. During the year ended December 31, 2007, the Company granted to an executive of the Company incentive stock options to purchase 68,027 shares of common stock of the Company and non-qualified stock options to purchase 598,973 shares of common stock of the Company. Such option grants have a term of ten (10) years. The stock options vest upon achievement of performance milestones; so that 22,676 incentive stock options and 200,324 non-qualified stock options will vest on the signing of a Board approved third party agreement for U.S. or worldwide rights of sumatriptan; 22,676 incentive stock options and 199,324 non-qualified stock options will vest on the signing of a Board approved third party agreement for U.S. or worldwide rights of zolpidem; and 22,675 incentive stock options and 199,325 non-qualified stock options will vest upon approval by the Board of any third party agreement whereby the Company obtains the right to develop a product incorporating an active pharmaceutical ingredient that is the subject of a then valid U.S. Patent (or in-process U.S. Patent Application) and already approved for sale by the U.S. Food and Drug Administration with sales in the U.S. of at least $100 million. Such options will expire on February 21, 2017. The exercise price of each option is $1.47 (the closing price of the Company's common stock on February 22, 2007, as listed on the American Stock Exchange).

- During the five months ended December 31, 2006, the Company did not grant any additional stock options other than the December 2006 grant of 900,000 performance-based stock options which vest upon reaching certain milestones. Previously, the Company had not granted performance-based stock options. In addition, during the five months ended December 31, 2006, the Company granted 100,000 shares of restricted stock to an executive of the Company with a grant price equal to the fair market value on the date of grant, or $1.71 per share. The restricted stock vests ratably over a three-year period ending on the third anniversary of the grant, or December 4, 2009. Such performance-based stock options and restricted stock had a deminimus impact on the Company's net loss for the five months ended December 31, 2006, and resulted in recognition of $180,000 in share-based compensation expense for the year ended December 31, 2007. As of December 31, 2007, unamortized stock-based compensation expense of $2.0 million remains to be recognized, which is comprised of $1.2 million to be recognized over a weighted average period of 1.4 years, $0.1 million related to restricted stock to be recognized over a weighted average period of 1.9 years, and $0.7 million related to performance-based stock options which vest upon reaching certain milestones. Expenses related to the performance-based stock options will be recognized if and when the Company determines that it is probable that the milestone will be reached.

The Company used the following weighted average assumptions in determining fair value under the Black-Scholes model for grants in the respective periods:

	Year Ended December 31,		Five Months Ended December 31,		Year Ended July 31,
	2007	2006 (unaudited)	2006	2005 (unaudited)	2006
Expected volatility	63%	65%	60%	64%	64%
Dividend yield	0%	0%	0%	0%	0%
Expected term until exercise (years)	4.9	3.9	2.5	4.3	4.5
Risk-free interest rate	4.8%	4.5%	4.4%	4.1%	4.3%

Expected volatility is based on historical volatility of the Company's common stock. The expected term of options is estimated based on the average of the vesting period and contractual term of the option. The risk-free rate is based on U.S. Treasury yields for securities in effect at the time of grant with terms approximating the expected term until exercise of the option. In addition, under SFAS 123R, the fair value of stock options granted is recognized as expense over the service period, net of estimated forfeitures. The Company is utilizing a 5% forfeiture rate, which it believes is a reasonable assumption to estimate forfeitures. However, the estimation of forfeitures requires significant judgment, and to the extent actual results or updated estimates differ from our current estimates, the effects of such resulting adjustment will be recorded in the period estimates are revised. The weighted average grant date fair value of options granted was $0.93 and $0.84 during the years ended December 31, 2007 and 2006; $0.63 and $0.86 during the five months ended December 31, 2006 and 2005; and $0.86 during the fiscal year ended July 31, 2006. The total intrinsic value of options exercised was $172,000 and $398,000 during the years ended December 31, 2007 and 2006, $137,000 and $0 during the five months ended December 31, 2006 and 2005, and $261,000 for the fiscal year ended July 31, 2006.

At December 31, 2007, there were approximately 2.6 million non-plan options reserved for issuance.

The following table summarizes information related to warrants outstanding at December 31, 2007:

Price Range	Number of Warrants Outstanding and Exercisable 000's	Remaining Contractual Life (Years)
$0.01 – 0.99	10,078	1.1
$1.00 – 1.99	15,775	2.6
$2.00	840	0.3
Totals	26,693	

NOTE 13 – SUBSEQUENT EVENTS

On February 6, 2008, the Company's Board of Directors, upon the recommendation of the Compensation Committee, approved grants of 750,000 shares of restricted common stock to the executive officers of the Company and an additional 350,000 shares of restricted stock to other employees of the Company. The restricted stock was awarded from the Company's 1998 Stock Option Plan.

The restrictions on the restricted stock shall lapse over a three-year period, subject to reduction as follows: (1) in the event of a $5 million non-dilutive financing by the Company on or before December 31, 2008, the three-year restriction shall be accelerated such that the restrictions on the restricted stock shall lapse over a two-and-one-half year period; (2) in the event of an additional $5 million (or $10 million in the aggregate) non-dilutive financing by the Company on or before December 31, 2008, the three-year restriction shall be accelerated such that the restrictions on the restricted stock shall lapse over a two-year period; and (3) in the event of a $20 million (or $20 million in the aggregate) non-dilutive financing by the Company, the restrictions shall immediately lapse.

Additionally, the Board, upon the recommendation of the Compensation Committee, agreed that, in the case of Mr. Ratoff, an additional 200,000 shares of restricted stock shall be granted as follows: (1) upon achieving a $5 million non-dilutive financing by the Company on or before December 31, 2008, an additional 100,000 shares of restricted stock shall be granted; and (2) upon achieving an additional $5 million (or

$10 million in the aggregate) in non-dilutive financing by the Company on or before December 31, 2008, an additional 100,000 shares of restricted stock shall be granted. The restrictions on such additional shares of restricted stock shall lapse over a three-year period.

NOTE 14 – QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)

Unaudited quarterly financial data for the year ended December 31, 2007, the five months ended December 31, 2006 and for the fiscal year ended July 31, 2006 follows:

	Three Months Ended				
	March 31, 2007	June 30, 2007	September 30, 2007	December 31, 2007	Year Ended December 31, 2007
Total Revenues	$ 40,000	$ 165,000	$ 206,000	$ 58,000	$ 469,000
Total Expenses	5,334,000	5,676,000	3,037,000	4,609,000	18,656,000
Loss from Operations	(5,294,000)	(5.511,000)	(2,831,000)	(4,551,000)	(18,187,000)
Other Income/(Loss)	(360,000)	—	294,000		(66,000)
Interest Income	230,000	187,000	127,000	88,000	632,000
Income Tax Benefit	—	—	—	658,000	658,000
Net Loss	$ (5,424,000)	$ (5,324,000)	$ (2,410,000)	$ (3,805,000)	$ (16,963,000)
Basic and Diluted Loss Per Common Share	$ (0.09)	$ (0.09)	$ (0.04)	$ (0.06)	$ (0.29)
Weighted Average Number of Shares of Common Stock Used in Computation of Basic and Diluted Loss Per Common Share	59,264,000	59,537,000	59,591,000	59,592,000	59,497,000

	Three Months Ended October 31, 2006	Two Months Ended December 31, 2006	Five Months Ended December 31, 2006
Total Revenues	$ 1,041,000	$ 1,026,000	$ 2,067,000
Total Expenses	3,656,000	2,863,000	6,519,000
Loss from Operations	(2,615,000)	(1,837,000)	(4,452,000)
Interest Income	106,000	74,000	180,000
Income Tax Benefit	—	(467,000)	(467,000)
Net Loss	$ (2,509,000)	$ (1,296,000)	$ (3,805,000)

Basic and Diluted Loss Per Common Share	$ (.05)	$ (.03)	$ (.08)
Weighted Average Number of Shares of Common Stock Used in Computation of Basic and Diluted Loss Per Common Share	49,213,000	49,987,000	49,522,000

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	Three Months Ended				Fiscal Year Ended
	October 31, 2005	January 31, 2006	April 30, 2006	July 31, 2006	July 31, 2006
Total Revenues	$ 150,000	$ 541,000	$ 1,159,000	$ 40,000	$ 1,890,000
Total Expenses	2,768,000	3,658,000	3,307,000	2,721,000	12,454,000
Loss from Operations	(2,618,000)	(3,117,000)	(2,148,000)	(2,681,000)	(10,564,000)
Interest Income	43,000	30,000	19,000	132,000	224,000
Income Tax Benefit	—	(256,000)	—	—	(256,000)
Net Loss	$ (2,575,000)	$ (2,831,000)	$ (2,129,000)	$ (2,549,000)	$ (10,084,000)
Basic and Diluted Loss Per Common Share	$ (0.06)	$ (0.07)	$ (0.05)	$ (0.05)	$ (0.23)
Weighted Average Number of Shares of Common Stock Used in Computation of Basic and Diluted Loss Per Common Share	40,606,000	40,648,000	41,715,000	48,991,000	43,000,000

The sum of the quarters may not equal the full year basic and diluted loss per share since each period is calculated separately.

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INDEX TO EXHIBITS

The following exhibits are included with this Annual Report on Form 10-K. All management contracts or compensatory plans or arrangements are marked with an asterisk.

EXHIBIT NO.	DESCRIPTION	METHOD OF FILING
3.1	Restated Certificate of Incorporation of the Company	Incorporated by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-QSB, as filed with the SEC on June 14, 2004
3.2	Certificate of Amendment to the Certificate of Incorporation of the Company	Incorporated by reference to Exhibit 3.1 of the Company's Annual Report on Form 10-K, as filed with the SEC on March 26, 2007
3.3	Amended and Restated By-laws of the Company	Incorporated by reference to Exhibit 3.1 of the Company's Form 8-K, as filed with the SEC on September 9, 2005
4.1	Form of Class C Warrant for the Purchase of Shares of Common Stock	Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC on January 12, 2004
4.2	Form of Warrant issued to certain accredited investors and placement agents	Incorporated by reference to Exhibit 4.1 of the Company's Form 8-K, as filed with the SEC on April 17, 2006
4.3	Form of Warrant issued to certain accredited investors and the placement agent	Incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on January 4, 2007
10.1*	1992 Stock Option Plan	Incorporated by reference to the Company's Registration Statement on Form SB-2, as filed with the SEC on August 8, 1997 (File No. 333-33201)
10.2*	Form of Incentive Stock Option Agreement under the 1992 Stock Option Plan	Incorporated by reference to the Company's Registration Statement on Form SB-2, as filed with the SEC on August 8, 1997 (File No. 333-33201)
10.3*	1997 Stock Option Plan	Incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form SB-2, as filed with the SEC on August 8, 1997 (File No. 333-33201)
10.4*	Form of Non-Qualified Option Agreement under the 1997 Stock Option Plan	Incorporated by reference to the Company's Registration Statement on Form SB-2, as filed with the SEC on August 8, 1997 (File No. 333-33201)
10.5*	1998 Stock Option Plan	Incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-8, as filed with the SEC on June 18, 2004 (File No. 333-116665)
10.6*	Form of Stock Option Agreement under the 1998 Stock Option Plan	Incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-8, as

		filed with the SEC on June 18, 2004 (File No. 333-116665)
10.7*	Form of Non-Qualified Stock Option Agreement	Incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-8, as filed with the SEC on June 18, 2004 (File No. 333-116665)

10.8	Common Stock and Warrant Purchase Agreement, dated December 12, 2001, by and among the Company and certain purchasers	Incorporated by reference to Exhibit A to the Schedule 13D as filed by Lindsay A. Rosenwald with the SEC on December 21, 2001
10.9	Amendment No. 1, dated January 6, 2002, to the Common Stock and Warrant Purchase Agreement dated December 12, 2001 between the Company and certain purchasers	Incorporated by reference to Exhibit 10.25 to the Company's Registration Statement of Form SB-2, as filed with the SEC on April 15, 2002 (File No. 333-86262)
10.10	Lease Agreement, dated March 19, 2003, by and between the Company and Macedo Business Park, II, L.L.C.	Incorporated by reference to Exhibit 10.28 to the Company's Quarterly Report on Form 10-QSB for the period ended April 30, 2003, as filed with the SEC on June 19, 2003
10.11	Amendment Number 1 to Lease Agreement dated March 19, 2003 between Macedo Business Park, II, L.L.C. and the Company, dated as of March 19, 2003	Incorporated by reference to Exhibit 10.29 to the Company's Quarterly Report on Form 10-QSB for the period ended April 30, 2003, as filed with the SEC on June 19, 2003
10.12	License and Development Agreement, effective as of April 4, 2003, by and between the Company and Manhattan Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-KSB, as filed with the SEC on March 11, 2004
10.13	Development, Manufacturing and Supply Agreement, dated July 28, 2004, by and between the Company and Par Pharmaceutical, Inc.	Incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-KSB, as filed with the SEC on November 15, 2004
10.14	Second Amendment to License and Development Agreement, dated as of June 22, 2004, by and between the Company and the Veterinary Company, Inc.	Incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-KSB, as filed with the SEC on November 15, 2004
10.15*	Employment Agreement, dated as of May 23, 2003, by and between the Company and Barry Cohen	Incorporated by reference to Exhibit 10.30 to the Company's Quarterly Report on Form 10-QSB for the period ending April 30, 2003, as filed with the SEC on June 19, 2003
10.16*	Disclosure and Release Agreement Related to the Exchange of Non-Plan Options for Stock Options under the NovaDel Pharma Inc. 1998 Stock Option Plan by and between the Company and Thomas E. Bonney	Incorporated by reference to Exhibit 10.3 of the Company's Form 8-K, as filed with the SEC on August 2, 2005
10.17*	Disclosure and Release Agreement Related to the Exchange of Non-Plan Options for Stock Options under the NovaDel Pharma Inc. 1998 Stock Option Plan by and between the Company and William F. Hamilton	Incorporated by reference to Exhibit 10.2 of the Company's Form 8-K, as filed with the SEC on August 2, 2005
10.18*	Disclosure and Release Agreement Related to the Exchange of Non-Plan Options for Stock Options under the NovaDel Pharma Inc. 1998 Stock Option Plan by and between the Company and Charles Nemeroff	Incorporated by reference to Exhibit 10.4 of the Company's Form 8-K, as filed with the SEC on August 2, 2005
10.19*	Employment Agreement, dated as of December 20, 2004, by and between the Company and Michael Spicer	Incorporated by reference to Exhibit 10.35 of the Company's Form 8-K, as filed with the SEC on December 23, 2004
10.20*		

	Amendment to Employment Agreement dated September 2, 2005, by and between the Company and Michael E.B. Spicer	Incorporated by reference to Exhibit 10.2 of the Company's Form 8-K, as filed with the SEC on September 9, 2005
10.21*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated July 28, 2005, by and between the Company and Thomas E. Bonney	Incorporated by reference to Exhibit 10.25 of the Company's Annual Report on Form 10-KSB for the period ended July 31, 2005, as filed with the SEC on October 31, 2005

10.22*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated July 28, 2005, by and between the Company and William F. Hamilton	Incorporated by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-KSB for the period ended July 31, 2005, as filed with the SEC on October 31, 2005
10.23*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated July 28, 2005, by and between the Company and Charles Nemeroff	Incorporated by reference to Exhibit 10.29 of the Company's Annual Report on Form 10-KSB for the period ended July 31, 2005, as filed with the SEC on October 31, 2005
10.24	Amendment No. 1 to License and Development Agreement dated as of August 8, 2005, by and between the Company and Hana Biosciences Inc.	Incorporated by reference to Exhibit 99.1 of the Company's Form 8-K, as filed with the SEC on August 12, 2005
10.25	Separation, Consulting and General Release Agreement effective as of July 25, 2007, by and between NovaDel Pharma Inc. and Jan H. Egberts, M.D.	Incorporated by reference to Exhibit 10.1 of the Company's Form 8-K, as filed with the SEC on September 20, 2007
10.26*	Nonqualified Stock Option Agreement dated September 26, 2005, by and between the Company and Jan H. Egberts, M.D.	Incorporated by reference to Exhibit 10.2 of the Company's Form 8-K, as filed with the SEC on September 28, 2005
10.27*	NovaDel Pharma Inc. 2006 Equity Incentive Plan	Incorporated by reference to Exhibit 10.1 of the Company's Form 8-K, as filed with the SEC on January 23, 2006
10.28*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated December 14, 2005, by and between the Company and J. Jay Lobell	Incorporated by reference to Exhibit 10.4 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006
10.29*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and Thomas Bonney	Incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006
10.30*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and William Hamilton	Incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006
10.31*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and Charles Nemeroff	Incorporated by reference to Exhibit 10.5 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006
10.32*	1998 Stock Option Plan Nonqualified Stock Option Agreement dated January 17, 2006, by and between the Company and Steven Ratoff	Incorporated by reference to Exhibit 10.6 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on March 15, 2006
10.33	Form of Securities Purchase Agreement by and between the Company and certain accredited investors (with attached schedule of parties and terms thereto)	Incorporated by reference to Exhibit 10.1 of the Company's Form 8-K, as filed with the SEC on April 17, 2006
10.34	Registration Rights Agreement by and between the Company and certain accredited investors (with attached schedule of parties and terms thereto)	Incorporated by reference to Exhibit 10.2 of the Company's Form 8-K, as filed with the SEC on April 17, 2006
10.35		

Placement Agent Agreement, dated March 15, 2006, by and between the Company, Griffin Securities, Inc. and Paramount BioCapital, Inc.	Incorporated by reference to Exhibit 10.1 of the Company's Form 8-K, as filed with the SEC on April 20, 2006

10.36*	Employment Agreement dated December 4, 2006 by and between the Company and David H. Bergstrom, Ph.D.	Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, as filed with the SEC on December 8, 2006
10.37*	Incentive Stock Option Award between the Company and David H. Bergstrom dated December 4, 2006	Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, as filed with the SEC on December 8, 2006
10.38*	Nonqualified Stock Option Award between the Company and David H. Bergstrom, dated December 4, 2006	Incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K, as filed with the SEC on December 8, 2006
10.39	Securities Purchase Agreement by and between the Company and certain accredited investors (with attached schedule of parties and terms thereto)	Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, as filed with the SEC on January 4, 2007
10.40	Placement Agent Agreement, dated as of November 21, 2006, by and between the Company and Oppenheimer & Co., Inc.	Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, as filed with the SEC on January 4, 2007
10.41*	Employment Agreement dated February 22, 2007 by and between the Company and Deni M. Zodda, Ph.D.	Incorporated by reference to Exhibit 10.1 of the Company's Current Report on form 8-K, as filed with the SEC on February 28, 2007
10.42*	Incentive Stock Option Award between the Company and Deni M. Zodda dated February 22, 2007	Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, as filed with the SEC on February 28, 2007
10.43*	Nonqualified Stock Option Award between the Company and Deni M. Zodda dated February 22, 2007	Incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K, as filed with the SEC on February 28, 2007
10.44*	Amendment No. 2 to Employment Agreement dated March 12, 2007 by and between the Company and Michael E. Spicer	Incorporated by reference to Exhibit 10.44 of the Company's Annual Report on Form 10-K, as filed with the SEC on March 26, 2007
10.45*	Amendment 2007-1 to the NovaDel Pharma Inc. 1998 Stock Option Plan dated March 2, 2007	Incorporated by reference to Exhibit 10.45 of the Company's Annual Report on Form 10-K, as filed with the SEC on March 26, 2007
10.46*	Amendment 2007-1 to the NovaDel Pharma Inc. 2006 Equity Incentive Plan dated March 2, 2007	Incorporated by reference to Exhibit 10.46 of the Company's Annual Report on Form 10-K, as filed with the SEC on March 26, 2007
10.47	Amended and Restated License and Development Agreement, dated as of July 31, 2007, by and between NovaDel Pharma Inc. and HANA Biosciences, Inc.	Incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on November 14, 2007.
10.48	Product Development and Commercialization Sublicense Agreement, dated as of July 31, 2007, by and among NovaDel Pharma Inc., HANA Biosciences and PAR Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q, as filed with SEC on November 14, 2007.
10.49	Termination Agreement, dated as of July 31, 2007, by and between NovaDel Pharma Inc. and PAR Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q, as filed with the SEC on November 14, 2007.

10.50*	Employment Agreement dated January 22, 2008 by and between the Company and Michael E. Spicer.	Filed herewith
21.1	Subsidiaries of the Registrant	The registrant has no subsidiaries
23.1	Consent of J.H. Cohn LLP	Filed herewith
31.1	Certification of Chief Executive Officer under Rule 13a-14(a)	Furnished herewith

31.2	Certification of Principal Financial Officer under Rule 13a-14(a)	Furnished herewith
32.1	Certifications of the Chief Executive Officer and Chief Financial Officer under 18 USC 1350	Furnished herewith