APOGEE TECHNOLOGY INC
Form 10-K
March 31, 2011

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

FORM 10-K

(Mark One)
[X] ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2010

OR

[ ] TRANSITION REPORT UNDER TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____to_____.

APOGEE TECHNOLOGY, INC.
(Exact name of registrant as specified in its charter)

Commission File No: 000-30656

DELAWARE	04-3005815
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
129 MORGAN DRIVE NORWOOD, MASSACHUSETTS (Address of principal executive offices)	02062 (Zip Code)

Registrant's telephone number, including area code: (781) 551-9450

Securities registered pursuant to Section 12(b) of the Exchange Act: None
Securities registered under Section 12(g) of the Exchange Act:
Common stock, $.01 par value per share

Indicate by check mark whether the issuer is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes o No x

Indicate by check mark whether the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act: Yes o No x

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Date File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the proceeding twelve months (or such shorter periods that the registrant was required to submit and post such files). Yes o No x

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

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

Large accelerated filer o	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller Reporting company)	Smaller reporting company ý

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

The aggregate market value of the registrant's voting stock held by non-affiliates of the registrant (assuming for the purposes hereof, that directors, executives and 10% or greater stockholders of the registrant are affiliates of the registrant), based upon the closing sale price of the registrant was $4,037,846, based on the closing price of the stock on the OTC Bulletin Board on March 18, 2011.

Portions of the registrant's definitive Proxy Statement for its 2011 Annual Meeting of Stockholders (the "2011 Proxy Statement") to be filed pursuant to the Securities Exchange Act of 1934 with the Securities and Exchange Commission within 120 days of December 31, 2010 are incorporated herein by reference into Part III of this Annual Report on Form 10-K.

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SPECIAL NOTE ABOUT FORWARD-LOOKING INFORMATION

This document contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Also, Apogee's management may make forward-looking statements orally or in writing to investors, analysts, the media and others. Forward-looking statements express our expectations or predictions of future events or results. They are not guarantees and are subject to many risks and uncertainties. There are a number of factors that could cause actual events or results to be significantly different from those described in the forward-looking statements. Forward-looking statements might include one or more of the following:

anticipated financing activities;

anticipated strategic alliances or arrangements with development or marketing partners;

anticipated research and product development results;

projected development and commercialization timelines;

descriptions of plans or objectives of management for future operations, products or services;

forecasts of future economic performance; and

descriptions or assumptions underlying or relating to any of the above items.

Forward-looking statements can be identified by the fact that they do not relate strictly to historical or current facts or events. They use words such as "anticipate", "estimate", "expect", "project", "intend", "opportunity", "plan", "potential", " words of similar meaning. They may also use words such as "will", "would", "should", "could", or "may".

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Moreover, we do not assume responsibility for the accuracy and completeness of such statements. We intend that the forward-looking statements will be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E, as amended, of the Securities Exchange Act of 1934, as amended. We do not intend to update any of the forward-looking statements after the date of this report to conform such statements to actual results except as required by law. Given these uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as of the date of this report. You should carefully consider all available information about Apogee before you make an investment decision. You should review carefully the risks and uncertainties identified in this Annual Report on Form 10-K.

PART I

Item 1. DESCRIPTION OF BUSINESS.

Corporate Overview

Apogee Technology, Inc., (“Apogee”, “we”, “us” or “our”) is developing PyraDerm™, a proprietary intradermal drug deliv system for vaccines and other pharmaceuticals that we intend to market to pharmaceutical and medical device companies. Until March 31, 2009, we were also engaged in the development of IntellaPAL™, a proprietary sensor-based health monitoring systems for the elderly care and other markets that we intended to manufacture and market to individuals and health organizations.

Our Life Science Group is developing PyraDerm, an advanced intradermal drug delivery system, to meet the needs of patients, health insurers, companies developing pharmaceuticals, as well as, governments and international health organizations. PyraDerm is designed to be a low-cost, effective, painless delivery system that can be self administered and easily stored while potentially providing pharmaceutical companies an extended patent position for their current drug formulations. We had previously demonstrated that PyraDerm system containing adjuvanted vaccine formulations is capable of improving the efficiency of immunization and providing a significant dose sparing effect in a relevant animal model. Technologies that reduce the required vaccine dose would allow faster and more efficient production of vaccines, which is especially important in case of vaccine shortages during epidemic emergencies, such as pandemic influenza. The results of these studies were published in 2009 in the Proceedings of the National Academy of Sciences of the USA serving as an important validation of our approach to intradermal vaccination. In 2009, we closed down the operations of the Health Monitoring Product Group. Costs associated with this cessation of operations and terminations of related employees were not material. In 2009 we had to scale down research and development efforts due to financial constraints and focused on the proof-of-concept stability studies of PyraDerm system and relevant formulation and process development activities. In 2010 Apogee, while still operating under the same conditions, has continued these efforts concentrating on the development of analytical and quality control systems, as well as further advancement of microneedle with improved stability. We believe that these development efforts are critically important for the successful commercialization of our microneedle platform. The Company also continued to pursue patent applications related to its technology. Upon completion of our studies, if successful, we intend to pursue licensing and partnership agreements for multiple product applications with pharmaceutical, and medical device companies, and government and world health organizations interested in drug delivery systems and technologies.

Subject to additional funding, Apogee's sole focus will remain on developing and growing the Life Science Group.

History

Apogee was organized as a Delaware corporation in 1987, and initially operated through its wholly owned subsidiary, Apogee Acoustics Incorporated, or Acoustics. Acoustics engineered, manufactured, and marketed high quality, high-end patented ribbon loudspeaker systems for use in home audio and video entertainment systems. This technology was considered so innovative that a pair of Apogee loudspeakers is on display at the Smithsonian Museum.

We discontinued our loudspeaker business in 1994 and utilized our audio experience on the development of the worlds' first all-digital, high efficiency audio amplifier integrated circuits, or ICs, which we trademarked as Direct Digital Amplification or DDX®. We transitioned our business to take advantage of the patent we received in 1991 for related technology and to pursue the market opportunity created by the industry adoption of digital audio transmission, recording and playback. In 1999, we released our first DDX IC and subsequently released over twenty additional DDX ICs. In addition to our IC product sales, we also licensed DDX technology to several IC companies, including STMicroelectronics NV, or ST, one of the world's largest semiconductor companies.

In May 2004, in order to expand our technology base and to further diversify our product and market opportunities, we acquired a portfolio of Micro Electro Mechanical Systems "(MEMS") and nanotechnology intellectual property, trade secrets and know-how developed by Standard MEMS, Inc. MEMS are devices produced using high volume IC manufacturing techniques that include both electrical circuits and microscopic mechanical systems. During this time, we also hired employees from the former Standard MEMS, Inc. and established a MEMS Division that we subsequently consolidated into our Norwood headquarters. Since this acquisition, we have been using this acquired know-how plus additional technologies to develop MEMS and nanotechnology-based drug delivery and sensor products.

On October 5, 2005, we sold our audio IC business, including the DDX technology and the associated royalties from our license agreement with ST, to SigmaTel, Inc., or SigmaTel, for approximately $9.4 million plus a one-year earn-out that subsequently amounted to $383,000. After the sale, we reorganized our remaining MEMS division into two major business groups, the Medical Products Group and the Sensor Products Group. We also closed our sales offices in China, Japan, Taiwan and Hong Kong and terminated our agreements with our independent sales representatives and distributors. The Sensor Products Group was subsequently closed September 2008.

In 2008, all our revenue was derived from royalties received as a result of an agreement between Apogee and Freescale (formerly SigmaTel, Inc.) whereby Freescale agreed to pay Apogee a percentage of the royalties it received from ST in exchange for supporting their royalty negotiations with ST, as well as revenue from the sale of the remaining DDX inventory. Upon acceptance by Freescale of lower royalty payments, the arrangement agreed to between Freescale and Apogee in April 2008 was cancelled. No further revenue is expected under this arrangement. We expect future revenue, if any, will initially be the result of licensing and development-related revenues resulting from the grant of rights to our intellectual property.

Since October 1, 2008, we have operated as a technology research and development-stage company, and have invested our resources substantially in the development of our Life Science Group. In order to support our operations, we intend to secure additional funding in 2011.

Apogee maintains an Internet site at http://www.apogeebio.com. The information contained on our Internet site is not incorporated by reference in this report and should not be considered part of this report. Apogee's Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments to those reports, are available free of charge on our website as soon as reasonably practicable after they are filed with, or furnished to, the Securities and Exchange Commission.

Life Science Business Overview

Background

The drug delivery market is driven by the needs of patients, health insurers, companies developing pharmaceuticals, as well as governments and international health organizations. Patients desire drug delivery systems that are effective, inexpensive, easy to use, can be self applied, are painless, and do not require any special storage or handling. We believe that health insurers desire similar standards in drug delivery systems as well as reduction of treatment cost. If such goals are realized, the ancillary benefits could be higher efficacy, as a result of improved patient compliance, and wider self-administration, avoiding the cost and inconvenience of doctor or hospital visits. We believe pharmaceutical companies desire delivery systems that improve efficacy, are safe, reduce side effects and the associated liabilities, and have the potential to extend the patent life of drugs to protect market position. Similarly, we believe that both government and international health organizations desire low cost drug delivery systems that can be applied without the involvement of health care professionals and can be easily stored and distributed efficiently.

We believe that existing drug delivery technologies of parenteral (i.e. intra muscular, subcutaneous and intra venous injection), oral, nasal, and transdermal administration do not meet all of the needs or stated goals for existing and emerging therapies. For example, protein drugs do not lend themselves to oral delivery because of poor bioavailability. Consequently, these drugs are delivered parenterally by health care professionals resulting in increased costs and reduced patient compliance. Traditional transdermal patches cannot be used to deliver large molecule drugs because they will not penetrate the skin under normal conditions. In order to overcome this problem, drug delivery companies are developing active transdermal systems that use electrical forces (iontophoresis), chemical enhancers and microporation methods, which include: RF energy, lasers, thermal energy and microneedles.

PyraDerm Solution

Our PyraDerm delivery system consists of an array of microneedles incorporating a solid-state formulation that can be utilized to deliver drugs and vaccines into the skin. We apply micro-fabrication techniques to create our microneedle arrays using biocompatible materials. We have developed unique methodologies to incorporate solid state formulations into our microneedles. Our formulation is designed to work with various types of drugs and vaccines, improve drug or vaccine shelf-life, and to have a desired release profile, for example, to dissolve rapidly or in a prolonged manner, to meet specific drug delivery requirements.

We believe PyraDerm offers several advantages over competitive transdermal delivery technologies and non-transdermal systems for vaccines, small-dose high-potency protein drugs and other active ingredients. We also believe that our technology has the potential to enhance the delivery rate of certain small-molecule drugs compared to existing passive transdermal systems or patches. When compared with other active transdermal systems that utilize electrical/thermal/RF/laser energy or particle ablation, we believe our system will be lower in cost, safely disposable and will have the potential for self-administration. We believe our system has the potential to reduce or eliminate pain, safer to dispose and decrease the reliance on controlled temperature chain supply. In addition, our system may provide improved efficacy for vaccines. Compared to oral administration, our approach avoids the digestion system, thereby potentially reducing side effects, and improving the bioavailability for specific drugs.

We are developing novel solid microneedle systems containing formulations capable of releasing biologically active compounds in a controlled manner when applied to the skin. We currently have rights to patents and have filed patent applications concerning polymer formulations for use in targeted applications and related manufacturing processes. We believe that our microneedle technology can offer significant benefits. A summary of our system’s performance in previously conducted in vivo and in vitro studies along with important potential advantages is presented below.

In Vivo Performance: We have demonstrated in a relevant large animal model that our microneedle system is capable of delivering formulations of biologically active compounds, such as formulations of vaccine antigens, intradermally. We found that some important vaccine formulations delivered intradermally using our microneedle systems are superior to similar formulations delivered by conventional routes, such as intramuscular route.

Stability/Shelf Life: We have demonstrated that our microneedle formulations appear to improve thermal stability of certain biologically active compounds as compared to liquid formulations. This advantage could provide a longer potential shelf-life without loss of efficacy, while at the same time reducing the cost of storage and reliance on cold chain supply.

Controlled Release: We have demonstrated that our formulation technology may be tailored to modulate the release of biologically active compounds. Our systems can be formulated either for almost instantaneous release or, if desired, for sustained release of biologically active compound.

Dose Control: We have demonstrated that our proprietary microneedle coating process appears to provide for high efficiency of drug incorporation to minimize losses, or wasted bio-active material, so that a precise dose of drug can be applied reliably.

Microneedle Design: We believe the advantages of our microneedle array designs are that: (i) the components of our microneedles are either excipients of approved formulations or have a history of human use (ii) the dimensions of our micro needles can be precisely manufactured to meet the needs of the optimal delivery depth in the skin, (iii) our design approach utilizes manufacturing methods that can be scaled to high volume production to meet cost goals.

We also believe that the design of our microneedles can provide additional simplifications and benefits to address the needs of patients, pharmaceutical companies, health insurers, government, and world health organizations.

Needs	Design Advantages
Patient	
Safety	- Single use - Lower probability of needle sticks - Less chance of accidental overdose
Reduced or no Pain	- Minimal or no pain due to size of microneedles - Patient friendly and easy to use applicator
Ease of Administration	- Easier administration with a possibility of self-administration limits need for doctor and hospital visits
Health Insurers	
Treatment Cost of Patient	- Low cost design - Designed for higher efficacy (vaccines) potentially reducing need for multiple administrations - Self administration limits cost of doctor/hospital visits - Painless and easy delivery improves compliance and patient realizes the benefits of enhanced compliance
Government/World Health Organizations	
Low Treatment Cost	- Low cost design
Long Term Storage/ Ease of Transport	- Solid-state formulation may provide extended shelf life and minimizes reliance on refrigerated chain supply
Rapidly Deployable	- Easy or self-administration – no health care professionals required

Disposable / No Reuse/Contamination	- Single use for no cross contamination - Easier to dispose - All of the drug is consumed; no disposal abuse
Pharmaceutical Companies	
Higher Efficacy	- Targeted intradermal delivery of vaccines may lead to higher immune responses (more effective vaccines), dose sparing, and potentially new vaccines
Improved Safety/Less Side Affects	- No potential for needle reuse and cross contamination - No gastric tract related side affects - Less chance of accidental overdose with the single use design
Extend Patent Life	- New formulation and delivery route may extend drug patent life
Release Control	- Solid-state drug formulation has potential to be customized for rapid or prolonged release
Platform Design for Wide Use	- Potentially suitable for vaccines, high potency large molecule drugs and active ingredients

Market Opportunities

We believe that the advantages of PyraDerm's design, targeted intradermal delivery, self-administration and controlled release, may have particular benefits for the delivery of vaccines, small dose high potency protein based therapeutics and non-pharmaceutical ingredients as summarized below.

Vaccines: Today most vaccines are delivered by painful intramuscular injection, even though below the top layer of the skin are cells whose function is to facilitate the body's protective immune response mechanism. PyraDerm is designed to deliver vaccines to the skin layer rich in such cells thereby potentially increasing efficacy over intramuscular injection. This targeted approach may have the potential to reduce the vaccine dose required for an effective immunization. In addition, new vaccines that currently do not meet efficacy requirements using an intramuscular injection may be viable using PyraDerm thus expanding market opportunities. Because our delivery system is designed for a possibility of self-administration, vaccines can be deployed rapidly to a large population in the event of a flu outbreak or a bioterrorism attack. We believe that the anticipated stability of our solid-state formulation will have benefits for the viability and utility of such vaccines.

The vaccine market is well established and is projected, by a leading research firm, to grow to $18.2 billion. We believe that emerging vaccines, such as for pandemic flu, cancer and bioterrorism, will be driving most of the vaccine market growth over the next 10 years. Over 80 million doses of flu vaccine are administered in the United States on an annual basis.

Protein/Polypeptide Drugs: Protein and polypeptide therapeutics are among the most effective treatments available today for certain diseases. These large molecule pharmaceuticals can be a challenge to deliver orally because they are usually inactivated during digestion and therefore are typically administered parenterally. The need for professional administration of these therapies is one of the challenges limiting their acceptance and market growth. For the protein drugs that only require a small dosage, PyraDerm may offer the following potential advantages:

- painless self administration thereby avoiding the need for a hospital or doctors visit,
- simplified storage and extended product shelf life of large molecule drugs, and
- extension to the patent life of specific drugs through the adoption of a new transdermal formulation protecting pharmaceutical market share and product revenue.

There currently are more than 40 marketed peptide/protein based drugs for the treatment of diseases such as diabetes, osteoporosis, hepatitis and cancer. The total market for these therapies is expected to grow to $90 billion in the foreseeable future.

Government Regulation

Drug delivery products require FDA approval for many of the applications discussed above before they can be sold in the United States. If these products are marketed abroad, they will also be subject to export requirements as well as to regulation by foreign governments. The FDA administers the Federal Food, Drug and Cosmetic Act, the FFDCA, and has adopted regulations to administer the FFDCA. These regulations include policies that: i) govern the introduction of new medical devices, drugs, and excipients; ii) require observing certain standards and practices in the manufacture and labeling of medical devices; and iii) require medical device and drug companies to maintain certain records and report related deaths, serious injuries and certain malfunctions to the FDA. The FDA approval process can last several years before a product can be marketed and sold. Because of these regulations we have retained experienced FDA consultants to support our research and development efforts.

Our Business Strategy

Upon completion of in vitro and in vivo evaluation of PyraDerm, if successful, we intend to pursue licensing/development and partnership agreements with pharmaceutical companies, government and world health organizations. We do not intend to enter clinical trials with PyraDerm due to the significant cost and time associated with the FDA approval process. Under a licensing/development agreement with a pharmaceutical company, we would provide rights to our intellectual property for specific applications in exchange for license fees, milestone payments and/or royalties tied to product sales. Under a partnership agreement, we would jointly invest in the product development and share on some basis the resulting revenues. We may also sell the rights to our technologies for specific applications.

Competition

As presented above, we believe that we are positioned to compete effectively in the drug delivery marketplace. However, our major competitors are substantially larger and have financial resources significantly greater than our own. Companies developing similar drug delivery technologies include 3M Company, Zosano Pharma, Becton Dickinson and Company and Corium International Incorporated.

Business Operations

Research and Development