GENETHERA INC Form 10QSB August 24, 2004

SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM 10-QSB

[ X ] Quarterly Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the Quarterly Period Ended June 30, 2004

Commission File No. 000-27237

GENETHERA, INC.

(Exact name of small Business Issuer as specified in its Charter)

Florida 66-0622463

(State or Other Jurisdiction of Incorporation or Organization)

(I.R.S. Employer Identification Number)

3930 Youngfield Street, Wheat Ridge CO 80033 (Address of principal executive offices) (Zip Code)

Issuer's telephone number, including area code: (303) 463-6371

Hand Brand Distribution, Inc.
(Former name, former address and former fiscal year,
if changed since last report)

Check whether the issuer (1) filed all reports required to be filed by Section 13 or  $15\,(d)$  of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the issuer was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days [ X ] Yes [ ] No

State the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 17,925,055 Shares of \$.001 par value Common Stock outstanding as of June 30, 2004.

GENETHERA, INC., AND SUBSIDIARIES

FORM 10-QSB

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AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)
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(UNAUDITED)
SIX MONTHS ENDED

JUNE 30, 2004

GENETHERA, INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)
CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)
SIX MONTHS ENDED JUNE 30, 2004

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#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors GeneThera, Inc. Wheat Ridge, Colorado

We have reviewed the accompanying consolidated balance sheet of GeneThera, Inc. (a development stage company) and its wholly-owned subsidiary as of June 30, 2004 (unaudited), and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for the periods ended June 30, 2004 and 2003 and for the period from October 5, 1998 (inception) to June 30, 2004. These financial statements are the responsibility of the Company's management.

We conducted our review in accordance with standards established by the Public Company Accounting Oversight Board (United States). A review of interim financial information consists principally of applying analytical procedures and making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with the standards of the Public Company Accounting Oversight Board, the objective of which is the expression of an opinion regarding the financial statements taken as a whole. Accordingly, we do not express such an opinion.

Based on our review, we are not aware of any material modifications that should be made to the accompanying interim consolidated financial statements for them to be in conformity with U.S. generally accepted accounting principles.

KANTOR, SEWELL & OPPENHEIMER, PA Certified Public Accountants

Hollywood, Florida July 23, 2004

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### PART 1 - FINANCIAL INFORMATION

### Item 1. Financial Statements

no shares issued and outstanding

17,925,055 issued and outstanding

Additional paid in capital

Accumulated deficit

Common stock \$.001 par value, authorized 100,000,000 shares;

GENETHERA, INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)
CONSOLIDATED BALANCE SHEET
JUNE 30, 2004
(UNAUDITED)

#### Assets

Current assets Cash Prepaid expenses	\$ 15,740 61,848
Total current assets	77,588
Property and equipment, net	460,840
Other assets Deposits Other assets	5,278 3,576
	8,854
	\$ 547,282 ======
Liabilities and Stockholders' Deficit	
Current liabilities Accounts payable Accrued expenses Lease payable Notes payable Convertible notes payable	\$ 105,951 556,144 5,370 44,517 121,101
	833,083
Stockholders' deficit Preferred stock, \$0.001 par value, 20,000,000 shares authori	zed;

17,925

22,496,059

(22,799,785)

\$ 547,282

See notes to financial statements.

GENETHERA, INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the period ended June 30,  Three months ended  2004  2003		SIX MONTHS 2004
Income Sales net of returns Research fees	\$ 	\$ 16,818 5,000	\$ 
Cost of sales	21,818	(9,865)	45 <b>,</b> 041 
Gross profit		11,953	
Expenses  General and administrative expenses  Sales expenses	87 <b>,</b> 310	55,442 7,168	211,102
Lab expenses Insurance	8,293 3,571	275 1,473	18,356 14,656
Consulting Professional fees Salaries	500,278 29,332 42,428	182,619 74,220	735,778 147,028 97,152
Other compensation Lease expense Depreciation and amortization	14,405,976 19,947 	2,120 11,553	14,405,976 54,269 25,541
	15,097,135	334,870	15,709,858
Loss from operations		(322,917)	
Other income (expenses)	(10,007,1007)		(10), (03), (00)
Other income (expenses), net Interest expense	(45,833)	(77,772) (28,826)	(1,188,797)
Net loss from operations Net loss from operations		\$ (429,515) \$ (429,515)	
Loss from discontinued operations			
Net loss	\$(15,142,968)	\$ (429,515)	\$(16,898,655)

Loss per common share \$ (0.84) \$ (0.22) \$ (0.94)

See notes to financial statements.

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GENETHERA, INC. AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

PERIOD FROM OCTOBER 5, 1998 (INCEPTION) TO JUNE 30, 2004

	Common Stock Shares	Amount	Paid in Capita
Issuance of common stock to founders for consulting services rendered at an aggregate of \$36,000	420,000	\$ 420	\$ 35 
Issuance of common stock in exchange for equipment supplies and cash	100,000	100	99
Issuance of common stock according to a contract for computer services and financing	60,000	60	59
Issuance of common stock in exchange for cash	5,000	5	4
Net loss, 1999			
Balance December 31, 1999	585,000	585	200
Issuance of common stock in exchange for consulting services rendered	25,000	25	24
sub-total	610,000	\$ 610	\$ 225
Issuance of common stock in exchange for an agreement for management and financing for \$80,000	40,000	40	39
Issuance of common stock in exchange for a consulting agreement	10,000	10	11
Net loss, 2000			
Balance December 31, 2000	660,000	660	277
Issuance of common stock to an officer in lieu of salary	1,125,000	1,125	238
Issuance of common stock to an employee in lieu of salary	60,000	60	59

Issuance of common stock to an employee in lieu of salary 15,000

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15

100,000	10	0	99
1,960,000	\$ 1,96	0	\$ 691
1,960,000	\$ 1,96	0	\$ 691
697 <b>,</b> 176	69	17	1,000
21,000	2	:1	10
60,000	6	50	29
	_	-	83
	-	-	285
2,738,176	2,73	18	2,101
	-		201
	-	-	200
			319
715,000	71	.5	607
3,453,176	\$ 3,45	3	\$ 3,429
600,000	60	0	1,163
663,302	66	3	330
80,000	8	0	191
			E 114
4,796,478	4,79	16	5,114
4,796,478 934,926	4 <b>,</b> 79		650
	93		
934,926	93	35	650
934,926 50,000	93 5 3	35	650 205
934,926 50,000	93 5 3	35 50 30	650 205 119
	1,960,000 1,960,000 697,176 21,000 60,000 2,738,176 715,000 3,453,176 600,000 663,302 80,000	1,960,000 \$ 1,96 1,960,000 \$ 1,96 697,176 69 21,000 2 60,000 6 2,738,176 2,73 715,000 71 3,453,176 \$ 3,45 600,000 60 663,302 66 80,000 8	1,960,000 \$ 1,960 1,960,000 \$ 1,960 697,176 697  21,000 21  60,000 60 2,738,176 2,738 715,000 715  3,453,176 \$ 3,453 600,000 600 663,302 663

	sub-total	14,926,076	\$ 14,926	\$ 21,437
Shares issued to officer (\$1.30)		455,000	455	591
Shares issued to consultants for services rendered (\$1.58; \$1.18)		161,000	161	231
Warrants exercised		2,382,979	2,383	235
Net loss, June 30, 2004			 	
Balance June 30, 2004 (Unaudited	1)	17,925,055	\$ 17,925	\$ 22 <b>,</b> 496

GENETHERA, INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)
CONSOLIDATED STATEMENTS OF CASH FLOWS

		ended June 30,	October 5, 1998 (inception) to June 30, 2004
Cash flows from operating activities: Net loss	\$(16,898,655) 		\$(21,683,729)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	25.541	19,740	157.381
Compensation in exchange for common stock	15,201,754		17,440,504
Beneficial conversion feature	· ·		
Loss on discontinued operations	. , ,		
(Increase) decrease in accounts receivable		(5,517)	
(Increase) decrease in inventory		(7,200)	
(Increase) decrease in other assets	(64,417)	(319,849)	(70,703)
Increase (decrease) in accounts payable			
and accrued liabilities	(107,025)	734,000	
Increase (decrease) in deferred income		5 <b>,</b> 899	
Total adjustments		427,073	
Net cash used in operating activities	(664,695)		(1,884,098)
Cash flows from investing activities:  Cash payments for the purchase of property	(5,508)		
Net cash used in investing activities		(11,534)	(14,088)

Cash flows from financing activities:

Bank overdraft		15,324		
Capital contributed as equipment				272,376
Principal payments on note/leases payable	(152,057)			
Proceeds from issuance of common stock		83,262		155,000
Proceeds from loans payable	 838 <b>,</b> 000	193 <b>,</b> 910		1,486,550
Net cash provided by financing activities	 685 <b>,</b> 943	 292 <b>,</b> 496		1,913,926
Net increase in cash and cash equivalents	15,740	4,497		15 <b>,</b> 740
Cash and cash equivalents, beginning of year	 	 		
Cash and cash equivalents, end of year	\$ 15 <b>,</b> 740	\$ 4,497	\$ ===	15,740
Supplemental disclosures of cash flow information:				
a) Cash paid during the period for: Interest expense	\$ 	\$ 	\$	1,616

GENETHERA, INC. AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

SIX MONTHS ENDED JUNE 30, 2004

#### NOTE 1 PRINCIPLES OF CONSOLIDATION

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, GeneThera, Inc. (Colorado). All significant inter-company balances and transactions have been eliminated.

### NOTE 2 BASIS OF PRESENTATION

The interim financial information included herein is unaudited; however, such information reflects all adjustments which are, in the opinion of management, necessary for a fair presentation of the Company's financial position, results of operations, changes in stockholders' deficit and cash flows for the interim periods. All such adjustments are of a normal, recurring nature. The results of operations for the first six months of the year are not necessarily indicative of the results of operations that might be expected for the entire year.

The accompanying consolidated financial statements of the Company have been prepared in accordance with the instructions to Form 10-Q and, therefore, omit or condense certain footnotes and other information normally included in financial statements prepared in accordance with generally accepted accounting principles. It is suggested that these condensed financial statements should be read in conjunction with the Company's financial statements and notes thereto included in the Company's audited financial statements on Form 10-K/A for the fiscal year ended December 31, 2003. (See Note 9)

#### NOTE 3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Recent Accounting Pronouncements

The Financial Accounting Standards Board (FASB) issued SFAS No. 141, Business Combinations, which establishes revised standards for accounting for business combinations, eliminating the pooling method, and providing new guidance for recognizing intangible assets arising in a business combination. Additionally, SFAS No. 141 requires more prominent and more frequent disclosures in financial statements about a business combination. This statement is effective for business combinations initiated on or after July 1, 2001. The adoption of this pronouncement on July 1, 2001 did not have a material effect on the Company's financial position, results of operations or liquidity.

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GENETHERA, INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)
SIX MONTHS ENDED JUNE 30, 2004

#### NOTE 3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES - continued

SFAS 142, Goodwill and Other Intangible Assets provides guidance on accounting for the acquisition of intangibles, except those acquired in a business combination, which is subject to SFAS 141, and the manner in which intangibles and goodwill should be accounted for subsequent to their initial recognition. This statement is effective for all fiscal years beginning after December 15, 2001. The adoption of SFAS 142 on April 1, 2002 did not have a material effect on the Company's financial position, results of operations, or liquidity.

SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets provides implementation guidance regarding when and how to measure an impairment loss, and expands the presentation to include a component of an entity, rather than strictly a business segment. SFAS 144 also eliminates the current exemption to consolidation when control over a subsidiary is likely to be temporary. This statement is effective for all fiscal years beginning after December 15, 2001. The adoption of SFAS 144 on April 1, 2002 did not have a material effect on the Company's financial position, results of operations or liquidity.

Earnings per Share

Basic earnings per share are computed based on the weighted average number of common shares outstanding during each year. Diluted earnings per share are computed based on the weighted average number of common shares outstanding during the period, plus the dilutive effect of potential future issuances of common shares relating to convertible notes.

### NOTE 4 PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

June 30, 2004 -----\$ \$ 38,030

Computers

Telephone System Furniture & fixtures Laboratory equipment	5,118 1,465 578,043
Less accumulated depreciation	622,656 (161,816)
	\$460,840

Depreciation expense for the six months ended June 30, 2004 and 2003 was \$25,541 and \$19,740, respectively.

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GENETHERA, INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)
SIX MONTHS ENDED JUNE 30, 2004

#### NOTE 5 CONVERTIBLE NOTES PAYABLE

NOTE 3 CONVENTIBLE NOTES TATABLE	 June 30, 2004
Various convertible notes payable to individuals, with interest ranging from 8-10%; due at various dates from April 14, 2003 through June 18, 2004; convertible into shares of common stock at prices of \$0.25 - \$0.50 per	
share.	\$ 121,101
Less: current portion	 (121,101)
Total long-term convertible notes payable	\$ 0

For the six months ended June 30, 2004 and 2003, interest expense related to the convertible notes payable amounted to \$10,690 and \$3,019, respectively.

# NOTE 6 STOCKHOLDERS' EQUITY (DEFICIT)

Common Stock

During the six months ended June 30, 2004, the Company issued 1,306,259 shares of common stock pursuant to conversion rights exercised by holders.

On January 16, 2004, the Company issued 30,000 shares pursuant to a one-year agreement with a consultant for a total of \$120,000, based on the closing price on January 14, 2004. The Company charged one-half, or \$60,000 to operations and the remaining \$60,000 has been capitalized and prorated over the life of the agreement.

On January 26, 2004, the Company issued 211,000 shares for a total of \$437,480 based on the closing price on date of issue. These shares were issued to a consultant for services rendered and resulted in an immediate charge to operations.

In June 2004, the Company issued 9,198,339 shares for a total of \$14,405,976

based on the closing prices on the dates of issue. These shares were issued to the officer by resolution of the board of directors in conjunction with the completion of the reverse acquisition.

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GENETHERA, INC. AND SUBSIDIARY

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

SIX MONTHS ENDED JUNE 30, 2004

### NOTE 7 GOING CONCERN UNCERTAINTY

These financial statements are presented assuming the Company will continue as a going concern. For the years ended December 31, 2003 and 2002, the Company showed operating losses of \$3,080,740 and \$2,431,761, respectively. The accompanying financial statements indicate that current liabilities exceed current assets by \$755,495 for the six months ended June 30, 2004.

In addition, the Company is in default for payments on notes payable in the amount of \$44,517, including accrued interest. These factors raise substantial doubt about its ability to continue as a going concern. Management's plan with regard to these matters includes raising working capital to assure the Company's viability, through private or public equity offering, and/or debt financing, and/or through the acquisition of new business or private ventures.

### NOTE 8 SUBSIDIARY- SUBSEQUENT EVENT

On January 14, 2002, the board of directors voted to sell the stock of The Family Health News, Inc., subject to stockholder approval. On August 1, 2004 a final agreement was signed to dispose of the subsidiary. This agreement was effective nunc pro tunc to October 1, 2003. Consequently, the financial statements for the year ended December 31, 2003 will be restated to reflect this subsequent event, as if it had taken place October 1, 2003.

### NOTE 9 RESTATEMENTS

The Company will restate the consolidated balance sheet at December 31, 2003 and the consolidated statements of operations, stockholders' equity (deficit) and cash flows for the year then ended. The restatement is being made to reflect the proper accounting in accordance with accounting principles generally accepted in the United States in connection with beneficial conversion features on convertible debentures, revaluation of fixed assets, consolidation and disposal of a previously unconsolidated subsidiary, and impairment of long-lived assets.

The effect on the financial statements of the Company is as follows:

	As Restated	As Originally Reported
Accumulated deficit - December 31, 2002 Loss	\$ (2,820,390) (3,080,740)	\$ (2,367,011) (2,431,761)
Accumulated deficit - December 31, 2003	\$ (5,901,130)	\$ (4,798,772)

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Item 2. Management's Discussion and Analysis or Plan of Operations

The following discussion and analysis should be read in conjunction with the financial statements and notes thereto that appear elsewhere herein.

#### RESULTS OF OPERATIONS

Gross profits for the three-month period ended June 30, 2004 were \$0.00 compared to \$11,953 for the same period last year. The above status is due to the research and development stage the company is in at the present time.

Personnel (salaries) decreased from \$74,220 for the prior three month period ending June 30, 2003 to \$42,428 for the three month period ending June 30, 2004. There is a \$13,805,732 in the expense category due to an accounting entry for a beneficial conversion as reflected in the financial statements to the Chief Executive Officer resulting from completion of the reverse merger with Hand Brand Distribution, Inc. Professional expenses (consulting and professional fees) comparing the three month period ending June 30, 2003, to the three month period ending June 30, 2004, expenses increased substantially from \$182,619 to 529,610. This increase is due to accounting for the beneficial conversion feature of issuance of restricted stock in lieu of cash to the consultants.

#### GENETHERA PLAN OF OPERATION

#### Background

GeneThera is a development stage company (as such term is defined by the Securities and Exchange Commission ("SEC") and Generally Accepted Accounting Principles and has had negligible revenues from operations in the last two years. As a development stage company, its research and development expenditures have not been capitalized as of this date. The Company acquired 100% of the outstanding stock of GeneThera Inc., a Colorado corporation, for the issuance of 1,960,000 shares of the Company's common stock.

GeneThera has developed proprietary diagnostic assays for use in the agricultural and veterinary markets. Specific assays for Chronic Wasting Disease (among elk and deer) and Mad Cow Disease (among cattle) have been developed and are available currently on a limited basis. E.coli (predominantly cattle) and Johnne's disease (predominantly cattle and bison) diagnostics are in development.

GeneThera provides genetics—based diagnostic and is currently working on vaccine solutions to meet the growing demands of today's veterinary industry and tomorrow's agriculture and healthcare industries. The company is organized and operated both to continually apply its scientific research to more effective management of diseases and, in so doing, realize the commercial potential of molecular biotechnology.

The Company believes it will require significant additional funding in order to achieve its business plan. Over the next 12 months, in order to have the capability of achieving its business plan, the Company will require at least \$1,200,000. There are no guarantees whether the Company will be able to secure such a financing, and if the financing is secured, there are no guarantees

whether the Company can achieve the goals laid out in its business plan fully.

#### RESEARCH AND DEVELOPMENT

R&D serves as the source for both assay development and vaccine design/development. As assays for different diseases are developed, the Company plans to formalize the procedure into a commercial application through a series of laboratories to be owned and operated by GeneThera. To date, we have introduced our diagnostic solution for Chronic Wasting disease and Mad Cow disease on a very limited basis. We cannot assure you that we will be successful in developing or validating any new assays or, if we are successful in developing and validating any such assays, that we can successfully commercialize them or earn profits from sales of those assays. Furthermore, we cannot assure you that we will be able to design, develop, or successfully commercialize any vaccines.

#### COMMERCIAL DIAGNOSTIC TESTING

The Diagnostic Testing labs are the second division of the Company. The Company intends to locate laboratories geographically proximate to the primary sources of individual diseases and/or according to specific available operating efficiencies. The specific number of labs to be built and operated will be based on assay demand (demand facilitated by the number of specific disease assays GeneThera develops), our ability to obtain the capital to build the labs, and our ability to successfully manage them from our principal office.

#### LICENSING

Through our third division, Licensing, we intend to manage the marketing and sale of the vaccines developed by GeneThera's Research & Development division. As GeneThera does not intend to be a vaccine manufacturer, we plan to use our Licensing division to license the technology related to any vaccines that may be developed and to manage the revenue potential available from the successful development and validation of specific vaccines. We cannot assure you that we will develop any vaccines or that, if they are developed, we will be able to license them successfully or that any such license will produce significant revenues.

### R&D SERVICES

Molecular, Cellular, Viral Biology Research and Consulting Services:

GeneThera Inc. is committed to providing global access to cutting edge biotechnology services to fellow scientists in academia, the pharmaceutical industry, and the biotechnology industry. Primarily, GeneThera's expertise focuses on technology relevant to animal and human immunotherapy. GeneThera is dedicated to furnishing dependable, high quality, cost-effective and prompt client consulting services. These services are backed by the cumulative experiences of greater than 100 years of research and development in both government and industry by GeneThera's senior scientists. GeneThera develops a commercial-scale implementation of Adenovector Purification Process to support R&D material production. Furthermore, GeneThera evaluates and tests commercially available expression vectors and incorporates them into its vector repertoire. These technologies are well established within the repertoire of GeneThera's scientific staff. Research & Development Services:

### Molecular Biology:

o Synthetic cDNA Construction

- o Prokaryotic Expression Vector Construction & Development
- o E. coli Expression Strain Evaluation
- o Pilot Scale Fermentation
- o Mammalian Expression Vector Construction & Development
- o Baculovirus Expression
- o Protein Isolation
- o Protein Engineering: Complement Determining Region Conjugated Proteins Monoclonal Antibody Production Chimerization & Humanization
- Vector design for Prokaryotic Expression of Antibody Fragments (Fab) and Single Chain Antibody (ScFv)
- o Pilot Scale- up Development
- o Process Purification & Characterization
- o Assay Development & Quality Control Pharmaceutical Dosage and Formulation

Molecular Biology Potential Agreement Structure

Stage (I): cDNA Construction & Expression Vector Development Stage (II): Pilot Scale Expression & Protein Purification Stage (III): Assay Development & Quality Control Development Stage (IV): Bioprocess Development & Optimization Stage (V): Dosage & Formulation

Gene Therapy Testing services

GeneThera Services offers GLP testing programs for somatic cell, viral and naked DNA-based gene therapies. With over eight years experience in providing fully integrated bio-safety testing programs for the cell and gene therapy fields, we have supported a number of successful BLA and IND applications.

Replication-Competent Viral Vector Testing

Sensitive in vitro cell culture assays are used to detect replication-competent retroviruses or adenoviruses. GeneThera can work with clients to provide custom replication-competent virus detection assays for the particular vector construct.

Complete Somatic Cell and Viral Vector Packaging and Producer Cell Line Characterization

GeneThera offers all of the assays mandated by regulatory authorities worldwide for the bio-safety analysis and characterization of cells and cell lines used in gene therapy products.

Vector Stock Characterization

Custom purity and potency testing is available for gene therapy viral vector stocks.

Vector Purification Process Validation for Viral Clearance

Most biopharmaceuticals require viral clearance studies to validate the removal of potential contaminants, such as those from bovine components or from helper viruses (adenovirus in AAV production). GeneThera can provide custom design and performance of viral studies for various vector purification processes.

Custom Bio-safety Testing Programs for Somatic Cell, Ex Vivo Cell, and Tissue Therapies  $\,$ 

GeneThera can guide our clients through the unique process of designing and implementing a bio-safety testing program that meets the needs of each specific project.

GeneThera is currently seeking contracts for these services. There is no assurance that any contracts will be signed or that the company will generate significant profits from these contracts. Business Model

GeneThera's business is based on its Integrated Technology Platform (ITP) that combines a proprietary diagnostic solution called Gene Expression Assay (GEA(TM)) with PURIVAX(TM), its system for analyzing large-scale DNA sequencing. The first part of this platform is the ongoing development of molecular diagnostic assays solutions using real time Fluorogenic Polymerase Chain Reaction (F-PCR) technology to detect the presence of infectious disease from the blood of live animals. The second part of the ITP is the development of therapeutic vaccines using RNA interference technology. It also allows for the efficient, effective, and continuous testing, management and treatment of animal populations. These facts distinguish the technology from any alternative testing and management methodology available to agriculture today -- all of which require the destruction of individual animals and even entire herds. Our testing and data analysis processes also allow us not only to separate infected from clean animals, but also to gain knowledge vital to development of preventative vaccines.

Each individual assay utilizes the proprietary Field Collection System (FCS) for the collection and transportation of blood samples to GeneThera's laboratory. The FCS allows GeneThera to maintain the integrity of each sample by the addition of specific reagents to test tubes contained in the system. GeneThera's FCS is designed to be an easy-to-use method of gathering blood samples from harvested or domesticated animals. It ensures consistency of samples as well as increased assurance of each sample's integrity.

To date, GeneThera has successfully developed the ability to detect Chronic Wasting Disease, a disease affecting elk and deer in North America. The release of commercialized Field Collection Systems and laboratory diagnostic testing occurred in October of 2003. GeneThera has also successfully developed an assay for the detection of Mad Cow Disease, a disease recently found in the United States, but has been in Europe for many years. The Field Collection Systems are available for purchase from the Company. Chronic Wasting Disease and Mad Cow Disease are both in the family of diseases called Transmissible Spongiform Encephalopathy (TSE). Diagnostic assays for E.coli 0157:H7 and Johnne's Disease are in the final stages of development. Vaccines for Chronic Wasting Disease and E.coli 0157:H7 are in advanced stages of development. The Company will need the approval of the USDA before the vaccines can be sold. There are no assurances that such an approval will be granted, or if granted, whether the Company will be able to produce and sell such vaccines following such an approval in commercial quantities or to make a profit from such production and sales.

INTEGRATED TECHNOLOGY PLATFORM (ITP)

GeneThera's integrated technology platform is the foundation for "fast-track" rDNA vaccine development. ITP is the assembly of GEA(TM) and PURIVAX(TM) rAD and rAAV systems. This integrated technology platform yields fast-track vaccine development. Leveraging its ITP, GeneThera can develop a prototype vaccine within 4 to 6 months versus the current standard of 18 to 24. The GEA(TM) applied modular unit system utilizes robotics and is based on nucleic acid extraction in conjunction with F-PCR technology to develop gene expression assays. Using GEA(TM) assays, vaccine efficacy can be measured in real time. This means not having to wait for the antibody response to measure how well the vaccine is working. F-PCR allows effective quantification of the precise number of viral or bacterial genetic particles before, during and after vaccine injection(s). The more effective the vaccine is, the stronger the decrease of the infectious disease particles will be.

#### GEA (TM) SYSTEM

GEA(TM) is a proprietary assay development system. The core of GEA(TM) is Fluorogenic Polymerase Chain Reaction technology (F-PCR). GeneThera solves the technical problems related to the use of conventional PCR in molecular diagnostics via our modular unit concept. Specifically, the modular unit consists of an Automated Nucleic Acid Workstation (ANAW) and a Sequence Detection System (SDS) that are fully integrated, allowing an operator to perform the entire procedure of DNA extraction and F-PCR analysis within a closed computerized system. This system results in minimal intervention and no post-PCR manipulation.

The Automated Nucleic Acid Workstation is a highly flexible robotic system that extracts and purifies acids from a variety of complex samples, preparing them for F-PCR analysis. Data management system software includes a database to manage all run phases and record sample processing.

The Sequence Detection System detects the fluorescent signal generated by the cleavage of the reporter dye during each PCR cycle. This process confers specificity without the need of post-PCR hybridization. Most important, the SDS offers the advantage of monitoring real time increases in fluorescence during PCR. Specifically, monitoring real-time progress of the PCR completely changes the approach to PR-based quantitation of DNA and RNA, most particularly in improving the precision in both detection and quantitation of DNA and RNA targets.

GeneThera currently faces no competition in the use of F-PCR technology and the modular unit concept for commercial testing of either infectious disease in animals or food pathogen contamination. Currently, most labs utilize conventional microbiology, immunological or conventional PCR methods for either veterinary diseases or food pathogen contamination detection. Specific to microbiology and immunological techniques, the drawbacks of these approaches are:

- the antibodies-based culture media used to detect the presence of infectious diseases has a low level of sensitivity;
- high background due to non-specific binding of antibodies and/or culture contamination;
- 3. sample preparation and storage creates artifacts; and
- 4. long, cumbersome protocols necessary to perform these tests.

A major technical limitation of conventional PCR is the risk of contaminating a specimen with the products of previously amplified sequences. Known as

cross-contamination, this phenomenon represents a constant challenge to any lab using conventional PCR. Managing these challenges is cumbersome and difficult to streamline.

Fluorogenic PCR (F-PCR) overcomes these drawbacks by making it possible for PCR to efficiently test large numbers of samples even when major laboratory facilities are not readily available. A novel methodology, F-PCR allows quantitative and qualitative detection of specific nucleic acid sequences in a very sensitive, highly accurate and rapid fashion.

#### PURIVAX (TM) TECHNOLOGY

GeneThera has developed a large-scale process for highly purified and high viral titer Adenovirus and AAV recombinant vectors. This technology enables GeneThera to develop Adenovirus and AAV based recombinant DNA vaccines for veterinary diseases and food pathogens.

GeneThera's PURIVAX(TM) is a multi-resin anion exchange chromatography system that dramatically improves biological purity and viral titer of recombinant Adenovirus and AAV vectors. PURIVAX(TM) completely eliminates toxic side effects associated with adenoviruses and AAV vectors thereby making it possible to develop highly immunogenic and safe recombinant DNA vaccines. Importantly, recombinant DNA (rDNA) vaccine technology represents a powerful tool for an innovative vaccine design process known as "genetic immunization."

Recombinant Adenovirus (rAD) and AAV (rAAV) vectors are the ideal candidates for a gene delivery system. These viruses can efficiently deliver genetic material to both dividing and non-dividing cells, thereby overcoming some of the obstacles encountered with first generation retroviral vectors.

Equally important, rAd and rAAV are engineered virus genomes that contain no viral gene. One of the key features for rAd and rAAV is their ability to transduce a large variety of cells. However, two technical challenges had to be overcome to fully utilize rAd and rAAV in the development of rDNA vaccines:

- lack of large scale purification system;
- 2. low viral titer

Traditional technologies and first generation chromatography processes are inadequate both in terms of purity and yield. And, due to the limitation of these purification technologies, adequate viral titers cannot be achieved. The result is no efficient system to deliver immunogenic genetic sequences into cells.

This is the significance of GeneThera's PURIVAX(TM), rAD and rAAV system for rDNA vaccine development. Succinctly stated, it is able to achieve both high purity and high viral titer (up to 10e16 viral particles/eulate) based on its proprietary multi-resin anion exchange chromatography system. Biological contaminants such as endogenous retrovirus, bacterial, mycoplasma, non-specific nucleic acids, lipids, proteins, carbohydrates and endotoxins are eliminated during the purification process.

#### FIELD COLLECTION SYSTEM

GeneThera's Field Collection System (FCS) is a commercial product designed to permit a standardized manner for drawing, stabilizing and handling blood samples intended for GeneThera's diagnostic assay testing. Each package is referred to as a "System" because it is just that. There are two different FCS packages: one

for hunters and one for breeders or ranchers. GeneThera's FCS is designed to be an easy-to-use method of gathering blood samples from harvested or domesticated animals. It ensures consistency of samples as well as increased assurance of each sample's integrity.

Common to each FCS are two test tubes, each containing a separate reagent. The process, as described in the packaging, ensures that each individual sample of blood will be stabilized, thereby increasing the integrity of that sample for diagnostic testing. Additionally, this common method of receiving blood samples at the GeneThera laboratory(s) increases the efficiency of handling the volume of samples received. We believe this will enable us to provide a fast, efficient process, capable of posting results within 24 hours of receipt at a low cost to the consumer. All testing using the FCS must be done by GeneThera and no third parties can test the blood collected. The Company is currently offering the FCS for hunters, breeders, or ranchers directly through the Company on a limited basis. The Company intends to begin a marketing campaign through the addition of key personnel to achieve higher volumes of sales for the FCS. The Company projects that no capital will be needed to hire the additional personnel as they will be hired on a strictly commission based.

### Liquidity and Capital Resources

The Company had a cash balance of \$11,861.01 as of June 30, 2004. It is estimated that it will require outside capital for the year 2004 for the commercialization of GeneThera's molecular assays as well as the development of their therapeutic vaccines. The Company intends to raise these funds by means of one or more private offerings of debt or equity securities or both. As discussed in this filing, the Company has raised \$868,000 through Convertible Notes to certain individuals in late 2003 and 2004. Except for \$17,000, these individuals have converted as of the date of this filing. Currently the company is in discussions with two groups to obtain financing through either debt and/or equity. No definitive agreements have been signed. There are no guarantees whether the Company will be able to secure such a financing, and if the financing is secured, there are no guarantees whether the Company can achieve the goals laid out in its business plan fully.

### Convertible Notes

To relieve its cash flow crisis, the Company has issued convertible notes to certain individuals.

On December 12, 2002, the Company issued a convertible promissory note bearing interest at the rate of 8% per annum in the principal amount of Fifty Thousand Dollars (\$50,000) to Fidra Holdings Ltd. Under the terms of the convertible promissory note, the holder of the note is entitled to convert all sums due under the December 12 Note for \$.50 per share. As of June 30, 2004, the note has not been converted.

On December 24, 2002, the Company issued a Convertible Promissory Note bearing interest at the rate of 8% per annum in the principal amount of Ten Thousand Dollars (\$10,000). Under the terms of the Convertible Promissory Note, the holder of the Note is entitled to convert all sums due under the December 24 Note for \$0.50 per share. As of April 28, 2004, Ten Thousand Dollars (\$10,000) has been converted into 20,000 shares.

On January 12, 2003, the Company issued a Convertible Promissory Note bearing interest at the rate of 8% per annum in the principal amount of One Hundred Twenty Thousand Dollars (\$120,000). The Company received Thirty Six Thousand Nine Hundred Dollars (\$36,900). Under the terms of the Convertible Promissory Note, the holder of the Note is entitled to convert all sums due under the

January 12th Note for \$0.50 per share. As of October 1, 2003, Thirty Six Thousand Nine Hundred Dollars (\$36,900) plus accrued interest has been converted into \$0,000 shares.

Between October 2003 and January 2004, the Company issued 2 separate Convertible Promissory Notes bearing interest at the rate of 8% per annum. An aggregate amount of Seven Hundred and Forty Five Thousand Dollars (\$745,000) was raised. Under the terms of the Convertible Promissory Notes, the holder of the Note is entitled to convert all sums due under the Note for \$1.00 per share with the notes maturing six months from the date the money is received by the Company. The Company received Thirty Thousand Dollars (\$30,000) as of December 31, 2003 and the balance of Seven Hundred Fifteen Thousand Dollars (\$715,000) was received as of February 1, 2004. As of June 30, 2004, Seven Hundred Twenty-Eight Thousand Dollars (\$728,000) was converted into 728,000 shares, \$17,000 still remains outstanding under the Note.

In May 2004, the Company issued a Convertible Promissory Note for \$100,000 bearing interest at the rate of 6% per annum. An aggregate amount of Ninety-Eight Thousand Dollars (\$98,000) was raised. Under the terms of the Convertible Promissory Notes, the holder of the Note is entitled to convert all sums due under the Note for \$1.00 per share with the notes maturing 6 months from the date the money is received by the Company. The Company received Ninety-Eight Thousand Dollars (\$98,000) as of June 18, 2004. As of June 18, 2004, Ninety-Eight Thousand Dollars (\$98,000) was converted into 98,000 shares.

On June 23 2004, the Company issued a Convertible Promissory Note for \$25,000 bearing interest at the rate of 6% per annum. An aggregate amount of Twenty-Five Thousand Dollars (\$25,000) was raised. Under the terms of the Convertible Promissory Notes, the holder of the Note is entitled to convert all sums due under the Note for \$0.75 per share with the notes maturing 6 months from the date the money is received by the Company. The Company received Twenty-Five Thousand (\$25,000) as of June 25, 2004. As of June 25, 2004, Twenty-Five Thousand Dollars (\$25,000) was converted into 33,333 shares.

### FORWARD-LOOKING AND CAUTIONARY STATEMENTS

Sections of this Form 10-QSB, including the Management's Discussion and Analysis or Plan of Operation, contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), Section 21E of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), and the Private Securities Litigation Reform Act of 1995, as amended. These forward-looking statements are subject to risks and uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the results, performance or achievements expressed or implied by the forward-looking statements. You should not unduly rely on these statements. Forward-looking statements involve assumptions and describe our plans, strategies, and expectations. You can generally identify a forward-looking statement by words such as "may," "will," "should," "would," could," "plan," "goal," "potential," "expect," "anticipate," "estimate," "believe," "intend," "project," and similar words and variations thereof. This report contains forward-looking statements that address, among other things,

- \* our financing plans,
- \* regulatory environments in which we operate or plan to operate, and
- \* trends affecting our financial condition or results of operations, the impact of competition, the start-up of certain operations and acquisition opportunities.

Factors, risks, and uncertainties that could cause actual results to differ materially from those in the forward-looking statements ("Cautionary Statements") include, among others,

- \* our ability to raise capital,
- \* our ability to execute our business strategy in a very competitive environment,
- \* our degree of financial leverage,
- \* risks associated with our acquiring and integrating companies into our own,
- \* risks relating to rapidly developing technology,
- \* regulatory considerations;
- \* risks related to international economies,
- \* risks related to market acceptance and demand for our products and services,
- \* the impact of competitive services and pricing, and
- \* other risks referenced from time to time in our SEC filings.

All subsequent written and oral forward-looking statements attributable to us, or anyone acting on our behalf, are expressly qualified in their entirety by the cautionary statements. We do not undertake any obligations to publicly release any revisions to any forward-looking statements to reflect events or circumstances after the date of this report or to reflect unanticipated events that may occur.

### ITEM 3. CONTROLS AND PROCEDURES.

As required by Rule 13a-15 under the Securities Exchange Act of 1934 (the "Exchange Act"), we carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures within the 90 days prior to the filing date of this report. This evaluation was carried out under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that due to recent developments within FHNI which are beyond the control of the Company as more fully explained below, our disclosure controls and procedures are ineffective in timely alerting management to material information relating to us that is required to be included in our periodic SEC filings. There have been no significant changes in our internal controls or in other factors that could significantly affect internal controls subsequent to the date we carried out our evaluation.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

PART II - OTHER INFORMATION

#### Item 1. Legal Proceedings

On or about March 8, 2004 GTHA commenced litigation against Milton and Keith Dailey individually and d/b/a "Hunting Lease Magazine" a/k/a "Hunting Lease Magazine The Show" for the recovery of damages for theft and tortious breach of contract. Trial has been set to be held on November 16, 2004. It is too early in the proceedings to determine any positive or negative outcome.

Item 2. Changes in Securities

None.

Item 3. Defaults upon Senior Securities

No defaults upon senior securities.

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

No matters were submitted to a vote of security holders as of June 30, 2004.

Item 5. Other Information

None.

Item 6. Exhibits and Reports on Form 8-K.

(A) Financial Statements

Reference is made to the financial statements listed on the Index to Financial Statements in this Form 10-OSB.

- (B) Exhibits
  - 99.1 Certification of the President and Chief Executive Officer
  - 99.2 Certification of the Chief Financial Officer
- 1. Reports on Form 8-K

### SIGNATURES

In accordance with the requirements of the Securities and Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GENETHERA, INC.

Date: August 23, 2004

By: /s/ Antonio Milici
-----Antonio Milici, M.D., Ph.D.
Chief Executive Officer