INTERLEUKIN GENETICS INC
Form 8-K
May 31, 2001

1

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Filed Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) May 29, 2001

INTERLEUKIN GENETICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of Incorporation)

0-23413	94-3123681
(Commission File Number)	(IRS Employer Identification No.)
135 Beaver Street, Waltham, Massachussetts	02452
(Address of Principal Executive Offices)	(Zip Code)

(781) 398-0700

(Registrant's Telephone Number, Including Area Code)

(Former Name or Former Address, if Changed Since Last Report)

2

Item 5. OTHER EVENTS.

This filing is being made for the purpose of updating the factors affecting Interleukin Genetics Inc.'s (the "Company") business, operating results and financial condition set forth in the Company's documents on file with the Securities and Exchange Commission and to provide investors with cautionary statements regarding any forward-looking statements that may be made from time to time by the Company in its filings with the Securities and Exchange Commission, press releases and other public statements.

CAUTIONARY STATEMENT REGARDING
FORWARD-LOOKING STATEMENTS AND FACTORS
AFFECTING THE COMPANY'S BUSINESS, OPERATING RESULTS
AND FINANCIAL CONDITION

Our filings with the Securities and Exchange Commission, our press releases and our other public statements may include, or may incorporate by reference, certain statements that may be deemed "forward- looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. All statements relating to our objectives, strategies, plans, intentions and expectations are forward-looking statements, as are all statements that address actions, events or circumstances that we expect, believe or intend will occur in the future (other than statements of historical facts). We do not undertake to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. All forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from historical results or those anticipated in the forward-looking statements. Those risks and uncertainties include the following:

RISK FACTORS

WE HAVE A HISTORY OF OPERATING LOSSES AND EXPECT THESE LOSSES TO CONTINUE IN THE FUTURE

We have experienced significant operating losses since our inception and expect these losses to continue for the foreseeable future. We incurred losses from operations of $0.7 million in fiscal year 1996, $4.1 million in 1997, $9.8 million in 1998, $6.2 million in 1999 and $5.2 million in 2000. As of December 31, 2000, our accumulated deficit was $31.0 million. Our losses result primarily from research and development and selling, general and administrative expenses. We have not generated significant revenues from product sales, and we do not know if we will ever generate significant revenues from product sales. We will need to generate significant revenues to continue our research and development programs and achieve profitability. We cannot predict when, if ever, we will achieve profitability.

IF WE FAIL TO OBTAIN ADDITIONAL CAPITAL, OR OBTAIN IT ON UNFAVORABLE TERMS, THEN WE MAY HAVE TO END OUR RESEARCH AND DEVELOPMENT PROGRAMS AND OTHER OPERATIONS

We anticipate that our current financial resources are adequate to maintain our current and planned operations through July 2002. If we cannot raise additional capital prior to July 2002, we will be unable to fund our business operations and probably declare bankruptcy.

Our future capital needs depend on many factors. We will need capital for the commercial launch of additional genetic tests, continued research and development efforts, obtaining and protecting patents and administrative expenses. Additional financing may not be available when needed, or, if available, it may not be available on favorable terms. If we cannot obtain additional funding on acceptable terms when needed, we

may have to discontinue operations, or, at a minimum, curtail one or more of our research and development programs.

THE MARKET FOR GENETIC SUSCEPTIBILITY TESTS IS UNPROVEN

The market for genetic susceptibility tests is at an early stage of development and may not continue to grow. Both we and the general scientific community have only a limited understanding of the role of genes in predicting disease. When we identify a gene or genetic marker that may predict disease, we

conduct clinical trials to confirm the initial scientific discovery and to establish the scientific discovery's clinical utility in the marketplace. The results of these clinical trials could limit or delay our ability to bring the test to market, reduce the test's acceptance by our customers or cause us to cancel the program, any of which limit or delay sales and cause additional losses. The only genetic susceptibility test we currently market is PST, and it has produced only minimal revenues to date. The marketplace may never accept our products, and we may never be able to sell our products at a profit. We may not complete development of or commercialize our other genetic susceptibility tests.

The success of our genetic susceptibility tests will depend upon their acceptance as medically useful and cost-effective by patients, physicians, dentists, other members of the medical and dental community and by third-party payors, such as insurance companies and the government. We can achieve broad market acceptance only with substantial education about the benefits and limitations of genetic susceptibility tests. Our tests may not gain market acceptance on a timely basis, if at all. If patients, dentists and physicians do not accept our tests, or take a longer time to accept them than we anticipate, then it will reduce our sales, resulting in additional losses.

WE RELY HEAVILY ON THIRD PARTIES TO PERFORM SALES, MARKETING AND DISTRIBUTION FUNCTIONS ON OUR BEHALF, WHICH COULD LIMIT OUR EFFORTS TO SUCCESSFULLY MARKET PRODUCTS

We have limited experience and capabilities with respect to distributing, marketing and selling genetic susceptibility tests. We have relied and plan to continue to rely significantly on sales, marketing and distribution arrangements with third parties, over which we have limited influence. If these third parties do not successfully market our products, it will reduce our sales and increase our losses. If we are unable to negotiate acceptable marketing and distribution agreements with future third parties, or if in the future we elect to perform sales, marketing and distribution functions ourselves, we will incur significant costs and face a number of additional risks, including the need to recruit experienced marketing and sales personnel.

WE RELY HEAVILY ON THIRD PARTIES TO PERFORM RESEARCH AND DEVELOPMENT ON OUR BEHALF, WHICH COULD LIMIT OUR EFFORTS TO SUCCESSFULLY DEVELOP PRODUCTS

We have limited research and development capabilities. In July 1999, we entered into a new contractual arrangement with the University of Sheffield, replacing the research and development agreement that had been in place since 1996. Under our arrangement with Sheffield, we will undertake the business development and commercialization of discoveries resulting from Sheffield's research. The agreement is non-cancellable for those discoveries on which we and Sheffield have reached a specific business development agreement, but otherwise either party can end the arrangement upon six months' notice. If Sheffield ends our arrangement and we are unable to make alternative arrangements, our ability to develop new products will be significantly diminished, causing us to discontinue our operations. This agreement with Sheffield has a five-year term with an automatic yearly renewal. As part of this arrangement, we issued an aggregate of 475,000 shares of our common stock to Sheffield and its researchers in exchange for patent rights and other interests held by Sheffield and its researchers under our previous project agreements. Our agreement with Sheffield

requires us to fund agreed upon research and development activities at the University of Sheffield on our behalf based upon annual budgets. This agreement automatically renews in one-year increments. We also entered into a five-year consulting agreement with Sheffield's key collaborator, Dr. Gordon Duff.

Reliance on third party research and development entails risks we would not be subject to if we performed this function ourselves. These risks include reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the agreement by the third party because of factors beyond our control and the possibility of termination or nonrenewals of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us. We may in the future elect to perform our own research and development, which will require us to raise substantial additional funds and recruit additional qualified personnel.

IF WE ARE UNSUCCESSFUL IN ESTABLISHING ADDITIONAL STRATEGIC ALLIANCES, OUR ABILITY TO DEVELOP AND MARKET PRODUCTS AND SERVICES WILL BE DAMAGED

Entering into strategic alliances for the development and commercialization of products and services based on our discoveries is an important element of our business strategy. We anticipate entering into additional collaborative arrangements with Sheffield and other parties in the future. We face significant competition in seeking appropriate collaborators. In addition, these alliance arrangements are complex to negotiate and time-consuming to document. If we fail to maintain existing alliances or establish additional strategic alliances or other alternative arrangements, then our ability to develop and market products and services will be damaged. In addition, the terms of any future strategic alliances may be unfavorable to us or these strategic alliances may be unsuccessful.

IF WE FAIL TO OBTAIN AN ADEQUATE LEVEL OF REIMBURSEMENT FOR OUR PRODUCTS OR SERVICES BY THIRD PARTY PAYORS, THEN OUR PRODUCTS AND SERVICES WILL NOT BE COMMERCIALLY VIABLE

The availability and levels of reimbursement by governmental and other third party payors affect the market for any healthcare service. These third party payors continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for medical products and services. Our ability to successfully commercialize our existing genetic susceptibility tests and others that we may develop depends on obtaining adequate reimbursement from third-party payors. The extent of third-party payor reimbursement will likely heavily influence physicians' and dentists' decisions to recommend genetic susceptibility tests, as well as patients' elections to pursue testing. If reimbursement is unavailable or limited in scope or amount, then we cannot sell our products and services profitably. In particular, third-party payors tend to deny reimbursement for services which they determine to be investigational in nature or which are not considered "reasonable and necessary" for diagnosis or treatment. To date, few third-party payors have agreed to reimburse patients for genetic susceptibility tests, and we do not know if third-party payors will, in the future, provide full reimbursement coverage for these genetic tests. If third-party payors do not provide adequate reimbursement coverage, then individuals may choose to directly pay for the test. If both third-party payors and individuals are unwilling to pay for the tests, then the number of tests we can sell will be significantly decreased, resulting in reduced revenues and additional losses.

IF WE FAIL TO OBTAIN PATENT PROTECTION FOR OUR PRODUCTS AND PRESERVE OUR TRADE SECRETS, THEN COMPETITORS MAY DEVELOP COMPETING PRODUCTS AND SERVICES, WHICH WILL DECREASE OUR SALES AND MARKET SHARE

Our success will partly depend on our ability to obtain patent protection, in the United States and in other countries, for our products and services. In

addition, our success will also depend upon our ability to preserve our trade secrets and to operate without infringing upon the proprietary rights of third parties.

We have 22 U.S. patent applications pending and a number of foreign counterparts to these applications, including applications covering some of our anticipated genetic susceptibility tests. Our patent positions, and those of other pharmaceutical and biotechnology companies, are generally uncertain and involve complex legal, scientific and factual questions. Our ability to develop and commercialize products and services depends on our ability to:

- Obtain patents;

- Obtain licenses to the proprietary rights of others;

- Prevent others from infringing on our proprietary rights; and

- Protect trade secrets.

Our pending patent applications may not result in issued patents or any issued patents may never afford meaningful protection for our technology or products. Further, others may develop competing products which avoid legally infringing upon, or conflicting with, our patents. In addition, competitors may challenge any patents issued to us, and these patents may subsequently be narrowed, invalidated or circumvented.

We also rely on trade secrets and proprietary know-how that we seek to protect, in part, by confidentiality agreements. The third parties we contract with may breach these agreements, and we might not have adequate remedies for any breach. Additionally, our competitors may discover or independently develop our trade secrets.

THIRD PARTIES MAY OWN OR CONTROL PATENTS OR PATENT APPLICATIONS AND REQUIRE US TO SEEK LICENSES, WHICH COULD INCREASE OUR COSTS OR PREVENT US FROM DEVELOPING OR MARKETING OUR PRODUCTS OR SERVICES

We may not have rights under patents or patent applications which are related to our current or proposed products. Third parties may own or control these patents and patent applications in the United States and abroad. Therefore, in some cases, to develop or sell any proposed products or services, with patent rights controlled by third parties, we or our collaborators may seek, or may be required to seek, licenses under third-party patents and patent applications. If this occurs, we will pay license fees or royalties or both to the licensor. If licenses are not available to us on acceptable terms, we or our collaborators may be prohibited from developing or selling our products or services.

If third parties believe our products or services infringe upon their patents, they could bring legal proceedings against us seeking damages or seeking to enjoin us from testing, manufacturing or marketing our products or services. Any litigation could result in substantial expenses to us and significant diversion of attention by our technical and management personnel. Even if we prevail, the time, cost and diversion of resources of patent litigation would likely damage our business. If the other parties in any patent litigation brought against us are successful, in addition to any liability for damages, we may have to cease the infringing activity or obtain a license.

TECHNOLOGICAL CHANGES MAY CAUSE OUR PRODUCTS AND SERVICES TO BE OBSOLETE

Our competitors may develop susceptibility tests that are more effective than our technologies or that make our technologies obsolete. Innovations in the treatment of the diseases in which we have products or product candidates could make our products obsolete. These innovations could prevent us from selling, and significantly reduce or eliminate the markets for, our products.

WE MAY BE DELISTED FROM NASDAQ RESULTING IN A LIMITED PUBLIC MARKET FOR OUR COMMON STOCK AND VOLATILITY IN OUR STOCK PRICE

Our common stock is currently listed on the Nasdaq SmallCap Market and the Boston Stock Exchange. During 1999, we received several notices from Nasdaq stating that we were not in compliance with their continued listing requirements. We believe that we currently comply with the continued listing requirements, but we have not been notified by Nasdaq that we are in compliance. Regardless, we may not be able to maintain our continued listing on the Nasdaq or the Boston Stock Exchange.

If Nasdaq or the Boston Stock Exchange delists our shares, then trading would be conducted in the over-the-counter market in the so-called "pink sheets" or the OTC Bulletin Board. Selling our common stock will be more difficult because of reduced trading volume and transaction size, transactions could be delayed, and security analysts' and news media's coverage, if any, of ILGN will be reduced. These factors may result in lower prices and larger spreads in the bid and ask prices for our shares. The delisting of our shares would also greatly impair our ability to raise additional necessary capital through equity or debt financing.

Historically, our common stock has experienced low trading volumes. The market price of our common stock also has been highly volatile, and it may continue to be highly volatile, as has been the case with the securities of other public biotechnology companies. Factors such as announcements by us or by our competitors concerning technological innovations, new commercial products or procedures, proposed government regulations and developments or disputes relating to patents or proprietary rights are likely to affect the market price of our common stock. Changes in the market price of our common stock may bear no relation to our actual operational or financial results.

WE MAY BE PROHIBITED FROM FULLY USING OUR NET OPERATING LOSS CARRYFORWARDS, WHICH COULD AFFECT OUR FINANCIAL PERFORMANCE

As a result of the losses incurred in 1998, 1999 and 2000, we have not recorded a federal income tax provision for those years and have recorded a valuation allowance against all future tax benefits. As of December 31, 2000, we had net operating loss carryforwards of approximately $23.3 million for federal income tax purposes, expiring in varying amounts through the year 2020. We also had a research tax credit of approximately $317,000 at December 31, 2000, that expires in varying amounts through the year 2020. Our ability to use these net operating loss and credit carryforwards is subject to restrictions contained in the Internal Revenue Code which provide for limitations on our utilization of our net operating loss and credit carryforwards following a greater than 50% ownership change during the prescribed testing period. We experienced a change in ownership interest in June 1999. As a result, approximately $15.6 million of our net operating loss carryforwards are limited in utilization to approximately $825,000 annually. The annual limitation may result in the expiration of the carryforwards prior to utilization.

WE ARE SUBJECT TO INTENSE COMPETITION FROM COMPANIES, WHICH MAY DAMAGE OUR BUSINESS

Our industry is highly competitive. Our competitors in the United States and abroad are numerous and include major pharmaceutical and diagnostic companies, specialized biotechnology firms, universities and other research institutions, including those receiving funding from the Human Genome Project. Many of our competitors have considerably greater financial resources, research and development staffs, facilities, technical personnel, marketing and other resources than we do. Furthermore, many of these competitors are more experienced than we are in discovering, commercializing and marketing products. These greater resources may allow our competitors to discover important genes or genetic markers before we do. If we, in conjunction with the University of Sheffield, do not discover disease predisposing genes and commercialize these discoveries before our competitors, then our ability to generate sales and revenues will be reduced or eliminated, and could make our products obsolete. We expect competition to intensify in our industry as technical advances are made and become more widely known.

WE ARE SUBJECT TO GOVERNMENT REGULATION WHICH MAY SIGNIFICANTLY INCREASE OUR COSTS AND DELAY INTRODUCTION OF FUTURE PRODUCTS

The sale, performance or analysis of our genetic tests do not currently require FDA or regulatory authority approval. Changes in existing regulations could require advance regulatory approval of genetic susceptibility tests, resulting in a substantial curtailment or even prohibition of our activities without regulatory approval. If our genetic tests ever require regulatory approval, then the costs of introduction will increase and marketing and sales of products may be significantly delayed.

WE MAY BE SUBJECT TO PRODUCT LIABILITY CLAIMS THAT ARE COSTLY TO DEFEND AND THAT COULD LIMIT OUR ABILITY TO USE SOME TECHNOLOGIES IN THE FUTURE

The design, development, manufacture and use of our genetic susceptibility tests involve an inherent risk of product liability claims and associated adverse publicity. Producers of medical products face substantial liability for damages in the event of product failure or allegations that the product caused harm. We currently maintain product liability insurance, but it is expensive and difficult to obtain and may not be available in the future on economically acceptable terms. We may become subject to product liability claims which, even if they are without merit, could result in significant legal defense costs. We could be held liable for damages in excess of the limits of our insurance coverage, and any claim or resulting product recall could create significant adverse publicity.

ETHICAL, LEGAL AND SOCIAL ISSUES RELATED TO GENETIC TESTING MAY REDUCE DEMAND FOR OUR PRODUCTS

Genetic testing has raised issues regarding the appropriate utilization and the confidentiality of information provided by genetic testing. Genetic tests for assessing a person's likelihood of developing a chronic disease have focused public attention on the need to protect the privacy of genetic assessment medical information. For example, concerns have been expressed that insurance carriers and employers may use these tests to discriminate on the basis of genetic information, resulting in barriers to the acceptance of genetic tests by consumers. This could lead to governmental authorities prohibiting genetic testing or calling for limits on or regulating the use of genetic testing, particularly for diseases for which there is no known cure. Any of these scenarios would decrease demand for our products and result in substantial losses.

OUR DEPENDENCE ON KEY EXECUTIVES AND SCIENTISTS COULD ADVERSELY IMPACT THE DEVELOPMENT AND MANAGEMENT OF OUR BUSINESS

Our success substantially depends on the ability, experience and performance of our senior management and other key personnel. If we lose one or more of the members of our senior management or other key employees, it could damage our development programs and our business. In addition, our success depends on our ability to continue to hire, train, retain and motivate skilled managerial and scientific personnel. The pool of personnel with the skill that we require is limited. Competition to hire from this limited pool is intense. We compete with numerous pharmaceutical and health care companies, as well as universities and nonprofit research organizations in the highly competitive Boston, Massachusetts business area. Loss of the services of Dr. Phillip J. Reilly, our Chairman and CEO, Dr. Kenneth Kornman, our President, or Dr. Paul M. Martha, our Chief Medical Officer, could delay our research and development programs and damage our business. We have entered into employment agreements with three to five year terms with Drs. Reilly, Kornman and Martha. Any of these employees can terminate his employment upon 30 days notice. We do not maintain key man life insurance on any of our personnel.

BECAUSE OUR PRINCIPAL SHAREHOLDERS, OFFICERS AND DIRECTORS CONTROL A LARGE PERCENTAGE OF OUR VOTING POWER, OTHER STOCKHOLDERS' VOTING POWER MAY BE LIMITED

As of February 1, 2001, our directors, executive officers and certain of their affiliates beneficially owned approximately 20% of our outstanding common stock. Accordingly, these shareholders, individually and as a group, may be able to influence the outcome of shareholder votes, including votes concerning the election of directors, the adoption or amendment of provisions in our Certificate of Incorporation or By-Laws and the approval of certain mergers and other significant corporate transactions, including a sale of substantially all of our assets. These shareholders may make decisions that are adverse to other shareholders' interests. This ownership concentration may also adversely affect the market price of our common stock.

WE DO NOT EXPECT TO PAY DIVIDENDS FOR THE FORESEEABLE FUTURE AND YOU SHOULD NOT EXPECT TO RECEIVE ANY FUNDS WITHOUT SELLING YOUR SHARES, WHICH YOU MAY ONLY BE ABLE TO DO AT A LOSS

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Therefore, you should not expect to receive any funds without selling your shares, which you may only be able to do at a loss.

SIGNATURES

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

INTERLEUKIN GENETICS, INC.

By /s/ Fenel M. Eloi

Fenel M. Eloi, Chief Financial Officer,

Secretary and Treasurer

DATE: May 30, 2001

S-1