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Think Globally

TOP VENTURE CAPITALIST OFFERS COLORADO INSIGHT



G. Steven Burrill: "Let the lemons ripen early."

If you don't believe the world is flat – consider this: You are competing with scientists across the globe from the moment you start a Colorado bioscience company. And your competitors' labor costs are a tenth of yours.

"Everywhere in the world today that they have a spare parking lot, they are trying to build a bioscience park," said G. Steven Burrill, the mega-venture capitalist, who has a tendency to shock listeners with his challenging notions.

"You need to start thinking globally, and partner like mad," he told a rapt crowd of 130 listeners at the February CBSA Bioscience Breakfast.

Burrill heads San Francisco's Burrill & Co., the world's biggest biotech venture capital firm, with more than \$1 billion under management. He came to Colorado last month to meet industry leaders and share insights gleaned from New York to Beijing.

He offered his advice on fostering an entrepreneurial culture, and stressed the rise of "Chindia," the importance of reducing costs and improving quality in healthcare, and the rise of personalized medicine.

Research shows that drugs are often ineffective for many patients. Personalized medicines work better because they are prescribed based on a patient's unique genetic profile.

Burrill takes that logic a step further. If doctors understand which genotypes are susceptible to an illness, they can develop individualized wellness plans.

"We're moving from defining disease by symptom to where we understand disease as a molecular function, a variation of individual cell growth," said Burrill. "And that leads us to personalized medicine. Finally, we'll be treating wellness, not disease."

The market for wellness products is enormous. People already voluntarily pay \$330 billion a year for nutraceuticals. By contrast, the worldwide market for pharmaceuticals is \$550 billion.

Neutraceuticals have been plagued by pseudo science, Burrill said, but with better research they could pose a formidable global opportunity – particularly for Colorado. The state is already a center for the natural foods industry and for those seeking healthy lifestyles. Burrill moved Efficas and Sciona – two nutraceutical companies – to Colorado recently "because we thought it would be easier to generate support."

Academics must research the role of nutrition in health in order for the field to mature.

"That's a field where Colorado could become a world leader," he said. "There's nobody out front. You could become a dominant player."

Getting there requires encouraging an entrepreneurial culture.

"You have to create a culture where it's okay to fail, where failure is looked upon as a learning opportunity," Burrill said. He contrasted his hometown of Madison, Wisconsin with Austin, Texas, both university hubs. In Madison, a person whose business fails is shunned. In Austin, people think, "I'll bet that entrepreneur learned something. I'll invest in his new company." They are both small cities, but Austin is the one with a world-class technology center.

"Let the lemons ripen early," he added, mentioning that he expects 30 percent of the firms in his vast portfolio to fail – a ratio necessary if you want to create a lot of strong healthy companies.

His tour of Colorado included the new Fitzsimons medical campus.

"I'll give the state a lot of credit," he said. "Organizations, development groups are doing all they can. The Bay Area doesn't have anywhere near the same kind of infrastructure. You've got an alignment of stars."

What's missing are some early success stories "to give others the confidence these things work," he said. He disputed the widely-held notion that Colorado's problem is a lack of biotech venture capitalists.

"If there were entrepreneurs on every corner with good business plans, venture capitalists would eventually move to Colorado because we'd get tired of flying here," he said. "We are completely agnostic about where we invest."

COMING EVENTS

CBSA has an exciting schedule of new programs and events planned for 2006. Check out our Web site for the latest details or to register for upcoming events: www.cobioscience.com

April 7th

Executive Compensation Seminar

April 9-12th

BIO Annual Conference and Expo, Chicago

April 18th

Annual meeting at University of Colorado Boulder

April 26th

BioBreakfast – Larry Gold

May 2nd

Finance Seminar

May 18th

Longmont Life Science Thursday – Boulder County Medical Device Companies

May 24th

BioBreakfast – Venture panel

June 7th

Bioscience Larimer County

June 22-23rd

Bio-bootcamp – Holland and Hart

SAVE THE DATE



BIOWEST

Start planning now to attend BioWest 2006 at the Colorado Convention Center August 23 and 24 and the CBSA annual awards dinner on August 24. Visit www.biowestconference.com for more information.

EXECUTIVE REPORT

Report from
Richard Duke,
Public Policy
Committee Chairman,
CFO and Co-Founder,
Globelimmune



Rick Duke joins the Speaker's press conference to unveil his economic development package at the Capitol.

THE CBSA PUBLIC POLICY COMMITTEE HAS BEEN VERY ACTIVE THIS YEAR.

We initiated three bioscience specific bills. The Bioscience Net Operating Loss bill, H.B.1308; the Proof of Concept Fund bill, H.B. 1360; and the Incentive to Contract with Core Labs bill, H.B. 1361, are at the forefront of our 2006 legislative agenda. (See below for more details.)

However, the bioscience industry needs to track not only bioscience specific bills, but legislation that stimulates economic development, like H.B. 1017. It would provide a \$1,000 – \$1,250 incentive per employee to companies that add at least 10 employees within one calendar year. Additionally, we need to support legislation that strengthens Colorado's higher education system, and track payment trends in entitlement programs that impact our industry.

To keep CBSA members updated, our lobbying team sends out weekly legislative updates. We invite any interested individuals to join the Public Policy Committee. Please contact CBSA staff if you are interested in joining the committee or if you

are not receiving the updates. All bills can be read on the Colorado Legislature's website at www.colorado.gov.

The 2006 Colorado legislative session adjourns on May 10. We hope by then we can report that these bills have all passed and are being signed into law.

2006 COLORADO BIOSCIENCE LEGISLATION

H.B. 1308 – Bioscience Net Operating Loss Bill

The Bioscience Net Operating Loss bill is part of Governor Owens' legislative agenda. CBSA is working with the Colorado Office of Economic Development and International Trade to ensure that this legislation is passed. H.B. 1308 would appropriate at least \$2.5 million from the general fund, to purchase net operating losses from eligible Colorado bioscience companies. This legislation would provide cash to a bioscience company at a time when it would need it most, rather than at a future time when it would use the net operating losses to

offset revenue. At press time, the bill passed the House Finance Committee and is in the House Appropriations Committee.

H.B. 1360 – Bioscience Discovery Evaluation Grant Program

H.B. 1360 would create a \$2 million grant program, administered by the Colorado Office of Economic Development in consultation with the Colorado BioScience Association, for the purpose of improving and expanding the evaluation of new bioscience discoveries at research institutions. The program provides grants to research institutions on a statewide basis in amounts of up to \$150,000 per bioscience research project. The bill passed the House Finance Committee.

H.B. 1361 – Incentive to Contract with Core Labs

H.B. 1361 provides an incentive to help Colorado bioscience companies offset the indirect costs associated with research services performed by Colorado research institutions. It creates a program, administered by the Colorado Office of Economic Development in consultation with the Colorado BioScience Association, to award incentives to help Colorado bioscience companies who are working with core labs at state universities and research institutions. The bill passed the House Finance Committee.

RxKinetix Phase III

BOULDER'S RxCINETIX EXCITED ABOUT UPCOMING PHASE III TRIAL

TEN YEARS AFTER START UP, A UNIVERSITY OF COLORADO LICENSEE IS PREPARING TO ENTER PHASE III CLINICAL TRIALS FOR ITS NOVEL CANCER CARE DRUG.

If successful, Boulder-based RxKinetix would be first to market with an oral rinse for a severely debilitating side effect of cancer treatment, oral mucositis. The 23-person firm would gain a foothold in a growing, multi-million dollar market for this unmet medical need.

"As we discuss the results with third parties, they get pretty excited," said Joanna Money, the firm's vice president of corporate development. "There have been quite a few attempts to develop oral rinses to prevent this disease and none have been successful this far. We are very encouraged by the results."

Oral mucositis is an illness characterized by painful mouth ulcers that result from radiation treatment. Among the most severely affected patient groups are those undergoing radiation for head and neck cancer - about 40,000 patients are diagnosed yearly with the disease in the US. But the total market is much bigger: estimates are that more than 400,000 patients a year suffer oral mucositis as a result of radiation or chemotherapy, presenting a \$1 billion opportunity.

Oral mucositis results in mouth ulcers throughout the oral cavity, making it difficult or impossible to eat or drink. "It's the primary rate limiting side effect of treatment for head and neck cancer patients," explained Money. Today the standard of care treatment is limited to viscous lidocaine or opiates.

RxKinetix's drug RK-0202 is based on a "reverse thermogelation" technology, another way of saying a gel that is a liquid at cool temperatures and thicker when warmed. When combined with a potent antioxidant, N-acetylcys-



teine, and swished around inside the mouth, RK-0202 thickens and coats the mucous membranes. The antioxidant helps prevent the radiation-induced damage.

Data from a Phase II trial showed that RK-0202 "doesn't eliminate oral mucositis, but it significantly reduces the incidence and severity," said Money. "Patients are in much less pain, and they're able to eat, drink and talk."

In February, the FDA agreed RxKinetix could move forward into Phase III development. The firm hopes to complete this trial by 2008.

RxKinetix, which won the life sciences company of the year award from the University of Colorado Technology Transfer Office last January, didn't always have such a clear vision of its future. Initially conceived of as a drug delivery firm, its scientists realized that a greater opportunity lay in developing new drugs.

"We did pretty extensive brainstorming to try to find unmet medical needs in the oral space,"

Above and below: Scenes from the RxKinetix labs.



said Vice President of Drug Development Gary Rosenthal.

Eventually, through a partnership with Elan Pharmaceuticals, the firm decided to pursue oral mucositis.

"We've always seen the value of local drug delivery," said Rosenthal. "There are fewer side effects, you can deliver higher doses and you're directly targeting the disease."

SPONSORS

CBSA is proud to salute our 2006 corporate sponsors. We honor their outstanding commitment to bioscience in Colorado and encourage you to thank them for their generous support.

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REGULATORY UPDATE

Understanding the Differences Makes All the Difference

BY CLAY ANSELMO

A good indication that the demand for quality assurance and regulatory affairs professionals in Colorado has increased dramatically is that not a day goes by when I don't get a call or an e-mail asking for a referral for someone with these specialties.

However, when I question most companies or recruiters regarding the position and its responsibilities, the answers I get often indicate a lack of understanding about the differences between "quality assurance" and "regulatory affairs". Understanding these differences will shorten your hiring process and can help you avoid problems down the road.

Many small and mid-sized biomedical companies clearly recognize the need for a strong QA/RA management professional, but struggle with how to describe their needs in a way that attracts the right kind of talent. This can be a significant problem for small companies that need an individual to fill a variety of roles, all of which are important to the success of the company. When planning for an important new hire in the QA/RA arena there are some very important points to consider.

First of all, the disciplines of quality assurance and regulatory affairs are not the same. While you do find individuals with experience in both, professionals tend to specialize in one or the other. It is difficult to find someone that is well versed at both, and you should not assume that just because an individual worked in, or managed a "QA/RA" organization that they can function equally well in both capacities.



QA/RA job functions generally fit into three broad categories:

1. Quality System Development and Execution
2. Regulatory Submissions / Product Standards Compliance
3. Management of Regulatory Inspections

As you would expect, item one is done primarily by QA personnel. Item two is typically handled by RA personnel without much overlap in most medium and large organizations. Item three crosses both groups, and the responsibility generally lies with the individual in an organization that has the most overall experience and success in managing inspections independent of which group they work with.

With this in mind, if the primary responsibilities of your position have to do with your quality system, you should advertise for your position as a QA professional. If you expect this new person to focus on product compliance and

submissions, you should advertise for an RA professional. Don't make the mistake of using the wrong title for the position, or simply calling it a "QA/RA" position. Be very specific in your description of the role. Asking for a generalist to cover everything while not understanding what is most important for your organization will compromise your overall results.

If you are actually hiring for skills related to item three, I recommend describing the position as an RA role, but make very clear that the primary responsibilities are inspection management. While nearly all quality and regulatory personnel have participated in a variety of inspections during their careers, you want to find someone that has served successfully as the inspectional leader in both good and bad situations. Keep in mind that someone that has only ISO or only FDA experience may not perform well when faced with the other group. Experience and results are the best way to judge prospective candidates for this type of job.

Lastly, if you truly need an individual that has detailed experience in all three categories, focus your search on people with startup or small company experience. Professionals with only medium or large company experience usually do not have expertise that extends beyond one category.

Clay Anselmo is president and COO of Reglera Corporation, providing regulatory consulting and resources to biomedical companies: www.reglera.com.

Fitz Incubator

NEW ERA FOR BIO ENTREPRENEURS



David Drake: "We are building a process that knows no boundaries."

**COLORADO'S YOUNG
BIOSCIENCE FIRMS
ARE POUNDING DOWN
THE DOORS OF A NEW
PROGRAM THAT HELPS
THEM GET FUNDED.**

And its director promises that at least one venture deal will come out of their efforts early this year.

"We are already swamped," said David Drake, director of the seven-month-old Fitzsimons BioBusiness Incubator, or FBBi, an innovative business building venture.

In the long term, the minds behind the incubator believe their program augurs a new era in the state's approach towards bioscience entrepreneurs.

The FBBi is a statewide program, not a place. Headquartered at the Fitzsimons medical campus, it has many facets: a business strategic consulting service, a network of volunteers, a job development program and a start-up in its own right.

In essence, the program grooms young companies and tweaks their business plans to get them ready for financing. To do so it relies on an extensive network of seasoned volunteer professionals. The end result is a

company with a plan and presentation ready for investors. The FBBi measures its success in two ways: first, by the number of deals that raise capital, and second, by the number of jobs these new companies generate.

"The FBBi is a process designed to get deals ready for funding and then get them funded," said Drake, who previously served as Executive Director of University License Equity Holdings Inc., a CU quasi-affiliate focused on building new companies from the university's research enterprise. "As FBBi companies get financing and grow their businesses, they naturally create jobs. Most of those jobs stay within Colorado."

Born of a desire to grow the state's bioscience industry, the FBBi is funded and supported by a diverse set of collaborators. Start-up capital was provided by the Colorado Office of Economic Development, the Fitzsimons Redevelopment Authority, the Metro Denver Economic Development Corp., the Aurora Economic Development Council and the University of Colorado. The Colorado BioScience Association, Adams County Economic Development and CU-Denver's Bard Center for Entrepreneurship provide much needed networking, education, and innovative financing.

"Right now, it doesn't cost anything," explained Drake. "But as we continue to demonstrate positive results, the business model will evolve and likely employ a fee structure." FBBi already has eight clients and has advised another 30 companies.

Here's how it works: a company contacts FBBi, then Drake and assistant director Adam Rubenstein work with a core team of advisors to determine if the company fits within the FBBi framework for providing targeted assistance. Although any size firm can apply, ventures that have already raised sufficient financing likely won't qualify, Drake says. Once accepted, Drake and his volunteer advisors scrutinize the firm's business from the ground up, analyzing every aspect of the

company. "It's an extremely iterative process," said Drake. "With those eight companies, there's a high probability we'll touch each one of them every week."

Business plans are often slightly off-target, Drake said.

"Quite often they are not targeting the right market. They have this wonderful technology, but what they're building with it isn't going to give them the biggest bang in the marketplace or excite the investment community," said Drake. "That's where we come in."

Colorado venture capitalists are made aware of the deals at an early stage, and can give feedback on strategy and focus. When the company is ready to raise capital, FBBi helps the company organize a "roadshow" to pitch to investors both in and out of state.

That informal feedback was invaluable for FBBi client Medshape Solutions, a Castle Rock medical device start-up.

"It's a great chance to get some pretty knowledgeable feedback on what our plans are, where we are placing our emphasis, and the key issues we are going to face," said President Harold Tyber.

FBBi is a multi-faceted collaboration, and Drake says it marks a sea change in Colorado's culture of bioscience entrepreneurship. The new era started when former CU President Betsy Hoffman emphasized a university without walls, he said.

"Likewise, we are building a process that knows no boundaries," said Drake. "We work with anyone who can help our clients build strong companies."

For more information about the FBBi, visit www.colobio.com/fbbi.

The Metro Denver Economic Development Corporation conducted a Bioscience Industry Cluster Profile for the Metro Denver Region. Some interesting facts and figures from the study about the biotech and medical device sectors are listed below. For the full report, go to www.metro-denver.org/denverprofiles/industryclusters/.

PHARMACEUTICALS AND BIOTECHNOLOGY COMPANIES

- 163 companies located in the Metro Denver area in 2004
- The number of companies grew 39.3% from 1999 to 2004
- The sector directly employs 3,920 people in the seven-county Metro area
- Employment increased 20.5% from 1999 to 2004

MEDICAL DEVICE AND INSTRUMENTS

- With over 7,700 workers, Denver ranks 9th in medical device and instruments employment concentration
- 191 medical device and instrument companies were located in the Metro area in 2004
- The number of companies increased 15.8% from 1999 to 2004
- The 2003 average salary was \$55,300 in Metro Denver

MEMBERSHIP BENEFITS

BIO Business Solutions for CBSA Members



Did you know that CBSA members receive discounts from BIO on essential business products and services? Tapping into the experience, expertise and significant savings available through BIO's strategic partnerships with industry-leading suppliers can easily cover the cost of your CBSA membership. And CBSA gets back a percentage of each signed contract to provide our members with even more benefits. Go to www.biobusinesssolutions.com for more information.

Here is a look at some of the companies offering benefits to CBSA members:

COMPUTER/TECHNOLOGY PRODUCTS
Tech Depot (a subsidiary of Office Depot) offers significant discounts on computer and technology products.

EMPLOYEE BENEFITS INSURANCE AND SOLUTIONS
Wachovia Insurance Services and ABD Insurance & Financial Services (ABD) offer special terms, preferred pricing and comprehensive coverage on group employee benefits insurance including medical, disability, life, dental, prescription drug, vision, and travel accident insurance.

EMPLOYMENT BACKGROUND AND DRUG TESTING SERVICES
Through ChoicePoint's Screen-

Now service, an online screening solution, members can conduct background investigations and order drug tests on potential employees in a fast, secure and cost-effective environment.

PACKAGED GASES, DRY ICE AND BULK GASES
BIO partners with two leading gases suppliers, **Airgas, Inc.** and **BOC Gases**, to offer members special pricing and terms on packaged gases (cylinders, dewars/cryogenics and micro-bulk), dry ice and bulk gases.

BROKER BUSINESS INSURANCE/ RISK MANAGEMENT
William Gallagher Associates has a long history of servicing biotech companies, minimizing risk, and customizing policies to cover the special needs of individual biotech companies. BIO's program with William Gallagher Associates offers business insurance from three industry-leading providers: directors and officers liability provided by Monitor Liability Managers; property and casualty provided by Chubb Group and clinical trials and products liability provided by Chubb Group.

CLINICAL TRIALS LIABILITY INSURANCE, ERRORS AND OMISSIONS LIABILITY INSURANCE, PRODUCTS LIABILITY INSURANCE AND PROFESSIONAL LIABILITY INSURANCE
Member insurers of the **Chubb Group of Insurance Companies** ("Chubb") provide cost-effective risk management and insurance protection tailored to the unique requirements of biotechnology companies. Benefits include a 10% premium credit (subject to regulatory limitations); very competitive premiums for companies

at all stages; low minimum premiums for early stage companies; and broad coverage tailored to meet the unique needs of the biotech industry.

DIRECTORS AND OFFICERS LIABILITY INSURANCE
Monitor Liability Managers provides directors and officers liability insurance to the biotechnology industry. Benefits include a 7.5% no-claims policy renewal credit; pre-negotiated, standard coverage terms; very competitive premiums for companies at all stages; low minimum premiums for early stage companies; loss control services, including the design of insider trading and corporate communication policies.

LABORATORY SUPPLIES, EQUIPMENT AND CHEMICALS
BIO partners with the leading distributor of laboratory supplies and equipment for the life sciences industry, **VWR International**. BIO has negotiated extremely aggressive pricing on more than 750,000 products from 5,000 manufacturers. In addition, BIO has arranged for special pricing agreements from value-added manufacturers.

MOVING AND STORAGE
Humboldt Storage and Moving can move an entire company or a single employee across town or overseas. Humboldt offers members a substantial discount. Benefits include maximum discounted pricing off federal tariffs allowed; guaranteed pickup and delivery; free full-replacement valuation; comprehensive employee relocation program; and laboratory and office moving expertise.

CONTINUED ON PAGE 8

CBSA BioNews

Pharmion Corporation in Boulder formed a license and collaboration agreement with MethylGene Inc., a biopharmaceutical company based in Montreal. Under the terms of the agreement, the two companies will research, develop and commercialize MethylGene's histone deacetylase inhibitors in North America, Europe, the Middle East and other markets.

Tapestry Pharmaceuticals Inc., a Boulder-based developer of proprietary therapies for the treatment of cancer, entered into definitive agreements with a number of institutional investors, led by Special Situations Funds, Tang Capital Partners LP and Baker Brothers Investments, for the sale of \$25.5 million of the company's common stock and warrants. The financing will support Tapestry's ongoing clinical development of TPI 287, a third generation taxane, which is currently in two Phase I clinical trials in the United States and overseas.

Array BioPharma Inc., in Boulder, and AstraZeneca PLC, an international health-care business, selected an additional clinical candidate for its small molecule anti-cancer program, triggering a \$1 million payment from AstraZeneca to Array. The two companies partnered for co-development and commercialization of oncology compounds.

Replidyne Inc., in Louisville, submitted a New Drug Application to the U.S. Food and Drug Administration for Orapem for the treatment of the following conditions: acute bacterial sinusitis, community acquired pneumonia, acute exacerbations of chronic bronchitis and uncomplicated skin and skin structure infections. This is the first NDA submission for the company.



ARCA Discovery, Inc., a company developing genetically-targeted therapies for heart failure and other cardiovascular diseases, announced the completion of a \$15 million venture capital Series A financing. The financing was led by Atlas Venture. Boulder Ventures, which provided the original seed financing for ARCA, and Pequot Capital Management also participated in the financing.

VA Hospital One Step Closer to a New Home at Fitzsimons

The Fitzsimons Redevelopment Authority (FRA) has reached an agreement with the Veterans Administration on an offer to sell a 24-acre piece of land for the new VA hospital at Fitzsimons. The offer, which was developed jointly by the FRA and the VA through months of negotiations, was approved by the FRA board of directors on February 22.

Corgenix Medical Corp. of Denver has closed two private placement financing agreements worth \$3.3 million. Corgenix (OTC BB: CONX) makes and sells diagnostic test kits for immunology disorders, vascular diseases, and bone and joint disorders.

Biotech company **Sirna Therapeutics Inc.**, said Tuesday that the United States Patent and Trademark Office granted Sirna a broad patent for the chemical synthesis and manufacturing of ribonucleic acids (RNA). The Boulder company said the patent covers a process that is critical for the efficient synthesis of RNA at high yields and high purity and is applicable to both small- and large-scale production.

Pharmion reported a loss in the fourth quarter but increased revenues and improved net sales and operating income for 2005. For the year, Pharmion posted a profit of \$4.5 million on revenue of \$221 million, compared with a loss of \$12 million on revenue of \$130 million in 2004.

Globelimmune raised \$38 million through a round of Series B financing – \$4 million more than the first close of \$34 million announced last September. The company, a maker of immunotherapy pharmaceuticals called Tarmogens, will use the funding to complete more placebo-controlled clinical trials for its products, GI-4000 and GI-5005.

Amgen Colorado is ramping up its operations in anticipation of the commercial launch of an experimental osteoporosis drug. In the past year, Amgen has hired 250 manufacturing and quality assurance employees in Boulder and Longmont to prepare for the marketing of "denosumab," and it may hire more depending on the drug's momentum. Amgen's Colorado manufacturing facilities are currently producing test lots of denosumab in preparation for FDA inspection.

Evolutionary Genomics, located at Fitzsimons, received a \$500,000 grant from the National Science Foundation to continue developing a unique approach to treating AIDS, based on the ability of chimpanzees to not develop AIDS when infected with HIV-type viruses.

MEMBERSHIP

BENEFITS, CONTINUED FROM PAGE 6

NEWS DISTRIBUTION

PR Newswire transmits news to health and science editors at daily newspapers, consumer and trade publications, broadcast stations and more than 3,600 Web sites, databases and online services - including www.bio.org. Benefits include free first year membership to PR Newswire; discounted wire distributions; free online news archive posted to member's website, www.prnswire.com and linked to member's profile on www.bio.org; periodic offers for discounts on PR Newswire services such as eWatchTM Internet monitoring and Online MEDIAtlasTM database.

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BioSurplus provides pre-owned laboratory and manufacturing equipment resale and management services, including an extensive inventory of pre-owned scientific equipment and instrumentation. It can also assist companies during corporate mergers, upsizing, downsizing, and liquidation transition periods.

RETIREMENT PLANS

Fidelity Investments helps members provide retirement plans that meet their employees' needs. Fidelity offers three distinct 401(k) plans to members at discounted pricing.

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