



A joint report of Life Science Tennessee and Waller Lansden Dortch & Davis, LLP



WELCOME

Life Science Tennessee and Waller are pleased to present this report regarding angel funding for the life science industry in Tennessee, including the current status of this unique investment model, the vital role that angel funding plays in our industry, and recommendations for improving access to angel money for promising life science businesses developing their technologies in Tennessee.

Feedback received from early-stage life science companies on the current angel investing climate in Tennessee was gathered through data collection, one-on-one interviews, and membership surveys to assess the challenges and opportunities faced by companies in Tennessee (and beyond) regarding the lack of angel investing. This problem is not unique to our state, but addressing the issue is important as the life sciences are an emerging industry in Tennessee. We are home to world-renowned research institutions and angel investing supports the development of technologies from these institutions. For this reason, Tennessee's life science industry feels the challenges greater than most.

Start-up and emerging life science companies require early-stage investment. You can't go at it alone in this industry as life science companies have inherently longer and extraordinarily expensive business development cycles due to the strict regulatory environment and high costs of clinical trials. And, commercialization of life science technologies is vital to continued success.

We hope you enjoy this report and find it helpful to deepen your understanding of angel investment for the life sciences.

Hunter Rost, Partner, Waller, Life Science Tennessee board member Josh Brown, Pfizer, Life Science Tennessee chairman

SUMMARY

The life science industry is a key economic driver in Tennessee. More than 40,000 Tennesseans work in life science fields across 1,275 public, private and nonprofit employers. Moreover, these workplaces provide

competitive salaries with the average salary in a life science job at approximately \$83,000.

In addition, Tennessee is home to powerhouse medical and device companies, start-ups, and research and development facilities. The state also has a wealth of nationally renowned academic institutions including Vanderbilt University, Oak Ridge National Laboratory, the University of Tennessee, and St. Jude Children's Research Hospital.

Yet, despite the state's promising life science ecosystem, entrepreneurs in the state need more support to commercialize basic life science research and technologies. The state's overall low rate of commercialization is problematic because it prevents life-saving drugs, diagnostics, and therapies from reaching physicians and patients.

Numerous commercialization roadblocks exist for Tennessee entrepreneurs.

These problems were outlined by Life Science Tennessee in its 2014 **Access to Capital** report, which recommended and successfully advocated for several programs to help early-stage life science companies in our state. These included the establishment of the following impactful, fiscally prudent programs in Tennessee:

- a statewide Mentor Network for young life science companies
- a matching grant program for federal SBIR and STTR awardees
- enhancement of the state's matching investment mechanisms that support emerging life science companies
- increased support of Tennessee's life science community

Despite these advances, The Life Science Mentor Network, in particular, has helped shed light on issues with a specific type of funding that could significantly impact the state's life science industry: angel investment.

The following report outlines the environment for angel investment in the life sciences, both nationally and in Tennessee, and suggests opportunities for improvement.

A CHALLENGING ENVIRONMENT

Tennessee is a stronger-than-average state for entrepreneurship with a vibrant life science community.

Tennessee start-ups are, however, susceptible to national and local investment trends that create challenges for entrepreneurs trying to raise angel funding and then proceed with venture capital investment.

Over the past several years, numerous companies, including successes such as Advanced Catheter Therapies and EDP Biotech, have used angel investment to create strong foundations for future growth. Despite these successes, true angel investments are becoming harder to obtain.

Why? In short, deals are getting bigger and there are fewer of them. It's particularly true for the larger venture capital community and the trend is filtering all the way down to the angel level.

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Size of Average Investment Deals (U.S.) 2010-2017

In 2015, 5,680 angel and seed deals were recorded in the United States, according to National Venture Capital Association (NVCA) data. Just two years later, the annual total had fallen to 3,793 — a drop of more than 33 percent.

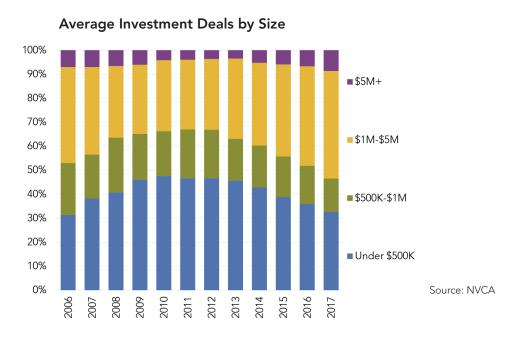
Just two years later, the annual total had fallen to 3,793 – a drop of more than 33 percent.

Conversely, the average investment for angel and seed deals rose by 33 percent in that same period, and have now reached a median deal size of \$1 million. That's more than double the median investment amount from just five years ago, according to the NVCA data.

In recent years, the early-stage funding gap has been filled in part by the 2009 TNInvestco and the 2011 INCITE programs, both implemented and supported by the state of Tennessee.

Through the sale of tax credits, TNInvestco awarded more than \$120 million across 10 venture capital funds for investment in Tennessee companies. INCITE awarded \$55 million in matching investment funds through Launch Tennessee.

TNInvestco funds helped generate real start-ups. In Nashville alone, the number of annual early-stage investment increased by 400 percent between 2009 and 2015, according to the 2016 **Nashville Venture Capital Association Report**.



As a result, Tennessee ranks 10th in the country in terms of growth entrepreneurship, according to **the Kauffman Index**, which is up from its rank of 20th in 2015. Growth entrepreneurship measures employment growth in the first five years of a start-up's existence. According to the study, companies founded in 2009 in Tennessee had grown by 76 percent in their first five years.

The bad news is that, as of now, the TNInvestco and INCITE funds have been fully accounted for. In tandem, early-stage investment has dropped off as those companies have matured.

Moreover, Tennessee has struggled in recent years to keep the future pipeline filled with enough very early stage companies, which are frequently the recipients of angel funding.

In 2012, the Kaufmann Index found that 360 out of every 100,000 adults in Tennessee became entrepreneurs in a given year. By 2016, that number had dropped to 230. Still, there are entrepreneurs seeking opportunities to connect with angels and other potential investors, they just aren't finding enough suitors willing to invest in them.

As a part of the Life Science Tennessee 2017 member survey, we specifically asked respondents their opinions regarding investment for early stage companies. Overall, about 30 percent of the respondents were seeking funding, and of those, **two-thirds were seeking angel funding** as opposed to larger investments at this time.

When asked about the biggest challenges in seeking funding, respondents confirmed these as the top three reasons:

- lack of understanding of their technology
- lack of investors in Tennessee
- inadequate connection to investors

Tennessee has several active angel networks that occasionally invest in a Tennessee-based life science company. These include such networks as Angel Capital Group, Angel Roundtable, Lighthouse Chattanooga Renaissance Fund and Nashville Capital Network, to name a few.

A challenge for the life science angel investing in Tennessee — as this report reveals — is that none of these networks are focused on life sciences exclusively. The complexity of a life sciences product or service can make it difficult to properly evaluate a successful proposition.

Life science investment typically needs a specialized approach in order to vet the right opportunities, provide relevant feedback and coaching and have the patience needed to see the opportunity through in the challenging, but fruitful, process of developing a life science start-up.

As one example, the Chattanooga Renaissance Fund (CRF) invests in seed-stage and early-stage technologies. The fund has invested in two Tennessee medical device companies, Tensor Surgical and Advanced Catheter Therapies, since the fund began in 2010.



CRF has raised two funds from its network of angels, the first being a \$3.1 million fund followed by a second seed capital fund of \$7.6 million raised in 2014.

The Fund's managing partner, David Belitz, is encouraged by the continued development of the med tech industry in Tennessee, which he sees as "growing and interesting." And he believes more technical support around the life science and medical technologies industry is vital to continued investment opportunities in Tennessee.

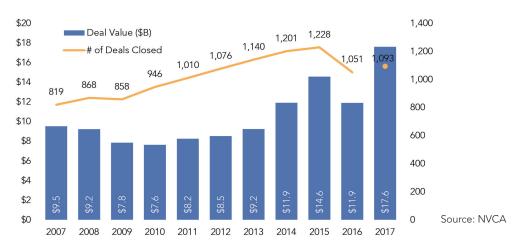
"Device opportunities seem to be amazing, but they take longer and a lot more money to be successful. Therefore, funds like ours can't be in this space alone in Tennessee. We need partners that can participate with us in understanding the formula for successful investment in medical technology."



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In Nashville specifically, venture investment in biotech and medical devices has been suppressed, relative to other arms of healthcare, between 2005 and 2015. "Biotech companies had an isolated year of significant funding in 2005, receiving \$38 million in one investment round, but remained suppressed through 2009," according to the Nashville Venture Capital Report." After 2009, biotech companies experienced an accelerating trend in funding that peaked in 2013 at nine investments totaling \$19.5 million." The report adds that Nashville medical device companies saw no such growth trends or spikes in funding.

Biotech Funding in the U.S.



This all comes at a time when life sciences funding is seeing spiking interest nationally. Total life science deals value topped \$17.6 billion in 2017. Most of that growth, however, is happening in the early venture capital stage. Angel and seed deals in the life science sector fell 20 percent between 2015 and 2017.

If Tennessee continues to falter in supporting life science start-ups, the state risks falling even further behind as deals escalate and companies grow in other parts of the country.

WHY IT MATTERS

There is significant anecdotal evidence in Tennessee's life science community to support both the importance of early-stage funding and the difficulty of raising it in the state, particularly for emerging life science technologies.

The following testimonials illustrate examples of real entrepreneurs seeking early-stage funding in Tennessee and their successes and challenges.

Advanced Catheter Therapies, Chattanooga



Paul J. Fitzpatrick Chief Executive Officer



Advanced Catheter Therapies, Inc. is a research and development medical device company started in Atlanta in 2008 by Dr. Rex Teeslink, an interventional radiologist, Dirk Hoyns, a medical device engineer, and the Medical Device Development Group, who provided early seed money. Paul J. Fitzpatrick joined the team as CEO in January 2009.

The company has a portfolio of innovative catheter technologies targeting vascular disease, such as thrombosis, inflammation, occlusions, and restenosis.

ACT moved to Chattanooga in 2011 after closing its \$2.9M Series A preferred equity round, receiving funds from several Chattanooga-based angel investors and investment funds including ACTI Investments, a local Chattanooga based angel group, Chattanooga Renaissance Fund, Innovate Here, the MacIellan Foundation, and DeMoss Alt Opp Fund.

"Because the vast majority of our funding in 2011 came from Tennessee, and most of that from Chattanooga, we determined a relocation closer to our investors and support network within Chattanooga and greater Tennessee made good sense for continued growth" Fitzpatrick said.

Since moving to Chattanooga, ACT has secured another \$7 million in funding through two rounds. Approximately \$5 million of that total has come from Chattanooga and Tennessee through various individual angels, venture funds, as well as state and local funding sources including Launch TN (Incite Fund) and the Memphis-based Innova Fund.

With these proceeds, ACT has received FDA clearance for its patented target drug delivery catheter and commercially launched it through a manufacturing, sales and marketing agreement with Toray Industries, a large public company. For the past two years, ACT has been generating revenue and is profitable.

The early stage investment in ACT by Tennessee-based angels and venture capital companies was vital to the company's survival and growth in Chattanooga. Today, ACT owns more than a dozen U.S. and a dozen international patents regarding endovascular catheter devices and is seeing further development and approval of its products.

EDP Biotech, Knoxville



Eric Mayer Chief Executive Officer



EDP Biotech Corporation, an in-vitro cancer diagnostics development company, focuses on the development and commercialization of immunodiagnostic tests to detect disease early. It researches and develops products to identify those proteins present in the early stages of biological changes for the production of in-vitro diagnostic tests. The company's first product will be a blood-based biomarker assay for use in the early detection of colorectal cancer and pre-cancerous polyps. The company was incorporated in 2005 and is based in Knoxville.

EDP has received angel and early-stage funding from individuals mainly in Knoxville and throughout Tennessee to support its development. EDP's angels have been its founders and other individuals within their networks. Mayer says clinical research studies should begin in the coming year with a goal of registration in the European markets and product launch in select European markets by the end of 2018.

Eric Mayer, CEO since 2015, overviews the recent market shift in Tennessee regarding angel funding.

"We have not seen that Tennessee has attracted new angel investors in recent years for diagnostics," said Mayer. "Angel investors and investment groups in Tennessee who once invested in the life sciences here are looking more like VCs rather than traditional angels. This caused fewer new deals, later-stage deals, and less opportunity in the state for companies like ours to continue to build here."



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Ariste Medical, Memphis



Lisa Jennings, Ph.D.Founder, Chief Scientific Officer



Founded in 2007 and located in Memphis, Ariste is a pre-commercial stage company that develops surgical implants to prevent common causes of device failure. Ariste has developed a unique, patented formula which enables the application and elution of drugs from devices designed to reduce infection, restenosis, and thrombosis, common complications that lead to medical device failure.

Ariste Medical received investments from two different anonymous angel investors — one at \$1.27 million and later the second for \$4.6 million — who the founders identified to help them as they continue development of their product, an innovative drug-delivering hernia mesh. This new investment supported product testing and regulatory filings for the mesh, as well as preparation for commercialization in the United States and Europe upon regulatory approval.

Ariste's founder and Chief Scientific Officer Lisa Jennings, Ph.D. believes that Tennessee has a great opportunity to build a network of angel investors who understand the long-term proposition and eventual financial up-side of investment in the life sciences.

"Much of our fundraising has been done without a network of support here," said Jennings. "We are a growing company at Ariste, we've just hired a new CEO from a top medical device company, and we've moved into an 18,000-square-foot building to manage our expected FDA approval coming later this year. Other emerging device technologies in Tennessee should have similar opportunities."

RECOMMENDATIONS & OPPORTUNITIES

Tennessee took a strong first step in 2017 to address the issues with angel funding.

Last year, the state legislature enacted an Angel Tax Credit for investors. The program offers a tax credit against the Hall income tax for pre-qualified angel investment. The Hall income tax is Tennessee's only personal income tax in Tennessee waged in interest and dividends from investment income.

The total amount allocated for the credit in 2017 was \$3 million. Of that total, about \$1.5 million in credits helped spur \$5.2 million in investment. Thirty percent of those using the credit had not made an investment in the last two years.

There is great opportunity for use of the Angel Tax Credit in Tennessee, and great opportunity for growth of the program. A focused network of angels committed to the life sciences and with an understanding of the Angel Tax Credit incentive could help grow the program. In 2018, the allocation from the state increases to \$4 million and increases again to \$5 million in 2019.

There are also lessons to be learned from our neighbors to the south.

ANGEL TAX CREDIT

Credits: \$1.5M

Investment Created: \$5.2M

% of New Investors: 30%

In 2014, Georgia Bio and the Georgia Research Alliance created an angel network, Bio/Med Investor Network, to connect early-stage biomedical and health innovation companies with angel investors interested in advancing technologies in the industry.

The angel network operates as a community rather than a fund, making connections between investment groups, high-net-worth individuals and life science investment opportunities. The Bio/Med Investor Network evaluates individual investment opportunities in early-stage life science companies investing in the range of \$200,000 - \$2 million. The organization's structure includes a screening committee that vets opportunities for applying companies to present to their network members at its quarterly meetings.

Georgia's Bio/Med Investor Network facilitates and supports the development of the life science community in Georgia and throughout the Southeast. The successful network established a platform in Georgia where emerging companies can make presentations to potential investors for investment opportunities, as well as make connections through its membership for opportunities for other resources for needed services and start-up support.

In 2017, companies in Georgia raised more than \$1.16 billion in total venture capital, nearly four times the total raised by companies in Tennessee.

As of 2016, Tennessee had six angel investors or groups with active life science portfolios in the state out of 45 total investors with active portfolios, according to PitchBook data compiled for Launch Tennessee. **We need to do more**.

NEXT STEPS

Tennessee should seek to build an angel network that is supportive of the life science industry and its research and commercial opportunities for our state.

Life Science Tennessee makes the following recommendations to support the building of an angel network and to ensure the continued growth and development of opportunities for start-ups in our industry.

- 1. Design and develop a network of individuals to anchor a life science angel network; make final determinations on the network's structure and operational support utilizing best practices from similar angel networks, including Georgia Bio's Bio/Med Investor Network.
- 2. Life Science Tennessee, Launch Tennessee and other economic ecosystem builders should **increase** marketing activities for Tennessee's Angel Tax Credit program to ensure this opportunity is fully realized. The Angel Tax Credit program should be marketed specifically to industries that are of importance to Tennessee's overall economic vitality, such as the life science and energy industries.
- 3. Continue to support the building of the life science ecosystem in Tennessee including support of capital formation programs from ideation to maturity as well as programs that aid in the development of successful early-stage life science companies. This includes entrepreneur training and support, as well as continued development of a workforce to support the growth of life science companies in the state.

CONCLUSION

In sum, Tennessee has a promising number of nationally renowned research institutions and a wealth of life science thought-leaders. The state has also intentionally developed its start-up community by allocating funds, through the 2009 TNInvestco program, to local entrepreneurs.

Now, those companies have matured. At the same time, national and local data show that the average amount of funding from angel investors is increasing and that life science companies are finding early-stage funding more difficult to raise.

While this creates a challenging environment for up-and-coming life science companies, it also provides an opportunity for Tennessee to step in and help fill the gap in angel investment in life science companies. Life Science Tennessee is working on several solutions, including targeted outreach and education among the Tennessee investor community, customizing the Life Science Mentor Network to meet the needs of the state's entrepreneurs, and researching the development of a life science angel network.

CONTRIBUTORS

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With more than 225 attorneys in Nashville and Memphis, Tenn., Birmingham, Ala., and Austin, Tex., Waller Lansden Dortch & Davis, LLP assists clients in complex transactional, regulatory and litigation matters. Waller is recognized among the largest and most experienced healthcare law firms in the United States. Our experience dates back to the enactment of Medicare in the 1960s. Waller advises healthcare clients in regulatory compliance and operations, mergers and acquisitions, joint ventures, syndications, divestitures, commercial finance, securities offerings, corporate restructuring, distressed asset transactions, real estate, tax, intellectual property and the expansion or relocation of business operations. Our clients include hospital and health systems; life sciences, pharmaceutical and medical device manufacturers; healthcare information technology companies; outpatient providers; hospice, home health and senior living companies as well as angel capital, venture capital and private equity firms, healthcare lenders and other investors.

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Life Science Tennessee is a member-driven association representing a range of Tennessee-based enterprises as well as educational and clinical research institutions engaged in a wide variety of life science sectors, including biotechnology, pharmaceuticals, medical devices, diagnostics, agricultural biosciences and research. Sometimes referred to as biosciences, life science is an industry cluster that applies knowledge of the ways in which plants, animals and humans function. The sector is constantly evolving to address the very latest research and scientific discoveries.

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