

# GROWING THE PHARMA BASE

BY CHRISTINA HALEY O'NEAL

AUNCHING
ITS SECOND
INITIAL PUBLIC
OFFERING IN ITS
35-YEAR HISTORY,
WILMINGTON-BASED PPD INC.
IN FEBRUARY DEBUTED ON THE
NASDAQ, RAISING MORE THAN
\$1.6 BILLION.

The milestone in PPD's journey builds on the growth the global contract research organization has experienced since its beginnings as a one-person firm in Maryland in 1985 to setting roots in the Port City the next year and building its name from the hub here for over three decades.

But the advantages of having the firm here go beyond the \$110 million investment in its worldwide headquarters downtown or the nearly 1,800 local jobs it provides today.

The seeds planted by Fred Eshelman, founder of PPD, along with other local pioneer firms - aaiPharma, known today as Alcami, and Quality Chemical Laboratories - have helped sow a burgeoning sector in the Cape Fear region, said Randall Johnson, executive director of the N.C. Biotechnology Center Southeastern Office."I think one of the most impressive things about the cluster is the diversity of companies in our local clinical research community - from small, entrepreneurial ventures to very large multinational corporations and various sizes in between," Johnson said. "This diversity makes our cluster stronger overall, including helping with our talent attraction and retention in the area because employees have a wide range of choices for employers."

The contract research organization, or

CRO, industry in Wilmington encompasses a variety of companies that conduct clinical trials and provide management and support services for the pharmaceutical industry. A range of other local pharmaceutical firms also helps this cluster in testing and manufacturing. Clinical research is an area of medicine that researches, tests and studies areas such as the safety, effectiveness and side effects of medications, vaccinations and other types of medical treatments.

From the early area firms starting decades, the clinical research cluster has grown to more than 60 companies represented in the region – contract research organizations and contract manufacturing organizations – with about 3,300 people in the workforce, according to a 2019 report by the N.C. Coast Clinical Research Initiative.

There are also support companies and employees that surround the field, as well as about 100 clinical trials ongoing in the area at any given time with medical practices and physicians conducting those trials, Johnson said.

The numbers have grown significantly in recent years and are on an upward trajectory, he said.

And despite the COVID-19 pandemic, many companies are adapting, finding work through coronavirus studies.

Because many employees in the industry can live and work anywhere in the country, a number have chosen Wilmington for its quality of life as well as growing employment opportunities and support services. Johnson said.

The quality-of-life aspect is what brought PPD here.

Eshelman relocated PPD to Wilmington in 1986 and incorporated the firm in North Carolina in 1989.



Since then, the firm has grown to nearly 100 offices in 46 countries with more than 24,000 employees, making PPD one of the largest CROs in the world, current PPD Chairman and CEO David Simmons said.

PPD, having started as a consulting firm, is now conducting drug development services for a variety of customers, ranging from pharmaceutical and biotechnology firms to government and academic institutions.

"The IPO helped position us to continue to invest in innovation and differentiating services, from a strong financial foundation, to help our customers provide life-changing therapies and pursue our mission to improve health," Simmons said recently.

A significant portion of PPD's history was as a publicly-traded organization. The company filed its first IPO in 1996, later returning to a private company in 2011 when it was acquired by affiliates of investment firms The Carlyle Group and Hellman & Friedman.

Wilmington is one of PPD's largest locations. It also has another North Carolina office in Morrisville in the Triangle with a similar employment size.

"From our Wilmington headquarters and extending across our global organization, PPD has a long history of leadership in defining the CRO industry and innovating for the future, with the goal of helping customers speed safe and effective medical therapies to improve patient health," Simmons said.

Besides the IPO, PPD this year has been a player in vaccine studies for the coronavirus and in August signed a new three-year agreement with New Yorkbased pharmaceutical giant Pfizer Inc. to provide drug development services.

"It has been encouraging to see how the rise of Wilmington's life science community continues to strengthen and diversify the local economy, which we hope will create even more opportunity in the future," Simmons said.

Another early clinical firm for the area was aaiPharma, which started in Wilmington in 1986.

Just a few years after the firm's founder Frederick Sancilio retired, the company filed for bankruptcy in 2005.

The firm emerged from bankruptcy, with Sancilio returning for a short stint with the company, which went through several different phases and ownership

### **CRO DEVELOPMENT**

THE CLINICAL RESEARCH
INDUSTRY HAS GROWN IN
RECENT YEARS IN SOUTHEASTERN
NORTH CAROLINA, BOLSTERED BY
MAJOR PLAYERS AND SMALLER
UPSTARTS. HERE IS A SNAPSHOT
OF THE INDUSTRY FROM 2019.

60

CONTRACT RESEARCH ORGANIZATION AND CONTRACT MANUFACTURING ORGANIZATIONS

3,300 CLINICAL RESEARCH EMPLOYEES

60

CONTRACT RESEARCH SUPPORT COMPANIES

(DRUG DEVELOPMENT, MEDICAL DEVICES AND EQUIPMENT)

1,400

**SUPPORT COMPANY EMPLOYEES** 

100

ONGOING CLINICAL RESEARCH TRIALS

MEDICAL PRACTICES CONDUCTING TRIALS

45 PHYSICIANS CONDUCTING TRIALS

SOURCE: N.C. BIOTECH CENTER SOUTHEASTERN OFFICE

#### 2020 IN HEALTH CARE

over the years.

In late 2013, it merged with Cambridge Major Laboratories and later became Alcami Corp. in 2016. The pharmaceutical development, testing and manufacturing firm, which has executive offices in Wilmington and Durham, announced Walt Kaczmarek as its new CEO this year.

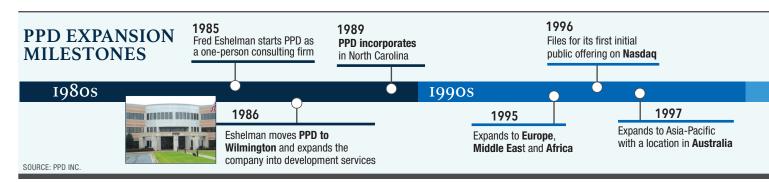
Through these early companies, the area has lured in a significant pool of workers over the years. Some of them have branched out, starting their own entrepreneurial ventures or joining other firms that helped grow the industry's base, Johnson said.

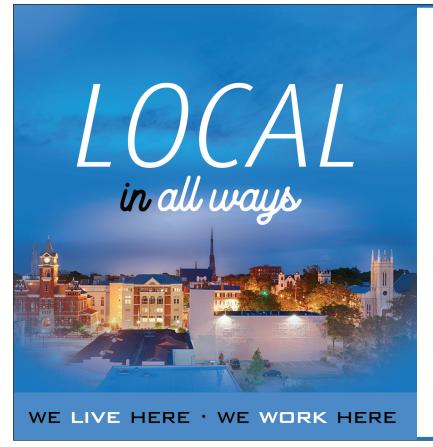
That was the case for Phil Dattilo, president of Wilmington-based Trial Management Associates LLC, who started in the industry with PPD in 2004 as an analyst and later joined TMA in 2011.

The clinical research management company was started by entrepreneur Danny Gillis in 2010. Dattilo was recruited from PPD to join TMA with a small stake in the company and eventually bought the business in 2014.

TMA is an 18-person firm today with a corporate office and a 5,000-square-foot research facility the firm moved into in August in midtown Wilmington. It also works with four physician sites.

"We will continue to grow in Wilmington. Our successful execution of the ongoing Moderna COVID vaccine trials and our continued success in gastroenterology and dermatology will allow us to win more groundbreaking research trials for the community," he said. "Clinical trials are seemingly becoming larger and larger in terms of the number of patients required to determine the safety and efficacy of new therapies. Our new space will give us the foundation we need to meet the needs





Our COMMITMENT to the health and well-being of our community is part of the fabric that drives the decisions we make every day at Wilmington Health. The core values of our organization include the words Respect, Integrity, Leadership, and Accountability.

- We use these ideals in the care we show our patients.
- We use these ideals in supporting our community and moving it forward.
- We use these ideals in the interactions we have with one another.

In these times of uncertainty and confusion, our dedication is not only important for the thousands of patients that we serve, but also for our outstanding team members and their families.

Because just like you, we live here, we work here, and we always will be committed to Wilmington in *all ways*.



of bigger trials."

The area's clinical research footprint grew organically for about 20 years, but intentional focus to build it started around 2006, Johnson said.

N.C. Biotech established its Southeastern office about that time, he said. And the University of North Carolina Wilmington's School of Nursing has since helped build the clinical research talent pipeline with bachelor's, master's and postbaccalaureate certificate programs in clinical research.

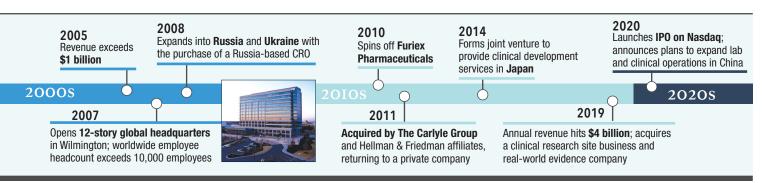
The support also includes the FuseCR (Center for Clinical Research

Workforce Development) at UNCW, which is a partnership of groups focused on bringing together resources for the clinical research field. In addition, the N.C. Coast Clinical Research Initiative was formed as a partnership between N.C. Biotech, UNCW and local clinical research firms to provide for workforce development opportunities, including education and networking.

The start of Quality Chemical Laboratories in 1998 was a natural evolution, between firm founder Yousry Sayed's years of teaching and the area's growing pharmaceutical industry, to help foster the jobs and training students need, Sayed said.

Sayed, president and CEO of the firm, started in the area consulting for pharmaceutical companies and teaching in the late 1970s and 1980s. He also has ties to UNCW.

Today, Quality Chemical Laboratories' breadth of business in the industry involves initial discovery, analytical studies, sample testing for raw materials and drug products and manufacturing. The firm is also looking to discover and develop new products, manufacturing technologies and drug delivery systems.





#### 2020 IN HEALTH CARE

Innovation has been a key component of Quality Chemical Laboratories in the past 23 years, Sayed said.

"I look at what we have done as kind of a nucleus to what has made Wilmington what it is today for the industry," Sayed said. "Part of our goal now is to try to basically have some new technologies in the manufacturing side, which will be developed in the next one to five years.

"Also, we're going to be bringing in manufacturing injectables, or sterile products, which is a very specialized area that requires a lot of technology, a lot of science, a lot of inspections from the FDA, and all that is going to be happening in our new building."

Much of the discovery will involve the evolution of Quality Chemical Laboratories' sister company, Pyramid Pharmaceutical Co. LLC. The firms will be housed in a 90,000-square-foot addition to Quality Chemical Laboratories' main facility in the North Chase area slated to be built over the next 16 months.

But building a talent pipeline with the knowledge and skill set needed for the work that Quality Chemical Laboratories does has been one of the company's biggest challenges, Sayed said. The company has about 250 people today but expects to need an additional 200 to 300 people in the coming years due to growth.

"We're going to be looking for a lot of people over the next couple of years, and I know it's going to be a challenge because we need highly technical people and there is a lot of training that goes into taking someone from having a degree to being able to step in the industry and be productive," Sayed said.

To continue to capitalize on the area, however, Sayed said there's also a need to expand infrastructure and technologies in Southeastern North Carolina to keep the region's pharmaceutical sector growing for decades to come.

"I think there is still some room for continued growth. I think we have to be mindful of providing infrastructure and help in attracting new technologies," Sayed said. "We have a lot of reputation in what we do, what Alcami does, what PPD does, and all the other clinical trial companies ... but I feel like there is definitely some room for attracting some technological advances that are still needed in this industry, something that will make this area unique."

## FROM THE ARCHIVES

"Hospital drives growth, both past and present" - April 2002



The year 2000 kicked off a series of expansion projects for New Hanover Regional Medical Center, the county-owned hospital that opened in 1967.

In the beginning of 2000, the new Zimmer Cancer Center was dedicated. The next year, an expanded emergency department opened, nearly doubling in size. In the following years more projects came online – the new Betty H. Cameron Women's and Children's Hospital, a surgical pavilion, a renovated patient tower, parking deck, medical building at Brunswick Forest and a heart and vascular tower at the hospital's main campus on 17th Street.

Besides the long string of construction projects and service expansions, NHRMC also grew its employee base and revenues – enough to make it an attractive acquisition for outside health groups.

In 2002, NHRMC was New Hanover County's largest employer with about 3,500 employees (another 570 were at Cape Fear Hospital, now known as NHMRC Orthopedic Hospital). Today the health system – it added a physician group along the way – counts about 7,500 employees.

Back then, the medical center had more than 26,800 admissions

during its 2001 fiscal year.

"We're now serving the most patients in our history," Scott Whisnant, then-hospital spokesman, said at the time.

In a few weeks hospital trustees and county commissioners are expected to vote on whether to sell NHRMC to Winston-Salem-based Novant Health.

If the deal is approved, more than \$1 billion would go to a community foundation for the county to address issues ranging from school system needs to police training.

"I've said this before, and it's fair because I've kind of sat in their seat before," said former Wilmington Mayor Spence Broadhurst, who co-chaired the Partnership Advisory Group that waded through the request for proposal process after the county and hospital said in 2019 they were exploring the possibility of selling. "It's not often that elected officials give away power and money, and they've done both in this case because it's the right thing to do for our community.

"I don't think we've begun to grasp the impact that the proceeds from that money will do to our community going forward. I think it's going to be dramatic."